Rajarshi Dashrath Autonomous State Medical College, Ayodhya

Call For Objection

File Reference: - / Proprietary Article /Surgery / R.D.A.S.M.C./ **Surgical** Workstation – An integrated RF Electrosurgical Unit , Vessel Sealer , Aron Plasma Coagulation Unit ,Water Jet, High End Suction Module & Smoke Plume Evacuation System for the **Department of Surgery**

Subject: Inviting comments/objection, If any before declaring proprietary article for procurement of) **Surgical Workstation** – An integrated RF Electrosurgical Unit, Vessel Sealer, Aron Plasma Coagulation Unit ,Water Jet, High End Suction Module & Smoke Plume Evacuation System for the **Department of Surgery, Rajarshi Dashrath Autonomous State Medical College, Ayodhya**.

Indenter: The De**partment of Surgery, Rajarshi Dashrath Autonomous State Medical College, Ayodhya** has to procure, **Surgical** Workstation – An integrated RF Electrosurgical Unit, Vessel Sealer, Aron Plasma Coagulation Unit, Water Jet, High End Suction Module & Smoke Plume Evacuation System on **Proprietary Article** basis.

The proposal submitted by **M/S Pee Vee Enterprises, 2137/M(8), Canal Road, Indralok Colony, Krishna Nagar, Lucknow**, who is authorised channel partner of M/S **ERBE Medical India Pvt Ltd** wholly owned subsidiary of **ERBE Elektromedizine GmbH. Germany** who are established and reputable sole manufacturers of **Complete Surgical Workstation** consist of - APC Unit, Erbe jet & Electro surgical Unit having production facilities at **Waldhorenlestrasse 17. D-72072. Tubingen,** along with relevant proprietary article certificate & patented document are attached & uploaded on website.

The above documents are being uploaded for open information to submit objections, comments if any from any manufacturer/supplier before declaring proprietary article of the said equipment / items to be procured **within 10 days [i.e. 31 , 12 2021)** from the date of issuance/uploading of the notification

The comments should be sent to the office of finance controller & In Charge Central Procurement on above address at **Rajarshi Dashrath Autonomous State Medical College, Ayodhya** in a sealed envelope with above reference on within end of objection call from the date of uploading on institutional website **[i.e. 31 , 12 2021**) , failing which it will be presumed that any other manufacture/vendor js having no comment to offer and case will be decided on merits.

Finance Controller **Principal**

Enclosure: - > Technical Specification, as per Master Suchi of DGME&T

> PAC Certificates by Department

> PAC Certificate by Manufacturer

Rajarshi Dashrath Autonomous State Medical College, Ayodhya

Certificate for Purchase of Proprietary Article

(1) Description of Article: **Surgical Workstation** –An integrated RT Electrosurgical Unit, Vessel Sealer, Argon Plasma Coagulation Unit, Water Jet, High End Suction Module & Smoke Plume Evacuation System

(2) Quantity: 01

(3) Approximate cost, if known: 71,35,637 (per Unit) + 12% GST = Rs. 79,91,913 (Grand Total Seventy Nine Lakh Ninety One Thousand Nine Hundred Thirteen Only)

(4) Maker's name and address: **M/S Erbe Medical India Pvt Ltd** wholly owned subsidiary of **M/S ERBE Elektromedizin GmbH, Germany**

(5) Name of Local Agents: **M/S PeeVee Enterprises**
2137/M(8), Canal Road, Indralok Colony, Krishna Nagar, Lucknow226023
Tel +91 0522 4025629, 941502096 E-mail ID : peevee132@gmail.com
Contact Person: Mr Vijay Agarwal 9415020996, 0522 4025629

(6) I approve the above purchase and I certify that:
(a) No other make/brand will be suitable.
(b) This is the only firm who is manufacturing/stocking this item.
(c) A similar article is not manufactured/sold by any other firm, which could be used in lieu.

Note: Delete (a) or (b) whichever is not necessary.

Signature

Designation of Officer

Date:

Counter Signed

M.S./D.D.A/DEAN

SPECIFICATION OF SURGICAL WORK STATION

1	**An integrated RF Electro Surgical Unit** (For electrosurgical Cut & Coagulation modes for optimum effect of HF surgery)
2	**Vessel Sealer** (For thermo fusion / sealing & dissection for vessels & tissues structures ,during open and laparoscopic surgeries)
3	**Argon plasma coagulation unit** (For homeostasis of bleeding tissues & devitalisation of pathological tissues & stops bleeding, non-contact technology for coagulation)
4	**Water Jet Technology**_(Hybrid technology for elevation & separation of tissue layers with minimal bleeding, Parenchyma can be dissected and Vessels & nerves prepared)
5	**High End Suction Module** : (For permitting good visibility of target surgical site automatically)
6	**Smoke Plume Evacuation System:** (For evacuation of cutting & coagulation of tissue smoke plume, for better visibility, reduced risk of viral & bacterial dispersion)
7	**Mobile Trolley:** Imported mobile trolley with locking castors, In build provision of - Argon Gas cylinder, Electro Surgical Unit, Vessel Sealer, APC Unit, Water jet Unit, and High End Suction & Smoke Plume Eor vacuation System.
8	
A	The equipment should be micro controller based & should adjust the power to get the desired surgical effect on the tissue. All settings should be controlled by the machine and according to the tissue deliver. Power should be display on the screen with graph facility to show the deliver power.
B	Diathermy machine should be microprocessor controlled, US-FDA & European Certificate marked in accordance with the medical devices directive (93/42/EEC), minimum 40 installation base in northern part of the India with regional after sales service center of the principal company in the north region for uptime guarantee.
C	Should have 8 cutting and more than 8 coagulation modes, namely Auto cut, High cut, Dry cut, Bipolar cut, Bipolar Resection cut (saline). Coagulation modes should have – Soft Coagulation, Swift Coagulation, Forced Coagulation, Spray coagulation, Bipolar soft coagulation, Bipolar forced coagulation, Bipolar Resection coagulation (Saline), Twin coagulation, Bielamp –Bipolar Thermo fusion and precise coagulation.
D	The system should have Monopolar Cut & Coagulation Mode, two Bipolar Modes with auto bipolar start & stop and Vessel fusion technology all integrated in one system.
E	Should have Power and Voltage automatic regulation feature to prevent tissue damage and charring. The output voltage should be regulated in various levels.
F	The System should have LCD Backlight adjustment for good visibility in operating room, patient plate monitoring facility, audiovisual alarm and deactivate output if contact between patient and patient plate is not proper to eliminate the risk of patient burns.

G	Special bipolar mode for coagulation of vascular tissue (Thermo 8fusion) upto 7 mm with reusable hand instrument for open as well laparoscopic surgeries.
H	Vessel sealing and cutting simultaneous.
I	The unit should be FDA approval for 7mm Vessel.
9	
A	For management of bleeding and devitalisation of tissue abnormalities achieved by optimal coordination with RF generator
B	The Argon Plasma Coagulation system should have automatic parameters setting for various types of instruments and automatic depth controlled plasma regulation.
C	Should have three different APC modes suitable for different Indications
D	Precise APC – adjustment made using the effect settings
E	Pulsed APC – adjustment made using the parameter power settings
F	Forced APC – adjustment made using the parameter power settings
G	Should have Adjustable argon flow rate from 0.1L/min to 8L/ min in steps of 0.1 L /min with automatic regulation of selected flow rate.
H	Should have the facility to use Argon plasma coagulation and monopolar coagulation simultaneously
I	Should have automatic monitoring of flow rate and Argon supply and auto purge facility. It should have the facility to connect with central gas supply.
J	Should give visual display of argon gas bottle content and should give Acoustic alarm when bottle content reaches a minimum.
K	Should have facility for activation of unit by foot pedal of the Electro Surgical unit.
L	Should have facility to use in double balloon endoscopy procedures.
M	Should have facility for Argon supported cutting and coagulation.
10	
A	For management of separating the different tissue types with their varying elasticity and firmness with the help of adjusted water pressure based on the kinetic energy principle.
B	Should have pressure range: 1–80 bars & Volume flow: 1–65ml/min. It should indicate delivered fluid vol.
C	Should adapt any sterile saline solution bag (disposable) as separation medium.
D	Should be integrated with Electro surgical workstation with other accessories and facility to connect Monopolar coagulation with the applicator
E	Should have facility to individually configure programs for different surgeries.
F	Water jet activation should be via footswitch and Remote facility for switching between two different user settings.
G	Should have facility for various applicators to be used in Laparoscopy, flexible endoscopy and open surgeries.
11	
A	Reusable hand pencil with facility for swapping between programs = 05

57

B	Reusable Thermo fusion hand instrument for Open Surgeries (for vasculatures up to 7mm)= 02 units
C	Reusable Thermo fusion hand instrument for Laparoscopic Surgeries (for vasculatures upto 7mm.) = 02 Units
D	Reusable Bipolar forceps with irrigation port & cable = 02 each
F	Sealing and Cutting hand instrument,5mm bowel shaped with maximum of 1.1 mm thermal spread = 02 each
F	Footswitch with facility for swapping between programs.
G	Reusable patient plate – Adult & Paediatrics with cable = 02 each
H	Patient plate with equipotential ring - 10 nos.
I	Argon Plasma Coagulation 3 button electrosurgical pencil, connecting cable, probes and applicators for both Laparoscopy & Open surgery. 02 units
J	Argon assisted cutting instrument for open surgery and laparoscopic surgery.
K	Water Jet accessories for Laparoscopy and Open Surgery.
L	Hybrid Accessories for Water Jet surgery. Work Station trolley with attached Suction unit
M	Work Station trolley with attached Suction unit.

Essential Criteria:

1. Demonstration mandatory at hospital premises at OEM cost.
2. CMC offered for the quoted equipment should not be more than 5% of the quoted model with not more than 5% escalation per year after completion of CMC period.
3. CMC offered for the quoted equipment must be on OEM letterhead for further years. (CMC offered on distributors/ Vendor letterhead will not be considered).
4. Installation process should be performed by OEM trained service engineer/ service representative on OEM's letter head/ service report, with a mandatory provision of providing preventive service visits of OEM trained service engineer/ service representative quarterly per year till completion of warranty period (i.e. 20 visits for first five years) and further quarterly visit (04 visits/ year) till the completion of CMC period.
5. The installation process must be completed by the OEM/ Service provider within 30 days of supply.
6. The accessories/ consumables utilized during the period of installation process should be taken care FOC by OEM/ Service provider.
7. The equipment complies with the requirement of the Medical Device Directive of class I equipment and Electromagnetic compatibility, all supporting documents must be provided.0
8. **Equipment should have brand name / model number embossed/ etched on the equipment.**
9. In case of technical snag/ failure/ breakdown, the response time for Inspection should be within 24 Hour and repair within 5 days, otherwise provide a service machine until the period of

recovery of breakdown of the unit. Failing which will attract penal action as per the decision of the University (Uptime guarantee of 95%).

10. The page of technical bid should be numbered and checklist should be duly filled as per the annexures and all annexures should be in accordance with the format, otherwise it may be the reason for disqualification.
11. All the technical specifications accepted in the compliance statement must be supported by Original Literature from the firm/ O.E.M with Highlighting, Numbering & flagging as per below mentioned format for the compliance statement.

S. No.	Technical Specification	Compliance Yes / No	Page No. in the proposal submitted where documentary evidence is enclosed as per tender Specs with highlighting, Numbering & flagging
1			
2			

power your performance.

Proprietary Certificate

To whom it may concern

Erbe VIO® 300D and APC 2

This is to certify that the Erbe VIO® 300 D with attached Argon Plasma Coagulation system (APC 2), that provides facility to change between programs by a ReMode button in the footswitch and also three different variations in Argon Plasma outputs namely FORCED APC, PULSED APC® and PRECISE APC® are proprietary products, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and these products are not manufactured elsewhere.

Date 2017-02-15

Axel Retzlaff, Director Regulatory Affairs

Erbe Elektromedizin GmbH Waldhoernlestraße 17 72072 Tuebingen Germany

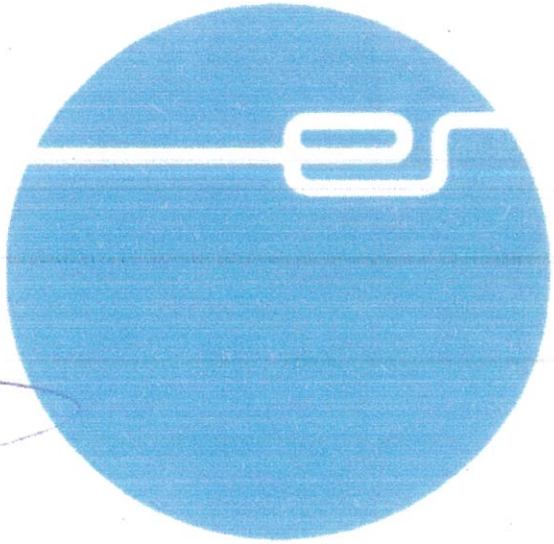
erbe
power your performance.

Proprietary Certificate

To whom it may concern

endoCUT® I and Q

This is to certify that the modes endoCUT® I and endoCUT Q for fractionated cutting on erbe VIO electrosurgical units are proprietary products, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and these products are not manufactured elsewhere.



Date 2019-01-21

Michael Reick, Director Business Management

Erbe Elektromedizin GmbH Waldhoernlestraße 17 72072 Tuebingen Germany

erbe
power your performance.

Proprietary Certificate

To whom it may concern

ERBEJET® 2

This is to certify that the ERBEJET 2 is a proprietary product, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and this product is not manufactured elsewhere.

Date 2017-02-15

Axel Retzlaff, Director Regulatory Affairs

Erbe Elektromedizin GmbH Waldhoernlestraße 17 72072 Tuebingen Germany

VALID PATENTS FOR THE ERBEJET 2

ERBE Elektromedizin GmbH hereby declares, that the following patents are registered for the device 'ERBEJET 2':

Waterjet surgical device with single-use pump cartridge

Country	Patent number	Description
Germany	DE102004031673B4	Medical pump
Japan	JP2008504086A	Medical pump
China	CN1980609A	Medical pump
Australia	AU2005259594B2	Medical pump

Filling function for a waterjet surgical device

Germany	DE10200705280584	Waterjet surgical device and process for operating such

Pump cartridge for WCI with controllable drive

Germany	DE102004031674B3	Medical pump for a water jet in liver surgery comprises a drive unit for opening and closing holders and/or coupling units
USA	US7955057	Surgical device using water jet and a method for operating said device
Japan	JP2011502563A	Surgical device using a water jet and a method for operating a device
China	CN000101848681A	Surgical device using water jet and method for operating said device
India	IN248194A1	Medical pump
Australia	AU2005259592B2	Medical pump

Transport device for sterile media

	EP1670371B2	Transport device for sterile media
USA	US8083493B2	Transport device for sterile media
Japan	JP2007507261A	Aseptic medium transport device
China	CN100548229C	Transport device for sterile media
India	IN1446CHENP2006A	Transport device for sterile media
Australia	AU2004279670B2	Transport device for sterile media

Tuebingen, 12 September 2012

i.A. Marketing, Dr. Jochen Queck

US007955057B2

(12) **United States Patent**
Kuehner et al.

(10) **Patent No.: US 7,955,057 B2**
(45) **Date of Patent: Jun. 7, 2011**

(54) **MEDICAL PUMP**

(75) Inventors: **Ralf Kuehner**, Stuttgart (DE); **Martin Hagg**, Wannweil (DE); **Jochen Queck**, Tübingen (DE)

(73) Assignee: **ERBE Elektromedizin GmbH**, Tübingen (DE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1201 days.

(21) Appl. No.: **11/630,578**

(22) PCT Filed: **Jun. 22, 2005**

(86) PCT No.: **PCT/EP2005/006753**

§ 371 (c)(1),
(2), (4) Date: **Dec. 22, 2006**

(87) PCT Pub. No.: **WO2006/002815**

PCT Pub. Date: **Jan. 12, 2006**

(65) **Prior Publication Data**

US 2008/0038124 A1 Feb. 14, 2008

(30) **Foreign Application Priority Data**

Jun. 30, 2004 (DE) 10 2004 031 674

(51) **Int. Cl.**
F04B 35/01 (2006.01)
A61B 17/3203 (2006.01)

(52) **U.S. Cl.** 417/360; 417/238; 417/415; 417/572; 192/48.1; 604/152; 606/167

(58) **Field of Classification Search** 417/238, 417/413.1, 415, 454, 477.2, 360, 572; 83/177; 192/48.1, 48.2, 48.3, 48.7; 604/152, 154, 604/22, 228; 606/167, 171

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,692,052	A		9/1972	Cattanach
3,958,898	A		5/1976	Abrahams et al.
4,087,213	A		5/1978	Hadama
5,061,241	A		10/1991	Stephens, Jr. et al.
5,066,282	A		11/1991	Wijay et al
5,295,967	A	*	3/1994	Rondelet et al. 604/154
5,667,102	A		9/1997	Keller
5,843,022	A		12/1998	Willard et al.
6,216,573	B1		4/2001	Moutafis et al
6,368,080	B1		4/2002	Sipin
6,382,928	B1		5/2002	Chang

(Continued)

FOREIGN PATENT DOCUMENTS

CN 2075260 U 4/1991

(Continued)

OTHER PUBLICATIONS

Summary for Azzolini IT MO20040028 including publication date of that reference and Abstract of corresponding document Azzolini EP 1561483, Publication date of Aug. 10, 2005.*

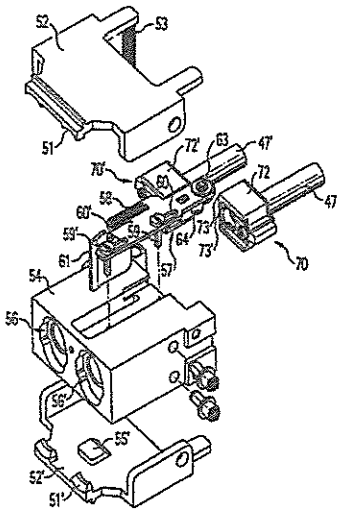
(Continued)

Primary Examiner — Devon C Kramer
Assistant Examiner — Leonard J Weinstein
(74) *Attorney, Agent, or Firm* — Dickstein Shapiro LLP

(57) **ABSTRACT**

The invention relates to a medical pump, especially for water jet surgery, in which a pump unit is assembled as a single use article and can be reversibly connected to a pump actuating device. Within the pump, the pump actuating device is also used to open up the connection between the pump unit and the pump actuating device.

6 Claims, 9 Drawing Sheets



U.S. PATENT DOCUMENTS

6,575,936	B1 *	6/2003	Kojima et al.	604/155
6,592,551	B1 *	7/2003	Cobb	604/155
6,610,027	B1	8/2003	El Hatu	
6,652,006	B1	11/2003	Digiacomo	
6,752,789	B2 *	6/2004	Duchon et al.	604/228
7,190,991	B2	11/2007	Staley et al	
7,347,837	B2 *	3/2008	Azzolini	604/154
2002/0025267	A1 *	2/2002	Lieber et al.	417/572
2002/0176788	A1	11/2002	Moutafis et al.	
2003/0149402	A1 *	8/2003	Gerlach et al	604/151
2004/0057854	A1 *	3/2004	Wakabayashi et al.	417/448
2005/0038371	A1	2/2005	Reich et al.	
2005/0220639	A1 *	10/2005	Sasaki et al.	417/415

FOREIGN PATENT DOCUMENTS

DE	42 22 918	1/1994
DE	203 09 616 U	11/2003
EP	0 551 920	7/1993
EP	1561483 A1 *	8/2005
JP	48-17127 Y1	5/1973
JP	62-85000 A	4/1987
JP	2-084068 A	6/1990
JP	4-288155 A	10/1992
JP	6-192 A	1/1994
JP	2000-508247 A	7/2000
WO	WO 99/33510	7/1999
WO	WO 02/095234	11/2002
WO	WO 03/013645	2/2003
WO	WO 2004/112623	12/2004
WO	WO 2005-014777	4/2005

OTHER PUBLICATIONS

English Translation of the Written Opinion of the International Searching Authority issued in related application PCT/EP2005/006753 (4 pages) (Jan. 2004).

* cited by examiner

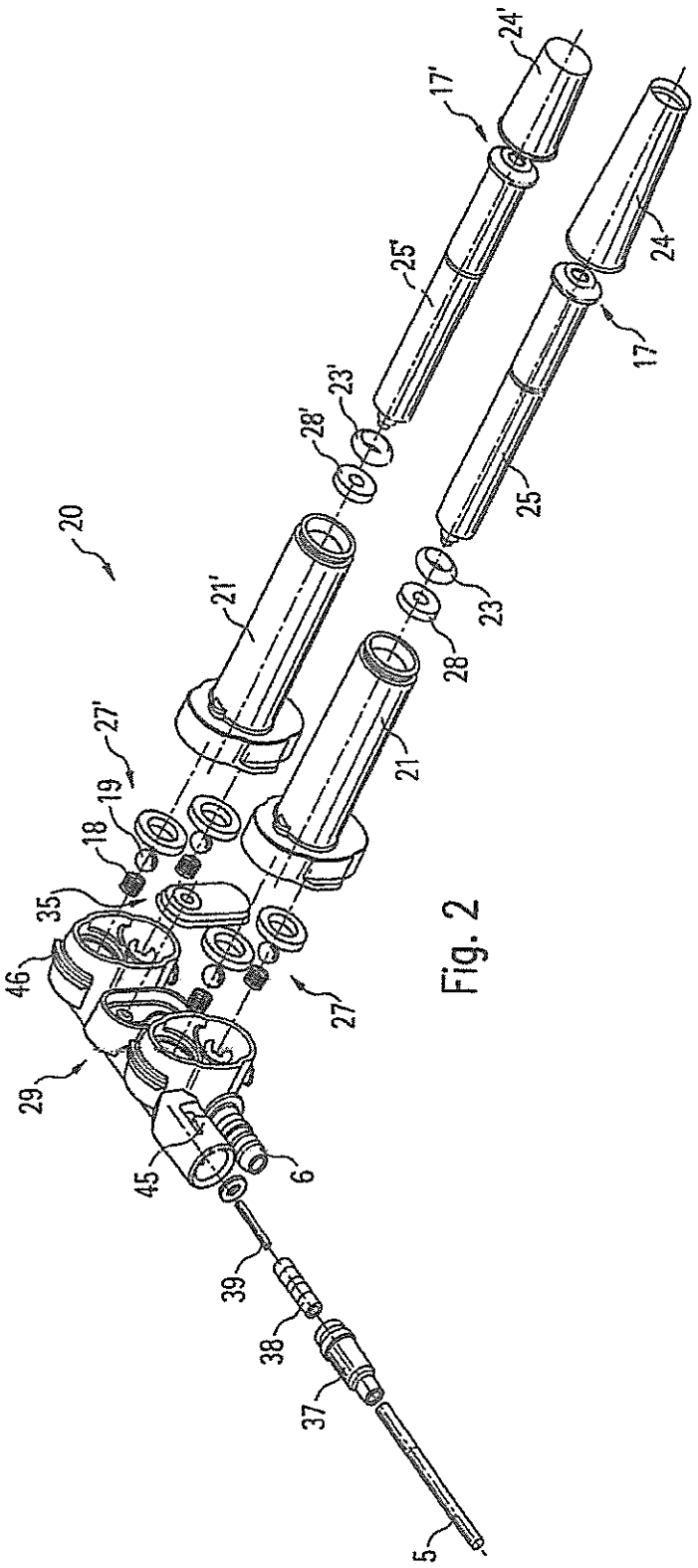

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Fig. 2

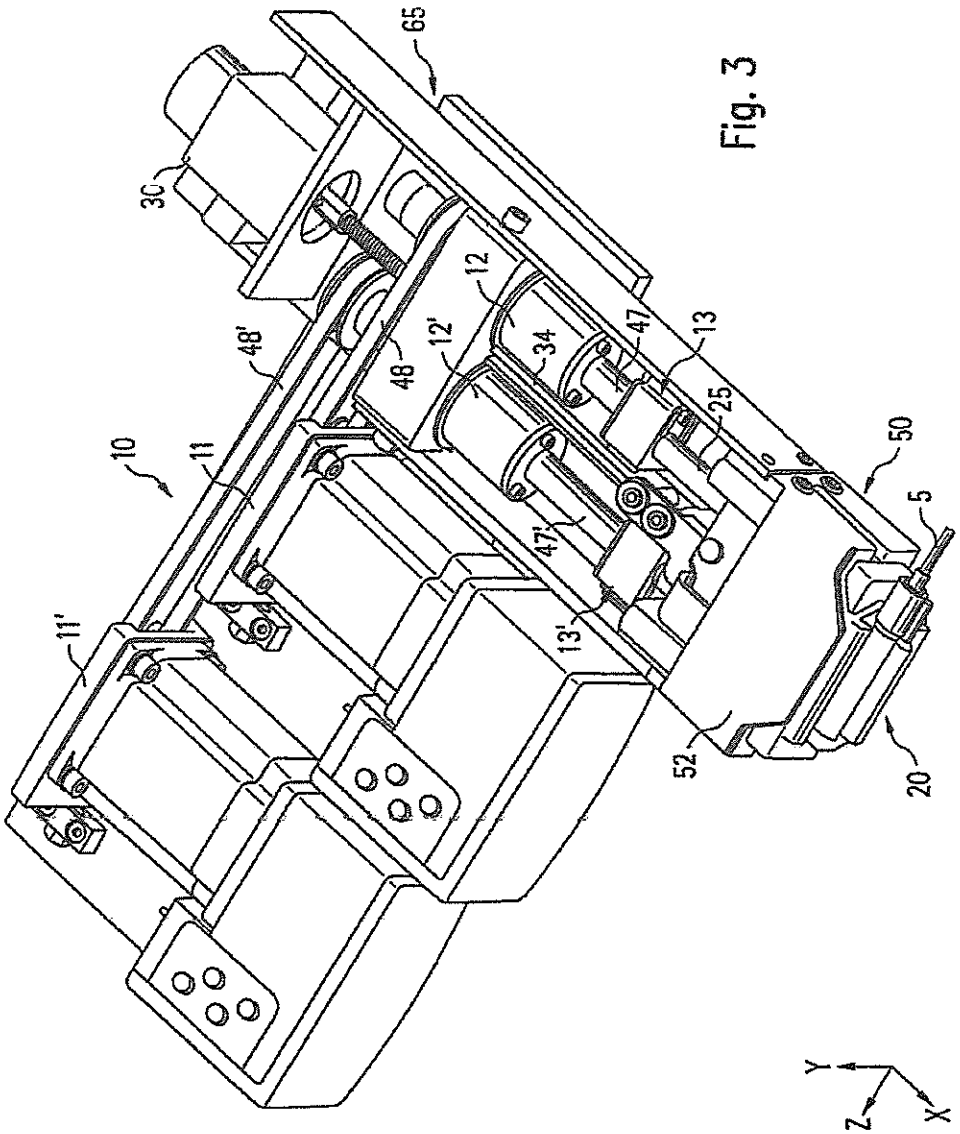


Fig. 3

Fig. 4

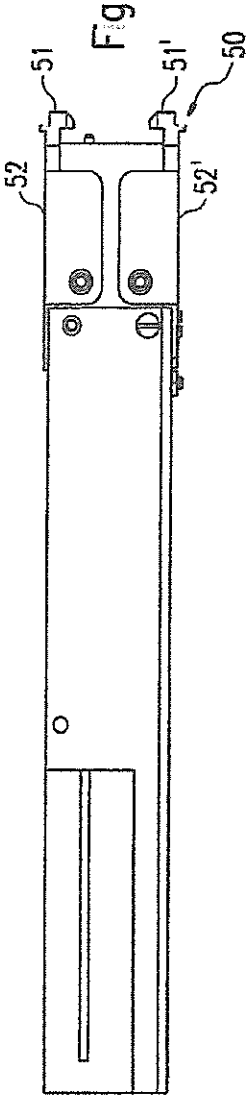


Fig. 5

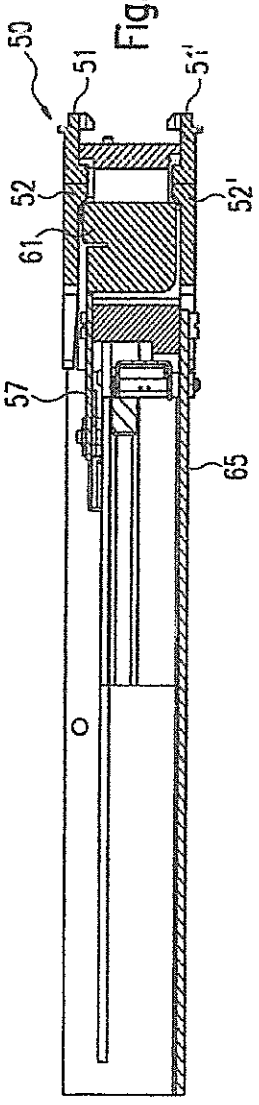
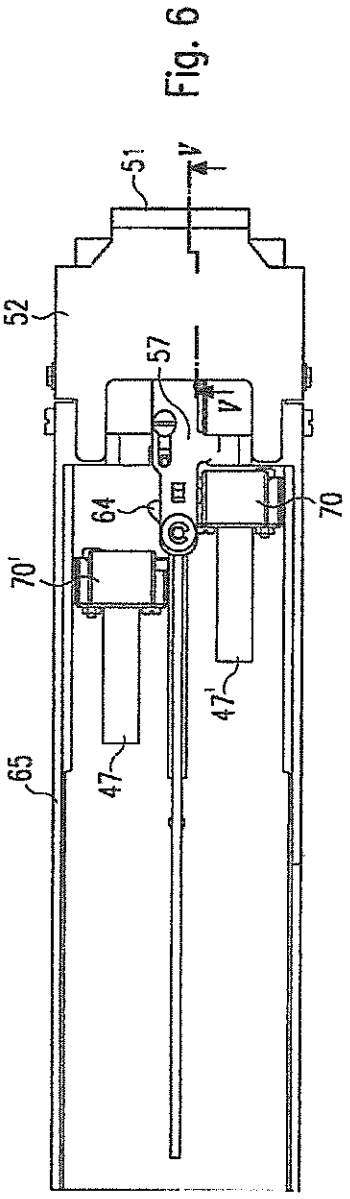


Fig. 6



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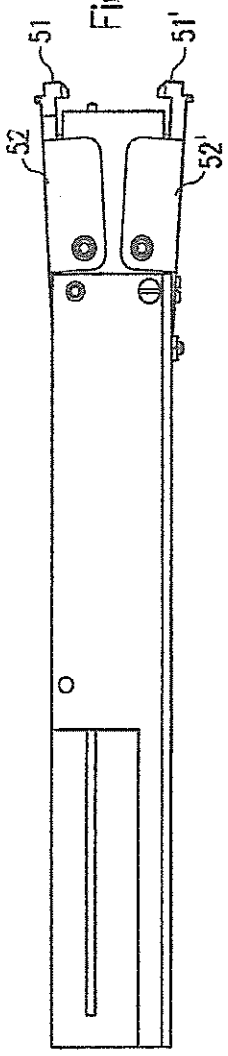


Fig. 8

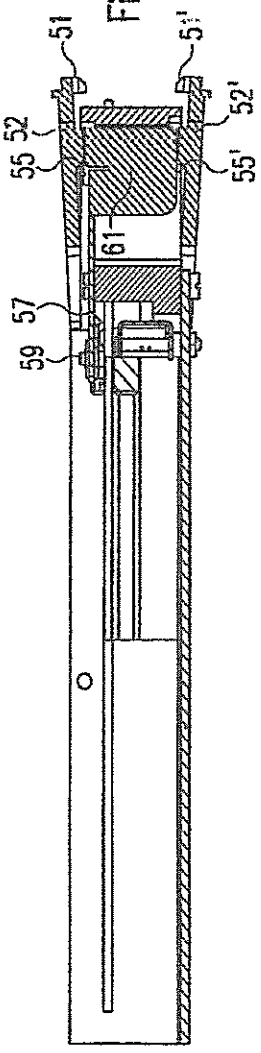
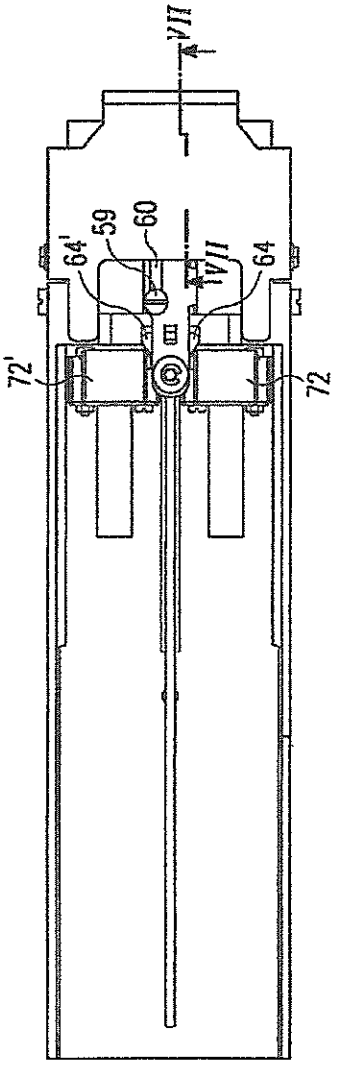


Fig. 9



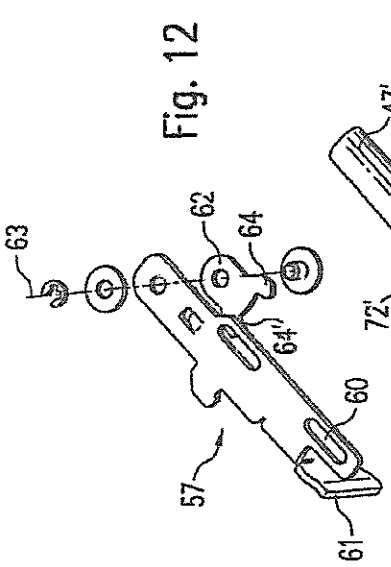


Fig. 12

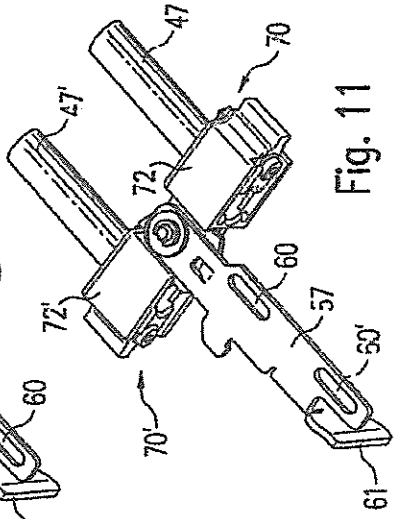


Fig. 11

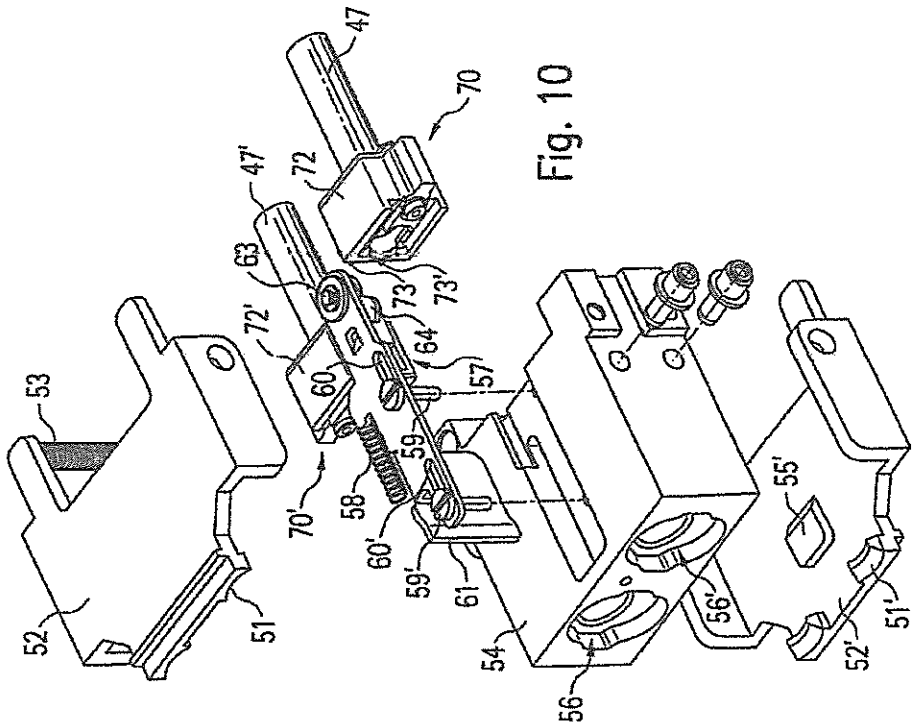


Fig. 10

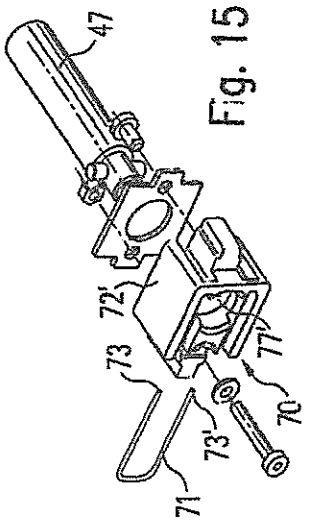
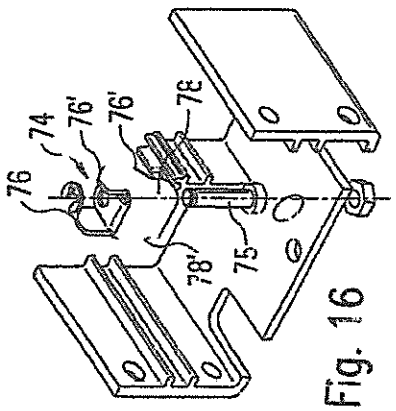


Fig. 15



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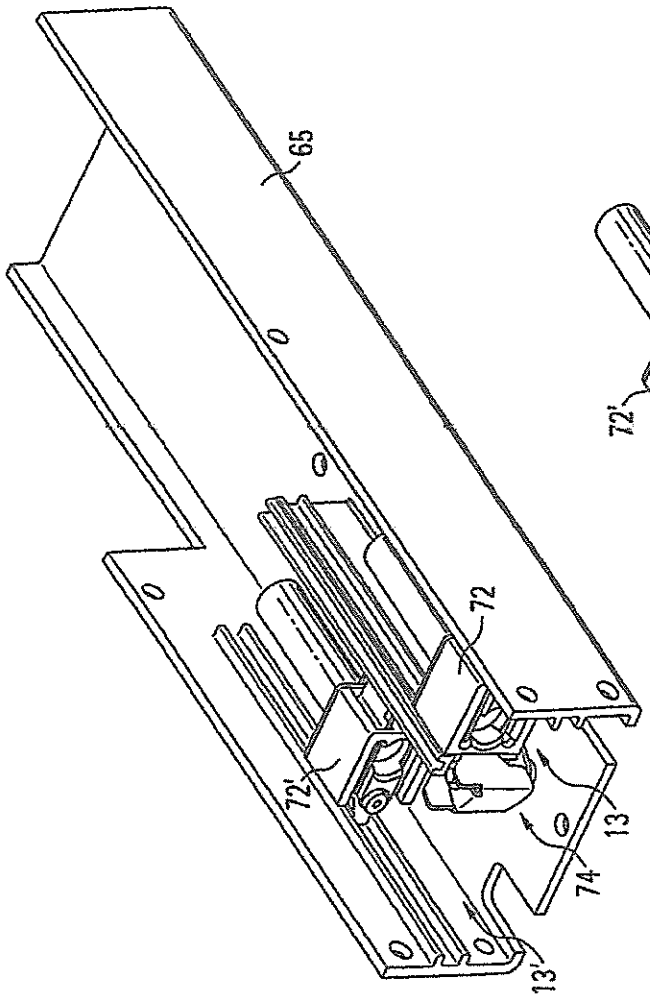

Fig. 13

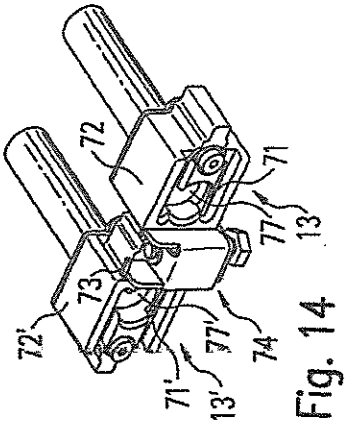

Fig. 14

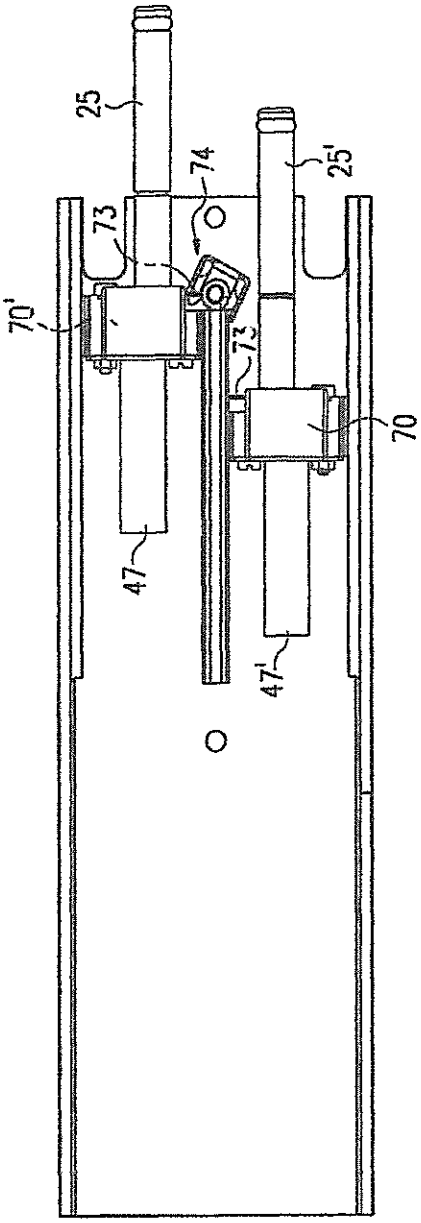

Fig. 17

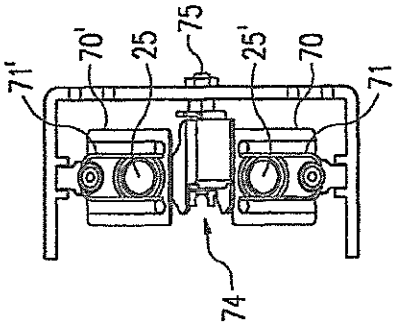

Fig. 18

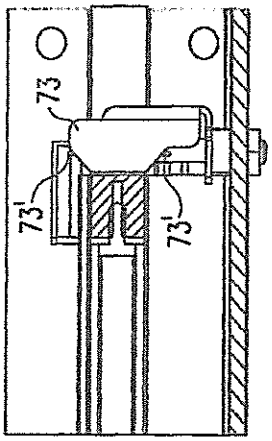

Fig. 21

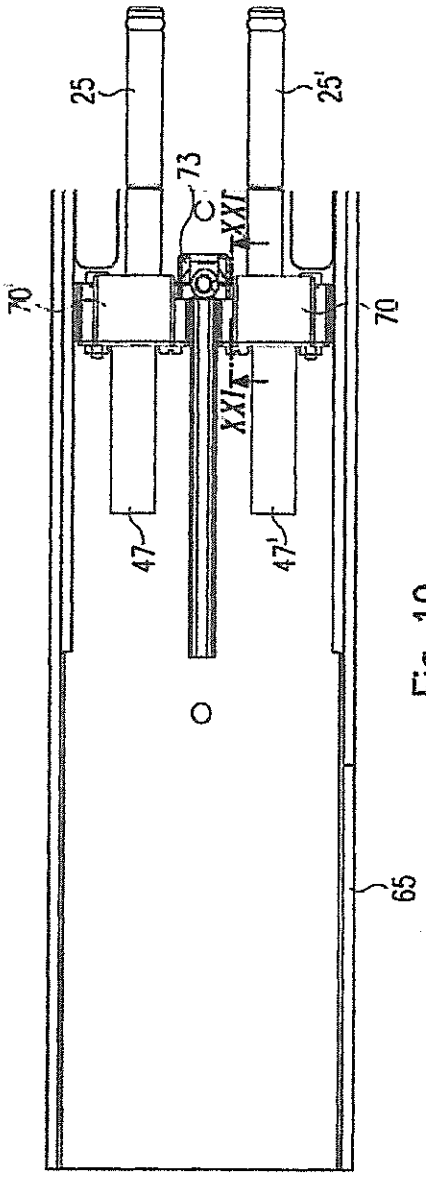

Fig. 19

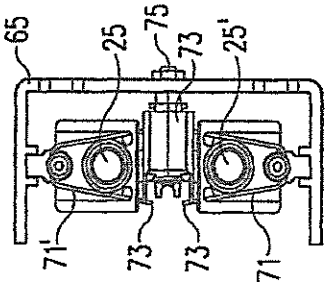

Fig. 20

MEDICAL PUMP

FIELD OF THE DISCLOSED EMBODIMENTS

The disclosed embodiments relate to a medical pump, in particular for water jet surgery.

BACKGROUND

Water jet surgery has been used for some time in liver surgery, as this organ has tissue structures of different firmness (parenchyma, blood vessels and bile ducts) unlike any other organs and the applied water jet separates the tissue being cut (parenchyma) yet leaves the blood vessels and bile ducts undamaged. Naturally, precise control of the cutting pressure is required for this type of operation.

A further problem with water jet surgery is that the cutting medium must be totally sterile (e.g. Ringer solution), as the liquid comes into contact with body tissue in the closest and most intensive way possible. Ordinary problems such as high reliability, simplicity and economic manufacture must also be considered.

Medical pumps for water jet surgery are known, for example, from U.S. Pat. No. 6,216,573 B1 and DE 203 09 616 U1, which comprise an exchangeable pump unit for single use, which can be connected to pump actuating devices. Changing of the pump devices is, however, very costly with the known setups. As relatively large forces are needed to generate high pressure with sufficient flow, the devices for connection of the pump device to the pump actuating devices must be very substantial so that they can maintain a "firm hold" on the pump device during operation.

SUMMARY

The disclosed embodiments include a medical pump wherein the connection between the pump unit and the pump actuating device is improved and easier to operate.

A medical pump according to disclosed embodiment includes a pump unit which is assembled as a single use article and which comprises at least one piston and piston rod for displacing the piston in an allocated cylinder defined by the pump unit; a pump actuating device comprising at least one controllable drive device and a motor control adapted to actuate the pump unit by displacing the at least one piston rod; holding devices which are adapted to open and close for reversible attachment of the pump unit to the pump actuating device; and clutch means which are adapted to open and close for reversible connection of the at least one piston rod to the at least one controllable drive device, wherein the at least one controllable drive device of the pump actuating device is further adapted to actuate the opening or closing of at least one of said holding devices or said clutch means.

In the disclosed embodiments, the drive device that pushes the piston back and forth additionally actuates or controls the holding devices and/or the clutch means as well. Simple operation by means of the drive device is thus possible and a large holding force can be exerted, as this is applied during opening to decouple the pump unit from the pump actuating device and not by the user.

The holding devices and/or the clutch devices are preferably snap fittings. The snap fittings are constructed so that closing of the holding devices and/or clutch devices can be achieved by snapping the holding devices and/or clutch devices in place and so that opening the holding devices and/or clutch devices can be achieved by means of the drive device opening the snap fittings. The energy required for connecting the pump device to the drive device can be generated very easily by the user. Opening is then carried out by the drive devices with a corresponding large holding force. In this way, only opening must be carried out by the drive devices but not closing as well. This simplifies the setup.

The snap fittings are preferably constructed so that the force required for closing is less than that for opening.

The drive device is preferably constructed so that the engagement devices fitted in the clutch devices are positioned at rest prior to attaching the pump unit to the pump actuating device so that, on connecting the pump unit to the pump actuating device, the engagement devices disengage from the piston rods and the clutch devices can be closed by actuating the drive devices. This means that the user does not have to carry out any great manipulation in relation to the pistons or piston positions in order to attach the pump unit to the pump actuating device.

In one preferred embodiment, two pistons with piston rods are provided in the cylinders and the pump actuating device is constructed to give alternate displacement of the pistons. This arrangement ensures an increased pump performance. In this embodiment, the pump actuating device is constructed either with two motors or a motor with controllable gearing preferably controllable such that the pistons can be displaced in one of two ways: (1) synchronously for alternate opening or closing of the holding device and/or the clutch devices and (2) alternately during normal pump operation. The pistons are operated alternately during (2) normal pump operation. A different modus operandi (e.g., synchronous operation) is selected for opening and closing of the holding device and/or the clutch devices using the same drive set as for normal pump operation. This results in a simplified setup of the pump.

The drive device is preferably a linear drive (or in an embodiment with two pistons, two linear drives) with shaft and motor so that the shaft is drivable in a controllable manner. Very accurate movements can be carried out via such linear drives, thereby protecting the pump with its piston/cylinder units.

The motor control is preferably constructed in such a way that the pistons can be displaced at a constant speed. This results in a smoother delivery of the medium to be pumped.

BRIEF DESCRIPTION OF THE DRAWINGS

Disclosed embodiments are now described by way of example with reference to the accompanying drawings.

FIG. **1** is a schematic block diagram of a medical pump arrangement according to a disclosed embodiment.

FIG. **2** is an exploded diagram of an embodiment of the pump.

FIG. **3** is a perspective view of the pump actuating device with coupled pump unit.

FIG. **4** is a side view of a holding device.

FIG. **5** is a view similar to FIG. **4**, partially-sectioned along the line V-V in FIG. **6**.

FIG. **6** is a plan view of the holding device shown in FIG. **4**.

FIGS. **7-9** are views similar to illustrations corresponding to those in FIGS. **4-6**, showing the holding device in an open position.

FIG. **10** is an exploded drawing of the holding device showing its functional elements.

FIG. **11** is a perspective diagram of a sub-unit shown in FIG. **10**.

FIG. **12** is an exploded drawing of the sub-unit shown in FIG. **11**.

FIG. **13** is a perspective drawing of clutch means

FIG. 14 is a view of the clutch means shown in FIG. 13 in a different displacement position.

FIG. 15 is an exploded view of one clutch means shown in FIG. 13 and FIG. 14.

FIG. 16 is an exploded view of a sub-unit of the clutch means shown in FIG. 13.

FIG. 17 is a plan view of the clutch means shown in FIG. 13 with coupled piston rods.

FIG. 18 is a front elevation of the clutch means shown in FIG 17

FIG. 19 is a view similar to FIG. 17, showing the clutch means in a different operational state.

FIG. 20 is a front elevation of FIG. 19.

FIG. 21 is a section along line XXI-XI in FIG. 19.

DETAILED DESCRIPTION

The same reference numbers will be used for the same parts and for parts with the same function.

In one disclosed embodiment depicted in FIG 1 a pump actuating device 10 is provided which encompasses a motor control 15 for the control of two motors 11, 11', which are connected via gearing 12, 12' and clutch devices 13, 13' to the piston rods 25, 25'. Ah operator B can operate the motor control 15 by means of suitable switches (foot switch or finger switch) so that the motors 11, 11' alternately displace the piston rod 25, 25' and thus the pistons 22, 22' in the cylinders 21, 21' of a pump unit 20 via the described train, so that the volume of the pressure chambers 16, 16' of the pump unit 20 is alternately enlarged and reduced.

In order to seal the pressure chambers 16, 16' and the pistons 22, 22' in relation to the cylinders 21, 21' seals 23, 23' are envisaged at the pistons 22, 22'. Moreover, the piston rods 25, 25' maintain sterility with cup seals 24, 24', which are firmly fixed to the cylinders 21, 21' on the one hand and to the pistons rods 25, 25' on the other. In this way germs from the ambient air which, without these cup seals 24, 24', would settle on the internal walls of the cylinders 21, 21' and pass through the seals 23, 23' can neither mix with the working fluid nor find their way into the same.

Suction valves 26, 26' as well as pressure valves 27, 27' are connected to the pressure chambers 16, 16'. The suction valves 26, 26' are connected via a fluid inlet 6 to a reservoir 9 for the working fluid. The pressure valves 27, 27' are connected to the pressure hose 5 which leads to an applicator 8 via a fluid outlet 7. The pump unit 20 forms a disposable part E together with the reservoir 9 including its contents, pressure hose 5 and applicator 8, which is disposed of after each operation, so that the entire setup meets the highest sterility requirements possible.

A butterfly valve 14 is provided by means of which (in addition to the motor control 15) operator B can switch off the fluid flow completely. The embodiment shown in FIG. 1 includes a pressure control valve 35 which with the aid of a valve membrane 36 can open and close a connecting channel between fluid outlet 7 and fluid inlet 6. The membrane 36 is operated by an actuator 30 via a push rod 34 and a spring 33 as well as a dynamometer 31. The dynamometer 31 supplies a power proportional output signal to a controller 32, by means of which an operator B can set a maximum pressure. Instead of a separate dynamometer 31 the operating current of the actuator 30 can be measured which is also power proportional.

This layout means that the fluid pressure can be accurately adjusted at the applicator 8. Moreover, pressure fluctuations resulting from piston operation are smoothed out by the control valve 35. The important point is that the pressure control valve 35 due to its construction operates with the membrane pressurized by fluid in a power-controlled and not a travel-controlled manner. No pressure adjustment error can therefore occur during coupling of the pump unit 20 to the pump actuating device 10 even with dimension tolerances as it is not the geometric dimensions (travel) which are important, but the power with which the pressure control valve 35 is operated

FIG. 2 shows an exploded view of a construction embodiment of the pump device 20. In this embodiment the pressure and suction valves 26/27 encompass balls 19 which are pressed onto the valve seats via springs 18 (not visible in the illustration) which principle is known.

The cylinder head 29 has two sections to which the cylinders 21, 21' are coupled, whereby the valves sit between the cylinders 21, 21' and the cylinder head 29.

It can further be seen from FIG. 2, that the piston rods 25, 25' have coupling projections 17, 17' at their distal ends which serve to create a mechanical connection with the coupling systems 13, 13'

The pistons in this embodiment are formed by the proximal ends of the piston rods 25, 25' fitted with caps 28, which simultaneously hold seals 23, 23' firmly on the piston rods 25, 25'.

The pressure hose 5 is fastened irreversibly to the cylinder head 29 via a connecting piece 37, a crimping piece 38 and an internal pipe which is inserted into the pressure hose 5, whereby after assembly (in a known way) the connecting piece 37 is held in the cylinder head 29 by means of a catch 45 which holds the connecting piece 37 irreversibly in the cylinder head 29.

FIG. 3 shows a perspective illustration of the pump actuating device 10 with a coupled pump unit 20. This illustration shows that the pump actuating device has a frame 65 to which the motors 11, 11' are attached. They are constructed as reversing motors which drive the shafts 47, 47' via cog belts 48, 48' and gearing 12, 12', so that the rotary movement of the motors 11, 11' is translated into a linear movement. Attached to the shafts 47, 47' are the clutches 13, 13' to which the piston rods 25, 25' can be coupled. The setup of the actuator 30 with the relevant push rod 34 is also visible in this illustration.

Moreover, the holding device 50 is attached to the frame 25 which is intended for holding the pump unit 20.

The holding device is explained in more detail with the aid of FIGS. 4-12.

The holding device 50 encompasses jaw holder 52, 52' with jaws 51, 51' at the end, the jaws 51, 51' being are constructed in such a way that they can engage with the lugs 46 (FIG. 2) provided in order to hold the pump unit 20.

The jaw holders 52, 52'—as shown in FIG. 4—are positioned on the frame 65 via swivel pins and pretensioned in the closed position (FIGS. 4-6) by means of springs 53 (see FIG. 10). In order to insert a pump unit 20 this is pushed into the holding device 50 in such a way that the jaws 51, 51' slip with front inclined surfaces over the lugs 46 of the pump unit 20 and are forced onto it. When the pump unit 20 has then been fully pushed on, the jaw holders 52, 52' snap shut and the jaws 51, 51' hold the pump unit 20 in this position until they are pushed apart again.

The mechanism for opening the holding device 50 or jaws 51, 51' is explained with the aid of FIGS. 10-12.

The holding device 50 encompasses a holding block 54, which has cylinder housings 56, 56' at its front which correspond to the rears of the cylinders 21, 21' of pump unit 20. The fit can be seen easily when FIGS. 2 and 10 are compared.

An opening slide 57 is fixed with fastening screws 59, 59' to the cylinder housing 56, whereby the opening slide 57 has

elongated holes 60, 60' so that it can be pushed back and forth. The opening slide 52 is pushed backwards, away from the pump unit 20, by means of a spring 58.

A rocker 52 which can be swiveled back and forth is fixed to the opening slide 57 by means of a rocker bearing 63 carrying symmetrically arranged tongues 64, 64'. The opening slide 57 has an opening tongue 61 at its front, facing the pump unit 20. The opening tongue 61 has a height which corresponds to the distance between the internal surfaces of the jaw holders 52, 52'. On these inner surfaces of the jaw holders 52, 52' opening ramps 55, 55' have been attached in the displacement path of the opening tongue 61 in such a way that the opening tongue 61, on meeting the opening ramps 55, 55' and during further displacement in the direction of the pump unit 50, pushes apart the jaw holders 52, 52', so that they change from the position shown in FIGS. 4-6 to the position in FIGS. 7-9. In this position (according to FIGS. 7-9) the jaws 51, 51' disengage from the lugs 46 on the pump unit 20 thus releasing it. Displacement of the opening slide 57 occurs as described as follows.

During a "normal" operation of the pump unit 20 the shafts 47, 47' are moved back and forth alternately, so that in an end position of a shaft 47 or 47' they hold the positions shown in FIG. 6 or 17. During these movements the holding blocks 72, 72' are moved by the piston holders 70, 70' at the end of the shafts 47, 47' past the tongues 64, 64' in such a way that the rocker 62 is either tilted anti-clockwise, as shown in FIG. 6, or in the other direction in which the holding blocks 72, 72' are in the reverse position—projecting or pulled back, as shown in FIG. 17. These alternating movements of the piston holders 70, 70' or the holding blocks 72, 72' can thus be carried out to operate the pump without displacing the opening slide 57 in the direction of the pump unit 20.

But when the shafts 47, 47' are driven in such a way that both piston holders 70, 70' or holding blocks 72, 72' run side by side, the rocker 62 cannot be avoided during displacement (in the direction of the pump unit 20), so that both holding blocks 72, 72' engage simultaneously with both holding tongues 64, 64'. As a result the opening slide 57 is pushed against the force of the spring 58 in its elongated holes 60, 60' in the direction of the pump unit 50 when the piston holders 70, 70' continue to move forward so that the opening tongue 61 slides over the opening ramps 55, 55' thus forcing the jaw holders 52, 52' apart. The engagement of the jaws 51, 51' in relation to the lugs 46 on the pump unit 20 is released as a result. This opening of the holding device 50 thus occurs exclusively by means of the motors 11, 11' and their corresponding control by means of the motor control 15.

Below the effect or actuation of the clutch systems 13, 13' is described in more detail with which the piston rods 25, 25' are coupled to the piston holders 70, 70' via their coupling projections 17, 17'. Attention is drawn in this respect to FIGS. 13-21.

The holding blocks 72, 72' are screwed onto the shafts 47, 47' as shown in FIG. 15 and comprise insertion openings 77, 77' into which the piston rods 25, 25' can be inserted with their coupling projections 17, 17'. Springs 71, 71' are attached to the holding blocks 72, 72' in such a way that the spring ends 73, 73' protrude into the insertion openings 77, 77'. The distance of the spring ends 73, 73' is such that the piston rods 25, 25' can be inserted into the insertion openings 77, 77' with their coupling projections 17, 17' and force the spring ends 73, 73' apart until they snap shut behind the coupling projections 17, 17'. For this the coupling projections 17, 17' have conical ends. After inserting the coupling projections 17, 17' into the piston holders 70, 70' the piston rods 25, 25' are connected to the piston holders 70, 70' and can neither be pushed nor pulled.

Between the displacement travel of the piston holders 70, 70' or the holding blocks 72, 72' a straddle lever 74 is attached on a swivel bearing 75 so that it can tilt, where on its upper and lower side it has straddle surfaces 76, 76' on the side facing away from the pump unit 20. On the other end, the end facing the pump unit 20, swivel edges 78, 78' are constructed on the straddle lever 74.

The layout and dimensioning of the straddle lever 74 with its straddle surfaces 76, 76' and swivel edges 78, 78' is such that with alternating movements of the holding blocks 72, 72' or piston holders 70, 70', as shown in FIGS. 13 and 17, the straddle lever 74 is tilted either to one side or to the other side depending on which of the piston holders 70, 70' or holding blocks 72, 72' slide past it in the direction of the pump unit 20. As result of this swivel action, the straddle surfaces 76, 76' are swiveled in such a way that they do not engage with the spring ends 73, 73' of the piston holder 70 or 70' as they slide past. But when both piston holders 70, 70' are pushed parallel next to each other in the direction of the pump unit 20 (see FIGS. 14 and 19-21) the straddle surfaces 76 or 76' engage with the spring ends 73, 73' (see in particular FIGS. 20 and 21) so that these slide along on the (chamfered) straddle surface 76 or 76' and are forced apart. As a result of this forcing apart the piston rods 25, 25' previously attached to their coupling projections 17, 17' (see holding position according to FIG. 18) are released as shown in FIG. 20. After this with the same and simultaneous parallel movement of the piston holders 70, 70' or holding blocks 72, 72' the holding device 50 as well as the jaws 51, 51' are forced open and thus their engagement with the lugs 46 of the pump unit 20 is released, the pump unit can be removed by the parallel displacement of the piston holders 70, 70' as far as their front position facing the pump unit 20 without the user having to overcome any force.

The motor control 15 is furthermore constructed in such a way that after removal of a pump unit 20 from the pump actuating device 10, both shafts 47, 47' retract the piston holders 70, 70'. If the user inserts the pump unit 20 into the pump actuating unit 10, it is only the force required for opening the holding device 50 that needs to be overcome. The piston rods 25, 25' then protrude with their coupling projections 17, 17' through the cylinder housing 56, 56' into the pump actuating device 10. The user can now control the motor 15 in such a way that the same moves the piston holders 70, 70' in the direction of the pump unit 20 in a "coupling mode" until the coupling projections 17 or 17' push apart the spring ends 73, 73' and snap shut. This snapping process is carried out separately one after the other for both coupling projections 17 or 17', so that the straddle lever 74 does not open the springs 71, 71'.

In disclosed embodiments, coupling of the pump unit 20 to the pump actuating device 10 is partially accomplished and decoupling is completely accomplished by means of the drive, which is provided for actuation of the pump itself. Separate drive devices are therefore not required to operate the pump actuation and the coupling/decoupling.

The invention claimed is:

1. A medical pump comprising:

a pump unit which is assembled as a single use article and which comprises two pistons and piston rods for displacing the pistons in allocated cylinders defined by the pump unit;

a pump actuating device comprising at least one controllable drive device and a motor control adapted to actuate the pump unit by displacing the two piston rods alternately;

holding devices which are adapted to open and close for reversible attachment of the pump unit to the pump actuating device; and

clutch means which are adapted to open and close for reversible connection of the two piston rods to the at least one controllable drive device,

wherein the at least one controllable drive device of the pump actuating device is further adapted to actuate the opening or closing of at least one of said holding devices or said clutch means, and

wherein said at least one controllable drive device for said pump actuating device comprises motor means which operates to displace said pistons such that said pistons are displaced alternately during operation of the pump unit and synchronously during opening or closing of the holding device and/or the clutch devices.

2. The medical pump according to claim 1, wherein at least one of said holding devices or said clutch means comprises a snap device adapted to operate by snapping shut and open by means of said at least one controllable drive device opening said snap device.

3. The medical pump according to claim 2, wherein said snap device is constructed such that a force needed to close it is lower than a force needed to open it.

4. The medical pump according to claim 1, wherein said clutch means comprise engagement means which are fitted in said pump actuating device and which are positioned in a rest position prior to attachment of said pump unit to said pump actuating device whereby on connection of said pump unit to said pump actuating device the engagement means are disengaged from said piston rods and said clutch means is closable by actuation of said at least one controllable drive device.

5. The medical pump according to claim 1, wherein said at least one controllable drive device comprises a linear drive having at least one shaft and at least one motor for controllable driving of said the shaft.

6. The medical pump according to claim 1, wherein said motor control displaces said pistons at a constant speed.

* * * * *

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Erbe IES 3

This is to certify that the smoke evacuation system IES 3 with 5-stage main filter cartridge, that contains a ULPA-15 filter that removes 99.9995% of all particles from 100 nm and that can be used for open surgical and laparoscopic applications, is a proprietary product, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and is not manufactured elsewhere.

This system is compatible with all models of the VIO® range proprietary to Erbe Elektromedizin GmbH.

Tuebingen, 12.05.2020

Michael Reick, Director Business Management

Erbe Elektromedizin GmbH Waldhoernlestraße 17 72072 Tuebingen Germany

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This is to certify that the listed Bipolar PREMIUM Forceps are proprietary products, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and these product are not manufactured elsewhere

Article No.	Catalogue Description
20195-501	Bipolar forceps PREMIUM, straight, tip 0.2 mm, pointed, length 120 mm
20195-502	Bipolar forceps PREMIUM, straight, tip 0.4 mm, very fine, length 120 mm
20195-503	Bipolar forceps PREMIUM, straight, tip 0.7 mm, fine, length 120 mm
20195-504	Bipolar forceps PREMIUM, straight, tip 0.7 mm, fine, angled, length 120 mm
20195-505	Bipolar forceps PREMIUM, straight, tip 0.2 mm, pointed, length 185 mm
20195-506	Bipolar forceps PREMIUM, straight, tip 0.4 mm, very fine, length 185 mm
20195-507	Bipolar forceps PREMIUM, straight, tip 0.7 mm, fine, length 185 mm
20195-508	Bipolar forceps PREMIUM, straight, tip 1 mm, blunt, length 185 mm
20195-509	Bipolar forceps PREMIUM, straight, tip 1 mm, blunt, angled, length 185 mm
20195-510	Bipolar forceps PREMIUM, straight, tip 0.2 mm, pointed, length 200 mm
20195-511	Bipolar forceps PREMIUM, straight, tip 0.4 mm, very fine, length 200 mm
20195-512	Bipolar forceps PREMIUM, straight, tip 1 mm, blunt, length 200 mm
20195-513	Bipolar forceps PREMIUM, straight, tip 1 mm, blunt, angled, length 200 mm
20195-514	Bipolar forceps PREMIUM, straight, tip 2 mm, blunt, angled, length 200 mm
20195-515	Bipolar forceps PREMIUM, straight, tip 2 mm, blunt, length 230 mm
20195-516	Bipolar forceps PREMIUM, straight, tip 1 mm, blunt, angled, length 260 mm
20195-517	Bipolar forceps PREMIUM, straight, tip 2 mm, angled, length 260 mm
20195-518	Bipolar forceps PREMIUM, straight, tip 2 mm, blunt, length 280 mm e.g. for urology
20195-531	Bipolar forceps PREMIUM, bayonet, tip 0.2 mm, pointed, length 155 mm
20195-532	Bipolar forceps PREMIUM, bayonet, tip 0.4 mm, very fine, length 155 mm
20195-533	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 155 mm
20195-534	Bipolar forceps PREMIUM, bayonet, tip 0.2 mm, pointed, length 170 mm
20195-535	Bipolar forceps PREMIUM, bayonet, tip 1 mm, blunt, length 170 mm
20195-536	Bipolar forceps PREMIUM, bayonet, tip 0.4 mm, very fine, length 200 mm
20195-537	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 200 mm
20195-538	Bipolar forceps PREMIUM, bayonet, tip 1 mm, blunt, length 200 mm
20195-539	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 200 mm
20195-540	Bipolar forceps PREMIUM, bayonet, tip 2 mm, blunt, length 200 mm
20195-541	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 200 mm angled downwards
20195-542	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 200 mm angled upwards

20195-543	Bipolar forceps PREMIUM, bayonet, tip 0.2 mm, pointed, length 230 mm
20195-544	Bipolar forceps PREMIUM, bayonet, tip 0.4 mm, very fine, length 230 mm
20195-545	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 230 mm
20195 546	Bipolar forceps PREMIUM, bayonet, tip 1 mm, blunt, length 230 mm
20195-547	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 230 mm
20195-548	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 230 mm angled upwards
20195-549	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 230 mm angled upwards
20195-550	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 230 mm angled downwards
20195-551	Bipolar forceps PREMIUM, bayonet, tip 0.2 mm, pointed, length 250 mm
20195-552	Bipolar forceps PREMIUM, bayonet, tip 0.4 mm, very fine, length 250 mm
20195-553	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 250 mm
20195-554	Bipolar forceps PREMIUM, bayonet, tip 1 mm, blunt, length 250 mm
20195-555	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 250 mm
20195-556	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 250 mm angled upwards
20195-557	Bipolar forceps PREMIUM, bayonet, tip 0.7 mm, fine, length 170 mm
20195-558	Bipolar forceps PREMIUM, bayonet, tip 2 mm, blunt, length 250 mm
20195-559	Bipolar forceps PREMIUM, bayonet, tip 2mm, blunt, length 170 mm
20195-560	Bipolar forceps PREMIUM, bayonet, tip 0.2 mm, pointed, length 200 mm
20195-561	Bipolar forceps PREMIUM, bayonet, tip 2 mm, blunt, length 230 mm

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Date 2021-02-18

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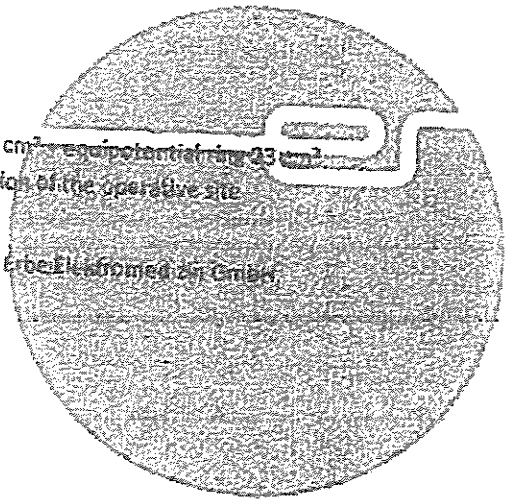

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April 4 2018 Michael Reich, Director Business Management

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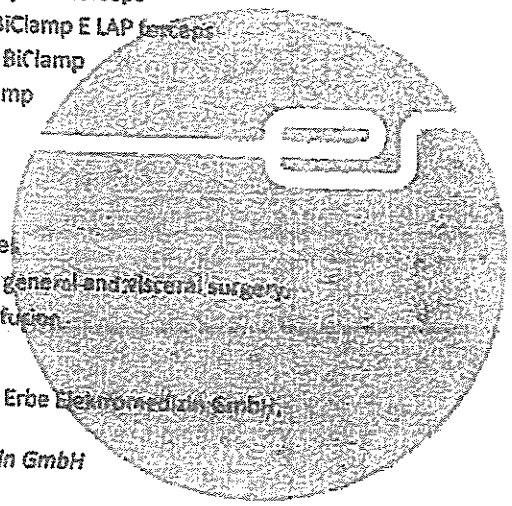
20195-229,-230,-246...-249; 21195-229,-246...-249 BiClamp E LAP forceps
20195-200,-202,-203,-213,-221,-222,-230,-280,-299 BiClamp
21195-190,-200,-202,-203,-221,-230,-280,-299 BiClamp



are specially designed to enable

- for open surgery and laparoscopic procedures
- vessel sealing in urology, gynecology, and in general and visceral surgery
- BiClamp and thermoSEAL modes for thermofusion

These are proprietary products, marketed exclusively by Erbe Elektromedizin GmbH,
Waldhoernlestrasse 17, 72072 Tuebingen, Germany

BiClamp® is a registered trademark of Erbe Elektromedizin GmbH

Michael Reith, Director Business Management

Erbe Elektromedizin GmbH Waldhoernlestraße 17 72072 Tuebingen Germany

power your performance.

Proprietary Certificate

To whom it may concern

Bipolar Instruments

This is to certify that the following products :

- 20195-132 Bipolar LAP forceps, Maryland, deep ribbed, shaft ø 5 mm, length 340 mm
- 20195-133 Bipolar LAP forceps, fenestrated, deep ribbed, shaft ø 5 mm, length 340 mm
- 20195-081 Bipolar fixation forceps, shaft ø 5 mm, insulated, length 330 mm
- 20195-226 Bipolar LAP scissors, Metzenbaum, shaft ø 5 mm, length 340 mm

are specially designed to achieve the desired surgical outcomes as stated in the Intended Use (see Notes on Use of each product) in different surgical procedures".

These are proprietary products, marketed exclusively by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany.

2021-05-14

Director Regulatory Affairs

MAR 16 2006

K060484

510K SUMMARY

Page 1 of 4

Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955 2577
Contact Person:	Julie Stephens, President/Consultant Regulatory Resources Group, Inc.
Date Prepared:	February 23, 2006
Common Name:	Electrosurgical Generator (ESU) System
Trade/Proprietary Name:	ERBE VIO ESU (Model VIO 300 D)
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)
Product Code:	GEI
Legally Marketed Predicate Device:	ERBE VIO ESU (Model VIO 300 D) with Accessories 510(k) Number: K023886

Device Description:

The ERBE VIO ESU with Accessories is an electrosurgical system that uses high frequency (HF) electrical current waveforms to cut and/or coagulate tissue. There were no modifications to the Accessories from the previously cleared 510(k) K023886; therefore, they are not included with this submission.

Unit (Model VIO 300 D)

General Description. The ESU has a color monitor display that provides the user with an on-screen tutorial as well as setting and operational information. The unit has various cutting and coagulation modes with defined effect levels to provide the physician flexibility in interventional applications (*i.e.*, its ability to generate HF current). The system has automatic start and stop features. The equipment is programmable and various accessories (*e.g.*, footswitches, hand instruments, etc.) as well as modes may be assigned to perform specific functions. When activated, the device has an audio and visual error system (i.e., malfunctions or user errors are detected with medical personnel being alerted visually and/or by sound with, in some cases, no energy being delivered). Upon activation, the energy delivered (in watts) from the ESU to the tissue is displayed on the display screen. Also, the unit can be used in association with an ERBE compatible Argon Plasma Coagulator (APC). The unit is supplied non-sterile and is reusable.

Note: VIO stands for Variable Cut and Coagulation.

K060484

510K SUMMARY

Page 2 of (4)

Indications for Use:

The ERBE VIO ESU with Accessories is intended to deliver high frequency (HF) electrical current for the cutting and/or coagulation of tissue.

Similarities and Differences of the Modified Device to the Current Device (Predicate Comparison/Substantial Equivalence):

ERBE VIO 300 D ESU

Similarities
The modified ESU (ERBE VIO 300 D ESU) has the same protective circuits and intended use as the predicate ESU (ERBE VIO 300 D ESU) and most of the performance specifications are the same. The modified ESU has the same protective circuits as the predicate ESU, which displays the Equipment Output Error on the monitor screen with a graphic representation so that you can readily determine the cause of the error. The modified ESU will also be manufactured by ERBE Elektromedizin GmbH in Germany and will be supplied as a non-sterile, reusable ESU system. The packaging and labeling (User Manual, etc.) components are similar except in the descriptions of specific user instructions.

Monopolar Modes:
The modified ESU has the same cut and coagulation modes, Effect levels, power maximums (wattages) and voltage maximums. The User Manual remains the same in the statement to the physician: "The power output setting should be set as low as possible for the desired tissue affect. The purpose of this is to help reduce the potential for capacitive coupling and inadvertent burning at higher wattages/ voltages."

Bipolar Modes:
The modified ESU has the same cut and coagulation modes, Effect levels, power maximums (wattages) and voltage maximums. The User Manual remains the same in the statement to the physician: "The power output setting should be set as low as possible for the desired tissue affect. The purpose of this is to help reduce the potential for capacitive coupling and inadvertent burning at higher wattages/voltages."

BiClamp, APC, and Argon-Assisted Modes:
The modified ESU has the same cut and coagulation modes, Effect levels, power maximums (wattages) and voltage maximums specific to BiClamp, APC, and Argon-Assisted Modes. The User Manual remains the same in the statement to the physician: "The power output setting should be set as low as possible for the desired tissue affect. The purpose of this is to help reduce the potential for capacitive coupling and inadvertent burning at higher wattages/ voltages."

The ENDO CUT is a function in which the incision is automatically controlled in such a way that alternating short cuts are combined with soft coagulation. Although both of these modes were available on the original 510(k) ESU, the product was not initially launched on the marketplace with this combination function available. The predicate ESU has this feature specified as ENDO CUT I and ENDO CUT Q and has been in use for approximately two years. The modified ESU will continue with these same features except for slight differences as described below.

Differences

Monopolar Modes.
The ENDO CUT function was modified to more consistently emulate the original ENDO CUT technology from the ERBE ICC Series (Models) of ESUs. The ENDO CUT program, "I" (for use with needle instruments), has the same settings as the predicate product. The ENDO CUT program, "Q" (for use with loop instruments), has modified default settings from the predicate product. The control/ regulation of the ENDO CUT Q Mode was improved based on the field experience of the predicate Mode. These modifications do not affect the safety or efficacy of the VIO 300 D ESU. The labeling reflects the changes.

Bipolar Modes:
The modified ESU has two additional modes than in the predicate ESU. Additional modes were added per feedback from the physicians. A Bipolar Cut + mode and a Bipolar Soft Coag + mode were added for greater flexibility of use with Bipolar resection instruments. The addition of these modes does not affect the safety or efficacy of the modified ESU. The labeling reflects the changes.

BiClamp, APC, and Argon-Assisted Modes:
A modification was completed on the internal hardware of the high frequency (HF) generator printed circuit board (PCB). An additional decoupling capacitor was added on the HF-generator board to reduce the neuromuscular stimulation (NMS) effect during APC Pulsed Mode usage. Many of the gastrointestinal (GI) operative procedures are completed under minimal usage of anesthesia; therefore, the additional capacitor will assist in reduction of NMS during the usage of the APC Pulsed Mode. While NMS is a known issue with all high frequency electrical current generators, the APC Pulsed Mode is ideal for some operative procedures and the addition of the capacitor lowers the susceptibility of patients to NMS during use of the mode.

All the unit modifications have been verified or validated in design control.

K060484

510K SUMMARY

Page 4 of (4)

Conclusion:

The ERBE VIO ESU (Model VIO 300 D) has the same intended use, principles of operation, and technological characteristics as the predicate ESU in the previously cleared 510(k). The main modifications in the ESU reflect an ongoing commitment by ERBE to satisfy customer feedback. In conclusion, there are no issues with the ERBE VIO ESU (Model VIO 300 D) that would raise additional safety or efficacy issues when compared to the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2006

ERBE USA, Incorporated
c/o Regulatory Resources Group, Inc.
Ms. Julie Stephens
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K060484
Trade/Device Name: ERBE USA Inc. – ERBE VIO ESU (Model VIO 300 D)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 23, 2006
Received: February 27, 2006

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807), labeling (21 CFR Part 801), good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-[illegible] or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060484

Device Name: ERBE USA Inc. ERBE VIO ESU (Model VIO 300 D)

Indications For Use:

The ERBE VIO ESU with Accessories is intended to deliver high frequency (HF) electrical current for the cutting and/or coagulation of tissue.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K060484

FEB 1 6 2006

K060170

510K SUMMARY

Page 1 of 2

Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	Julie Stephens, President/Consultant Regulatory Resources Group, Inc.
510(k) Number:	
Date Prepared:	January 20, 2006
Common Name:	Bipolar Electrosurgical Open and Laparoscopic Instruments
Trade/Proprietary Name:	ERBE BiClamp™ Open and Laparoscopic Instruments
Classification Name:	Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400) and Gynecologic electrocautery and accessories (21 CFR Part 884.4120)
Product Code:	GEI and HGI
Legally Marketed Predicate Devices:	ERBE BiClamp™ Open and Laparoscopic Instruments, 510(k) Number: K033421 Valleylab Inc. LigaSure™ Open and Laparoscopic Instruments, 510(k) Number: K981916

Device Description:

The ERBE BiClamp™ Open and Laparoscopic Instruments are used with an ERBE VIO Electrosurgical Generator (ESU) System having the Optional Bipolar Mode, BiClamp. High Frequency (HF) energy from the ESU is delivered through the jaws of the ERBE BiClamp™ Instruments to coagulate/desiccate tissue. The ERBE BiClamp™ Open Instruments are made of stainless steel with plastic and ceramic insulation except at the jaw surfaces (which isolates the energy to only the jaw surfaces). The ERBE BiClamp™ Open Instruments range in size from 200 mm (7.9 inches) to 270 mm (10.6 inches) in length with bent jaws that have a smooth surface. The ERBE BiClamp™ Laparoscopic Instruments are made of metals and plastics with the electrical energy isolated to the jaws. They have various jaw types, which are standard in the industry. The ERBE BiClamp™ Laparoscopic Instruments have a 5 mm outside diameter (O.D.) and a 340 mm (13.4 inches) working length. The instruments are provided non-sterile and are reusable (Note: The cleaning and sterilization processes have been validated and are provided in the Notes on Use to the customer.).

Intended Use:

The ERBE BiClamp™ Open and Laparoscopic Instruments are intended for use in general surgery, laparoscopic gynecologic urological, and thoracic procedures where fusion of vessels or tissues is desired. The devices can be used on vessels up to 7 mm and bundles as large as will fit in the jaws of the instrument. A vessel fusion is created by the application of bipolar electrosurgical RF energy (coagulation) to the vessels placed between the jaws of the instrument.

The ERBE BiClamp™ Open and Laparoscopic Instruments are designed for use with an ERBE VIO Electrosurgical Generator (ESU) System having an Optional Bipolar Mode/ BiClamp™

upgrade and the multi-function receptacle. Not recommended for use with other manufacturer's generators

The indications for use with Open Instruments include: general surgery, gynecologic, urological, and thoracic procedures where fusion of vessels and tissue bundles is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), Nissen fundoplication, adhesiolysis (lysis of adhesions), oophorectomy, etc.

The indications for use with Laparoscopic Instruments include: all laparoscopic procedures (including gynecologic, general, urological, and thoracic surgery) where fusion of vessels or tissue bundles is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies (gall bladder procedures), Nissen fundoplication, adhesiolysis (lysis of adhesions), oophorectomy, etc.

CAUTION: Vessel fusion can be affected by patient factors such as age, elasticity of vessels, thickness of vessel walls, etc.; therefore, the physician should review each vessel fusion for seal integrity. This device is not effective for use in tubal sterilization/tubal coagulation for sterilization purposes.

Similarities and Differences of the Proposed Devices to the Predicate Devices Comparison/Substantial Equivalence):

Similarities
The ERBE BiClamp™ Open Instruments have similar physical and dimensional characteristics as the predicate devices. They have the same basic technological characteristics and the intended use is the same. There are no changes to the ERBE BiClamp™ Laparoscopic Instruments.

Differences within this 510(k)
The ERBE BiClamp™ Open Instruments are different in that the jaws have a sealed ceramic coating around the outside jaw area. This new coating around the outside of the jaws gives the instrument a greater resistance to hospital cleaning and sterilization techniques. The jaw area has the greatest susceptibility to wear due to the removal of blood and tissue There are no changes to the ERBE BiClamp™ Laparoscopic Instruments.

All the instrument design changes have been verified or validated in design control by ERBE Elektromedizin GmbH.

Conclusion:

The ERBE BiClamp ™ Open and Laparoscopic Instruments have the same intended use, principles of operation, and technological characteristics as the predicate devices that were previously cleared for market in a 510(k).

The ERBE BiClamp™ Open Instruments differ only in that they have a sealed ceramic coating around the outside of the jaw area that has a greater durability with regards to cleaning and sterilization.

In conclusion, there are no issues with the ERBE BiClamp™ Open and Laparoscopic Instruments that would raise additional safety or efficacy issues when compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 6 2006

ERBE USA, Inc.
c/o Ms Julie Stephens
Consultant
Regulatory Resources Group, Inc.
111 Laurel Ridge Drive
Alpharetta, Georgia 30004

Re: K060170
Trade/Device Name: ERBE BiClamp™ Open and Laproscopic Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 20, 2006
Received: January 25, 2006

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060170

Device Name. ERBE BiClamp™ Open and Laparoscopic Instruments

Indications For Use:

The ERBE BiClamp™ Open and Laparoscopic Instruments are intended for use in general surgery, laparoscopic, gynecologic, urological, and thoracic procedures where fusion of vessels or tissues is desired. The devices can be used on vessels up to 7 mm and bundles as large as will fit in the jaws of the instrument. A vessel fusion is created by the application of bipolar electrosurgical RF energy (coagulation) to the vessels placed between the jaws of the instrument.

The ERBE BiClamp™ Open and Laparoscopic Instruments are designed for use with an ERBE VIO Electrosurgical Generator (ESU) System having an Optional Bipolar Mode/ BiClamp™ upgrade and the multi-function receptacle. Not recommended for use with other manufacturer's generators.

The indications for use with Open Instruments include: general surgery, gynecologic, urological, and thoracic procedures where fusion of vessels and tissue bundles is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), Nissen fundoplication, adhesiolysis (lysis of adhesions), oophorectomy, etc.

The indications for use with Laparoscopic Instruments include: all laparoscopic procedures (including gynecologic, general, urological, and thoracic surgery) where fusion of vessels or tissue bundles is performed including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholecystectomies (gall bladder procedures), Nissen fundoplication, adhesiolysis (lysis of adhesions), oophorectomy, etc.

CAUTION: Vessel fusion can be affected by patient factors such as age, elasticity of vessels, thickness of vessel walls, etc.; therefore, the physician should review each vessel fusion for seal integrity. This device is not effective for use in tubal sterilization/tubal coagulation for sterilization purposes.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number_____

K024047

510K SUMMARY

JAN 0 8 2003

Applicant:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person for ERBE USA:	Julie Stephens Consultant/President Regulatory Resources Group, Inc.
Contact Information:	550 Belgrave Lane Tucker, GA 30084 Tel: 770-923-7219 Fax: 770-216-1530
Date Prepared:	12/06/02
Common Name:	Argon Plasma Coagulator (APC) System
Trade/Proprietary Name:	ERBE VIO APC (Model APC 2) with Accessories

Note: VIO stands for Variable Cut and Coagulation.

Classification Name:	Electrosurgical cutting and coagulation device and accessories (21CFR878.4400)
Product Code:	79GEI
Legally Marketed Predicate Device:	ERBE Argon Plasma Coagulator (Model APC 300) and Accessories 510(k) Number: K963189

Device Description:

The ERBE Model APC 2 with Accessories is an argon plasma coagulation system and is used in conjunction with an ERBE VIO Electrosurgical Unit (ESU). The ESU provides high frequency (hf) voltage to electrically charge argon gas from the APC unit to form plasma in the gas stream when in close proximity to tissue. Current density upon arrival at the tissue surface from an APC instrument (applicator or probe) causes coagulation. The APC with the ESU has a color monitor display that provides the user with an on-screen tutorial as well as setting and operational information. The VIO APC/ESU system has various argon as well as argon assisted coagulation and cut modes. These modes have defined effect levels to provide the physician flexibility in interventional applications. Software in the ESU controls the microprocessor chip in the APC unit and APC Handles. The VIO ESU/APC system is programmable and has error monitoring features. There is an ERBE Communications Bus (ECB) Cable for the ESU to

communicate with the APC unit. A Pressure Reducer with Sensor is provided to regulate the argon gas going into the APC unit. Two types of APC Handles are available to activate the system. One of the Handles has a "ReMode" feature so that the physician can change between two pre-programmed modes via the Handle instead of having to touch the display screen. Specific technical information on the APC and Accessories can be found in Section IV. The APC unit and these accessories are supplied non-sterile and are reusable. Cleaning/Disinfection and as applicable sterilization instructions are provided in the respective User Manual or Notes on use. See Device Labeling in Section V, Attachment 2 An APC Membrane Filter is also apart of the system. A Filter is to be used for each case/interventional application. The Filter is connected between the APC unit (at the argon gas port) and an APC Handle or Connector Hose. The Filter creates a barrier to protect the APC unit from potential contamination. Filters are supplied sterile by means of ethylene oxide and are disposable (single use). They are contract manufactured and the sterilization cycle has been validated. See specific technical information in Section IV and general use information in the Notes on use in Section V, Attachment 1 for the Filter (Note: It is the same Filter used on the predicate device.).

Intended Use:

The ERBE VIO APC with Accessories is intended to deliver argon gas for argon plasma coagulation of tissue when used in conjunction with a compatible ERBE VIO Electrosurgical Generator (ESU) and applicators or probes.

Similarities and Differences of the Modified Device to the Current Device (Predicate Comparison/Substantial Equivalence):

The ERBE VIO APC (Model APC 2) with Accessories has the same intended use, principles of operation, and technological characteristics as the predicate APC in the previously cleared 510(k). Also, materials, size, protective circuits, performance characteristics, packaging, and labeling (except in the descriptions of the specific user instructions) are the same or similar.
Changes involve having an on-screen tutorial and interface display through the ESU for the APC. The modification also includes having the software of the ESU control the APC unit. In comparison to the predicate, other changes involve the ESU providing all the power to the APC through built in "HF Contacts" in the case of the units with footswitch activation being directly through the ESU. Furthermore, the gas flow rate range was made slightly lower with a one second shorter purge time. Modifications to the APC unit also include slight variations to existing modes and more effect levels over larger voltage ranges. All of the APC unit changes were done to have a user-friendlier platform with a less complicated system but provide the physician more flexibility in interventional applications. The specifics of the similarities and differences of the modes can be found in the Comparison Table. Technical information on the modes can be found in the APC 2 User Manual in Section V, Attachment 2. For the accessories a Sensor was added to the Reducer and a "ReMode" button was added to a Handle. The Sensor provides the VIO ESU/APC system with in-put gas pressure data. The

"ReMode" button on the VIO APC Handle allows the physician to change between modes without having to touch the monitor of the equipment during a procedure. The performance standards/tests used/met were AAMI/ANSI HF 18, Electrosurgical Devices; EN 60601-1/IEC 60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety; EN 60601-1-2/IEC 60601-1-2, Medical Electrical Equipment Part 1: General Requirements for Safety; 2. Electromagnetic Compatibility Requirements and Tests; EN 60601-2-2/IEC 60601-2-2, Medical Electrical Equipment Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment; and EN 60529, Degrees of Protection Provided by Enclosures (IP Code).
The software of VIO ESU controls the microprocessor chip in the APC 2 and APC Handles. It was upgraded to perform all the features/functions of the any compatible equipment. The Software is revision 1.1.2. General Principles of Software Validation; Final Guidance for Industry and FDA Staff, 01/11/02; Guidance for FDA Reviewers and Industry, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, 05/29/98; and EN 60601-1-4/IEC 60601-1-4, Medical Electrical Equipment Part 1: General Requirements for Safety, 4. Collateral Standard: Programmable Electrical Medical Systems were followed. Per the FDA Software Guidance Documents the software was determined to be a moderate level of concern.

Conclusion:

The 510(k) Guidance Document for General Surgical Electrosurgical Devices, 5/10/95 was followed for this submission. The Risk Analysis method used to assess the impact of the modification on the device performance and its components followed EN 1441: 1998, Medical Devices Risk Management. All of the changes were verified or validated. The changes did not raise safety or efficacy concerns nor adversely affect safety or effectiveness. That is the modified device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 8 2003

ERBE USA, Inc.
c/o Ms. Julie Stephens
Regulatory Resources Group, Inc.
550 Belgrave Lane
Tucker, Georgia 30084

Re: K024047
Trade/Device Name: ERBE VIO APC (Model APC 2) with Accessories
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 6, 2002
Received: December 9, 2002

Dear Ms. Stephens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594 4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K024047

DEVICE NAME: Argon Plasma Coagulator (APC) System (VIO APC with Accessories)

INDICATIONS FOR USE:

The ERBE VIO APC with Accessories is intended to deliver argon gas for argon plasma coagulation of tissue when used in conjunction with a compatible ERBE VIO Electrosurgical Generator (ESU) and applicators or probes.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K024047

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER P
IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-
(Per 21 CFR 801.109) (Optional Forma

K072404

ERBE USA Incorporated **CONFIDENTIAL**
Abbreviated 510(k) – ERBE ERBEJET® 2 System

510K SUMMARY

OCT 3 1 2007

Submitted By:	ERBE USA, Inc. 2225 Northwest Parkway Marietta, GA 30067 Tel: 770-955-4400 Fax: 770-955-2577
Contact Person:	John Tartal QA/RA Manager
Date Prepared:	August 23, 2007
Common Name:	Water Jet Dissector
Trade/Proprietary Name:	ERBE ERBEJET® 2 System
Classification Name:	Jet Lavage (21 CFR Part 880.5475)
Product Code:	FQH
Legally Marketed Predicate Devices:	ERBE Helix Hydro-Jet™ System, 510(k) Numbers: K033590; K022613; K012464

Device Description:

The ERBEJET® 2 System delivers pressurized normal saline solution (0.9% saline solution for irrigation) to cut and dissect soft tissue. The ERBEJET® 2 Unit together with its accessories is an active invasive surgical product. The sterile normal saline solution is the "cutting medium" which is projected under pressure through a nozzle. The pressure is generated by a sterile single-use double piston Pump Cartridge and is controlled by means of a Footswitch. The Footswitch has a "ReMode" button that allows the user to switch between two established or "set" programs during the surgical procedure. The ERBEJET® 2 Unit has a display screen that allows the user to adjust the desired pressure settings using effect levels (1 to 80). The user may use the BASIC program that comes preprogrammed or set up to nine additional personalized programs. The cutting medium is isolated from the pressure generation Unit (i.e. the ERBEJET® 2 Unit) except at the sterile Pump Cartridge. A range of Applicators with a nozzle diameter of 120 µm is available for a wide range of applications. An integrated suction function (i.e. the Suction Module, Model ESM 2 which is separate and optional) can be used with the Unit and is adjustable up to -12 psi. Settings for the suction are adjusted on the display screen of the ERBEJET® 2 Unit.

Intended Use:

The ERBEJET® 2 System is intended for the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as endoscopic surgery.

510K SUMMARY

Similarities and Differences of the Proposed Devices to the Predicate Devices Comparison/Substantial Equivalence):

Similarities
The ERBEJET® 2 System has the same indications for use as the predicate device. The mechanical and technical aspects of creating the pressurized "cutting medium" have changed; however, the performance (i.e. the pressure and volume flow) is substantially equivalent. See Section I, Chart on I-10 as well as Section III, Comparison of System Outputs and Performance Testing. The Applicators are similar to the predicate device with slight differences. See Section III, Comparison Table. However, the volume flow and pressures through the nozzle are equivalent. Under testing, the ERBEJET® 2 System shows improved linear distribution than the predicate device. See Section I, Chart on I-10. Although the suction pump (i.e. Suction Module, Model ESM 2) is separate from the ERBEJET® 2 Unit, the functions are integrated into the ERBEJET® 2 Unit via its display screen which is equivalent to the predicate device. While both systems have a display screen, the display of the ERBEJET® 2 Unit is easier for the user to understand and navigate through.

Differences
The ERBEJET® 2 System uses a two head piston Pump Cartridge to create the pressurized "cutting medium" while the predicate device uses a hydraulic piston. The predicate device has a high-pressure range up to 2,175 psi; however, it was determined by user feedback that this high-pressure range was not utilized. The modified device has a high-pressure range up to 1,160 psi (80 bar). With the removal of the large hydraulic piston, the size and weight of the ERBEJET® 2 Unit has decreased substantially and the maintenance of the proposed unit has improved because there is no hydraulic oil to change. The Applicators have differences in materials, which were tested under biocompatibility. See Section III, Biocompatibility. In addition, the Applicators have slight differences in their dimensions. See Section III, Comparison Table. The changes were made as a result of user feedback. There is a small amount of fluid, less than 0.2 ml, released at the end of activation with the ERBEJET® 2 System due to the way the flow shutoff valves close off. Conversely, the Helix Hydro-Jet has shown almost no water released at the end of activation. No safety or efficacy issues are expected from the release of the small amount of residual fluid at the end of activation with the ERBEJET® 2 System.

The ERBEJET® 2 System has been verified or validated in design control by ERBE Elektromedizin GmbH.

Conclusion:

The ERBEJET® 2 System has the same intended use, principles of operation, and technological characteristics as the predicate device. The ERBEJET® 2 System is smaller and easier to use. In conclusion, all the changes were verified or validated. As a result, the changes did not raise safety or efficacy concerns nor adversely affect safety or effectiveness.

COMPARISON TABLE

Characteristics	Predicate Device	Proposed Device
Manufacturer	HumanMed AG [Used to be Andreas Pein Medizintechnik GmbH]	ERBE Elektromedizin GmbH
510(k) Applicant	ERBE USA, Inc and Andreas Pein Medizintechnik GmbH	ERBE USA, Inc.
510(k) Number	K033590; K022613; K012464	Pending
Classification Regulation Product Code, Name	Class II, 21 CFR 880.5475 FQH, Jet Lavage	Same
Device Name	Helix Hydro-Jet™ System [Includes Fluid Cartridge, Applicators, etc.]	ERBEJET® 2 System [Includes Pump Cartridge, Applicators, Separate/Optional Suction Module ESM 2, etc.]
Indications For Use	The Helix Hydro-Jet™ is intended for the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as endoscopic surgery.	Same
Materials		
• Unit	Metal Sheet, Glass Display Screen, Plastics, Wiring	Same
• Components		
▫ Connecting Cables	Insulation Plastic, Wiring, Metals	Same
▫ Footswitch	Aluminum, Plastics, Insulation Plastics, Rubber	Same
▫ Fluid (Application) Cartridge	0.9% Normal Saline Solution, Plastics (Polyethylene), Silicone	Not Applicable
▫ Pump Cartridge	Not Applicable	Plastics (PA, TPE, PC, PVC), Silicone
▫ Applicators	Plastics (PEEK, PA, PVC), Stainless Steel, Silicone, Synthetic Jewel (Corundum)	Plastics (ABS, PA, PVC), Stainless Steel, Silicone, Rubber, Synthetic Jewel (Corundum)
▫ Suction Module (ESM 2)	The suction system of the Helix Hydro-Jet™ is integrated inside the Unit's case (see above).	Metal Sheet, Plastics, Wiring

COMPARISON TABLE

Characteristics	Predicate Device	Proposed Device
▫ Suction Accessories	Container and Top: Polycarbonate and thermoplastic elastomer Bag: Two layers (Polyethylene inner lining with polypropylene) Hose: Silicone, Rubber O-rings Filter: Not Applicable Switching Valve: Not Applicable Rails & Brackets: Not Applicable	Container: Shock-resistant polycarbonate Top: Reinforced polyamide with santoprene seal Bag: Three layers for durability and odor protection (polyethylene/ polyamide / polyester) Hose: Silicone, Rubber O-rings Filter: Plastics Switching Valve: Plastics Rails & Brackets: Aluminum Note: The suction accessories are manufactured by Medela AG in Switzerland (see additional information at the end of the Table).
Physical and Dimensional Attributes		
• Unit		
▫ Length	13.8" (35 cm)	14.6" (37 cm)
▫ Width	13.8" (35 cm)	16.1" (41 cm)
▫ Height	4.0' (122 cm)	5.1" (13 cm)
▫ Mounting	Included, 19.6" (50 cm) x 19.6" (50 cm) [Base including wheels]	Mountable to VIO Cart or Boom
▫ Weight	163 lbs (74 kg)	24.3 lbs (11kg)
• Components		
▫ Connecting Cables	Main Cable (Power Cord), UL-Version, Length 4 m (13.2') Not Applicable – Suction is integrated inside the Unit	Same ECB Connecting Cable, Connects ERBEJET 2 with Suction Module, ESM 2
▫ Footswitch	One Pedal Footswitch, AP and IP X8 Equipment	One Pedal Footswitch, AP and IP X8 Equipment, with ReMode
▫ Fluid Cartridge	Sterile 0.9% Normal Saline Solution in Plastic Bottle, 485 ml	Not Applicable (see Pump Cartridge)

COMPARISON TABLE

Characteristics	Predicate Device	Proposed Device
▫ Pump Cartridge	Not Applicable (see Fluid Cartridge)	User connects Sterile 0.9% Normal Saline Solution for Irrigation to Pump Cartridge; Saline is purchased separately from other sources
▫ Applicators	Applicator, Blunt Dissector, Outer Diameter (OD) 5mm x Length 180mm, Curved Tip	Same except Length 183mm
	Applicator, Blunt Dissector, Outer Diameter (OD) 5mm x Length 336mm, Curved Tip	Same
	Applicator with Suction, Length 60 mm Flexible Sheath/Rigid Tip	Same - except Length 65 mm
	Applicator with Suction, Outer Diameter (OD) 6 mm x Length 300 mm Rigid Sheath/Tip	Same - except Length 306 mm
	Applicator with Suction, Outer Diameter (OD) 2.6 mm x Length 60 mm Bayonet Sheath/Tip	Same - except O.D. 2.8 mm and Length 90 mm
▫ Suction System	Integrated within the Helix Hydro-Jet Unit	Integrated for use with the ERBEJET 2 Unit but separate/ optional module - ESM 2
	Suction Container (2,000 ml)	ESM Suction Container (2,000 ml)
	Suction Bag (2,000 ml)	ESM Suction Bag (2,000 ml)
	Suction Container Top (included with Suction Container above)	ESM Suction Container Top (sold separately from Container)
	Suction Hose	ESM Suction Hose, Length 30 cm
	Not Applicable	ESM Membrane Filter, 0.3 µm
	Not Applicable	Switching Valve w/ Suction Hoses & Mounting Bracket
	Not Applicable	Mounting Bracket to Connect to Side Rails
	Not Applicable	Brackets/Side Rails, Length 260 mm and 390 mm
Energy Delivered	Pressurized sterile saline for cutting and dissecting	Same
Supply Voltage and Current	100-120 V; 10 A	120-240 V; 3 A
Frequency	60 Hz	Same

COMPARISON TABLE

Characteristics	Predicate Device	Proposed Device
Pressure Range	1 to 2,175 psi	14.5 to 1,160.3 psi
Suction Range	-1.45 to -11.6 psi (-12 psi on display)	Same
Nozzle Diameter	120 µm	Same
Volume Flow	1 to 55 ml/min (As measured within same pressure range as the proposed device)	1 to 55 ml/min
Target Population	Patients requiring open or endoscopic surgery in neurosurgery and in and around the abdomen	Same
Anatomical Sites	Soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as endoscopic surgery	Same
Condition Provided and Method of Sterilization As Applicable		
• Unit, Connecting Cables, Footswitches	Non-Sterile, Reusable	Same
• Fluid Cartridge	Sterile, Single-Use, Radiation (R)	Not Applicable
• Pump Cartridge	Not Applicable	Sterile, Single-Use, Radiation (R)
• Applicators	Sterile, Single-Use, Ethylene Oxide (EO)	Same
• Suction System Unit/Module Bags Containers and Hoses	Within Helix Unit (see above) Non-Sterile, Disposable Non-Sterile, Reusable	Non-Sterile, Reusable Same Same (includes Brackets/Rails)
Performance Standards Met	EN 60601-1; UL 2601-1; EN 60601-1-2; IEC 60529 (Footswitch Only)	EN 60601-1; UL 60601-1; EN 60601-1-1; EN 60601-1-2; EN 60601-1-4; EN 60601-1-6; EN ISO 10079-1; IEC 60529 (Footswitch Only)
Other Standards Used or Applied/Met	ISO 10993-1; ISO 10993-4; ISO-10993-5; ISO 10993-10; ISO 10993-11; EN 556; EN 980; EN 868-1; EN 550; EN 552; EN 1441	Same except for replaced or newer standards: ISO 11607; ISO 14971

COMPARISON TABLE

Characteristics	Predicate Device	Proposed Device
FDA Guidance Documents Used	• Not Known • General Principles of Software Validation, Version 1.1, dated June 9, 1997 • Guidance for FDA Reviewers and Industry; Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 29, 1998	• Guidance Document for Powered Suction Pump 510(k)s: Sep. 30, 1998 • General Principles of Software Validation; Final Guidance for Industry and FDA Staff; Jan. 11, 2002 • Guidance for FDA Reviewers and Industry; Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; May 11, 2005
Packaging and Labeling	▪ Unit ▫ Unit Label ▫ Instruction Sheet/Quick Guide ▫ User Manual ▪ Components ▫ Not Applicable ▫ Not Applicable ▫ Applicators Outer Package Labels ▫ Applicators Notes on Use Labeling ▫ Fluid Cartridge Outer Package Labels ▫ Fluid Cartridge Notes on Use Labeling ▫ Not Applicable ▫ Not Applicable ▫ Suction Accessories Outer Package Labels ▫ Not Applicable	▪ Unit ▫ Unit Label ▫ Not Available ▫ User Manual ▪ Components ▫ ESM 2 Module Label ▫ ESM 2 User Manual ▫ Applicators Outer Package Labels ▫ Applicators Notes on Use Labeling ▫ Not Applicable ▫ Not Applicable ▫ Pump Cartridge Outer Package Labels ▫ Pump Cartridge Notes on Use Labeling ▫ Suction Accessories Outer Package Labels ▫ ESM 2 Filter Package Label

Suction Accessories:
Medela AG 3002807523 in Switzerland has 510(k)s for their "powered suction pumps" under the product code "BTA" [510(k) # K061205 for the Vario 8/18ci Systems and 510(k) # K043544 for the Dominant 35c/i System] which includes their suction accessories. The ESM 2 suction module is designed and manufactured by ERBE Elektromedizin GmbH and distributed by ERBE USA, Inc. The suction accessories that are being recommended and distributed for use with the ESM 2 suction module are the Medela AG suction accessories as designated under the Medela AG 510(k)s.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 1 2007

ERBE USA Inc.
% Mr. John Tartal
QA/RA Manager
2225 Northwest Parkway
Marietta, Georgia 30067-9317

Re. K072404
Trade/Device Name: ERBE USA, Inc.'s ERBEJET® 2 System
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet lavage
Regulatory Class: II
Product Code: FQH
Dated: August 23, 2007
Received: August 27, 2007

Dear Mr. Tartal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 072404

Device Name: ERBE USA, Inc.'s ERBEJET® 2 System

Indications For Use:

The ERBEJET® 2 System is intended for the cutting and dissection of soft tissue in neurosurgery and soft tissue such as the liver, kidney, etc. within the abdomen, including Total Mesorectal Excision (TME), in open as well as endoscopic surgery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K 072404

CERTIFICATE

Number: 2247808

The management system of the organization(s) and locations mentioned on the addendum belonging to:

ERBE Elektromedizin GmbH

Waldhornlestrasse 17
72072 Tübingen
Germany

Manufacturer DUNS 316116623

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Australia:	Therapeutic Goods (Medical Devices) Regulations, 2002 and Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil:	RDC ANVISA N. 16/2013, 23/2012 and 67/2009
Canada:	Medical Devices Regulations - Part 1- SOR 98/282
Japan:	MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States:	21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:
Development, production, sales and service of reusable and disposable medical devices: Electrosurgical generators, smoke evacuation units, electrosurgical instruments, cables, adapters, patient plates, electrodes, handles and accessories for electro surgery (carts, foot switches, fastening sets), argon plasma coagulation units, argon plasma coagulation probes and applicators, irrigation pump and irrigation pump accessories (tubing sets, suction containers, foot switch, adapter for endoscopes), water jet surgery units, suction units, applicators, probes and accessories for water jet surgery (pump cartridges, foot switches), cryosurgery units, cryo probes and accessories for cryosurgery (carts, foot switches, extension cables, gas bottle adapters, valves, filters), physical therapy units.

Certificate expiry date: 2023-07-01
Certificate effective date: 2020-07-13
Certified since: 2020-07-13

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https://www.dekra-product-safety.com/en/certified-organizations

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

ADDENDUM

To certificate: 2247808

The management system of the organization(s) and/or location(s) of:

ERBE Elektromedizin GmbH

Waldhornlestrasse 17
72072 Tübingen
Germany

Certified organization(s) and/or locations:

	Different scope
ERBE Elektromedizin GmbH Rudolf-Diesel-Str. 29 72414 Rangendingen Germany DUNS: 313482108	Development and production of reusable and disposable medical devices: Electrosurgical instruments, electrodes, handles and accessories for electro surgery (carts, foot switches, fastening sets), argon plasma coagulation probes and applicators, irrigation pump accessories (tubing sets, suction containers, foot switch, adapter for endoscopes), applicators, probes and accessories for water jet surgery (pump cartridges, foot switches), probes and accessories for cryosurgery (carts, foot switches, extension cables, gas bottle adapters, valves, filters).

Addendum expiry date: 2023-07-01
Addendum effective date: 2020-07-13

EG-KONFORMITÄTSERKLÄRUNG

EC DECLARATION OF CONFORMITY | DÉCLARATION DE CONFORMITÉ CE

im Sinne des Anhanges II der EG-Richtlinie über Medizinprodukte 93/42/EWG und des Anhanges VI der EG-Richtlinie 2011/65/EU
according to Annex II of Directive 93/42/EEC concerning Medical Devices and according to Annex VI of Directive 2011/65/EU
suivant Annexe II des Directives Européennes relative aux dispositifs médicaux 93/42/CEE et suivant Annexe VI des Directives Européennes 2011/65/UE

Hersteller:	Erbe Elektromedizin GmbH
Manufacturer:	Waldhörnlestraße 17
Fabricant:	D 72072 Tübingen

Wir erklären in alleiniger Verantwortung, dass das Produkt
Hereby we declare under our sole responsibility, that the product
Nous déclarons sous notre seule responsabilité que le produit

HF-Chirurgiegerät / HF surgical unit / Bistouri électronique

Model	REF	SN	Software
VIO 300D	10140-100	≥ 11287577	V2.1.0, V2.1.1, V2.1.3, V2.1.4, V2.2.1, V2.3.0, V2.3.4, V2.3.5, V2.7.0
VIO 200D	10140-200	≥ 11290636	V2.1.0, V2.1.1, V2.1.3, V2.1.4, V2.2.1, V2.3.0, V2.3.4, V2.3.5

Medizinprodukt der Klasse
Medical Device of Class / Dispositifs Médicaux de Classe **IIb**

Optional mit / optional with / optionnel avec

Model	REF	LOT
VIO Cart	20180-000	≥ A-1015, ≥11296168, ≥VC000001
Basic Cart	20185-100	≥ 11353359
Basic Cart	20185-101	≥ 11353359
Universal Cart	20185-204	≥ 11235126, ≥UC000001
Universal Cart	20185-205	≥ 11235136, ≥UC000001
Cart	20185-202	≥ 11248718
Nervstimulator NT2	10142-000	≥ NT2-005-22-2008

den Bestimmungen der nachstehenden Richtlinien entspricht.
meets the requirements of the following directives.
correspond aux arrêtés des Directives mentionnées ci-après.

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte und Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011
Directive 93/42/EEC of the Council of June 14, 1993 for Medical Devices and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011
Directive 93/42/CEE du Conseil du 14 Juin 1993 relative aux dispositifs médicaux et Directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011

Tübingen, 29.06.2016
Ort, Datum / Place, Date / Lieu, Date

Quality assurance Testing laboratory

Dekra Certification GmbH
Handwerkstraße 15
D 70565 Stuttgart

CE 0124
Benannte Stelle / Notified Body / Organisme notifié
93/42/EWG / 93/42/EEC / 93/42/CEE

12.07.2023
Gültig bis / Valid until / Valide jusqu'à

10140100.M23/18

(Leiter des Qualitätswesens / VP Quality assurance / Chef du Service qualité)

EG-KONFORMITÄTSERKLÄRUNG

EC DECLARATION OF CONFORMITY | DÉCLARATION DE CONFORMITÉ CE

im Sinne des Anhanges II der EG-Richtlinie über Medizinprodukte 93/42/EWG und des Anhanges VI der EG-Richtlinie 2011/65/EU
according to Annex II of Directive 93/42/EEC concerning Medical Devices and according to Annex VI of Directive 2011/65/EU
suivant Annexe II des Directives Européennes relative aux dispositifs médicaux 93/42/CEE et suivant Annexe VI des Directives Européennes 2011/65/UE

Hersteller:	Erbe Elektromedizin GmbH
Manufacturer:	Waldhörnlestraße 17
Fabricant:	D 72072 Tübingen

Wir erklären in alleiniger Verantwortung, dass das Produkt
Hereby we declare under our sole responsibility, that the product
Nous déclarons sous notre seule responsabilité que le produit

NESSY® RePlate, RU

Model	**REF**	**LOT**
NESSY® RePlate 200	20193-090	≥ C1

Medizinprodukt der Klasse *Medical Device of Class / Dispositifs Médicaux de Classe*	**IIb**

Verwendbar mit / Use with / utilisable avec Model	REF
NESSY® RePlate Fixierung / NESSY® RePlate Fixation/ NESSY® RePlate Fixation	20193-091
NESSY® RePlate Kontaktspray	20193-092

Ist enthalten in / is included in / Est contenu dans	REF
NESSY® RePlate kit I / NESSY® RePlate kit I / NESSY® RePlate kit I (the kit I consists of model REF 20193-090; 20193-091 and 20193-092)	20193-093
NESSY® RePlate kit II / NESSY® RePlate kit II / NESSY® RePlate kit II (the kit II consists of model REF 20193-090 and 20193-091)	20193-094

den Bestimmungen der nachstehenden Richtlinien entspricht.
meets the requirements of the following directives.
correspond aux arrêtés des Directives mentionnées ci-après.

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte und Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011
Directive 93/42/EEC of the Council of June 14, 1993 for Medical Devices and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011
Directive 93/42/CEE du Conseil du 14 Juin 1993 relative aux dispositifs médicaux et Directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011

Tübingen, 25.05.2021

Ort, Datum / Place, Date / Lieu, Date

(Leiter des Qualitätswesens / VP Quality assurance / Chef du Service qualité)

Quality assurance
Testing laboratory

Dekra Certification GmbH
Handwerkstraße 15
D 70565 Stuttgart

CE 0124

Benannte Stelle / Notified Body / Organisme notifié
93/42/EWG / 93/42/EEC / 93/42/CEE

26.05.2024

Gültig bis / Valid until / Valide jusqu'à

20193090 M02/21

EC CERTIFICATE

for the Quality Assurance System

according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

ERBE Elektromedizin GmbH

Waldhörnlestraße 17, 72072 Tübingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50954-Z5-00, the decision dated 2018-06-13 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-07-13 to 2023-07-12

Registration No.: 50954-16-04

DEKRA Certification GmbH D-70565 Stuttgart Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-06-13
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Annex to the EC Certificate No. 50954-16-04

Valid from 2018-07-13 to 2023-07-12

Revision status of the annex: 0 dated 2018-07-13

Devices/device categories included in the certificate:

Class II a:

- Tubing set for irrigation pump
- Handle for smoke evacuator
- Irrigation pump
- Instruments for Cryosurgery (cryo probes)
- Suction module, surgical
- Membrane filter-Set
- Instruments for waterjet dissection, pump
- Adapter, electrosurgical unit (adapter for bipolar resection)
- Electrode holder, electrosurgical
- Electrode holder, electrosurgical, sterile
- Electrode, electrosurgical, active electrode, hand actuated
- Electrode, electrosurgical, active electrode, footswitch actuated

Class II b:

- Electrosurgical unit
- Neutral electrodes for electrosurgical, reusable and single use
- Electrode holder, electrosurgical
- Electrode holder, electrosurgical, sterile
- Electrode, electrosurgical, active electrode
- Electrode, electrosurgical, active electrode, sterile
- Electrode, electrosurgical, active electrode, hand actuated
- Electrode, electrosurgical, active electrode, hand actuated, sterile
- Electrode, electrosurgical, active electrode, footswitch actuated
- Electrode, electrosurgical, active electrode, footswitch actuated, sterile
- Electrode, electrosurgical, active electrode, hand actuated, single use
- Adapter for Electrosurgery
- Coagulator unit, argon (argon plasma coagulator)
- Instruments for argon coagulation, single use
- Instruments for argon coagulation, reusable, hand actuated
- Instruments for argon coagulation, reusable, footswitch actuated
- Waterjet dissector
- Instruments for waterjet dissector, single use
- Instruments for waterjet dissector, applicator
- Cryosurgical unit

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2018-06-13
Notified Body ID-number: 0124

Ref. Certif. No.

DK-10368-A2

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE CERTIFICATS D'ESSAIS DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE
CERTIFICAT D'ESSAI OC

Product Produit	**High Frequency Surgical Units : VIO 300D / 300S / 200D / 200S/ APC2**
Name and address of the applicant Nom et adresse du demandeur	**ERBE ELEKTROMEDIZIN GMBH WALDHOERNLESTRASSE 17 D-72072 TUEBINGEN GERMANY**
Name and address of the manufacturer Nom et adresse du fabricant	**ERBE ELEKTROMEDIZIN GMBH WALDHOERNLESTRASSE 17 D-72072 TUEBINGEN GERMANY**
Name and address of the factory Nom et adresse de l'usine Note: *When more than one factory, please report on page 2* Note: *Lorsque il y plus d'une usine, veuillez utiliser la 2ème page*	**ERBE ELEKTROMEDIZIN GMBH WALDHOERNLESTRASSE 17 D-72072 TUEBINGEN GERMANY**
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	**Input:100 - 120 V / 220 - 240 V, 8A / 4A, 50 / 60 Hz, Output VIO300D/300S: 350kHz, max. 375W@500ohm Output VIO200D/200S: 350kHz, max. 200W@500ohm**
Trademark (if any) Marque de fabrique (si elle existe)	**ERBE**
Model / Type Ref. Ref. De type	**VIO 300D, VIO 300S, VIO 200D, VIO 200S, VIO APC2, VEM 2 (where VIO300D represent the max options of all models)**
Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire, peuvent être indiqués sur la 2ème page)	**Also investigated to EN 60601-1: 1990 + A1:1993 + A2:1995 This is an amendment to DK-10368-A2 issue date 2008-04-22 due to alternate transformer, interface board and optocoupler**

A sample of the product was tested and found to be in conformity with Un échantillon de ce produit a été essayé et a été considéré conforme à la	PUBLICATION	EDITION
	IEC 60601-1:1988 + A1:1991+ A2:1995	2nd
	IEC 60601-2-2:1998	3rd

As shown in the Test Report Ref. No. which forms part of this Certificate Comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat	**E176621-A1-CB-2 Amendment 2 issue date 2009-04-30**

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme **National de Certification**

Underwriters Laboratories

Date:
2009-05-04

UL International Demko A/S
Lyskaer 8, P.O. Box 514, DK-2730 Herlev, Denmark
Tel: +45 44856565, Fax: +45 44856500

Signature:

Jan-Erik Storgaard
Certification manager

power your performance.

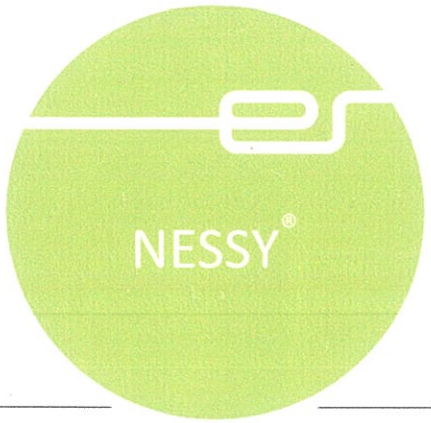
Use of third-party accessories

In order to avoid damage caused by third party accessories and the associated warranty issues, and furthermore to minimize the risk for the patient, ERBE Elektromedizin GmbH recommends the exclusive use of ERBE's own accessories. Only then can the functionality of the equipment be guaranteed.

In case of professional use of the NESSY Omega patient plate, ERBE even guarantees in writing that burns are excluded.

Erbe Elektromedizin GmbH

Customer Support



(7a)

King George's Medical University

Uttar Pradesh, Lucknow - 226 003, India

Department of Trauma Surgery

Date: 15.11.2018 Ref: TS/18/18

TO WHOM SO EVER IT MAY CONCERN

SATISFACTORY PERFORMANCE REPORT

This is to certify that installed Surgical Workstation (including :Electrosurgical Unit, Model – VIO 300 D, Argon Plasma Coagulation, Model – APC2, Waterjet 2, and ERBE Suction Module, Model – ESM 2), High End Electrosurgical Unit with APC and ERBE VIO 300 S installed in our operation theatres & all units are in working condition and we are satisfied with its performance.

S/N	Description	Unit serial number
1-	Art No. 10140-100 Model: VIO 300 D	11429765, 11429770, 11429774, 11429767
2-	Art No. 10134-000 Model: APC 2	11430112, 11430118, 11430121, 11430113
3-	Art No. 10150-000 Model: Waterjet 2	11430129, 11430128
4-	Art No. 10340-000 Model: ESM 2	11429589, 11429587
5-	Art No. 10140-300 Model: VIO 300 S	11427463, 11420830

Yours Truly,

Head of Department of Trauma Surgery
K.G. Medical University
Authorized Signatory

Department of Trauma Surgery
King George's Medical University
Lucknow, Uttar Pradesh

Erbe Medical India Pvt. Ltd.

(78)

Phone Office No. 0522-2256543

King George's Medical University, Lucknow-3 U.P.

DEPARTMENT OF UROLOGY

Ref. No.. 407/Uro

Date 6-11-18

SATISFACTORY PERFORMANCE REPORT

This is to certify that installed Surgical Workstation (Including :Electrosurgical Unit, Model – VIO 300 D, Argon Plasma Coagulation, Model – APC2, Waterjet 2, and ERBE Suction Module, Model – ESM 2) and High End Electrosurgical Unit with APC installed in our operation theatres & is in working condition and we are satisfied with its performance.

S/N	Description	Unit serial number
1-	Surgical Workstation	
A	Electrosurgical Unit Model - VIO 3 Art No. 10160-000	11430179
B	Argon Plasma Coagulation Model – APC3 Art No. 10135-000	11430126
C	Waterjet Model – Waterjet 2 Art No. 10150-000	11426814
D	ERBE Suction Module Model – ESM 2 Art No. 10340-000	11429590
2-	High End Electrosurgical Unit with APC	
A	Electrosurgical Unit Model - VIO 3 Art No. 10160-000	11430182
B	Argon Plasma Coagulation Model – APC3 Art No. 10135-000	11430125
3-	High End Electrosurgical Unit with APC	
A	Electrosurgical Unit Model - VIO 300 D Art No. 10140-100	11447612
B	Argon Plasma Coagulation Model – APC2 Art No. 10134-000	11448243

Yours Truly

3-11-18

Head of Department of Urology
King George's Medical University
Lucknow, Uttar Pradesh

Prof. S. N. Sankhwar
MS (Surg.), MCh(Uro), FICS (Uro)
MIIA, MNAMS, FODIIUM
Head, Department of Urology
King George's Medical University,
Lucknow

Erbe Medical India Pvt. Ltd.

King George's Medical University U.P.
Department of Pediatric Surgery
Lucknow - 226 003, India
e-mail : snkkgmu@rediffmail.com

Ref: 377/2018/Ped Surg

Date: Date: 3.11.2018

SATISFACTORY PERFORMANCE REPORT

This is to certify that installed Surgical Workstation (including Electrosurgical Unit, Model – VIO 300 D, Argon Plasma Coagulation, Model – APC2, Waterjet 2, and ERBE Suction Module, Model – ESM 2) and ERBE VIO 300 S installed in our operation theatres & is in working condition and we are satisfied with its performance.

S/N	Description	Unit serial number
1-	Electrosurgical Unit Model - VIO 300 D Art No. 10140-100	11420024, 11417494, 11447615
2-	Argon Plasma Coagulation Model – APC2 Art No. 10134-000	11418533, 11420045, 11448521
3-	Waterjet Model – Waterjet 2 Art No. 10150-000	11420048, 11409760, 11443773
4-	ERBE Suction Module Model – ESM 2 Art No. 10340-000	11420048, 11413299, 11442443
5-	Electrosurgical Unit Model - VIO 300 S Art No. 10140-300	11444248

Authorized Signatory

Department of Paediatric Surgery
King George's Medical College
Lucknow, Uttar Pradesh

PROF. & HEAD
DEPT. OF PEDIATRIC SURGERY
K.G. MEDICAL UNIVERSITY U.P.
LUCKNOW-226003 U.P. INDIA

Erbe Medical India Pvt. Ltd.

King George's Medical University

Uttar Pradesh, Lucknow - 226003, India

Department of Medical Gastroenterology

e-mail: gastromedicine@kgmcindia.edu

Date: 03/11/2018

Ref No - 560/Medgastro/11/D

Dt — 03/11/2018

SATISFACTORY PERFORMANCE REPORT

This is to certify that installed Surgical Workstation and ERBE VIO 300 S installed in our Endoscopy Room. All units are in working condition and we are satisfied with its performance.

S/N	Description	Unit serial number
1-	Surgical Workstation	
A	Electrosurgical Unit Model - VIO 300 D (10140-100)	11429769
B	Argon Plasma Coagulation Model – APC2 (10134-000)	11427764
C	Waterjet Model – Waterjet 2 (10150-000)	11430130
D	ERBE EIP 2 (10325-000)	11431147
2-	Electrosurgical Unit Model - VIO 300 S (10140-300)	11420832

Authorized Signatory

Department of Gastroenterology

King George's Medical University

Dr. Sumit Ranjan

(D.M. Gastroenterology)

Assistant Professor & Head

Department of Medical Gastroenterology

King George's Medical University

Erbe Medical India Pvt. Ltd.

King George's Medical University, Lucknow, U.P.
Department Of Neurosurgery
Phone No. 0522-2257606, E-mail.: neurosurgerykgmu@gmail.com

Ref No. NS/1737 Date 5/11/19

TO WHOM SO EVER IT MAY CONCERN

SATISFACTORY PERFORMANCE REPORT

This is to certify that installed High End Electrosurgical Unit with APC and ERBE VIO 300 S installed in our operation theatres & all units are in working condition and we are satisfied with its performance

S/N	Description	Unit serial number
1-	High End Electrosurgical Unit with APC	
A	Electrosurgical Unit Model - VIO 300D	11429768
B	Argon Plasma Coagulation Model – APC2	11427438
2-	High End Electrosurgical Unit with APC	
A	Electrosurgical Unit Model - VIO 300 D	11429766
B	Argon Plasma Coagulation Model – APC2	11430114
3-	Electrosurgical Unit Model - VIO 300 S	11424108

Working Satisfactorily
05/11/19

05/11/19

Head Deptt. of Neurosurgery,
K.G's Medical University,
Lucknow.

Head of Neurosurgery Department
K. G. Medical University
Lucknow-226 003

Erbe Medical India Pvt. Ltd.

To
The Principal
Rajarshi Dashrath Autonomous State Medical College,
Ayodhya

Subject: Price offered for the Complete SURGICAL WORK STATION - Electro Surgery Unit with Vessel Sealing , Argon Plasma Coagulation ,Water Jet Technology Suction Module & Smoke Plume Evacuation System

Name of the Equipment : SURGICAL WORK STATION - Electro Surgery Unit with Vessel Sealing , Argon Plasma Coagulation ,Water Jet Technology Suction Module & Smoke Plume Evacuation System

Make & Model: : ERBE Elektromedizin GmbH, Germany

S.L	Description	Value	HSN Code	GST %	GST Value	Total Value
1	**Complete SURGICAL WORK STATION - Electro Surgery Unit with Vessel Sealing , Argon Plasma Coagulation ,Water Jet Technology Suction Module & Smoke Plume Evacuation System**	**7135637**	90189029	12%	**856276.44**	**7991913.44**

BILL OF QUANTITY

1	2	3	4	5		6	7	8	9
		A. High End Electro Surgical Unit							
Sr No	**Art No**	**Item Name**	**Qty**	**Value**	**Qty x Value**	**HSN Code**	**GST %**	**GST Value**	**Total Value**
1	10140-100	ERBE VIO® 300 D Electrosurgical Unit With ERBE VIO® Remode two pedal Footswitch (20189-303), ERBE VIO® One pedal Footswitch (20189-300)	1	1266922	1266922	90189029	12%	152030.64	1418952.64
2	20193-083	Nessy Omega Patient Plate (Single Use) Box of 50 Pcs	2						
3	20190-106	Electro Surgical Pencil - Bx of 10 Pcs	1	3200	3200	90189029	12%	384	3584
4	20195-000	Reusable - Bipolar Forcep Classic Straight Tip 01 mm Blunt Length 190 mm	1	20562.15	20562.15	90189029	12%	2467.458	23029.608
5	20196-055	Reusable - Bipolar connecting cable VIO, ICC, ACC international, for bipolar forceps,length 4 m	1	7103	7103	90189029	12%	852.36	7955.36
		B. VESSEL SEALER							
6	20195 -134	Reusable - Bi clamp Lap forceps, Maryland semi deep, OD 5mm,length 340 mm (Lap Surgery)	1	207397	207397	90189029	12%	24887.64	232284.64
7	20195-202	Reusable - Biclamp 201T- (Open Surgery)	1	124295	124295	90189029	12%	14915.4	139210.4
		C. ARGON PLASMA COAGULATION SYSTEM							
8	10134-000	APC 2 (for VIO) Argon Plasma Coagulation Unit with APC 2 (for VIO) with Pressure Reducer (20134-004)	1	769415.94	769415.94	90189029	12%	92329.9128	861745.8528
9	20132-171	Argon gas cylinder; 5 liter; empty to DIN 477 No. 6 m	1	38258.12	38258.12	90189029	12%	4590.9744	42849.0944
10	20132-200	VIO APC-handle with 3 buttons for APC2	1	65199	65199	90189029	12%	7823.88	73022.88
11	20132-054	APC-Applicator, 5 mm rigid, Length 35 mm with adjustable needle electrode.	1	15912	15912	90189029	12%	1909.44	17821.44
12	20132-056	APC-Applicator, rigid, insulated shaft, Ø 5 mm, 100 mm long,	1	18713	18713	90189029	12%	2245.56	20958.56
		D. WATER JET SYSTEM							
13	10150-000	Erbe Jet 2 with Erbe Jet 2 One Pedal Foot Switch with remode (20150-101	1	3132762	3132762	90189029	12%	375931.44	3508693.44
14	20150-301	Pump Cartridge - Box of 05 Pcs	1	63762	63762	90189029	12%	7651.44	71413.44
15	20150-030	Applicator Straight - L-65MM Dia 06 mm with suction - Box of 05 Pcs	1	77095	77095	90189029	12%	9251.4	86346.4
		E ESM SUCTION 2 MODULE			0			0	0
16	10340-000	ERBE ESM 2 Suction with Suction Hose , ESM Membrane Filter & Suction Container 2.5 ltr	1	283706.38	283706.38	90189029	12%	34044.7656	317751.1456
17	20340-013	Suction bag; 2.5l; disposable; ESM	1	18022	18022	90189029	12%	2162.64	20184.64
18	20340-100	ESM Membrane filter	1	12415	12415	90189029	12%	1489.8	13904.8
		F- SMOKE PLUME EVACUATION SYSTEM							
19	10323-000	IES 3 Smoke Evacuator With One Pedal Foot Switch for IES 3 (20322-101) & Indeginious mobile Trolley for	1	595864	595864	90189029	12%	71503.68	667367.68
20	20323-000	mm	1	23362	23362	901890 9	12%	2803.44	26165.44
21	20323-002	Automatic Activation Device	1	55000	55000	90189029	12%	6600	61600
22	20321-022	Pre Filter for smoke Evacuator (Ctn of 15 Pcs x 3 Box)	1	35200	35200	90189029	12%	4224	39424
23	20323-003 / 006	Lap tubing set IES-3, 3m / 5m for Lap application	1	6570	6570	90189029	12%	788.4	7358.4
24	20323-004	Self sealing water tap for protecting main filter	1	930	930	90189029	12%	111.6	1041.6
25	20323-005	T-Piece for simultaneous application	1	5500	5500	90189029	12%	660	6160
26	20321-009	Suction Hose, with connection dia 22 mm, length 2.7	1	8370	8370	90189029	12%	1004.4	9374.4
27	20321-010	Evacuation funnel, with connection ø 22 mm	1	1402	1402	90189029	12%	168.24	1570.24
		G. IMPORTED VIO CART TROLLEY - VIO SYSTEM + APC 2 + ERBEJET + ESM2 + APC CYLINDER							
28	20180-000	VIO CART System carier for VIO family and modules Dimenssion 680 x 940 x 650 mm (WXHXD) + Fastening Set (20180-131) + Fastening Set (20150-050)	1	278699.36	278699.36	90189029	12%	33443.9232	312143.2832
					7135637		12%	856276.434	**7991913.384**

PEE VEE enterprises
peevee 132@gmail.com, Vijaylko8@gmail.com
City Office : 42, Valmiki Marg, Lalbagh, Hazratganj, Lucknow 226001. U.P. India.
Fac. Address : 2137M(8), Canal Road, Indralok Colony, Krishna Nagar, Lucknow-226023
Contact No. : +91 522-4025629 Mob. : +91 94150-20996, +91 88535-30595

Warranty Period: The main equipment i.e – **10140-100 ERBE VIO 300 D, 10134-000 ERBE VIO APC 2 , 10150-000 ERBE VIO ERBE JET 2 , 10340-000 ERBE VIO ESM 2 &10323-000 ERBE IES 3** is only covered under warranty period for **60 months (05 Years)** under proper use for faulty material or workmanship or manufacturing defect for 60 months (05 Years) from date of the installation. Warranty period doesn't apply on reusable accessories or disposable consumables supplied along with the main unit as they have their standard shelf life. Shelf life declaration regarding reusable Instruments and accessories enclosed

Warranty Condition: The supplier shall not be responsible for any defect or damage caused to the equipment, directly or indirectly, due to mishandling, miss conduct or negligence on the part of the purchaser or his employees. The supplier shall not be responsible for any defect or damage caused to the socket of the equipment, directly or indirectly, due to usage of non-recommended accessories/ instruments. We strongly recommend to use Erbe range of products (accessories/ instruments) only with the main generator to avoid damages & failure of power supply. The warranty will be void in case of failure to operate the equipment as recommended, failure to run the equipment with proper specified utilities or failure to maintain the environmental conditions as recommended. The warranty does not extend to wear & tear parts. During trouble shooting the hospital / User department are requested to inform O.E.M service team thru mail or in writing of any defect in equipment noticed during the warranty period. On receipt of purchaser's written notice, we will immediately try our level best to rectify the fault with the support of O.E.M trained service engineer's team. The option to repair or replace any parts shall be solely rest with the principal O.E.M trained service engineer's team. The hospital/ user department are requested that before receiving any correspondence or confirmation from our O.E.M Sales or trained service engineers team the equipment or any part of the main unit should not be returned or send to anywhere

Comprehensive Maintenance Contract Conditions: After expiry of Warranty Period Comprehensive Maintenance Contract would be performed directly by our O.E.M M/S Erbe Medical India Pvt Ltd

S,L	Year	Rates of CMC after Expiry of Warranty Period for 01 Unit Per Year	Taxes @18%	Total CMC value Including Service Tax per year for 01 Unit without any esclation	Covered Part of Equipment under CMC	Uncovered Part of Equipment under CMC
1	6th - 10th Year	Rs 1,81,500.00 Per Unit Per Year	₹ 32,670.00	Rs 214170 Per Unit Per Year	**10140-100 ERBE VIO 300 D, 10134-000 ERBE VIO APC 2 , 10150 000 ERBE VIO ERBE JET 2 , 10340-000 ERBE VIO ESM 2 &10323-000 ERBE IES 3** Only	**Accessories , Instrument, Foot Pedal, Cart (Reusable / Single Use)**

Supply Period: The complete Equipment with offered accessories will be delievered within 04-05 weeks / as per tender condition from the date of receipt of PO Copy, however will not be liable for delay in transportation direct or indirect due to forced majeure, natural disaster, any strike or lockdown condition , in such case the supply will be executed after the recovery of such issues.

Recurring Accessories required for future to operate Unit: As offered accessories are reusable / single use in nature , hence after usage of their shelf life following accessories will be required in future for performing varrious surgeries, as Erbe Medical India strongly recomends to use only original accessories , third party accessories are not compatible & are reported to be one of the major cause of breakdown of units & warranty will be not cover for damaged sockets for that reason . The prices for essential accessories can be freezed for the period of next 12 months from the date of issuance of PO Copy . **Price Justification of offered accessories attached**

S.L	Item Code	Description	Rates Per Unit	QTY	Total QTY X Basic Price Excluding Gst	GST as per HSN @12%	GST Value	Net Value Including Gst
1	20183-110	Adapter Bipolar Resection; Only for VIO 300 D with MF socket from version 2.2.1 or 1.8.0 (Accessories Reuse)	₹ 69,750	1	₹ 69,750	12%	₹ 8,370.00	₹ 78,120.00
2	20195-202	BiClamp 201 T, bent 18°, smooth, length 200 mm; with connecting cable 4 m and MF plug, with thermal insulation, for open surgical procedures, e.g. intestinal surgery (Instrument Reuse)	₹ 1,24,295	1	₹ 1,24,295	12%	#######	₹ 1,39,210.40
3	20195-204	LAP BiSect Micro, shaft ø 5 mm, length 350 mm; complete instrument (Instrument Reuse)	₹ 2,21,104	1	₹ 2,21,104	12%	#######	₹ 2,47,636.48
4	20195-221	BiClamp 150 C, bent 23°, smooth, length 150 mm; with connecting cable 4 m and MF plug, with ceramic coating, e.g. for thyroidectomy (Instrument Reuse)	₹ 1,22,150	1	₹ 1,22,150	12%	#######	₹ 1,36,808.00
5	20195-134	BiClamp LAP forceps, Maryland, semi-deep ribbed, shaft ø 5 mm, non-adhesive coating, length 340 mm; with connecting cable 4 m and MF plug, complete instrument (Instrument Reuse)	₹ 2,07,397	1	₹ 2,07,397	12%	#######	₹ 2,32,284.64
6	20195-509	Bipolar forceps PREMIUM, straight, tip 1 mm, blunt, angled, length 185 mm (Instrument Reuse)	₹ 48,488	1	₹ 48,488	12%	₹ 5,818.56	₹ 54,306.56
7	20195-541	Bipolar forceps PREMIUM, bayonet, tip 1.2 mm, blunt, length 200 mm; angled downwards (Instrument Reuse)	₹ 63,149	1	₹ 63,149	12%	₹ 7,577.88	₹ 70,726.88
8	20196-055	Bipolar connecting cable, Valleylab and non-Erbe units (2-Pin 28 mm), 4 m; for bipolar forceps with european flat plug (Accessories Reuse)	₹ 7,103	2	₹ 14,206	12%	₹ 1,704.72	₹ 15,910.72
9	20196-118	Bipolar connecting cable, for STORZ resectoscopes, with MF plug, 4 m; for VIO 3 and VIO 300 D from version V.1.6.2 on (Accessories Reuse)	₹ 17,045	1	₹ 17,045	12%	₹ 2,045.40	₹ 19,090.40
10	20183-067	Monopolar adapter, units International ø 8 mm (Bovie Jack); for connecting plug ø 2-7 mm (single-pole) (Accessories Reuse)	₹ 10,169	1	₹ 10,169	12%	₹ 1,220.28	₹ 11,389.28

PEE VEE enterprises
peevee 132@gmail.com, Vijaylko8@gmail.com
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Fac. Address : 2137M(8), Canal Road, Indralok Colony, Krishna Nagar, Lucknow-226023
Contact No. : +91 522-4025629 Mob. : +91 94150-20996, +91 88535-30595

11	20192-113	Monopolar connecting cable, VIO, ICC, ACC, International ø 8 mm (Bovie Jack), 4 m; for CUT and COAG MIS instruments, with connection ø 4 mm (Accessories Reuse)	₹	9,416	1	₹ 9,416	12%	₹ 1,129.92	₹ 10,545.92
12	20192-117	Monopolar connecting cable, VIO, ICC, ACC, International ø 8 mm (Bovie Jack), 4 m; for OLYMPUS polypectomy snares, with connection ø 3 mm (Accessories Reuse)	₹	9,416	1	₹ 9,416	12%	₹ 1,129.92	₹ 10,545.92
13	20190-106	Electrosurgical pencil with 2 buttons, VIO, ICC, ACC, non-Erbe units, International; with connecting cable 3 m, with spatula electrode without protective holster (Accessories Reuse)	₹	3,200	10	₹ 32,000	12%	₹ 3,840.00	₹ 35,840.00
14	20197-094	Nessy Split Return electrode (Accessories Reuse)	₹	25,000	1	₹ 25,000	12%	₹ 3,000.00	₹ 28,000.00
15	20194-078	Return electrode cable, VIO, ICC, ACC, International, 5 m; for Nessy Split (Accessories Reuse)	₹	10,500	1	₹ 10,500	12%	₹ 1,260.00	₹ 11,760.00

Looking forward towards your valuable Purchase Order.

Regards

M/S Pee Vee Enterprises

Authorised Signatory

PEE VEE ENTERPRISES ★ LKO-IN

Encl.: Prequalification (K.G.M.U.-Lucknow Purchase Order Copy, S.G.P.G.I.M.SlUcknow Purchase Order Copy.

PEE VEE enterprises
peevee 132@gmail.com, Vijaylko8@gmail.com
City Office : 42, Valmiki Marg, Lalbagh, Hazratganj, Lucknow 226001. U.P. India.
Fac. Address : 2137M(8), Canal Road, Indralok Colony, Krishna Nagar, Lucknow-226023
Contact No. : +91 522-4025629 Mob. : +91 94150-20996, +91 88535-30595

To,
The Principal,
Rajarshi Dashrath Autonomous State Medical College, Ayodhya,
Ayodhya

Subject: Declaration regarding Price Offer for the SURGICAL WORK STATION - Electro Surgery Unit with Vessel Sealing , Argon Plasma Coagulation ,Water Jet Technology Suction Module & Smoke Plume Evacuation System

Dear Sir,

We hereby confirm that:

1. That the firm have not been black listed or debarred by any Central/State Government/Agency of Central/State Government/Public Sector Undertaking/Regulatory Authority of India.
2. That this is to certify that the rates quoted for the **Surgical Workstation** to your Institute, is the lowest subject to the offered bill of quantity as per technical specification of master suchi. We hereby confirm that in current FY we have not quoted / Supplied said equipment as per offered bill of quantity as per technical specification lower prices to any other organization.
3. That we further agree that any price discrepancy is found at the later date for current FY we will be liable to refund the difference.
4. That we agree all terms & condition of the institute/college in support of Purchase Order issued by the institute/college.
5. We hereby agree to provide Performance Bank Guaranty @ 3% for the entire 5 years warranty period.
6. We hereby agree that the CMC after the completion of warranty period will be taken care directly our Principal Company.
7. We hereby confirm that we already submitted P.O. Copy of K.G.M.U Lucknow-75/P&PS/FO/2016-17 dated 29.03.2017 mentioning prices separately for all offered articles, the prices offered are the same we haven't taken any price increment for the same.

Looking forward for your valuable Purchase Order.

Thanking You,
For Pee Vee Enterprises

PEE VEE ENTERPRISES LUCKNOW

Authorised Signatory

PEE VEE enterprises
peevee 132@gmail.com, Vijaylko8@gmail.com
City Office : 42, Valmiki Marg, Lalbagh, Hazratganj, Lucknow 226001. U.P. India.
Fac. Address : 2137M(8), Canal Road, Indralok Colony, Krishna Nagar, Lucknow-226023
Contact No. : +91 522-4025629 Mob. : +91 94150-20996, +91 88535-30595

King George's Medical University U.P.,
Lucknow-226003 (U.P.) INDIA

Ph. 91-0522-2257540 Fax :91-0522-2257539 Website : www. kgmcindia.edu

Ref. ...75...../P&PS/FO/2016-17 Date: 21./3.../2017

To,

M/s Pee Vee Enterprises,
42, Valmiki Marg, Lalbagh, Hazratganj,
Lucknow - 226023
Mob. No. 9415020996, 8853530595

Dear Sir,

We are pleased to inform you that in reference to Tender Notice No. 156/PS/FO/2016-17 dt. 26.05.2016 the rate quoted by you towards the supply & installation of **Item No. 21 Surgical Workstation for Department of Common Equipment** as per quoted specifications, have been approved by Hon'ble Vice Chancellor. As per the details given below:-

A. High End Electro Surgical Unit with Electro Surgery unit with Vessel Sealing					
Sr No	Art No	Item Name	Qty	Rate Per Unit	Total Amt. (INR)
1	10160-100	ERBE VIO® 300 D Electrosurgical Unit	1	1266922.00	1266922.00
2	20189-303	VIO two pedal footswitch with ReMode; AP & IP X8 Equipment	1	73013.38	73013.38
3	20188-300	VIO one pedal footswitch; AP & IP X8 Equipment	1	51629.66	51629.66
4	20193-008	Erbe Silicone Electrode - conductive area 516 cm square	1	13507.42	13507.42
5	20193-016	Erbe Silicone Electrode - conductive area 187 cm square	1	11161.12	11161.12
6	20194-075	Erbe Patient Plate Cable VIO, ICC, ACC International, 4 m for silicone plates	2	9721.74	19443.48
7	20195-134	Bi clamp Lap forceps, Maryland semi deep, OD 5mm, length 340 mm (Lap Surgery)	1	181488.28	181488.28
8	20190-115	VIO Re Mode Electro Surgical Pencil E4 with 3 buttons, cable 04 m long	1	21851.40	21851.40
9	20195-202	Biclamp 201T	1	108767.20	108767.20
					1747783.94

B. Argon Plasma Coagulation System					
1	10134-000	APC 2 (for VIO) Argon Plasma Coagulation Unit	Qty	Rate Per Unit	Total Amt. (INR)
2	20134-004	Pressure reducer with sensor	1	769415.94	769415.94
3	20132-171	Argon gas cylinder, 5 liter; empty to DIN 477 No. 6 m	1	71447.60	71447.60
4	20132-200	VIO APC-handle with 3 buttons for APC2	1	38258.12	38258.12
5	20132-054	APC Applicator 5mm Length 35mm	1	57053.80	57053.80
			1	13924.54	13924.54
					950100.00

C. Water Jet System					
1	10150-000	ERBEJET 2®	Qty	Rate Per Unit	Total Amt. (INR)
2	20150-101	ERBEJET 2 one pedal footswitch with ReMode, AP & IP X8 Equipment	1	3132762.00	3132762.00
			1	60183.00	60183.00
					3192945.00

D. ESM Suction 2 Module					
1	10340-000	ERBE ESM 2, suction module	Qty	Rate Per Unit	Total Amt. (INR)
2	20150-050	Fastening set for ERBEJET 2 to connect to VIO/APC 2/VEM 2	1	283706.38	283706.38
3	20340-002	Mounting bracket to connect to side rail	1	5736.98	5736.98
4	20340-003	Switching valve w/suction hoses & mounting bracket	1	4498.26	4498.26
5	20340-004	Suction hose, 60 cm length	1	13332.04	13332.04
6	20340-013	Suction bag, 2.5l, disposable; ESM	1	1167.62	1167.62
7	20340-103	Suction container, 2.5l, ESM	1	15769.98	15769.98
8	20340-100	ESM membrane filter 0.3 µm	1	8119.62	8119.62
			1	10864.08	10864.08
					343194.96

E. Disposable Consumables & Accessories of Electro Surgical Unit With Vessel Sealing					
1	20193-008	Erbe Silicone Electrode - conductive area 516 cm square	Qty	Rate Per Unit	Total Amt. (INR)
2	20193-016	Erbe Silicone Electrode - conductive area 187 cm square	1	13507.42	13507.42
3	20194-075	Erbe Patient Plate Cable VIO, ICC, ACC International, 4 m	1	11161.12	11161.12
			2	9721.74	19443.48

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4	20192-115	VIO Re Mode Electro Surgical Pencil B4 w/ 3 buttons, cable 5.0 m long	9	21851.40	196662.[illegible]
5	[illegible]	Biclamp 150 C, Curved 23 degree, smooth, length 150 mm (Open Surgery)	2	105880.16	211760.[illegible]
6	[illegible]	BiC [illegible] Small 5 mm, shaft length 280 mm	[illegible]	[illegible]	[illegible]
7	20195-511	BiCision Medium 5 mm, shaft length 350 mm	1	227299.66	227299.[illegible]
8	20195-132	Bipolar irrigation forceps, bayonet, L 20 cm, tip 1.0 mm [illegible]	2	60265.94	120531.88
9	20196-0[illegible]	Bipolar connecting cable VIO, ICC, ACC international, for bipolar forceps, length 4 m	2	9314.16	18628.[illegible]
10	20192-097	Monopolar Adapter Banana Jack MO 03 Socket 03 mm	1	10168.88	10168.88
11	20191-064	Spatula electrode, 2x18mm, straight, [illegible] 85mm, [illegible] 4mm	1	[illegible]	[illegible]
12	[illegible]	Spatula electrode, 2x18mm, straight [illegible]	[illegible]	[illegible]	[illegible]
13	[illegible]	Small Surgical Set	[illegible]	[illegible]	[illegible]
					1072[illegible]

F. Disposable Consumables & Accessories of Argon Plasma Coagulation System			Qty	Rate Per Unit	Total Amt. (INR)
1	[illegible]	APC [illegible], rigid, [illegible] mark, Ø 5 mm, 360 mm long, with [illegible]	4	[illegible]	[illegible]
2	[illegible]	Argon gas cylinder, 5 liter, empty to DIN 477 No. 6 m	1	38258.12	38258.12
					[illegible]

G. Disposable Consumables & Accessories of Water Jet Technology			Qty	Rate Per Unit	Total Amt. (INR)
1	20150-720	Pump cartridge	2	38703.26	77406.52
2	20150-030	Applicator, straight, L 65 mm, ø 6 mm, with suction	1	67464.42	67464.42
3	20150-031	Applicator, flexible tip, L 65mm, ø 6mm, w/ suction	1	71393.[illegible]	71393.[illegible]
					216264.68

H. Mobile High End Imported Vio Cart Trolley - Vio System + Apc 2 + Erbejet + Esm2 + APC Cylinder			Qty	Rate Per Unit	Total Amt. (INR)
1	20180-0[illegible]	VIO CART System cart for VIO family and modules Dimensions [illegible] x 940 x 650 mm (WXHXD)	1	267225.4	267225.40
2	20180-131	Fastening Set	1	5736.96	5736.96
3	20180-050	Fastening Set	1	5736.98	5736.98
					2786[illegible]

Total cost of Surgical Workstation - High End Electro Surgical Unit with Electro Surgery unit with Vessel Sealing, Argon Plasma Coagulation System, Water Jet System, ESM Suction 2 Module, Disposable Consumables & Accessories of Electro Surgical Unit With Vessel Sealing, Disposable Consumables & Accessories of Argon Plasma Coagulation System, Disposable Consumables & Accessories of Water Jet Technology & Mobile High End Imported Vio Cart Trolley - Vio System + Apc 2 + Erbejet + Esm2 + APC Cylinder Total amount in words (Rs. Seventy Eight Lac Seventy Three Thousand Eight Hundred Forty One only)	7873841.[illegible]
Supply & install For Department of - Medical Gastroenterology Qty -1, Surgical Gastroenterology Qty -1, Surgical Oncology Qty-1, Human organ Transplant Qty-01, Trauma - II Qty -1 & Trauma Surgery Qty -1	

A. High End Electro Surg Unit with Electro Surgery unit with Vessel Sealing

Sr No	Art No.	Item Name	Qty	Rate Per Unit	Total Amt. (INR)
1	10140-100	ERBE VIO® 300 D Electrosurgical Unit	1	1266922	1266922.00
2	20189-303	VIO two pedal footswitch with ReMode: AP & IP X8 Equipment	1	73013.38	73013.38
3	20188-300	VIO one pedal footswitch, AP & IP X8 Equipment	1	51629.66	51629.66
4	20193-008	Erbe Silicone Electrode - conductive area 510 cm square	1	13507.42	13507.42
5	20193-016	Erbe Silicone Electrode - conductive area 197 cm square	1	11161.12	11161.12
6	20194-075	Erbe Patient Plate Cable VIO, ICC, ACC International, 4 m for silicone plates	2	9721.74	19443.48
7	20195-134	Bi clamp Lap forceps, Maryland semi deep, OD 5mm, length 340 mm (Lap Surgery)	1	181486.28	181486.28
8	20192-115	VIO Re Mode Electro Surgical Pencil B4 with 3 buttons, cable 5.0 m long	1	21851.4	21851.40
9	20195-202	Biclamp 201 T	1	108767.2	108767.20
					1747582.04

B. Argon Plasma Coagulation System			Qty	Rate Per Unit	Total Amt. (INR)
1	10134-000	APC 2 (for VIO) Argon Plasma Coagulation Unit	1	769415.94	769415.94
2	20134-004	Pressure reducer with sensor	1	71447.60	71447.60
3	20132-171	Argon gas cylinder, 5 liter, empty to DIN 477 No. 6 m	1	38258.12	38258.12
4	20132-200	VIO APC handle with 3 buttons for APC2	1	57603.80	57603.80
5	20132-064	APC Applicator 5mm Length 35mm	1	13924.54	13924.54

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					950100.00
C. Water Jet System			Qty	Rate Per Unit	Total Amt. (INR)
1	10150-000	ERBEJET 2®	1	3132762.00	3132762.00
2	20150-101	ERBEJET 2 one pedal footswitch with ReMode, AP & IP X8 Equipment	1	60183.00	60183.00
					3192945.00
D ESM Suction 2 Module			Qty	Rate Per Unit	Total Amt. (INR)
1	20150-050	Fastening set for ERBEJET 2 to connect to VIO/APC 2/VEM 2	1	283706.38	283706.38
2	10340-000	ERBE ESM 2, suction module	1	5736.98	5736.98
3	20340-002	Mounting bracket to connect to side rail	1	4498.26	4498.26
4	20340-003	Switching valve w/suction hoses & mounting bracket	1	13332.04	13332.04
5	20340-004	Suction hose, 60 cm length	1	1167.62	1167.62
6	20340-013	Suction bag, 2.5l; disposable; ESM	1	15769.08	15769.08
7	20340-103	Suction container, 2.5l, ESM	1	8119.62	8119.62
8	20340-100	ESM membrane filter 0.3 µm	1	10864.08	10864.08
					343194.96
F Disposable Consumables & Accessories of Electro Surgical Unit with Vessel Sealing			Qty	Rate Per Unit	Total Amt. (INR)
1	20193-008	Erbe Silicone Electrode - conductive area 516 cm square	1	13507.42	13507.42
2	20193-016	Erbe Silicone Electrode - conductive area 187 cm square	1	11161.12	11161.12
3	20194-075	Erbe Patient Plate Cable VIO, ICC,ACC International, 4 m for silicone plates	2	9721.74	19443.48
4	20190-115	VIO Re Mode Electro Surgical Pencil E4 wit 5 buttons, cable 04 m long	9	21851.40	196662.60
5	20195-221	Bi clamp 150 C, Curved 23 degree, smooth, length 150 mm (Open Surgery)	1	106890.16	106890.16
6	20195-310	BiCision Small 5 mm, shaft length 200 mm	1	227799.66	227799.66
7	20195-311	BiCision Medium 5 mm, shaft length 350 mm	1	227799.66	227799.66
8	20195-152	Bipolar irrigation forceps, bayonet, L 20 cm; tip 1.0 mm, blunt	1	60265.94	60265.94
9	20196-053	Bipolar connecting cable VIO, ICC, ACC international, for bipolar forceps,length 4 m	1	9314.10	9314.10
10	20183-067	Monopolar Adapter Bovie Jack MQ 08 Socket 04 mm	1	10168.88	10168.88
11	21191-004	Spatula electrode; 2x18mm; straight; L 85mm; ø 4mm	1	5945.54	5945.54
12	21191-158	Spatula electrode; 2.3x19mm straight; insul.; L 180mm; ø 2.4mm	1	2607.00	2607.00
13	21191-080	Small Surgical Set	1	5809.66	5809.66
14	20183-110	Bipolar TURP Adapter	1	69750.00	69750.00
15	20196-118	Bipolar connecting cable VIO, ICC, ACC international, for Storz resectoscope	1	38750.00	38750.00
					1005875.22
E. Disposable Consumables & Accessories of Argon Plasma Coagulation System			Qty	Rate Per Unit	Total Amt. (INR)
1	20132-056	APC-Applicator, rigid, insulated shaft, Ø 5 mm, 100 mm long, with adjustable spatula	1	32750.24	32750.24
2	20132-171	Argon gas cylinder, 5 liter; empty to DIN 477 No. 6 m	1	38258.12	38258.12
					71008.36
G. Disposable Consumables & Accessories Of Water Jet Technology			Qty	Rate Per Unit	Total Amt. (INR)
1	20150-300	Pump cartridge	2	35703.26	71406.52
2	20150-025	Applicator, curved tip, L 183 mm, ø 5 mm	1	70100	70100.00
3	20150-060	HybridKnife T-Type I-Jet; Ø 2.3 mm; L 1.9 m	1	72627.92	72627.92
4	20150-026	Applicator, curved tip, L 336 mm, ø 5 mm	1	70100	70100.00
					284234.44
H. Mobile High End Imported Vio Cart Trolley - Vio System + Apc 2 + Erbejet + Esm2 +Apc Cylinder			Qty	Rate Per Unit	Total Amt. (INR)
1	20180-000	VIO CART System carier for VIO family and modules Dimenssion 680 x 940 x 650 mm (WXHXD)	1	267225.4	267225.40
2	20180 131	Fastening Set	1	5736.98	5736.98
3	20150 050	Fastening Set	1	5736.98	5736.98
					278699.36
Total cost of Surgical Workstation - High End Electro Surgical Unit with Electro Surgery unit with Vessel Sealing, Argon Plasma Coagulation System, Water Jet System, ESM Suction 2 Module, Disposable Consumables & Accessories of Electro Surgical Unit With Vessel Sealing, Disposable Consumables & Accessories of Argon Plasma Coagulation System, Disposable Consumables & Accessories of Water Jet Technology & Mobile High End Imported Vio Cart Trolley - Vio System + Apc 2 + Erbejet + Esm2 + APC Cylinder Total amount in words : Rs. Seventy Eight Lac Seventy Three Thousand Eight Hundred Forty One only					7873841.12
Supply & install For Department of Urology					

Finance Officer
K. G's. Medical University, U.P.
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A. High End Electro Surgical Unit with Electro Surgery unit with Vessel Sealing			Qty	Rate Per Unit	Total Amt. (INR)
1	10140-100	ERBE VIO® 300 D Electrosurgical Unit	1	1266922.00	1266922.00
2	20189-303	VIO two pedal footswitch with ReMode; AP & IP X8 Equipment	1	73013.38	73013.38
3	20188-300	VIO one pedal footswitch, AP & IP X8 Equipment	1	51629.66	51629.66
4	20193-008	Erbe Silicone Electrode - conductive area 516 cm square	1	13507.42	13507.42
5	20193-016	Erbe Silicone Electrode - conductive area 187 cm square	1	11161.12	11161.12
6	20194-075	Erbe Patient Plate Cable VIO, ICC, ACC International, 4 m for silicone plates	2	9721.74	19443.48
7	20195 -134	Bi clamp Lap forceps, Maryland semi deep, OD 5mm, length 340 mm (Lap Surgery)	1	181488.78	181488.28
8	20190-115	VIO Re Mode Electro Surgical Pencil E4 wit 3 buttons, cable 04 m long	1	21851.40	21851.40
9	20195-202	Biclamp 201T	1	108767.20	108767.20
					1747783.94

B. Argon Plasma Coagulation System			Qty	Rate Per Unit	Total Amt. (INR)
1	10134-000	APC 2 (for VIO) Argon Plasma Coagulation Unit	1	801573.5	801573.50
2	20134-004	Pressure reducer with sensor	1	71417.6	71417.60
3	20132-171	Argon gas cylinder, 5 liter, empty to DIN 477 No. 6 m	1	38250.12	38258.12
4	20132-200	VIO APC-handle with 3 buttons for APC2	1	57053.8	57053.80
5	20132-054	APC Applicator 5mm Length 35mm	1	13924.54	13924.54
					982257.56

C. Kryo Surgery System			Qty	Rate Per Unit	Total Amt. (INR)
1	10448 000	Erbe Kryo CA Mobile Cryo Surgery - Unit with Main Cable	1	420223.02	420223.02
2	20711-008	Foot-switch, explosion-protected	1	52500.34	52500.34
3	20448 000	Gas Tube	1	34492.25	34492.25
4	20410 006	Gas Filer for N20	2	53133.58	106267.16
5	20416-034	Connecting adapter for flexible cryo probes Erbekryo CA/AE	1	26865.75	26865.75
6	20410-034	Steri-tray for cryoprobes, 305 x 165 x 100 mm	1	33052.5	33052.50
7	20410-039	Cover for N2O-gascylinder, grey	1	27628.5	27628.50
8	NIL	CYLINDER	1	20000.00	20000.00
					721029.52

D. Disposable Consumables & Accessories of Electro Surgical Unit with Vessel Sealing			Qty	Rate Per Unit	Total Amt. (INR)
1	20193-008	Erbe Silicone Electrode - conductive area 516 cm square	1	13507.42	13507.42
2	20193-016	Erbe Silicone Electrode - conductive area 187 cm square	1	11161.12	11161.12
3	20194-075	Erbe Patient Plate Cable VIO, ICC, ACC International, 4 m for silicone plates	2	9721.74	19443.48
4	20190 115	VIO Re Mode Electro Surgical Pencil E4 wit 3 buttons, cable 04 m long	9	21851.4	196662.60
5	20195-221	Bi clamp 150 C, Curved 23 degree, smooth, length 150 mm (Open Surgery)	2	106890.16	213780.32
6	20195 - 202	Bi clamp 270 T, Bent 18 degree, smooth, length 200 mm (Open Surgery)	1	111520	111520.00
7	20195-310	BiCision Small 5 mm, shaft length 200 mm	1	227799.66	227799.66
8	20195-311	BiCision Medium 5 mm, shaft length 350 mm	1	227799.66	227799.66
9	20195-152	Bipolar irrigation forceps, bayonet, L 20 cm, tip 1.0 mm, blunt	2	60265.94	120531.88
10	20196-053	Bipolar connecting cable VIO, ICC, ACC international, for bipolar forceps,length 4 m	2	9314.1	18628.20
11	20183-067	Monopolar Adapter Bovie Jack MO 08 Socket 04 mm	1	10168.88	10168.88
12	21191-004	Spatula electrode, 2x18mm; straight; L 85mm; ø 4mm	1	5945.54	5945.54
13	21191-158	Spatula electrode, 2.3x19mm straight, insul ; L 180mm; ø 2.4mm	1	2607	2607.00
14	21191-080	Small Surgical Set	1	5809.66	5809.66
					1185368.42

E. Disposable Consumables & Accessories of Argon Plasma Coagulation System			Qty	Rate Per Unit	Total Amt. (INR)
1	20132-054	APC-Applicator, rigid, insulated shaft, Ø 5 mm, 35 mm long, with adjustable needle	2	16375.12	32750.24
2	20132-056	APC-Applicator, rigid, insulated shaft, Ø 5 mm, 100 mm long, with adjustable spatula	2	16375.12	32750.24
3	20132-171	Argon gas cylinder, 5 liter, empty to DIN 477 No. 6 m	2	38258	76516.00
					142016.48

F. Disposable Consumables & Accessories of Flexible Biopsy Probes			Qty	Rate Per Unit	Total Amt. (INR)
1	20416-033	Flexible cryo probe, Ø 2.4 mm, L 780 mm	3	207886.57	623659.71
2	20416-038	Flexible cryo probe, Ø 1.9 mm; L 780 mm	3	207886.57	623659.71
3	20416-032	Flexible cryo probe, Ø 2.4 mm, L 900 mm	2	207886.57	415773.14

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4	20416-037	Flexible cryo probe, O 1.9 mm, L 900 mm	2	207886.57	415773.14
5	20447-005	Bronchoscopy-probe, O 3 mm, L 530 mm	2	161025.00	322050.00
6	20416-032	Flexible cryo probe, O 2.4 mm, L 900 mm	2	207886.57	415773.14
					2816688.84

G. Mobile High End Imported Vio Cart Trolley For Vio System + Apc 2 + Apc Cylinder			Qty	Rate Per Unit	Total Amt. (INR)
1	20180-000	VIO CART System carier for VIO family and modules Dimension 680 x 940 x 650 mm (WXHXD)	1	267225.4	267225.40
2	20180 131	Fastening Set	1	5736.98	5736.98
3	20150 050	Fastening Set	1	5736.98	5736.98
					278699.36

Total cost of Surgical Workstation - High End Electro Surgical Unit with Electro Surgery unit with Vessel Sealing, Argon Plasma Coagulation System, Water Jet System, ESM Suction 2 Module, Disposable Consumables & Accessories of Electro Surgical Unit With Vessel Sealing, Disposable Consumables & Accessories of Argon Plasma Coagulation System, Disposable Consumables & Accessories of Water Jet Technology & Mobile High End Imported Vio Cart Trolley - Vio System + Apc 2 + Erbejet + Esm2 + APC Cylinder Total amount in words : Rs. Seventy Eight Lac Seventy Three Thousand Eight Hundred Forty One only	78,73,841.12
Supply & install for Department of Pulmonary Critical Care With Erbe Cryo With Biopsy Probes	

Total cost of Surgical Workstation		78,73,841.12
Add. VAT @5% =		3,93,692.06
G. Total =		82,67,533.18
Req. Qty	08	6,61,40,265.44
Amount In Words : Six Crore Sixty One Lakh Forty Thousand Two Hundred Sixty Five and Paisa : Forty Four only (Inclusive of all Taxes)		
Warranty: 05 years + 01 Year (72 Months) Additional Warranty on main units - 10140-100 ERBE VIO 300 D, 10134-000 ERBE VIO APC 2, 10150-000 ERBE JET 2, 10340-000 ERBE ESM 2. CMC: (Per unit): After expiry of warranty period CMC for 7th year Rs. 63,909.00, 8th Yr. 63,909.00, 9th Yr. 63,909.00, 10th Yr. 63,909.00 including service tax on 10140-100 ERBE VIO 300 D, 10134-000 ERBE VIO APC 2, 10150-000 ERBE JET 2, 10340-000 ERBE ESM 2 (Service Tax Inclusive). Note: 1. Warranty for a period of 72 months will be count from the date of satisfactory installation on Original Equipment Manufacturer / Principal Company's letter head. 2. Original Equipment Manufacturer / Principal Company have to provide Quarterly Preventive Maintenance of the Equipment without any additional cost.		

Therefore, you are requested to supply & install the above item in the **Department of Common Equipment,** as per terms and conditions of the tender quoted in your tender addressed to the Finance Officer/Head/Incharge of **Department of Common Equipment** K.G.M.U. U.P. Lucknow.

Please note the following terms and conditions: —

1. The confirmation of the receipt of the purchase order should reach within seven days of date of dispatch of order.
2. Security money to the tune of 10% of ordered value must be submitted to the Finance Officer, King George's Medical University U.P., Lucknow only in shape of FDR of Nationalized Bank for **06 years** (payable at Lucknow) in favour of Finance Officer, King George's Medical University, U.P., Lucknow within fifteen days from the date of dispatch of this order.
3. Goods must reach the concerned Departments within **04-06 weeks (30 – 45 days)** of dispatch of this order.
4. After supply installation, and commissioning of the equipment, the bill in triplicate be submitted separately first to the concerned HOD/Incharge. The HOD/Incharge shall verify the bill in manner mentioned as below. The duly verified bill in triplicate then shall be sent by the HOD to the Finance officer for making payment. The Finance Officer shall process the

Finance Officer
K. G's. Medical University, U.P.
LUCKNOW

payment only after the received goods have also been properly recorded by the Finance Officer in the Central Stock Book of the University.

5. Please Note: —

1) In addition to those mentioned in this order, all the terms and conditions of the tender documents referred above shall be applicable and are deemed to be integral part of this Purchase Order.
2) Prices are on FOR destination basis, with no scope of escalation.
3) The place of delivery shall be the **Department of Common Equipment** in the King George's Medical University U.P. Lucknow. The equipment has to be installed at such a place as may be identified and instructed by the Head/incharge, **Department of Common Equipment**. The installation shall be at your cost.
4) In the case of non-supply of materials/equipments/machines within stipulated period, it will be at the discretion of the King George's Medical University UP, Lucknow to accept delivery with late delivery clause. If the delivery is not effected on due date, the Vice Chancellor, King George's Medical University, U.P., Lucknow will have the right to impose penalty as under:

First extension for month or part thereof	----@2%.
Second extension for an additional month of part thereof.	-----@ 3%
In case of non-supply	-----@ 7.5%

Or

In case of default in delivery or if it is found that the goods supplied are not in accordance with the specifications of the contract and are not replaced within a reasonable time frame of the warranty conditions being invoked, the University will have the right to procure the ordered item from open market /another party under risk purchase clause.

5) The delivery of equipment shall be deemed to have been made only on the date of installation of the equipment. Any delay in the same shall attract penal charges as contained in the tender documents.
6) You are bound to provide on site/off site warranty for the items mentioned above for a period of **72 months** from the date of satisfactory installation. Thereafter, the equipments shall be covered under **CMC** at the rates provided above:
7) The challan accompanying the goods shall contain the following information:
   a. Challan No. & Date
   b. Purchase order no. & Date.
   c. Name & Brief description of the item.
   d. Details of accessories supplied.
   e. Quantity of items supplied.
   f. Date of Manufacturing & Product Identification No., if any.
8) Bill has to be submitted in triplicate separately to the **Department of Common Equipment** which should have the following information :
   a. Bill No. & Date
   b. Challan No. & Date

Finance Officer
K.G's. Medical University, U.P.
LUCKNOW

c. Purchase order no. & date.
d. Name & Brief description of the item.
e. Details of accessories supplied.
f. Quantity of items supplied.
g. Date of Manufacturing & Product Identification No., if any.
h. Cost in Rs.

6. Payment shall be released on completion of all formalities to the satisfaction of the Finance Officer, K.G.M.U. U.P. Lucknow.

Yours sincerely,

(M.K. Agarwal)
Finance Office

Ref: ...../P&PS/FO/2016-17 Date: 1 /2017

Copy to. :

1. The *Chairman/Secretary*, **Department of Common Equipment** with the request to kindly make it convenient to receive the supply of the above ordered equipment(s), issue instructions for installation and verify the satisfactory commissioning of the equipment along with :
   a. Proper verification of the goods as per tender specifications.
   b. Installation verification certificate to your satisfaction. To be recorded on reverse of original Bill.
   c. Commissioning verification certificate to your satisfaction to be mentioned, on the reverse of the original Bill.
2. In-Charge Contingency Section, Finance Office, K.G.M.U. U.P. Lucknow.

(M. K. Agarwal)
Finance Officer

Contract

Contract No: GEMC-511687738305304
Generated Date: 01-Nov-2021
Bid/RA/PR No: GEM/2021/B/1347313

Organisation Details

Type:	State Autonomous
Ministry.	-
Department:	Medical Education Department Uttar Pradesh
Organisation Name:	Sanjay Gandhi Post Graduate Institute of Medical Sciences Lucknow
Office Zone:	Sgpgims Raibarelly Road Lucknow

Buyer Details

Designation:	Senior Technical Officer
Contact No.:	0522-2495510-
Email ID:	buyer3.sgpgimsl.up@gembuyer.in
GSTIN:	09AAAJS3913N2ZN
Address:	SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES LUCKNOW 226014, LUCKNOW, UTTAR PRADESH-226014, India

Financial Approval Detail

IFD Concurrence:	No
Designation of Administrative Approval.	DIRECTOR, SGPGI
Designation of Financial Approval.	FINANCE OFFICER, SGPGI

Paying Authority Details

Payment Mode.	Offline
Designation:	Assistant Account Officer
Email ID.	pao2.sgpgimsl.up@gembuyer.in
GSTIN:	N
Address.	SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES LUCKNOW 226014, LUCKNOW, UTTAR PRADESH-226014, India

Seller Details

GeM Seller ID:	22C2180000116141
Company Name:	Pee Vee Enterprises
Contact No.:	09415020996
Email ID:	peevee132@gmail.com
Address:	M-396,AASHIANA, Lucknow, UTTAR PRADESH-226012, -
MSME verified:	Yes
MSME Registration number:	UDYAM-UP-50-0014276
MSE Social Category:	General
MSE Gender:	Male
GSTIN:	09ADWPA7911R1ZO , 09ADWPA7911R1ZO

*GST / Tax invoice to be raised in the name of - Buyer

Product Details

#	Item Description	Category Name & Quadrant	Model	HSN Code	Ordered Quantity	Unit	Lead Time(Days)	Price (Inclusive of all Duties and Taxes in INR)
1	**Product Name :** CMC 10th year **Brand :** ERBE **Brand Type :** Unbranded **Catalogue Status :** Catalogue not verified by OEM **Selling As :** Reseller not verified by OEM	BOQ (Q3)	VIO-300D	998719	2	INR	-	37,000
2	**Product Name :** Surgical Work Station with APC (with 05 years unconditional warranty) **Brand :** ERBE **Brand Type :** Unbranded **Catalogue Status :** Catalogue not verified by OEM **Selling As :** Reseller not verified by OEM	BOQ (Q3)	VIO-300D	90189029	2	piece	-	17,600,000
3	**Product Name :** CMC 6th year **Brand :** ERBE **Brand Type :** Unbranded **Catalogue Status :** Catalogue not verified by OEM **Selling As :** Reseller not verified by OEM	BOQ (Q3)	VIO-300D	998719	2	INR	-	37,000
4	**Product Name :** CMC 7th year **Brand :** ERBE **Brand Type :** Unbranded **Catalogue Status :** Catalogue not verified by OEM **Selling As :** Reseller not verified by OEM	BOQ (Q3)	VIO-300D	998719	2	INR	-	37,000
5	**Product Name :** CMC 8th year **Brand :** ERBE **Brand Type :** Unbranded **Catalogue Status :** Catalogue not verified by OEM **Selling As :** Reseller not verified by OEM	BOQ (Q3)	VIO-300D	998719	2	INR	-	37,000

6	**Product Name :** CMC 9th year **Brand :** ERBE **Brand Type :** Unbranded **Catalogue Status :** Catalogue not verified by OEM **Selling As :** Reseller not verified by OEM	BOQ (Q3)	VIO-300D	998719	2	INR	-	37,000
Total Order Value (in INR)								**17,785,000**

Consignee Detail

S.No	Consignee	Item	Lot No.	Quantity	Delivery Start After	Delivery To Be Completed By
1	Designation: - Email ID: con1.sgpgi.lko@gembuyer.in Contact: 0522 2494087- GSTIN: 09AAAJ5391L1N2ZN Address: SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES LUCKNOW 226014, LUCKNOW, UTTAR PRADESH 226014, India	Surgical Work Station with APC (with 05 years unconditional warranty)	-	2	01-Nov-2021	01-Dec-2021
		CMC 6th year	-	2	01-Nov-2021	01-Nov-2022
		CMC 7th year	-	2	01-Nov-2021	01-Nov-2022
		CMC 8th year		2	01-Nov-2021	01-Nov-2022
		CMC 9th year	-	2	01-Nov-2021	01-Nov-2022
		CMC 10th year	-	2	01-Nov-2021	01-Nov-2022

Specification 1

Specification Document

Buyer BOQ Document

Seller BOQ Document

Note: Seller has given an undertaking that it has made arrangements for getting the stores from an authorized distributor / dealer / channel partner of the OEM of the offered product. At the time of delivery of goods, Seller will provide necessary chain documents (in the form of GST Invoice) to prove that the supplied goods are genuine and are being sourced from an authorized distributor / dealer / channel partner of the OEM. In case of any complaint about genuineness of the supplied products, Seller shall be responsible for providing genuine replacement supplies.

Terms and Conditions

1. General Terms and Conditions-

1.1 This Contract between the Seller and the Buyer, is for the supply of the Goods and/ or Services, detailed in the schedule above, in accordance with the General Terms and Conditions (GTC) as available on the GeM portal (unless otherwise superseded by Goods / Services specific Special Terms and Conditions (STC) and/ or BID/Reverse Auction Additional Terms and Conditions (ATC), as applicable

1.2 Terms of delivery: Free Delivery at Site including loading/unloading. In respect of items requiring installation and / or commissioning and other services in the scope of supply (as indicated in respective product category specification / STC / ATC), and the cost of the same is also included in the Contract price.

1.2.1 Contracted goods should be delivered at the consignee or designated delivery location as per the working time of the buying organisation. Seller may get the same confirmed from consignee before scheduling delivery.

1.2.2 A copy of the contract should be available with the messenger / dispatching agency that delivers the Goods at consignee / delivery location (preferably pasted / attached outside the consignment / package) for easy reference and ease in delivery acceptance.

1.3 Delivery period: The Delivery Period/Time shall be essence of the Contract and delivery must be completed not later than such date(s). Any modification thereto shall be mutually agreed and incorporated in the Contract as per the provisions of the GTC.

1.4 Performance Security: If the Seller fails or neglects to observe or perform any of his obligations under the contract it shall be lawful for the Buyer to forfeit either in whole or in part, the Performance Security furnished by the Seller.

1.5 Taxes and Duties: Contract Prices are all inclusive i e including all taxes, duties, local levies / transportation / loading unloading charges etc. Break up of GST shall be indicated by the Seller while raising invoice / bill on GeM. While submitting the bill / invoice Seller shall undertake that the Goods and Services Tax (GST) charged on this bill is not more than what is payable under the provision on the relevant Act or the Rules made there under and that the Goods on which GST has been charged have not been exempted under the GST Act or the Rules made there under and the charges on account of GST on these goods are correct under the provision of that Act or the rules made there under.

1.6 Octroi Duty and / or other local taxes:Contract Prices are all inclusive hence no reimbursement over and above the contract price(s) shall be allowed to seller towards payment of local taxes (such as levy of town duty, Octroi Duty, Terminal Tax and other levies of local bodies etc).

1.7 Limitation of Liability: The provisions of limitation of liability between Buyer and Seller as given in the GTC shall be applicable here.

1.8 Resolution of disputes: The provisions of DISPUTE RESOLUTION BETWEEN BUYER AND SELLER as given in the GTC shall be applicable here.

1.9 Liquidated Damages: If the Seller fails to deliver any or all of the Goods/Services within the original/re-fixed delivery period(s) specified in the contract, the Buyer will be entitled to deduct/recover the Liquidated Damages for the delay, unless covered under Force Majeure conditions aforesaid, @ 0.5% per week or part of the week of delayed period as pre-estimated damages not exceeding 10% of the contract value without any controversy/dispute of any sort whatsoever. In case, Service Level Agreement (SLA) is applicable the same shall be applicable for the Contract.

1.10 Financial Certificate:

1.10.1 The expenditure involved for this purpose has received the Sanction of the competent financial authority.

1.10.2 The funds are available under the proper head in the sanction budget allotment for the concern financial year.

1.10.3 I have been fully authorized by the department to sign the supply order or incur the liability of the Goods being ordered.

1.11 The bidder should submit a self declaration to the effect in bidder's official letter head that their agency have not been black listed by any Agency whatsoever till date.

2. Additional Terms and conditions-

2.1 Buyer uploaded ATC documentClick here to view the file.

Note: This is system generated file. No signature is required. Print out of this document is not valid for payment/ transaction purpose.

Manufacturer's Authorization

To,
The Principal,
Rajarshi Dashrath Autonomous State Medical College, Ayodhya,
Ayodhya

WHEREAS we ERBE Medical India Pvt. Ltd. wholly owned subsidiary of ERBE Elektromedizine GmbH Germany who are established and reputable manufacturers of Surgical Workstation having production facilities at Waldhorenlestrasse 17. D-72072. Tubingen do hereby authorize as Indian Agent **M/s Pee Vee Enterprises – 2137/M(8), Canal Road, Indralok Colony, Krishna Nagar, Lucknow – 226023** to submit a proposal, and sign the contract with you for **Surgical Workstation**.

We hereby extend our full guarantee and warrantee for the above specified goods against the bidding documents for full five years as well as confirm to provide AMC/CMC for next five years after the expiry of guarantee and warrantee period.

No company or firm individual other than **M/s Pee Vee Enterprises, No: 2137/M (8), Canal Road, Indralok Colony, Krishna Nagar Lucknow** are authorized to tenders and conclude the contract for all the goods manufactured by us.

We further guarantee that in the event we change our dealer / Indian agent, we will continue to provide all the services as assured in the tender document and are also as required by the concerned Principal /Director of respective medical college/ Institute as the case may be, through our new dealer / Indian Agent or directly as may be required.

We also confirm that we will not supply refurbished equipment.

Yours Truly,
For ERBE Medical India Pvt Ltd.

Authorized Signatory

Erbe Medical India Private Ltd., Plot No : 447, Pocket B, Sector-19, Dwarka, New Delhi - 110075, India Phone +91 11 41009808 www.erbe-india.com erbe@erbe-india.com

Deutsche Bank AG
Chennai Branch
Current Acc. No: 5006846-00-0
Swift Code: DEUT0916CNN
CIN: U33119TN2007PTC062336

Elektromedizin GmbH
Walhoernelstrasse 17
72072 Tuebingen,
Germany
erbe-med.com

Kreissparkasse Tuebingen
Konto 141
SWIFT - BIC: SOLADES1TUB
IBAN : DE546415 0020 0000 0001 41
BLZ: 641 500 20

GSTIN
Delhi : 07AABCE7430L1ZK
Chennai : 33AABCE7430L1ZP
Mumbai : 27AABCE7430L1ZI
Kolkata : 19AABCE7430L1ZF

(THE COMPANIES ACT, 1956)

MEMORANDUM

AND

ARTICLES OF ASSOCIATION

OF

ERBE MEDICAL INDIA PRIVATE LIMITED

(COMPANY LIMITED BY SHARES)

सत्यमेव जयते

Form 1

Certificate of Incorporation

Corporate Identity Number : U33119TN2007PTC062336 2006 - 2007

I hereby certify that ERBE Medical India Private Limited is this day incorporated under the Companies Act, 1956 (No. 1 of 1956) and that the company is limited.

Given under my hand at Chennai this NINTH day of FEBRUARY TWO THOUSAND SEVEN.

REGISTRAR OF COMPANIES TAMIL NADU

S. Meenakshi
(MEENAKSHI S)

Registrar of Companies
Tamil Nadu, Chennai

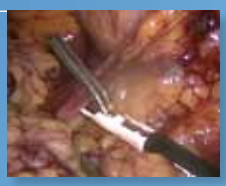
VIO® 300 D (electrosurgery)
APC 2 (argon plasma coagulation)
ERBEJET® 2 (waterjet surgery)
ESM 2 (secretion aspirator)

MY SURGICAL WORKSTATION FROM ERBE

VIO® System
Master module with all electrosurgical modes for CUT and COAG, with output dosage

APC 2
Devitalizes tissue and stops bleeding, non-contact technology

BiCision®
Thermofusion and dissection for vessels and tissue structures, easy to operate



ERBEJET® 2
Dissection can be performed selectively and for specific tissue layers with minimal bleeding

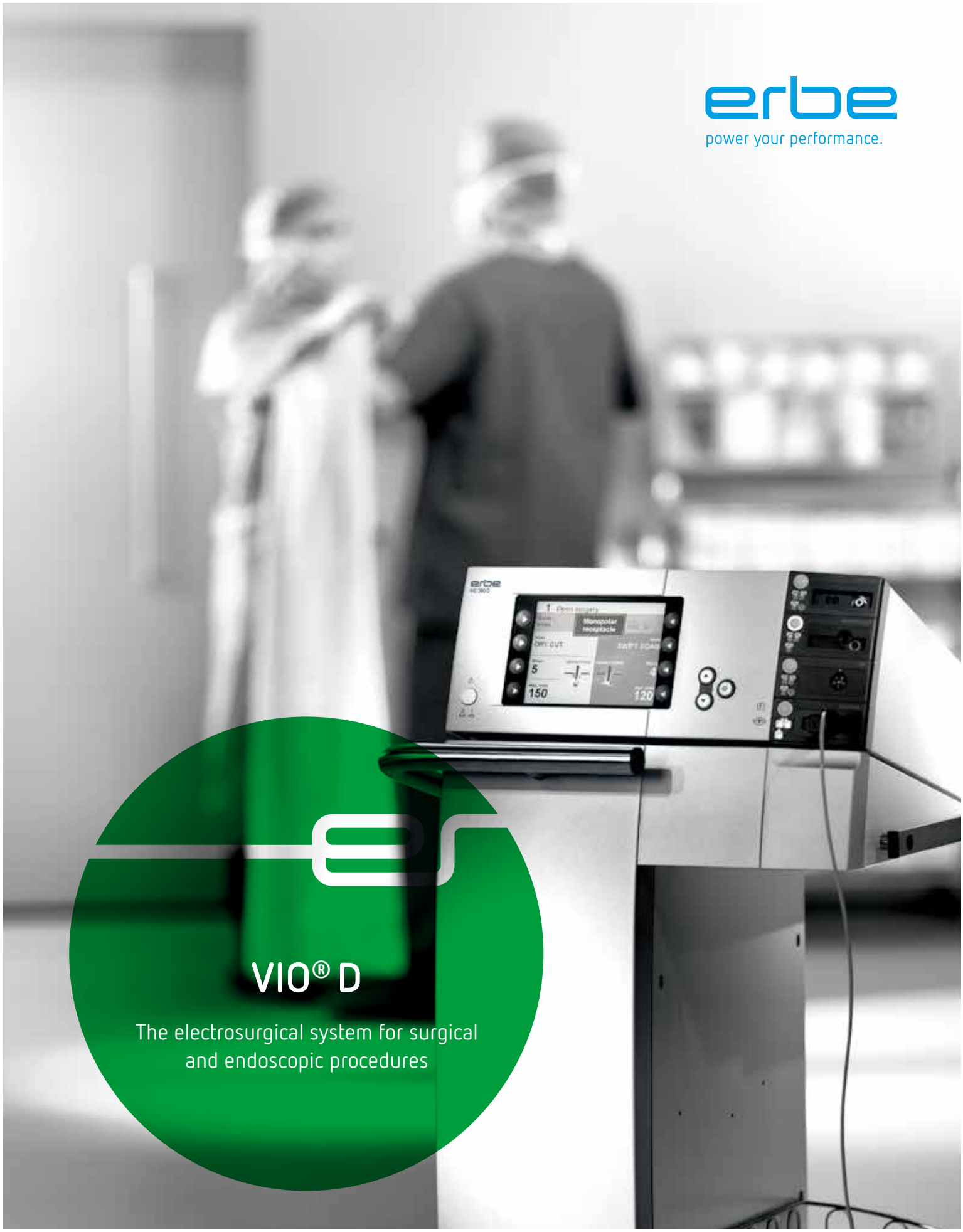
Further information on medical procedures can be found on our web site.

ERBE Elektromedizin GmbH | Tuebingen | Germany | Phone +49 7071 755-0 | www.erbe-med.com

ERBE

Perfection for Life

erbe
power your performance.



VIO® D

The electrosurgical system for surgical and endoscopic procedures

VIO® 300 D and VIO® 200 D:

Electrosurgery tailored to perfection.

With the VIO electrosurgical system, Erbe has set innovative standards aimed at providing optimum surgical support for almost any discipline as well as including a range of additional indications.

Erbe VIO 300 D and 200 D generator modules offer automatic power adjustment for all control technologies:

- ☑ **Voltage control for gentle, reproducible cutting and coagulation**
- ☑ **Arc control for high-energy cutting or coagulation and for cutting under water**
- ☑ **Power control to maintain constant power levels during coagulation and devitalization**

TAILORED PRECISELY TO YOUR NEEDS – BOTH IN TERMS OF HARDWARE AND SOFTWARE

- ☑ Can generally be fitted flexibly with socket modules and functions
- ☑ All the latest electrosurgical control technologies in a single unit – with automatic power adjustment
- ☑ New and enhanced CUT and COAG functions
- ☑ Can be configured for custom setups based on the relevant discipline, indication or procedure
- ☑ Plug & play: plug in the instrument, start working
- ☑ ReMode function: remote control using the handle or footswitch „right from the operating table"
- ☑ The VIO D range – the master control units for other modules in the VIO electrosurgical system, for example argon plasma coagulation, smoke plume evacuation, the endoscopy irrigation pump, and other components
- ☑ VIO 300 D – the master module for vessel sealing with BiClamp and BiCision

Versatile operating and safety concept that offers complete convenience.

PreView function on the display

When setting the parameters, changes to the CUT and COAG symbols in the user interface already indicate how the setting is likely to affect tissue on application.

Activating ReMode from the operating table

With its modern ReMode activation concept, Erbe has developed a "remote control" for even greater operating convenience. Using the VIO footswitch or VIO handle, surgeons can alternate independently between preselected instrument settings – without a second user.

Vessel sealing

With VIO 300 D, BiClamp mode optimizes vessel sealing in open surgery and in laparoscopic procedures in urology and gynecology, and in general and visceral surgery.

Consistent enhancement: the NESSY patient plate safety system

With the NESSY safety concept and the Erbe patient plate NESSY Ω, VIO sets new standards with regard to the safety of monopolar electrosurgery.

For use in clinic ORs or specialist surgical ORs

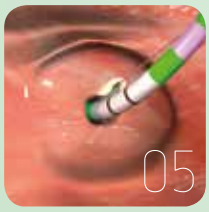
	VIO 300 D	VIO 200 D
Gynecology	■	-
Urology	■	-
General surgery	■	-
Gastroenterology / Endoscopy	⬓	■
Pulmonology	⬓	■
ENT	■	-
Orthopedics	■	-
Dermatology	■	-
OMS	■	⬓
Ophthalmology	-	-

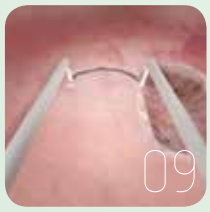
Legend:

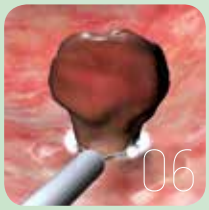
■ *strongly recommended*
⬓ *recommended*

CUT

Precise cutting using these modes.







HIGH CUT 01

Suitable for cutting inside fatty structures or under water (e.g. TUR). Strong hemostasis at the incision edges. Control of arc intensity.

AUTO CUT 02

Standard mode for cutting with minimum necrosis and reproducible cutting quality.

ARGON AUTO CUT 03

Mode for argon-supported cutting. Minimum carbonization, minimum smoke plume development. Results in a good post-operative healing process.

PRECISE CUT 04

For very fine cutting with precise power adjustment in effect levels. For example, in microsurgery with very fine cutting instruments.

ENDO CUT I 05

Fractionated cutting mode for papillotomy or other needle / wire applications in endoscopy.

ENDO CUT Q 06

For endoscopic polypectomy with a snare. Fractionated cutting and coagulation cycles.

DRY CUT 07

Cutting mode with pronounced hemostasis as a result of voltage control and modulated forms of current.

BIPOLAR PRECISE CUT 08

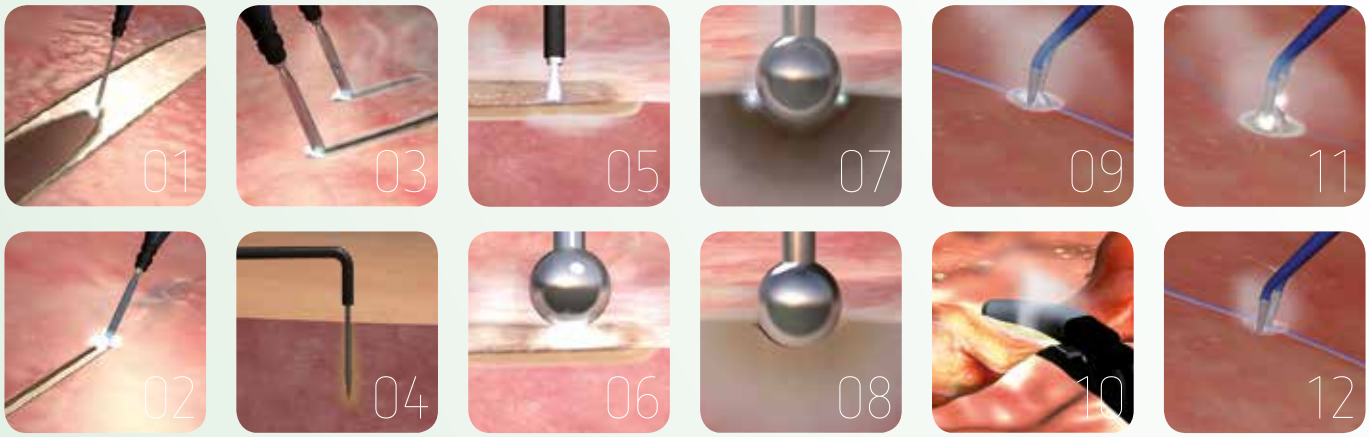
For exposure and dissection of very fine structures, for example in microsurgery.

BIPOLAR CUT | BIPOLAR CUT+/++ 09

For resection of the prostate, bladder or uterus. Fast arc generation, immediate cutting. Homogeneous, controlled arc generation with low application of energy.

COAG

Modes for exact coagulation and devitalization.



CLASSIC COAG 01

Exposure mode for visceral and cardiac surgery. Exact, layer-specific exposure and dissection. Minimum carbonization of the incision edges.

SWIFT COAG 02

Effective and fast coagulation with pronounced hemostasis that is also suitable for exposure.

TWIN COAG 03

For simultaneous activation of two instruments with only one electrosurgical unit – consistent power output.

PRECISE COAG 04

For microsurgical coagulation in the lower power range. Precise power settings and effects.

FORCED APC, PULSED APC, PRECISE APC 05

cover the entire spectrum of all types of non-contact APC coagulation. For hemostasis during endoscopy or open surgery or for surface coagulation and devitalization.

SPRAY COAG 06

Non-contact and efficient surface coagulation with low thermal penetration. Suitable for tissue devitalization or for stopping diffuse bleeding. Extensive carbonization effects.

FORCED COAG 07

Fast and effective standard coagulation with moderate thermal penetration. Slight carbonization effects.

SOFT COAG 08

Gentle coagulation with deep penetration, without carbonization, resulting in minimum adhesion of the electrode. Supported by the power control.

BIPOLAR SOFT COAG BIPOLAR SOFT COAG+/++ 09

Mode for safe coagulation during bipolar resection in saline solution as well as for forceps coagulation.

BICLAMP 10

Supports Erbe BiClamp by providing current for optimum sealing of vessels and tissue structures.

BIPOLAR FORCED COAG 11

Fast, effective, bipolar standard coagulation with moderate hemostasis.

BIPOLAR PRECISE COAG 12

For the exposure and coagulation of very fine structures, for example in microsurgery.

These modes and upgrades are available with the VIO 300 D and VIO 200 D models

CUT mode

	VIO 300 D	VIO 200 D
AUTO CUT	■	■
HIGH CUT	■	–
DRY CUT	■	⬓
DRY CUT°	■	–
BIPOLAR CUT	■	■
BIPOLAR CUT +	■	–
BIPOLAR CUT ++	■	–
PRECISE CUT	⬓	⬓
BIPOLAR PRECISE CUT	⬓	⬓
ENDO CUT Q	⬓	⬓
ENDO CUT I	⬓	⬓
ARGON AUTO CUT	■	■
ARGON HIGH CUT	■	–
ARGON DRY CUT	■	⬓
ARGON DRY CUT°	■	–

COAG mode

	VIO 300 D	VIO 200 D
SOFT COAG	■	■
SWIFT COAG	■	■
SWIFT COAG°	■	–
CLASSIC COAG	■	–
FORCED COAG	■	■
SPRAY COAG	■	–
BIPOLAR SOFT COAG	■	■
BIPOLAR SOFT COAG +	■	–
BIPOLAR SOFT COAG ++	■	–
BIPOLAR FORCED COAG	■	■
PRECISE COAG	⬓	⬓
BIPOLAR PRECISE COAG	⬓	⬓
TWIN COAG	⬓	–
BICLAMP	⬓	–
FORCED APC	■	■
PRECISE APC	■	■
PULSED APC	■	■
ARGON SOFT COAG	■	■
ARGON SWIFT COAG	■	■
ARGON SWIFT COAG°	■	–
ARGON FORCED COAG	■	■
ARGON TWIN COAG	⬓	–

Legend:

■ *included*
⬓ *supports UPGRADE*

FOR PERFECT CUTTING

- ☑ Newly-developed electrosurgical monopolar and bipolar CUT modes
- ☑ Power adjustment as a result of Erbe voltage control, for reproducible cutting
- ☑ Power adjustment as a result of Erbe arc control, for reproducible, efficient cutting in high-impedance tissue
- ☑ Additional area of application from microsurgery through to power-intensive vaporization
- ☑ Cutting results largely independent of cutting speed, shape of the electrode and tissue
- ☑ Bipolar cutting for more safety
- ☑ Power Peak System for optimum cutting behavior

FOR PERFECT COAGULATION

- ☑ Newly-developed electrosurgical COAG effects
- ☑ Power adjustment as a result of voltage control, for reproducible coagulation with optimally adjusted power output
- ☑ Power control for fast “non-stick” coagulation without carbonization
- ☑ Monopolar and bipolar coagulation for all your requirements
- ☑ AUTO-START and AUTO-STOP functions
- ☑ TWIN COAG: simultaneous activation of two electrodes / instruments for exposure

Technical data

VIO 300 D and VIO 200 D

Power output	
Maximum cut power (VIO 300 D)	300 watts at 500 Ohm (with PPS, briefly 400 watts)
Maximum cut power (VIO 200 D)	200 watts at 500 Ohm
Maximum COAG power	up to 200 watts
NE safety system	NESSY
Frequency	350 kHz

Power connection	
Line voltage	100 V – 120 V / 220 V – 240 V ± 10 %
Power frequency	50 / 60 Hz
Line current	max. 8 A / 4 A
Power consumption in standby mode	40 watts
Power consumption at max. HF power	500 watts / 920 VA
Potential equalization connection	Yes
Power fuse	T 8 A / T 4 A
Dimensions	Width x Height x Depth 410 x 160 x 370 mm
Weight	9.5 kg

VIO 300 D **VIO 200 D**
No. 10140-100 **No. 10140-200**

8/4 mm,
bipolar
No. 20140-610

2Pin-22 mm,
bipolar
No. 20140-612

2Pin-22-28-8/4 mm,
bipolar
No. 20140-613

9/5 mm,
monopolar
No. 20140-620

3Pin-Bovie,
monopolar
No. 20140-622

3Pin-9/5 mm,
monopolar
No. 20140-623

Multifunction
No. 20140-630
(VIO 300 D only)

6 mm
patient plate
No. 20140-640

2Pin
patient plate
No. 20140-641

6 mm-2Pin
patient plate
No. 20140-642

For additional information on device configuration, see the catalog chapter on units and modules (85100-172) or the VIO product range brochure (85140-190).

ISO 9001
ISO 13485
CERTIFICATION

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erbe
power your performance.

APC® 2

The full range of
Argon Plasma Coagulation (APC)

ARGON PLASMA COAGULATION

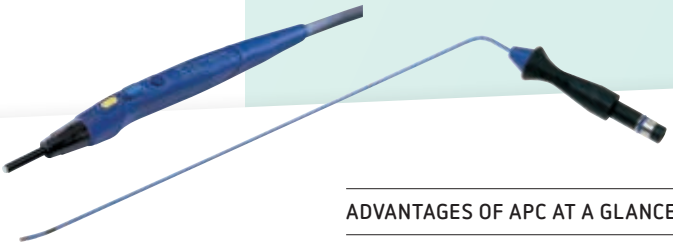
Effective hemostasis and devitalization

with Argon Plasma Coagulation (APC) – A success story…

APC is an electrosurgical technique for the management of bleeding and the devitalization of tissue abnormalities. During the procedure electrosurgical current is transferred to the tissue via ionized argon gas. The procedure has few complications and is safe: creating effective hemostasis and a homogenous surface coagulation with a limited penetration depth. Since transmission of the electrosurgical current is by a non-contact technique, (the instruments do not come into direct contact with tissue), the instruments almost never stick to the tissue. The current can be applied axially, laterally or radially, depending on the indication.

The equipment consists of an APC unit, an electrosurgical generator and APC instruments. In the Erbe VIO System the APC 2 and the VIO generator are optimally coordinated. Operation of the instruments and their interaction is carried out via the central display of the VIO master module.

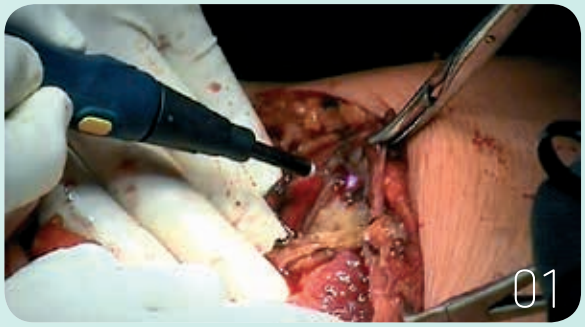
A wide range of applicators and probes are available for APC procedures in open surgery, endoscopy and laparoscopy (Please note. Catalogue for Electrosurgical Accessories). We have developed this range of instruments for the medical specialties of gastroenterology, ENT, bronchoscopy, laparoscopy, open surgery, etc., to meet the needs of different applications and anatomical sites in close cooperation with specialists from these different medical fields – all over the world.
Numerous scientific studies have demonstrated the therapeutic successes of these procedures. More information available on request!

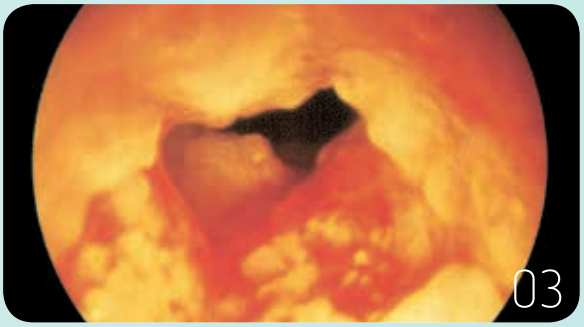


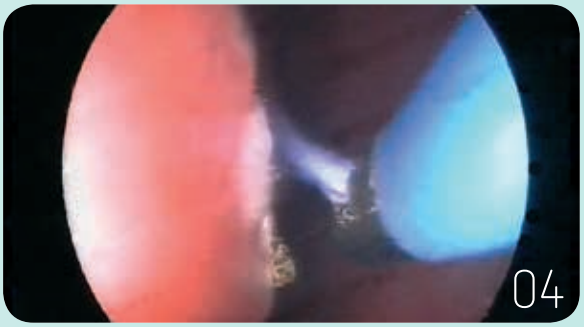
ADVANTAGES OF APC AT A GLANCE

- ☑ Non-contact procedure, no sticking of the instrument tip to the tissue
- ☑ Effective, even surface coagulation, for uniform hemostasis and devitalization
- ☑ Better dosage of penetration depth leads to safer application
- ☑ Limited perforation of risk
- ☑ Minimal carbonization and smoke plume formation, minimal pollution through unpleasant odors
- ☑ Safe procedure with few complications

Examples of indications in different medical specialties







01 Surgery/Gynecology

Homogenous coagulation of large surfaces and Argon-supported cutting, for example in

- ☑ Abdominal surgery
- ☑ Laparoscopy
- ☑ Liver surgery
- ☑ Breast surgery
- ☑ Visceral surgery

02 Gastroenterology

- ☑ Superficial and small vascular hemorrhages
- ☑ Tumor reductions
- ☑ Tumor bleeding
- ☑ Devitalization and coagulation of the right colon
- ☑ Stent ingrowth/overgrowth
- ☑ Radiation proctitis
- ☑ GAVE syndrome

03 Interventional Bronchology

- ☑ Superficial and small vascular hemorrhages
- ☑ Tumor reductions
- ☑ Tumor bleeding
- ☑ Recanalization
- ☑ Granulation
- ☑ Fistula conditioning
- ☑ Stent ingrowth/overgrowth

04 ENT

- ☑ Rhinology: rhinorrhagia, hyperplasia of the nasal turbinates, hemostasis in turbinectomies, Osler's disease
- ☑ Larynx: granulomas, laryngeal papillomatosis
- ☑ Oral cavity: leukoplakia, hemangiomas, granulomas, papillomas/fibromas, precancerosis
- ☑ Trachea: granulomas after laser surgery, papillomatosis, subglottal stenosis

… with a sequel:

APC now with new modes and plasma regulation for a wider choice during applications …

The many advantages of argon plasma coagulation have now been perfected with the APC 2 and the VIO System. The VIO APC 2 offers three new modes:

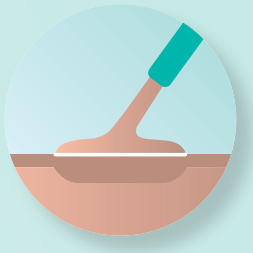
PRECISE APC PULSED APC FORCED APC

These modes cover a unique range of argon plasma coagulation procedures and provide even more safety as well as offering additional applications: from minimal surface coagulation to deep devitalization. Optimal ignition properties make handling even easier.
On the one hand "ignition" of the argon plasma is now possible even with very low power output settings – while maintaining the same, regular ignition intervals. For the first time a homogenous, carefully dosed surface application is possible even with very low energy outputs. On the other hand the achievable coagulation depth, for example in tumor reductions, has been greatly improved.*

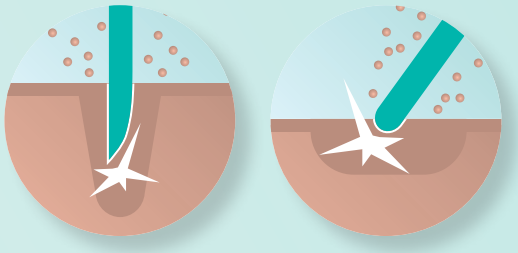
THE MODE PULSED APC, IN PARTICULAR, BRINGS A NUMBER OF IMPORTANT ADVANTAGES:

- ☑ particularly large ignition interval
- ☑ safe "ignition" of the plasma
- ☑ homogenous surface coagulation
- ☑ large range of coagulation / devitalization effects
- ☑ can be well controlled, with good level of safety

*Fujishiro, M., Yhagi, N. et al: Comparison of tissue damage in different settings of new argon plasma coagulation apparatus (VIO), Endoscopy 2003, 35 (suppl II), A 167



Argon plasma coagulation

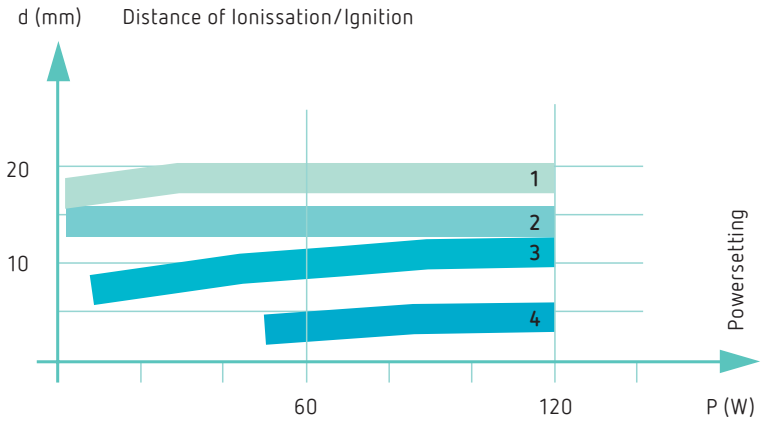


Argon Cut/Coag:
Argon-supported cutting and coagulation

ADVANTAGES OF THE NEW APC 2 AT A GLANCE

- ☑ Greatly increased range of options for argon plasma coagulation
- ☑ Optimized adjustment of the thermal effect with new modes and parameter settings
- ☑ Very good ignition properties even at very low output settings
- ☑ Homogenous surface coagulation
- ☑ Improved control of APC leads to more safety
- ☑ Easy operation with Plug & Play
- ☑ Argon-supported cutting with the full range of possibilities provided by the new VIO System

A comparison of the ignition properties of the APC 2

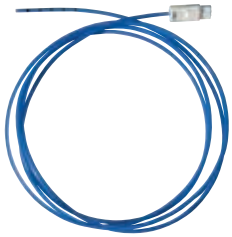


1	Pulsed APC effect 2
2	Pulsed APC effect 1
3	Forced APC effect 1
4	conventionel APC technique

… and even more user-friendly.

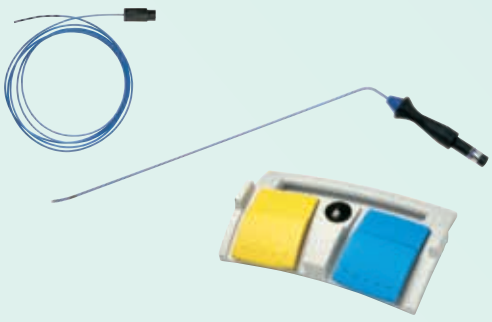
ARGON EXTENSION SOCKET
For all VIO/APC unit configurations requiring an additional socket. The APC 2 can include an additional, fourth socket in addition to the 3 active sockets of the VIO.

ARGON-SUPPORTED CUTTING AND COAGULATION
Argon CUT/COAG reduces smoke plume and carbonization and can be activated for many of the VIO functions.



The **3M APC PROBE** is particularly suitable for double balloon enteroscopy (DBE) procedures. The APC 2 supports such applications with the PULSED APC mode, thus making it possible to adjust the coagulation depth in minute steps. For the minimization of risks, particularly in the small intestine which otherwise carries a high risk of perforation.

PLUG & PLAY WITH DIGITAL INSTRUMENT RECOGNITION
The APC 2 automatically sets the appropriate parameters for the instrument plugged in, whether it is an APC handle or probe. The operating physician can start work immediately.



REMODE FUNCTION
With the third button on the APC handle remote activation from the operating table is possible. Without directly operating the VIO System via the panel the operating physician can use the APC handle to alternate between two instrument settings.

Erbe instruments such as applicators and probes optimized for different procedures are available for almost every APC indication.

Technical data

APC 2		
No. 10134-000	Type of gas	Argon 4.8 (99.998%) and higher degree of purity
	Initial pressure	5 ± 2 bar 72.5 ± 29 psi
	Max. final pressure	2 ± 0.4 bar 29 ± 5.8 psi
	Adjustable gas flow	0.1 – 8 l/min depending on the respective instrument attached; adjustable in steps of 0.1 l
	Flushing flow	Depends on the instrument (corresponds to the target flow of the attached instrument)
	Flushing duration	3 sec
	Dimensions: Width x Height x Depth	410 x 80 x 370 mm
	Weight	4.8 kg
	Classification in accordance with EU Directive 93/42/EWG	II b
	Type according to EN 60601-1CF	CF

For more information about the Erbe VIO refer to brochures, VIO product family, VIO D, VIO S; more information is also available at www.erbe-med.com

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HYDROSURGERY

Gentle interventions in surgery and endoscopy

Hydrosurgery with hybrid technology

Hydrosurgery has been successfully used in medicine for many years. Tissue structures are dissected selectively and gently by waterjet. Blood vessels and nerves remain intact up to a certain pressure. Thereafter, vessels may be treated according to with their size. Waterjet elevation can also be used to create fluid cushions in the tissue and to separate anatomical layers from one another.

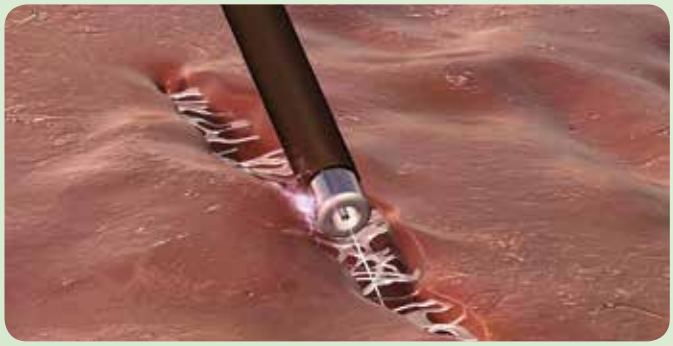


Fig. 1: Selective dissection:
The waterjet function of the applicator reveals vessels which may be selectively coagulated using electrosurgery (example: liver surgery).

Fig 2: Elevation:
Before endoscopic submucosal dissection (ESD) using electrosurgery, the mucosa is raised via the waterjet function. The HybridKnife® makes ESD simpler and safer.

ADVANTAGES OF HYDROSURGERY AT A GLANCE

- ☑ Gentle on blood vessels, nerves and organs (fig. 1)
- ☑ Minimized bleeding, controlled management of bleeding
- ☑ High degree of tissue selectivity during preparation and dissection of tissue layers
- ☑ Needleless high-pressure elevation to create a fluid cushion (fig. 2)
- ☑ Good visibility at the operative site due to integrated irrigation and suction
- ☑ Saves time overall in the OR

Besides surgical procedures on the liver, the technique has become established in further areas of application, especially by virtue of the development of new hybrid instruments. Thus, the waterjet is not only expanding the range of possible interventions, but in combination with electrosurgery, is setting new standards worldwide.

ERBEJET® 2

the basic module for hybrid technology in the system

- Time can be saved in the OR, since no change of instrument is necessary
- Both technologies are available at the same time and may be used simultaneously or in alternation
- The devices and instruments are ideally matched to one another

Hybrid technology: A strong partnership – electrosurgery combined with hydrosurgery

The ERBEJET 2 is compatible with the Erbe Workstation and may be used as a module or as an individual device on a cart and ceiling arm in the OR. The combination of two technologies – electrosurgery and hydrosurgery – is unique and offers the following advantages:

01 The **VIO 300 D/VIO 200 D** provides the appropriate cutting and coagulation modes for optimum electrosurgical effects

02 **APC 2** for hemostasis of bleeding tissues and devitalization of pathological tissue

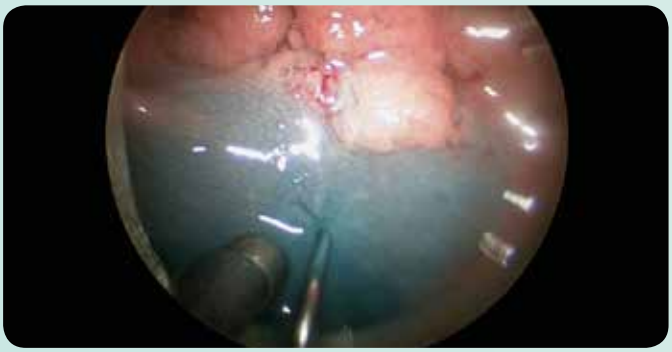
03 **ERBEJET 2** is the basic module for the hybrid technology. The waterjet is used for elevation and separation of tissue layers. Parenchyma can be dissected and vessels and nerves prepared

04 The **ESM 2** suction module permits good visibility of the target site. Suction may be activated individually or automatically, i.e. synchronously with the waterjet.

05 Activation of the waterjet and change of program via **footswitch**

The application spectrum of the ERBEJET® 2

Electrosurgery and hydrosurgery integrated in one instrument (e.g. for liver surgery)



For TEM, the resection plane is raised by submucosal elevation

GENERAL SURGERY/VISCERAL SURGERY
LIVER SURGERY

During **resection of the liver**, the blood vessels and bile ducts are separated selectively from the parenchyma and their size is revealed by the waterjet. By means of the instrument **(applicator, straight, with monopolar HF function)**, small vessels may be coagulated simultaneously with hybrid technology, all without changing instrument. Large vessels are treated separately with ligature or clip.

The duration of the procedure is shorter than that of other surgical techniques. Intraoperative blood loss is reduced, as is the need for blood transfusions. In many cases, there is no need for the Pringle maneuver – occlusion of the blood supply.
That's what well-designed management of bleeding should look like!

Further advantages of the applicator with hybrid function:

- ☑ **Synchronous and well-designed coagulation, as required**
- ☑ **Selectivity protects tissue and adjoining structures**

Applicator, straight
with monopolar HF function
No. 20150-036

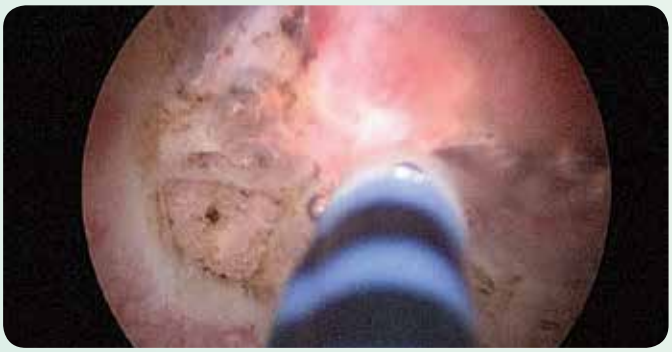
GENERAL SURGERY/VISCERAL SURGERY
COLORECTAL SURGERY

The waterjet is used in **TME (Total Mesorectal Excision)** for preparation and mobilization of the mesorectal layers. By virtue of the selectivity, nerves and vessel structures are treated gently. The risk of post-operative bladder and sexual function disorders is reduced.

For **TEM (Transanal Endoscopic Microsurgery)** in ESD technology, the resection plane is raised beforehand by submucosal elevation using the high-pressure waterjet. As a result, the tissue may be resected more safely with thermally and mechanically protective water cushions.

Applicator, curved tip
No. 20150-026

Elevation of the mucosa before endoscopic submucosal dissection (ESD)



Elevation before resection of the bladder tumor

GASTROENTEROLOGY

The **HybridKnife®** is a flexible probe with integrated electrosurgical and hydrosurgical functions. It is used for **ESD** (Endoscopic Submucosal Dissection) in the gastrointestinal tract. All 4 steps of the procedure – marking of the tumor, elevation of the mucosa, resection and subsequent coagulation – are performed with the multifunctional HybridKnife, without any change of instrument.

The high-pressure waterjet creates a submucosal water cushion that raises the tumorous mucosa. The cushion protects the muscularis from thermal and mechanical injury during the subsequent resection. In this way, the HybridKnife offers maximum safety in ESD.

Further applications in hybrid technology:

- ☑ **Submucosal tunneling and endoscopic resection (STER)**
  for therapy of submucosal benign tumors with HybridKnife T-Type, I-Type
- ☑ **Peroral endoscopic myotomy (POEM)**
  for therapy of achalasia with HybridKnife T-Type, O-Type, I-Type
- ☑ **Endoscopic mucosal resection (EMR)**
  for therapy of early-stage carcinoma in the gastrointestinal tract using the flexible probe
- ☑ Devitalization of **Barrett's esophagus** with HybridAPC, a combination instrument using waterjet and APC technology

HybridKnife O-Type, I-Jet
safe and simple resection after elevation,
e.g. during ESD in the gastrointestinal tract
No. 20150-062

UROLOGY

By applying the waterjet function of the **HybridKnife** in **early-stage bladder carcinoma**, the tumorous mucosal layer is raised selectively. The fluid accumulates in the form of a safety cushion in the submucosa. During the subsequent resection of the tumor via electrosurgery, the cushion protects the muscularis from perforation and mechanical injury. In this way, even large tumors that have not invaded the muscularis may be resected en bloc and with tumor-free margin.

A current multi-center study at large urological institutions is investigating possible advantages of the technique. The resected tissues of both technologies will be compared with respect to their pathological assessment, which will influence further therapy.

Further applications of the waterjet technology in urology:

- ☑ **Nerve-preserving prostatectomy (by laparoscopy and open surgery)**
- ☑ **Partial kidney resection**

HybridKnife T-Type, I-Jet
1 instrument, 4 functions
No. 20150-060

Instruments

for open surgery, laparoscopy and endoscopy

As sterile disposable products, the applicators and probes of the ERBEJET 2 can be used immediately. They offer consistent quality and safety. With different geometries and lengths, they are ideal for the disciplines listed below. Hybrid instruments offer advantages during application thanks to the double function that is available at any time.

01 **HybridKnife, T-Type, I-Jet**
No. 20150-060

02 **HybridKnife, I-Type, I-Jet**
No. 20150-061

03 **HybridKnife, O-Type, I-Jet**
No. 20150-062

Gastroenterology: ESD in esophagus, stomach, colon POEM for achalasia therapy
STER of submucosal tumors

Urology: en-bloc resection of early-stage bladder carcinomas

04 **HybridAPC**
No. 20150-015

Gastroenterology: for well-designed devitalization (ablation) of Barrett's esophagus;
1 instrument for all esophagus lumens

05 **Flexible probe**
No. 20150-020

Gastroenterology:
for elevation before EMR

06 **Applicator, straight,**
with monopolar HF function
No. 20150-036

General/visceral surgery (by open surgery):
Liver surgery, partial liver resection

Urology: partial nephrectomy

07 **Applicator, straight**
No. 20150-030

General/visceral surgery (by open surgery):
Liver surgery

08 **Applicator, curved tip**
No. 20150-026

Urology: nephrectomy
General/visceral surgery (by laparoscopy):
Liver surgery, TEM

Technical data

ERBEJET 2		
No. 10150-000	Supply voltage	120 – 240 V
	Mains current	0.4 – 1.2 A
	Frequency	50 Hz / 60 Hz
	Mains fuse	2 x T 3.15 A
	Pressure generation	Sterile single-use double piston pump
	Pressure range with 120µm jet nozzle (± 20 %)	1 – 80 bar (100 – 8000 kPa)
	Volume flow (±10 %)	3,5 – 55 ml / min
	Effect settings	Parameters adjusted according to individual specifications with storage space for 9 program settings
	Activation	Foot switch
	Width x height x depth	410 mm x 130 mm x 370 mm
	Weight	11 kg
	Separation medium	Sterile physiological saline solution
	Jet nozzle diameter of the applicators	120 µm
	Protective class acc. to EN 60 601-1	I
	Type acc. to EN 60 601-1	CF
	Class acc. to the EC-Directive 93 / 42 / EEC	IIb

ESM 2 Suction module		
No. 10340-000	Max. negative pressure (± 50 mbar)	Adjustable from -100 to -800 mbar (sea level)
	Suction capacity (± 10 %)	Depends on the setting of max. negative pressure max. 25 l / min
	Protective class acc. to EN 60 601-1	I
	Type acc. to EN 60 601-1	CF
	Class acc. to the EC-Directive 93 / 42 / EEC	IIa

Instruments and accessories	
HybridKnife T-Type, I-Jet	**No. 20150-060**
HybridKnife I-Type, I-Jet	**No. 20150-061**
HybridKnife O-Type, I-Jet	**No. 20150-062**
HybridAPC	**No. 20150-015**
Flexible probe, length 2.2 m, ø 1.3 mm	**No. 20150-020**
Applicator, straight with monopolar HF function	**No. 20150-036**
Applicator, straight, length 65 mm, ø 6 mm, with suction	**No. 20150-030**
Applicator, curved tip, length 336 mm, ø 5 mm, with suction	**No. 20150-026**
Applicator, bayonet (no fig.), length 90 mm, ø 6 mm, with suction	**No. 20150-041**
ERBEJET 2 ReMode two-pedal footswitch	**No. 20150-100**
ERBEJET 2 ReMode one-pedal footswitch	**No. 20150-101**
Pump unit for disposable use	**No. 20150-301**

See the Accessories Catalog for further instruments and accessories.

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erbe
power your performance.

IES 3

The smoke evacuation system for clean air at your workplace

ELECTROSURGERY

IES 3 smoke evacu

Our solution for a safe working environment

Eliminate surgical smoke with all its potentially dangerous substances from operating rooms, outpatient facilities and medical practices.

Smoke evacuation with IES 3 reduces the smoke concentration in the operating room – and thus also your smoke exposure.[1,2] A face mask allows too many particles to pass through.[2,3]

Direct evacuation with an electrosurgical pencil just a few millimeters above the source is more efficient than conventional ventilation systems.[4] This always gives you a good view of the surgical field and the surgical site itself.[3]

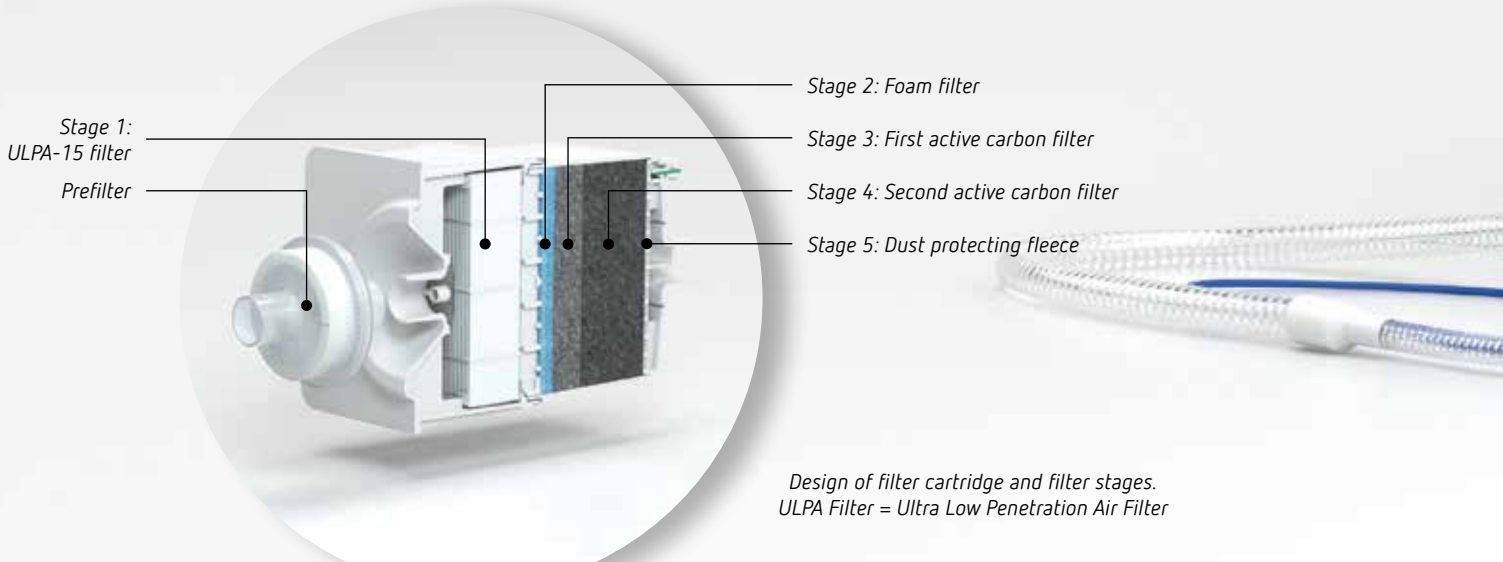
HAZARD DETECTED. RISK AVERTED. INFORMATION AT: SMOKE.ERBE-MED.COM

Protection through ULPA-15 filter

One core component of the 5-stage main filter cartridge is the ULPA-15 filter which removes 99.995 % of all 0.1 µm particles.[5] It offers the best possible safety.[3,4] The active carbon barrier in the main filter reduces odors. The display indicates the remaining filter capacity at all times.[6] Changing the filter is simple and convenient.[7]
The optional prefilter protects the main filter cartridge against penetration of liquids and impurities via coarser tissue particles.

Good response, quiet operation

The innovative bi-turbo technology ensures a clean and safe working environment within a very short time through effective and fast evacuation. Due to the enhanced noise insulation, the IES 3 is noticeably quieter and more pleasant than comparable devices.[7,8]



Design of filter cartridge and filter stages.
ULPA Filter = Ultra Low Penetration Air Filter

uation system

Extended range of applications

The different operating modes of the IES 3 allow versatile use:

- ☑ **Open surgical mode (OPEN Mode)**
- ☑ **Laparoscopic mode (LAP Mode) with special accessories such as the LAP tubing set with trumpet valve (3 m and 5 m)**
- ☑ **Presettings and configurations allow immediate use for different clinical requirements**

Flexible activation

You have the following options for activating the IES 3 individually – regardless of working with one or two instruments simultaneously:

- ☑ **Automatically via the VIO®activation**
- ☑ **Via the automatic activation device for all electrosurgical units**
- ☑ **Via the foot switch for laser and ultrasonic applications**

91 %
OF RESPONDENTS REGARD THE IES 3 AS QUIET AND PLEASANT.[7]

Our complete package

Smoke evacuation made by Erbe

Benefit from our almost 100 years of experience in electrosurgery, our worldwide presence and international support. The IES 3 is our contribution to a safe working environment.[1,3]

90 %
OF ALL RESPONDENTS REGARD THE IES 3 USER INTERFACE AS INTUITIVELY EASY.[7]

HORIZONTAL

VERTICAL

INTEGRATED IN THE VIO® 3 WORKSTATION

Easy and intuitive to use

- ☑ **Compatible with all models of the VIO® range**
- ☑ **Fast and user-friendly operation:[7]**
  - → Proven user interface, similar to the VIO® 3 touchscreen
  - → Display shows all parameters at a glance (settings, filter runtime, notes for the user)

High flexibility, compact design

- ☑ **Smoke evacuation for every surgical discipline**
- ☑ **In the operating room as well as in outpatient facilities and medical practices**
- ☑ **For electrosurgery, laser, ultrasound**
- ☑ **Can be integrated into the VIO® workstation**
- ☑ **Can be used as stand-alone device**
- ☑ **Can be positioned horizontally or vertically**

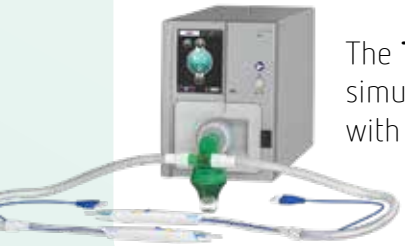
A system with variable configurations – all from one source

Water trap and prefilter protect the high-efficiency filter.

The **connection to the central evacuation system** removes particles and odors from the operating field.

The **automatic activation device** enables starting the IES 3 with all electrosurgical devices.

Good view of the target area in LAP mode with the **LAP tubing set.**



The **T-piece** offers optimal simultaneous evacuation even with 2 instruments.

The **one-pedal footswitch** activates the IES 3 in combination with laser and ultrasonic devices.

The **single-use smoke evacuation pencils** extract surgical smoke directly at its source.

Instruments	
20321-028	Electrosurgical pencil for IES, telescoping with spatula electrode
20321-040	Smoke evacuation pencil, single-use, short with spatula electrode, connecting cable 3 m
20321-041	Smoke evacuation pencil, single-use, short with coated spatula electrode, connecting cable 3 m
20321-042	Smoke evacuation pencil, single-use, short with spatula electrode, connecting cable 5 m
20321-043	Smoke evacuation pencil, single-use, short with coated spatula electrode, connecting cable 5 m
20321-007	Clip-on handle for Slim-Line electrosurgical pencils, tip short 12 mm with evacuation tubing 3 m and connection ø 22 mm, without electrosurgical pencil
20321-020	Clip-on handle for Slim-Line electrosurgical pencils, tip long 100 mm with evacuation tubing 3 m and connection ø 22 mm, without electrosurgical pencil
20321-044	Clip-On handle for smoke evacuation To be used in combination with Erbe Slim-Line electrosurgical pencils (20190-065, 20190-066, 20190-067, 20190-074, 20190-075)
20321-045	Extension tip for Clip-On handle To be used in combination with 20321-044

All instruments including accessories are listed in our catalog.

Technical data

Power connection	
Rated supply voltage	100 – 240 V AC (± 10 %)
Rated supply frequency	50 / 60 Hz
Line current	max. 3 A
Power consumption	max. 300 watts
Stand-by	12 watts at 230 V, 12 watts at 115 V
Potential equalization connection	Yes
Power fuse	T 4 A H / 250 V
Type of operation	
Continuous operation	
Unit data	
Filter specifications	ULPA-15 in accordance with EN 1822-3:2011 and EN 1822-5:2011, corresponds to the requirements of ISO 16571 smoke evacuation devices
Noise development	At 60 % evacuation power ≤ 49 dB(A) according to DIN EN ISO 3744 At max. evacuation power ≤ 59 dB(A) according to DIN EN ISO 3744
Extraction performance	≤ 730 l / min (maximum turbine power, th) ≤ 300 l / min (with main filter cartridge, automatic shut-off)
Dimensions and weight	
Width x height x depth	205 x 280 x 404 mm
Weight	9.7 kg including main filter cartridge
Display size	5.7 inches
Ambient conditions for operating the unit	
Temperature	+10 °C to +40 °C
Relative humidity	15 % – 85 %, non-condensing
Air pressure	54 kPa – 106 kPa
Max. operating height	5000 m over SL
Acclimatization	
If the unit has been stored or transported at temperatures below +10 °C or above +40 °C, the unit will take approximately 3 hours to acclimatize to room temperature.	
Standards	
Classification in accordance with MDD 93 / 42 EEC	I
Protection class in accordance with EN 60 601-1	I
Type in accordance with EN 60 601-1	CF

Smoke evacuation system and accessories

Smoke evacuation system consisting of:	
10323-000	IES 3 smoke evacuation unit
20323-000	Main filter cartridge IES 3

Accessories for protecting the main filter cartridge	
20321-022	Prefilter for smoke evacuation
20323-004	Self-sealing water trap; right angled, medium volume

Accessories for laparoscopic application and simultaneous application	
20323-003	LAP tubing set IES 3 with trumpet valve 3 m
20323-006	LAP tubing set IES 3 with trumpet valve 5 m
20323-005	T-piece 22 mm outer diameter, 22 mm inner diameter, 22 mm outer diameter

Accessories for open surgical application	
20321-004	Evacuation tube with optimized streaming
20321-009	Evacuation tubing, ø 22 mm
20321-010	Evacuation funnel connection, ø 22 mm
20321-012	Evacuation tubing, ø 22 mm, length 2.1 m (reusable)

Accessories for connection to central evacuation system	
20323-001	Evacuation element IES 3 for central evacuation
20323-009	Smoke evacuation tubing, ø 32 mm, length 1.8 m, type VT 10106

Attachment sets	
20180-132	Attachment set IES 2 / IES 3 to VIO® CART 20180-000
20323-008	Attachment set VIO® C to IES 3
20323-007	Attachment set IES 3 to VIO® 3

Accessories for activation options	
20323-002	Automatic activation device for IES 3 for VIO® C, electrosurgical external devices or stand-alone operation
20322-101	One-pedal footswitch IES 2 / IES 3 AP & IP X8 equipment

References

1 Schultz L: Can efficient smoke evacuation limit aerosolization of bacteria? AORN J. 2015 Jul; 102(1):7-14.
2 R S Parsa, N J Dirig, I N Eck, W K Payne III.: Surgical Smoke and the Orthopedic Implications. The Internet Journal of Orthopedic Surgery. 2015 Volume 24 Number 1
3 BRENDA C. ULMER, RN, MN, CNOR: The Hazards of Surgical Smoke; AORN J.2008, Vol 87, No. 4: 721-734.
4 Karsai S et al: Smoking guns: hazards generated by laser and electrocautery smoke. J Dtsch Dermatol Ges. 2012 Sep;10(9): 633-6.
5 Internal data: VB_Filter qualification ULPA15 IES 3; D158650
6 Internal data: filter service life IES 3; D138347
7 Internal data: results of summary evaluation II; D158302
8 Internal data: VB_sound measurements IES 3; D162979

Important information

We have prepared this medium with care. Nonetheless, we cannot completely rule out errors in this medium.

The information, recommendations and other data („Information") contained in this medium reflect our state of knowledge and the state of science and technology at the time of preparing the medium. The information is of a general nature, non-binding and serves solely for general information purposes and does not represent user manuals or instructions for use.

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power your performance.

Accessories for units and modules

ELECTROSURGERY

Important notes

The authors and Erbe Elektromedizin GmbH have taken the greatest possible care while compiling the catalogue with electrosurgical accessories. Nevertheless, it is impossible to exclude the possibility that errors may be contained herein.

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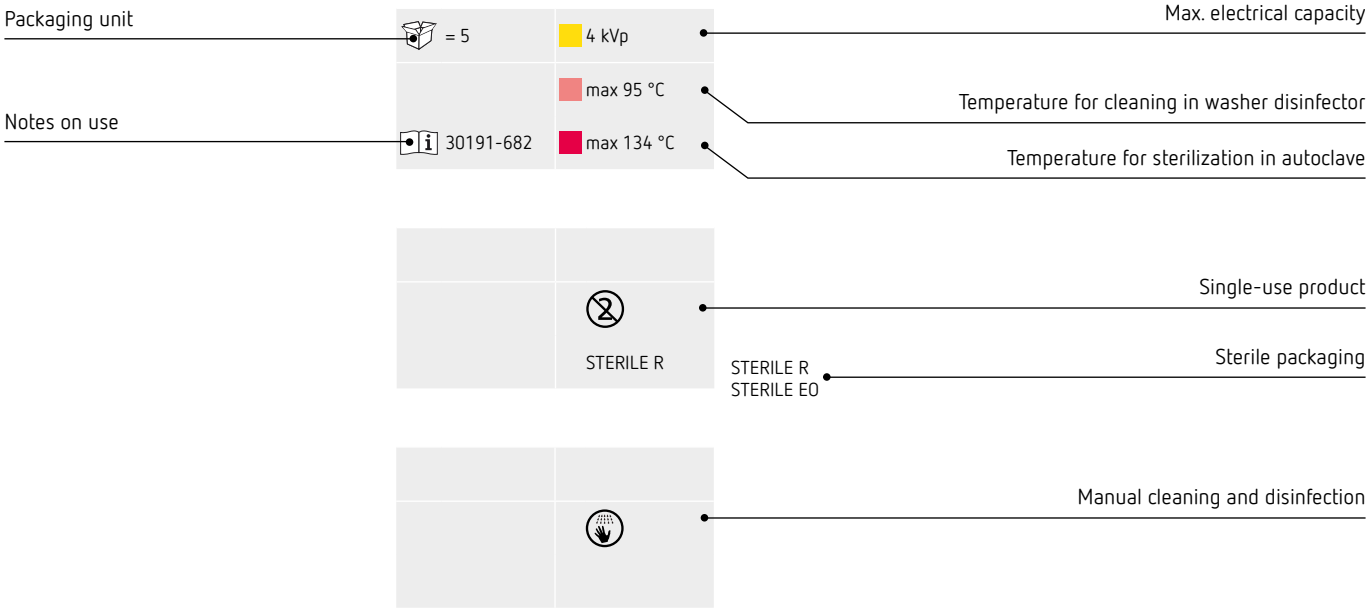
The data on the use of instruments is based on clinical experience. Medical science is subject to a process of permanent change based on research and clinical experience. Therefore the products are subject to alterations in design and technique. Because of production tolerances dimensions in the catalogue may marginally differ.

We confirm that none of our products contain latex, except the rubber straps, Art. No. 20592-009 and 20592-011.

Further product information



Please read carefully the corresponding notes on use before using any instrument.

Contents

Electrosurgery

Accessories for ESU

Accessories for modules

Overview

Subsystems

APC 2

IES 2 smoke evacuation

EIP 2 irrigation pump

Nerve test NT 2

with electrosurgical unit

VIO

Stand-alone solution

e.g. for laser surgery and further disciplines

Carts and accessories

VIO CART, system carrier for VIO family and modules

dimensions: 630 x 940 x 650 mm (WxHxD)
weight: 31 kg
4 conductive castors ø 100 mm, with fixing brake
1 power input
3 power outlets

incl. following accessories:
1 grab handle out of stainless steel
2 cable holders
1 foot switch bracket (for currently available foot switches)

No. 20180-000	
= 1	
80180-018	

Wire basket, 339 x 100/155 x 205 mm (W x H x D)

No. 20180-010	
= 1	

Cable holder

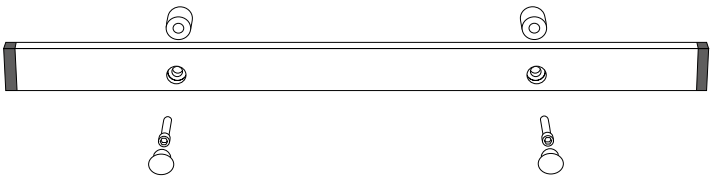
No. 20180-020	
= 1	

Upper bracket for VIO CART, length 260 mm

No. 20180-040	
= 1	

Lower bracket for VIO CART, length 390 mm

for use with secretion suction



No. 20180-042	
= 1	

Carts and accessories

Foot switch support, plastic

for currently available VIO foot switches

No. 20180-051	
= 1	

Cylinder pad for argon gas cylinder

No. 20180-080	
= 1	

Fastening strap for argon gas cylinder

No. 20180-120	
= 1	

Carts and accessories

Universal CART (CE) for VIO D/S, APC 2, VEM 2, ICC, APC 300, IES 300

dimensions: 520 x 890 x 465 mm (WxHxD)
weight: 30 kg
4 castors ø 100 mm, of which front 2 conductive with fixing brake
1 power input
3 power outlets

incl. following accessories:
1 instrument tray 339 x 155 x 205 mm (W x H x D)
1 grab handle
2 cable holders
1 foot switch support 20180-051 for currently available foot switches
2 cylinder pads for argon gas cylinder
2 fastening straps for argon gas cylinder

No. 20185-205	
= 1	

BASIC CART with 1 drawer for VIO D/S, NT 2, VEM 2

dimensions: 510 x 790 x 560 mm (WxHxD)
weight: 22 kg
4 conductive castors ø 100 mm, of which two with fixing brake

No. 20185-101	
= 1	

BASIC CART without drawer for VIO D/S, NT 2, VEM 2

dimensions: 510 x 790 x 560 mm (WxHxD)
weight: 22 kg
4 conductive castors ø 100 mm, of which two with fixing brake

No. 20185-100	
= 1	

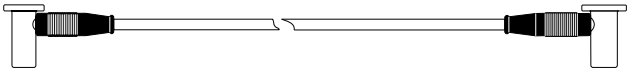
Further asseccories	No.
Cable holder, 2 pieces required	20185-107

Accessories for units

Fastening sets

Fastening sets	No.
VIO D/S / APC 2 / VEM 2 on VIO CART 20180-000	20180-131
VIO D/S / APC 2 / VEM 2 on Universal Cart 20185-205	20180-131
VIO D/S / APC 2 / VEM 2 on BASIC CART 20185-100, 20185-101	20180-131
VIO D/S / APC 2 / VEM 2 on console	20180-133
VIO D/S on APC 2 / VEM 2 (version since 2005)	20180-134
VIO D/S on APC 2 / VEM 2 (version until 2004)	20180-130
EIP 2 on VIO CART 20180-000	20180-135
EIP 2 on Universal Cart 20185-205	20185-203
IES 2 on VIO CART 20180-000, incl. ECB cable 15 cm	20180-132
ICC 200 / ICC 300 / ICC 350 on Universal Cart 20185-205	20132-061
ICC 200 / ICC 300 / ICC 350 + APC 300 on Universal Cart 20185-205	20132-061
ICC 200 / ICC 300 / ICC 350 + APC 300 + IES 300 on Universal Cart 20185-205	20132-061 20321-019
IES 300 on Universal Cart 20185-205	20321-019
ICC 200 / ICC 300 / ICC 350 + IES 300 on BASIC CART 20185-100, 20185-101	20321-019

Potential equalization lines / Power cords

Potential equalization lines	Length	No.
Potential equalization line, for all types of units, connections acc. to DIN 42801 	5 m	20194-025

Power cords	Country	Length	No.
Power cord 10A	Germany	0.5 m	51704-046
Power cord 10A	Germany	2.5 m	51704-037
Power cord 10A	Germany	4 m	51704-032
Power cord 10A	Germany	5 m	51704-042
Power cord 10A	Great Britain	2.5 m	51704-038
Power cord 10A	Great Britain	5 m	51704-043
Power cord 10A	Italy	2.5 m	51704-040
Power cord 10A	Italy	5 m	51704-045
Power cord 10A	Canada	4 m	51704-039
Power cord ICC / IES 300		0.35 m	51704-033

Foot switches

ReMode two-pedal foot switch for VIO D with bracket, AP & IP X8 equipment

with connecting cable 5 m, ReMode function only available with VIO D

No. 20189-301	
= 1	
	max 75 °C
30189-301	

ReMode two-pedal foot switch for VIO D, AP & IP X8 equipment

with connecting cable 5 m, ReMode function only available with VIO D

No. 20189-303	
= 1	
	max 75 °C
30189-301	

Two-pedal foot switch for VIO D/S with bracket, AP & IP X8 equipment

with connecting cable 5 m

No. 20189-300	
= 1	
	max 75 °C
30189-301	

Two-pedal foot switch for VIO D/S, AP & IP X8 equipment

with connecting cable 5 m

No. 20189-302	
= 1	
	max 75 °C
30189-301	

ReMode one-pedal foot switch for VIO D, AP & IP X8 equipment

with connecting cable 5 m, for VIO D from version V 1.7.6

No. 20188-302	
= 1	
	max 75 °C
30189-301	

Accessories for units

Foot switches

One-pedal foot switch for VIO D/S, AP & IP X8 equipment

with connecting cable 5 m

No. 20188-300	
= 1	
	max 75 °C
30189-301	

Two-pedal foot switch for VIO C, AP & IP X8 equipment

with connecting cable 5 m

No. 20189-107	
= 1	
30189-108	

One-pedal foot switch for VIO C, AP & IP X8 equipment

with connecting cable 5 m

No. 20188-102	
= 1	
30189-108	

Further accessories for VIO foot switch	No.
Hoop guard for VIO two-pedal foot switch	20189-306
Cover for foot switch	20189-307
Middle piece for two-pedal foot switch	20189-308
Cable for VIO foot switch, length 5 m	20189-309
Extension for VIO foot switch, length 0.6 m	20189-103

Foot switches

Two-pedal foot switch for ICC, ACC, T-series, AP & IP X8 equipment

with connecting cable 5 m, connecting plug 4 poles

	No. 20189-009
= 1	
30189-028	

Two-pedal foot switch for ICC 80, ICC 50, ICC Bipolar, IP X8 equipment

without AP protection, with connecting cable 5 m,
with connecting plug 4 poles

	No. 20187-003
= 1	
30189-028	

One-pedal foot switch for ICC, ACC, T-Series, AP & IP X8 equipment

with connecting cable 5 m, connecting plug 4 poles

	No. 20188-007
= 1	
30189-028	

One-pedal foot switch, only for use with ICC 350, AP & IP X8 equipment

activation only ‚bipolar', with connecting cable 5 m,
with connecting plug 4 poles

	No. 20188-013
= 1	
30189-028	

Foot switches

One-pedal foot switch for ICC, ACC, IP X8 equipment

without AP protection, with connecting cable 3 m,
with connecting plug 4 poles

	No. 20186-007
= 1	
30189-028	

Foot switch adapter from VIO D/S to ICC two-pedal foot switch (4 poles), length 0.7 m

for OR-System e.g. DaVinci

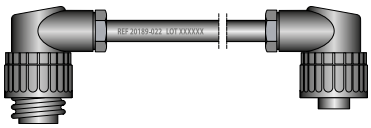
	No. 20140-004
= 1	
30140-212	

Foot switch adapter from VIO D/S to ICC one-pedal foot switch (7 poles), length 0.7 m

for OR-System e.g. DaVinci

	No. 20140-007
= 1	
30140-212	

Connecting cable from ICC, ACC (4 poles) to APC 300, length 0.35 m



	No. 20189-022
= 1	

Accessories for units

Upgrades

VIO Upgrades for VIO D from V.2.x	No.
VIO Upgrade Interface	20140-006
VIO Upgrade Connector BiClamp	29140-214
VIO Upgrade Connector DRY CUT	29140-215
VIO Upgrade Connector TWINCOAG	29140-216
VIO Upgrade Connector PRECISE	29140-217
VIO Upgrade Connector ENDO CUT	29140-218

Socket modules

Socket modules	No.
Assembly kit without socket, for APC 2 / VEM 2	20134-600
Assembly kit for second APC socket, for APC 2	20134-601
Socket module APC	20134-650
FiAPC socket module for APC 2	20134-651
Socket module BI 8/4, as an upgrade kit	20140-610
Socket module BI 2Pin 22-28-8/4, as an upgrade kit	20140-613
Socket module MO 3Pin-Bovie, as an upgrade kit	20140-622
Socket module MO 3Pin-9/5, as an upgrade kit	20140-623
Cover MO 3Pin	20140-625
Socket module MF-0, as an upgrade kit	20140-630
Slot cover without function, as an upgrade kit	20140-660
Socket module NE 6 - NE 2Pin, as an upgrade kit	20140-642

APC pressure reducers and argon gas cylinders

Country-specific gas cylinder connectors APC 2 / APC 300

A

DIN 477, Nr. 6 m

for Afghanistan, Algeria, Andorra, Argentina **B***, Austria, Bangladesh **D***, Belgium, Bhutan, Brazil **B***, Brunei, Caribbean Countries, Chile **B***, China, Croatia, Cyprus, Czech Republic, Egypt, Estonia, France, Germany, Greece, Hungary, Iceland, India **D***, Indonesia, Iran, Ireland, Israel, Japan, Korea North, Korea South, Kuwait **D***, Latvia, Lebanon, Libya, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malaysia, Malta, Mauritius, Morocco, Myanmar, Namibia, Nepal **D***, Oman **D***, Pakistan **D***, Peru **B***, Philippines, Poland, Portugal, Qatar **D***, Romania, Russia, Saudi Arabia **D***, Singapore, Slovakia, Slovenia, South Africa, Spain, Sri Lanka **D***, Sudan, Switzerland, Taiwan (ROC), Thailand **D***, Tunisia, Turkey, Ukraine, United Arab Emirates **D***, Uruguay, Vietnam **D***, Yemen **D***, Yugoslavia

B

CGA Nr. 580 m

for Argentina **A***, Bolivia, Brazil **A***, Canada, Chile **A***, Columbia, Dominican Republic, Ecuador, El Salvador, Guam, Guatemala, Haiti, Honduras, Italy, Mexico, New Zealand, Panama, Peru **A***, USA, Venezuela

C

DIN 477, Nr. 10 m

for Denmark, Finland, Ivory Coast, Netherlands, Norway, Sweden

D

BS 341, Nr. 3 m

for Australia, Bangladesh **A***, Great Britain, India **A***, Kuwait **A***, Nepal **A***, Northern Ireland, Oman **A***, Pakistan **A***, Qatar **A***, Saudi Arabia **A***, Sri Lanka **A***, Thailand **A***, United Arab Emirates **A***, Vietnam **A***, Yemen **A***

** further gas cylinder connectors possible*

Accessories for modules

APC pressure reducers and argon gas cylinders

Pressure reducer with sensor for APC 2, with manual connection

gas cylinder connector to DIN 477 No. 6 m, W 21,8 outside,
with hose 0,5 m with manual connection

No. 20134-004

= 1

30134-008

A

Argon gas cylinder, 5 liters, empty

gas cylinder connector to DIN 477 No. 6 m
dimensions: height 60 cm, ø 14 cm
weight 8,8 kg

No. 20132-171

= 1

A

Argon gas cylinder, 5 liters, 200 bar (2800 psi) filled with 4.8 argon gas (99,998%)

gas cylinder connector to DIN 477 No. 6 m
dimensions: height 60 cm, ø 14 cm
weight 10,7 kg

No. 20132-004

= 1

A

Pressure reducer with sensor for APC 2, with manual connection

gas cylinder connector to CGA No. 580 m, 0,965'' inside,
with hose 0,5 m with manual connection

No. 20134-002

= 1

30134-008

B

Pressure reducer without sensor for APC 300, with manual connection

gas cylinder connector to CGA No. 580 m, 0,965'' inside,
with hose 0,5 m with manual connection

No. 20132-065

= 1

30132-154

B

Accessories for modules

APC pressure reducers and argon gas cylinders

Argon gas cylinder, 5 liters, empty

gas cylinder connector to CGA No. 580 m
dimensions: height 60 cm, ø 14 cm
weight: 8,1 kg

No. 20132-165

= 1

B

Pressure reducer with sensor for APC 2, with manual connection

gas cylinder connector to DIN 477 No. 10 m, W 24,32 outside,
with hose 0,5 m with manual connection

No. 20134-001

= 1

30134-008

C

Pressure reducer with sensor for APC 2, with manual connection

gas cylinder connector to BS 341 No. 3 m, G 5/8" inside,
with hose 0,5 m, with manual connection

No. 20134-003

= 1

30134-008

D

Pressure reducer with sensor

No. 20134-005

= 1

30134-008

Japan

Pressure reducer with sensor

No. 20134-006

= 1

30134-008

B

Accessories for modules

Further APC accessories

Bacteriological filter set, APC 2, APC 300, 0.2 µm, steril

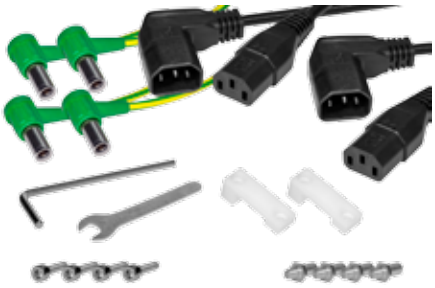
No. 20132-059	
= 50	
30132-275	STERILE EO

Connecting tube for central gas supply, APC 2. APC 300, length 1 m

No. 20132-085	
= 1	

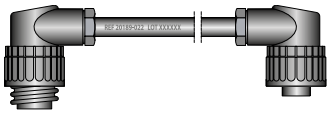
Fastening set for APC 300 and ICC on cart

APC 300 and ICC



No. 20132-061	
= 1	

Connecting cable from ICC, ACC (4 poles) to APC 300, length 0.35 m



No. 20189-022	
= 1	

Socket modules	No.
Socket module APC	20134-650
FiAPC socket module for APC 2	20134-651

Accessories for modules

IES smoke evacuation

Filter cartridge for IES 2, IES 300, with connection ø 22 mm

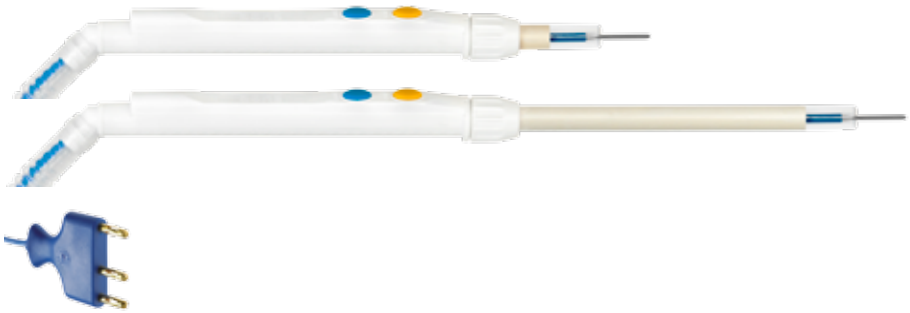
No. 20321-000	
= 1	
30321-010	

Prefilter for use with smoke evacuators, with connection ø 22 mm

No. 20321-022	
= 15	

Electrosurgical pencil with 2 buttons, VIO, ICC, ACC, ø 10 / 22 mm, International

with connecting cable 3 m, with spatula electrode and integrated smoke evacuationshaft extension 100 mm.



No. 20321-028	
= 25	4.5 kVp
30321-001	STERILE EO

Clip-on handle for Slim-Line electrosurgical pencils, tip short 12 mm

with evacuation tubing 3 m and connection ø 22 mm, without electrosurgical pencil

No. 20321-007	
= 25	
30321-000	STERILE EO

Clip-on handle for Slim-Line electrosurgical pencils, tip long 100 mm

with evacuation tubing 3 m and connection ø 22 mm, without electrosurgical pencil

No. 20321-020	
= 25	
30321-000	STERILE EO

Accessories for modules

IES smoke evacuation

Suction hose, with connection ø 22 mm, length 2.1 m

No. 20321-012
= 1
max 95 °C
max 134 °C

Suction hose, with connection ø 22 mm, length 2.7 m

No. 20321-009
= 1
max 95 °C
max 134 °C

Evacuation tube, optimized streaming, with connection ø 22 mm

No. 20321-004
= 1
max 95 °C
max 134 °C

Evacuation funnel, with connection ø 22 mm

No. 20321-010
= 1
max 95 °C
max 134 °C

Hose coupling ø 22 mm to ø 22 mm

No. 20321-005
= 3
max 95 °C
max 134 °C

Accessories for modules

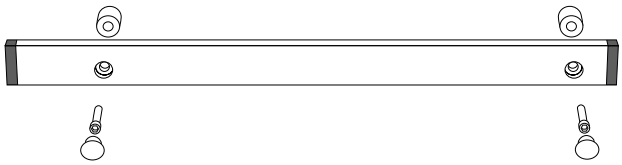
IES smoke evacuation

Holding arm for tube with 3 joints, length 1.3 m

for fastening on bracket 20180-040

No. 20321-014	
= 1	
	max 95 °C
30321-008	max 132 °C

Bracket for IES 300, length 355 mm



No. 20321-015	
= 1	
30321-008	

Evacuation element with connector ø 22 mm for IES 2

No. 20322-010	
= 1	

IES smoke evacuation

One-pedal foot switch for IES 2, AP & IP X8 equipment

with connecting cable 5 m, with connecting plug 7 poles

No. 20322-101

= 1

max 75 °C

30189-301

One-pedal foot switch for IES 300, AP & IP X8 equipment

with connecting cable 5 m, connecting plug 6 poles

No. 20321-001

= 1

30189-028

Power cord and foot switch cable	No.
Power cord ICC / IES 300, length 0.35 m	51704-033
Cable for IES 2 foot switch with connecting cable 5 m, with connecting plug 7 poles	20322-103

Fastening sets	No.
Fastening set IES 2 to VIO Cart 20180-000 incl. ECB cable	20180-132
Fastening set ICC 200 / ICC 300 / ICC 350 + IES 300 on cart UNIVERSAL 20185-100, 20185-101 ICC 200 / ICC 300 / ICC 350 + IES 300 on cart UNIVERSAL 20185-100, 20185-101	20321-019

Accessories for modules

EIP 2 irrigation pump

Tubing set EIP 2, for flexible endoscopes with Luer Lock connection, length 2.5 m

No. 20325-001	
= 5	
30325-001	STERILE EO

One-pedal foot switch for EIP 2, AP & IP X8 equipment

with connecting cable 3 m, connecting plug 4 poles

No. 20325-000	
= 1	
30189-028	

Hook for irrigation liquid bag on bracket / VIO Cart

No. 20325-002	
= 1	
	max 95 °C
	max 134 °C

Tubing set for irrigation forceps, length 2,8 m, without connecting cable

for single use, for EIP 2

No. 20325-020	
= 5	
30325-001	STERILE EO

Accessories for modules

EIP 2 irrigation pump

Irrigation adapter for Olympus, Fujifilm G5, STORZ

No. 20325-003	
= 1	

Irrigation adapter for Fujifilm

No. 20325-004	
= 1	

Irrigation adapter for PENTAX

No. 20325-005	
= 1	

Fastening sets	No.
Fastening set EIP 2 / ESM 2 to VIO Cart 20180-000	20180-135
Fastening set EIP 2 to Universal Cart, EIP 2 to Universal Cart	20321-203

Accessories for modules

Fluid management system

Reusable, with one suction unit

Single components	Pieces	No.
Silicone hose, length 600 mm	1	20340-004
Rail bracket, plastic	1	20340-002
Upper bracket for VIO CART, length 260 mm	1*	20180-040
Bracket for IES 300, length 355 mm	1*	20321-015

* optional

Reusable, with two suction units

Single components	Pieces	No.
Silocone hose, length 600 mm	1	20340-004
Reversing valve, rail bracket with two silicone hoses, length 300 mm	1	20340-003
Rail bracket, plastic	2	20340-002
Lower bracket for VIO CART, length 390 mm	1	20180-042
Upper bracket for VIO CART, length 260 mm	1	20180-040

Accessories for modules

Fluid management system

Silicone hose, length 600 mm

No. 20340-004	
= 1	
	max 95 °C
	max 134 °C

Rail bracket, plastic

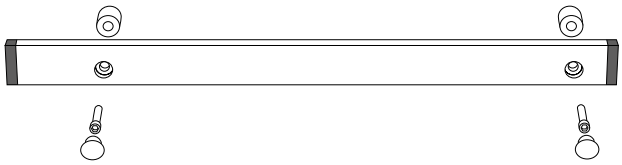
for use with suction container 20340-102 and 20340-103

No. 20340-002	
= 1	
	max 95 °C
	max 134 °C

Switching valve, rail bracket and 2 silicone hoses, length 300 mm

No. 20340-003	
= 1	
	max 95 °C
	max 134 °C

Bracket for IES 300, length 355 mm



No. 20321-015	
= 1	

Accessories for modules

Fluid management system

Suction container, 2.5 liters

for use with suction bag 20340-013

	No. 20340-103
= 1	

Suction bag, 2.5 liters

for use with suction container 20340-103

	No. 20340-013
= 30	
	⊗

Suction container, 1.5 liters

for use with suction bag 20340-012

	No. 20340-102
= 1	

Suction bag, 1.5 liters

for use with suction container 20340-102

	No. 20340-012
= 30	
	⊗

Nerve test / NT 2

Electrosurgical pencil for nerve test with 1 button, for silver ball electrode, NT 2, ICC 350 ZMK

with connecting cable 4 m

	No. 20190-148
= 1	0.25 kVp
	max 95 °C
30190-262	max 138 °C

Silver ball electrode for nerve test, ø 1 mm, length 40 mm	Shape / Forming	Piece	No.
	straight	1	21191-052

Patient plates for NT 2, without connecting cable

No. 20142-200
= 20

Patient plate cable for NT 2, length 5 m

No. 20142-100
= 1

Test box

Test box 3 for checking of electrosurgical accessories

	No. 20183-042
= 1	

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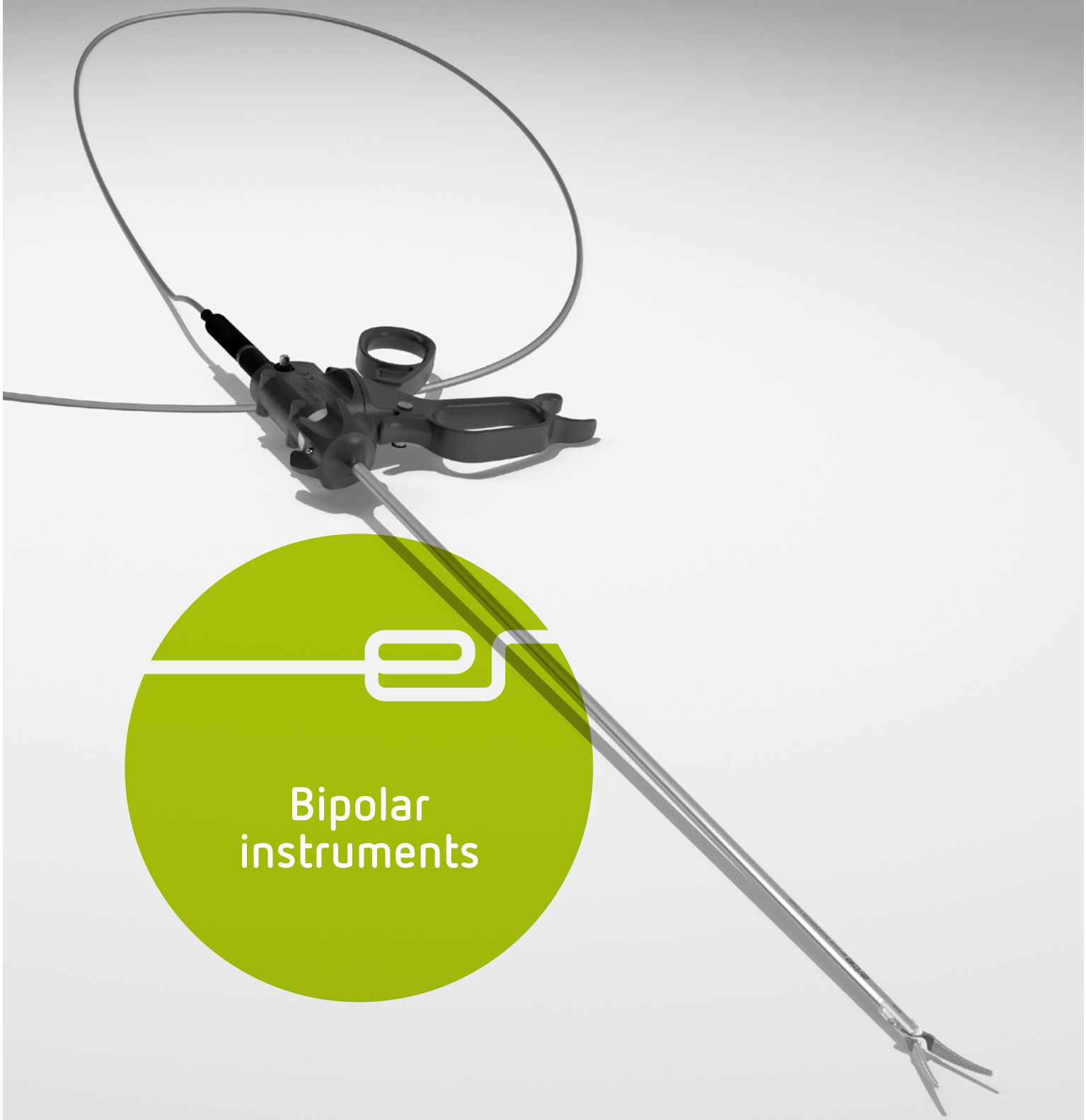


Bipolar instruments

Important notes

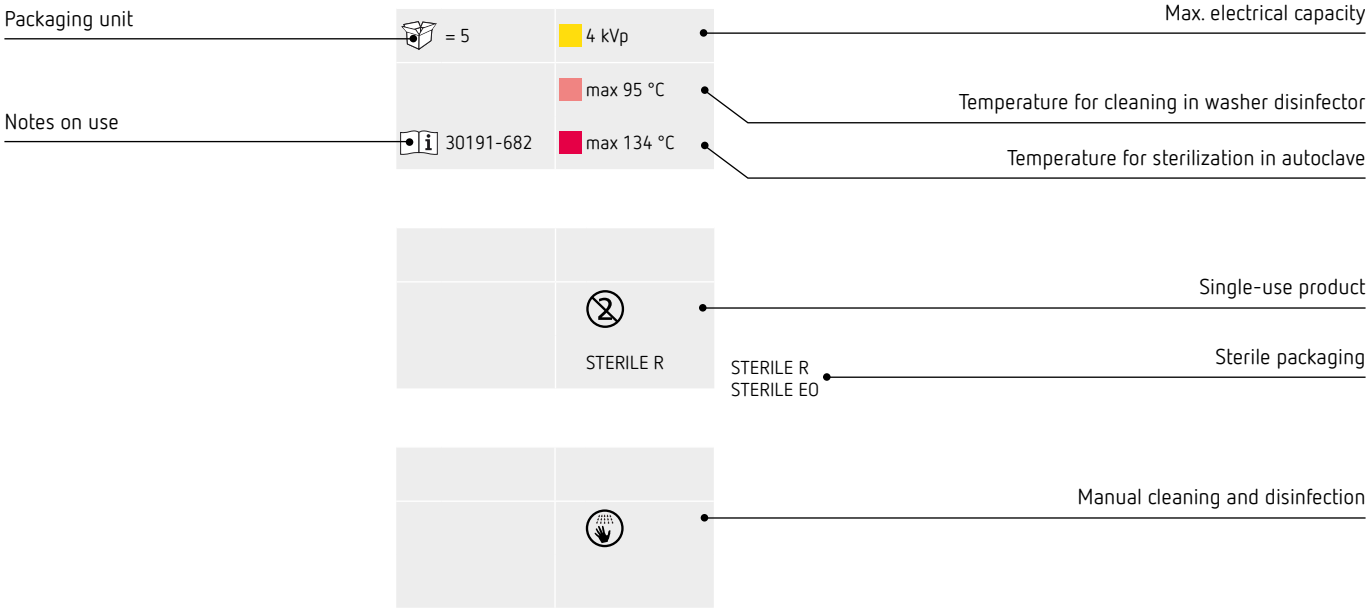
The authors and Erbe Elektromedizin GmbH have taken the greatest possible care while compiling the catalogue with electrosurgical accessories. Nevertheless, it is impossible to exclude the possibility that errors may be contained herein.

The information and recommendations given here may not be construed as constituting any basis for any claims against Erbe Elektromedizin GmbH. Should legal regulations stipulate liability, such liability shall be limited to intentional misconduct or gross negligence.

The data on the use of instruments is based on clinical experience. Medical science is subject to a process of permanent change based on research and clinical experience. Therefore the products are subject to alterations in design and technique. Because of production tolerances dimensions in the catalogue may marginally differ.

We confirm that none of our products contain latex, except the rubber straps, Art. No. 20592-009 and 20592-011.

Further product information



Please read carefully the corresponding notes on use before using any instrument.

Contents

Electrosurgery

Bipolar Instruments

Overview

Field of application

Endoscopy / laparoscopy

Open surgery

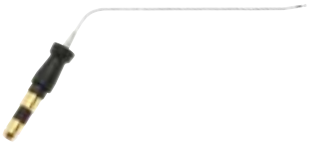
Type of instrument

Cutting instruments

Coagulation instruments

Discipline

ENT Ear-Nose-Throat



MIS Minimally Invasive Surgery

LAP forceps

Bipolar LAP forceps, Maryland, deep ribbed, shaft ø 5 mm, length 340 mm

complete instrument incl. insert 20195-143

No. 20195-132	
= 1	0.25 kVp
	max 95 °C
30195-119	max 138 °C

Bipolar LAP forceps, fenestrated, deep ribbed, shaft ø 5 mm, length 340 mm

complete instrument incl. insert 20195-144

No. 20195-133	
= 1	0.25 kVp
	max 95 °C
30195-119	max 138 °C

Bipolar E LAP forceps, fenestrated, deep ribbed, shaft ø 5 mm, length 340 mm

complete instrument incl. insert 20195-144

No. 20195-224	
= 1	0.25 kVp
	max 95 °C
30195-119	max 138 °C

Bipolar E LAP forceps, Maryland, deep ribbed, shaft ø 5 mm, length 340 mm

complete instrument incl. insert 20195-143

No. 20195-225	
= 1	0.25 kVp
	max 95 °C
30195-119	max 138 °C

Bipolar instruments

LAP forceps

Single components	Piece	No.
Insert for LAP forceps, Maryland and E LAP forceps, Maryland, deep-ribbed, ø 5 mm, length 340 mm (for 20195-132 and 20195-225) 	1	20195-143
Insert for LAP forceps, fenestrated and E LAP forceps, fenestrated deep-ribbed, ø 5 mm, length 340 mm (for 20195-133 and 20195-224) 	1	20195-144
Shaft tube for bipolar LAP forceps and BiClamp LAP forceps, ø 5 mm, length 340 mm 	1	20195-141
Shaft tube for bipolar E LAP forceps and BiClamp E LAP forceps, ø 5 mm, length 340 mm 	1	20195-241
Handle for LAP forceps, without connecting cable 	1	20195-140
Handle for E LAP forceps, without connecting cable 	1	20195-245

Accessories for treatment	Piece	No.
Cleaning brush, length 650 mm, for manual cleaning and disinfection	1	20191-279
Rinsing tube with Luer Lock connector, length 500 mm, for cleaning and disinfection by machine 	1	20195-201

Bipolar connecting cables	Connection	Length	Piece	No.
Bipolar connecting cable, VIO, ICC, ACC, T-Series, Standard 	Standard Standard	4 m 5 m	1 1	20196-045 20196-057
Bipolar connecting cable, VIO, ICC, ACC, International (2-Pin 22 mm) 	International International	4 m 5 m	1 1	20196-053 20196-061
Bipolar connecting cable, Martin Standard 	Martin Standard Martin Standard	4 m 5 m	1 1	20196-047 20196-059
Bipolar connecting cable, Valleylab and non-Erbe units (2-Pin 28 mm) 	Vallylab (2-Pin 28 mm)	4 m	1	20196-055

LAP BiSect and bipolar LAP scissors

LAP BiSect Micro, shaft ø 5 mm, length 350 mm

complete instrument

	No. 20195-204
= 1	0.475 kVp
	max 95 °C
30195-114	max 138 °C

LAP BiSect Macro, shaft ø 5 mm, length 350 mm

complete instrument

	No. 20195-205
= 1	0.475 kVp
	max 95 °C
30195-114	max 138 °C

Single components	Piece	No.
Insert for LAP BiSect Micro (20195-204), ø 5 mm, length 350 mm 	1	20195-206
Insert for LAP BiSect Macro (20195-205), ø 5 mm, length 350 mm 	1	20195-207
Shaft tube for LAP BiSect Micro and Macro, ø 5 mm, length 350 mm 	1	20195-208
Insulated tube for LAP BiSect Micro and Macro, ø 5 mm, length 350 mm	1	20195-209
Handle for LAP BiSect Micro and Macro 	1	20195-210

LAP BiSect and bipolar LAP scissors

Bipolar LAP scissors, Metzenbaum, shaft ø 5 mm, length 340 mm

	No. 20195-226
	0.25 kVp
	max 95 °C
30195-119	max 138 °C

Bipolar E LAP scissors, Metzenbaum, shaft ø 5 mm, length 340 mm

	No. 20195-227
	0.25 kVp
	max 95 °C
30195-119	max 138 °C

Single components		Piece	No.
Insert for bipolar LAP scissors Metzenbaum and bipolar E LAP scissors Metzenbaum, shaft ø 5 mm, length 340 mm (for 20195-226 and 20195-227)		1	20195-242
Shaft tube for bipolar LAP scissors, ø 5 mm, length 340 mm		1	20195-141
Shaft tube for bipolar E LAP scissors, ø 5 mm, length 340 mm		1	20195-241
Handle for LAP scissors, without connecting cable		1	20195-140
Handle for E LAP scissors, without connecting cable		1	20195-245

LAP BiSect and bipolar LAP scissors

Bipolar connecting cables	Connection	Length	Piece	No.
Bipolar connecting cable, VIO, ICC, ACC, T-Series, Standard 	Standard Standard	4 m 5 m	1 1	20196-045 20196-057
Bipolar connecting cable, VIO, ICC, ACC, International (2-Pin 22 mm) 	International International	4 m 5 m	1 1	20196-053 20196-061
Bipolar connecting cable, Martin Standard 	Martin Standard Martin Standard	4 m 5 m	1 1	20196-047 20196-059
Bipolar connecting cable, Valleylab and non-Erbe units (2-Pin 28 mm) 	Vallylab (2-Pin 28 mm)	4 m	1	20196-055

Accessories for treatment	Piece	No.
Cleaning brush, length 650 mm, for manual cleaning and disinfection	1	20191-279
Rinsing tube with Luer Lock connector, length 500 mm, for cleaning and disinfection by machine 	1	20195-201

Bipolar scissors BiSect

Bipolar scissors BiSect 180, bent, length 180 mm

incl. protector 20195-193

No. 20195-170	
= 1	0.6 kVp
	max 95 °C
30195-106	max 138 °C

Bipolar scissors BiSect 230, bent, length 230 mm

incl. protector 20195-194

No. 20195-171	
= 1	0.6 kVp
	max 95 °C
30195-106	max 138 °C

Bipolar scissors BiSect 280, bent, length 280 mm

incl. protector 20195-195

No. 20195-172	
= 1	0.6 kVp
	max 95 °C
30195-106	max 138 °C

Protectors for BiSect		Piece	No.
for BiSect 180		1	20195-193
for BiSect 230		1	20195-194
for BiSect 280		1	20195-195

Bipolar connecting cables	Connection	Length	Piece	No.
Bipolar connecting cable, VIO, ICC, ACC, T-Series, Standard 	Standard	4 m	1	20196-106
Bipolar connecting cable, VIO, ICC, ACC, International (2-Pin 22 mm) 	International	4 m	1	20196-107

Cutting instruments for MIS

Needle electrode, straight, ø 5 mm, shaft insulated, length 100 mm

needle adjustable to:0 / 0.8 / 1.6 / 2.5 mm, non-adhesive coating, Luer-Lock irrigation connection, only for VIO, ICC 350

No. 20191-191	
= 1	0.5 kVp
	max 95 °C
30191-491	max 134 °C

Needle electrode, straight, ø 5 mm, shaft insulated, length 320 mm

needle adjustable to:0 / 0.8 / 1.6 / 2.5 mm, non-adhesive coating, Luer-Lock irrigation connection, only for VIO, ICC 350

No. 20191-158	
= 1	0.5 kVp
	max 95 °C
30191-491	max 134 °C

Needle electrode, straight, ø 5 mm, shaft insulated, length 470 mm

needle adjustable to:0 / 0.8 / 1.6 / 2.5 mm, non-adhesive coating, Luer-Lock irrigation connection, only for VIO, ICC 350

No. 20191-188	
= 1	0.5 kVp
	max 95 °C
30191-491	max 134 °C

Needle electrode, bent, ø 5 mm, shaft insulated, length 100 mm

needle adjustable to:0 / 0.8 / 1.6 / 2.5 mm, non-adhesive coating, Luer-Lock irrigation connection, only for VIO, ICC 350

No. 20191-190	
= 1	0.5 kVp
	max 95 °C
30191-491	max 134 °C

Cutting instruments for MIS

Needle electrode, bent, ø 5 mm, shaft insulated, length 320 mm

needle adjustable to:0 / 0.8 / 1.6 / 2.5 mm, non-adhesive coating, Luer-Lock irrigation connection, only for VIO, ICC 350

	No. 20191-143
= 1	0.5 kVp
	max 95 °C
30191-491	max 134 °C

Needle electrode, bent, ø 5 mm, shaft insulated, length 470 mm

needle adjustable to:0 / 0.8 / 1.6 / 2.5 mm, non-adhesive coating, Luer-Lock irrigation connection, only for VIO, ICC 350

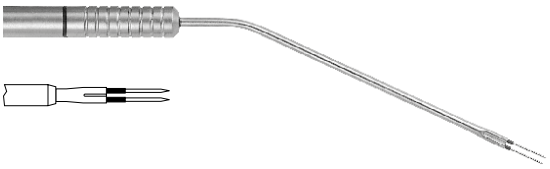
	No. 20191-189
= 1	0.5 kVp
	max 95 °C
30191-491	max 134 °C

Bipolar connecting cables	Connection	Length	Piece	No.
Bipolar connecting cable, VIO, ICC, ACC, T-Series, Standard 	Standard	4 m	1	**20196-054**
Bipolar connecting cable, VIO, ICC, ACC, International (2-Pin 22 mm) 	International	4 m	1	**20196-051**

Contact and puncture electrodes for MIS

Bipolar puncture coagulation needle, bent 25°, needle length 10 mm, length 100 mm

e.g. for puncture coagulation of the concha nasalis



No. 20195-025	
= 1	0.5 kVp
	max 95 °C
30195-011	max 138 °C

Bipolar connecting cables	Connection	Length	Piece	No.
Bipolar connecting cable, VIO, ICC, ACC, T-Series, Standard 	Standard Standard	4 m 5 m	1 1	20196-045 20196-057
Bipolar connecting cable, VIO, ICC, ACC, International (2-Pin 22 mm) 	International International	4 m 5 m	1 1	20196-053 20196-061
Bipolar connecting cable, Martin Standard 	Martin Standard Martin Standard	4 m 5 m	1 1	20196-047 20196-059
Bipolar connecting cable, Valleylab and non-Erbe units (2-Pin 28 mm) 	Vallylab (2-Pin 28 mm)	4 m	1	20196-055

Contact electrodes

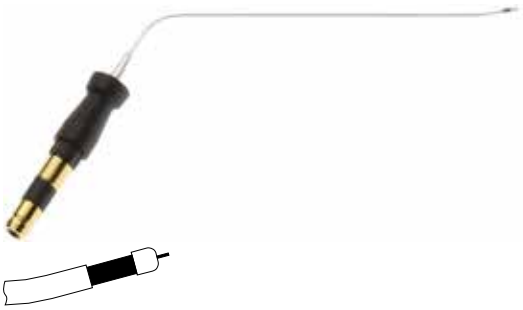
Bipolar contact electrode, bent 22.5°, tip angled 45°, length 100 mm

No. 20195-003	
= 1	0.5 kVp
	max 95 °C
30195-011	max 138 °C

Cutting instruments for ENT

Micro needle 100, ø 1.5 mm, rigid, metal shaft insulated, length 100 mm

needle ø 0,15 mm, needle length adjustable from 0-1,5 mm, for VIO, ICC 350, non-adhesive coating



No. 20191-309	
= 1	0.5 kVp
	max 95 °C
30191-649	max 138 °C

Micro needle 240, ø 1.5 mm, rigid, metal shaft insulated, length 240 mm

needle ø 0,15 mm, needle length adjustable from 0-1,5 mm, for VIO, ICC 350, non-adhesive coating

No. 20191-314	
= 1	0.5 kVp
	max 95 °C
30191-649	max 138 °C

Handle for micro needle, Standard (BI 8/4 mm), with connecting cable 4 m

needle length adjustable from 0-1,5 mm, secure against rotation

No. 20191-307	
= 1	0.5 kVp
	max 95 °C
30191-647	max 138 °C

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power your performance.
BiSect and LAP BiSect
Electrosurgical scissors:
reusable, with a long life span
New LAP BiSect Micro for precise
bipolar dissection

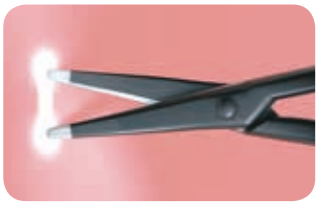
Bipolar BiSect scissors for open surgery

The "multifunctional scissors" with a long life span.

Mechanical cutting

Cutting with bipolar coagulation

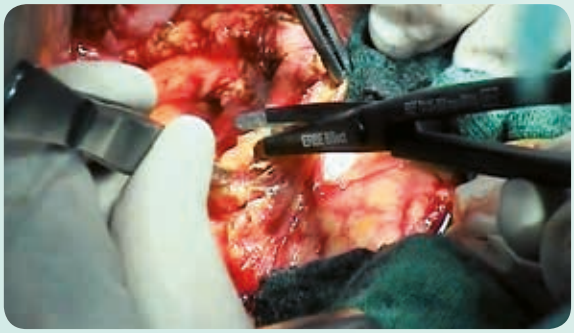
Pre-coagulation



Surface coagulation

Selective coagulation

The electrosurgical, bipolar BiSect scissors can be used for various steps in open surgery procedures. Using a single instrument, the surgeon has a choice of several different functions – without having to change the instrument. During mechanical cutting, the tissue is coagulated at the same time, with the option of pre-coagulation for improved hemostasis. Surfaces can be either selectively coagulated with closed scissor blades or coagulated over larger areas with open scissor blades and by placing them on the tissue. The VIO system provides the suitable current form with adjusted energy output, for example, with the BIPOLAR SOFT mode. Interventions can be performed quicker with less blood loss while saving on suture material at the same time.



Durable instrument with a long life span = highly economical

The BiSect can be reprocessed and reused numerous times. The high-quality plastic insulation provides lasting safety. The ceramic coating between the scissor blades assures consistent quality from the first to the last cut. The BiSect ceramic protector offers reliable protection during reprocessing of the instrument.

LAP BiSect

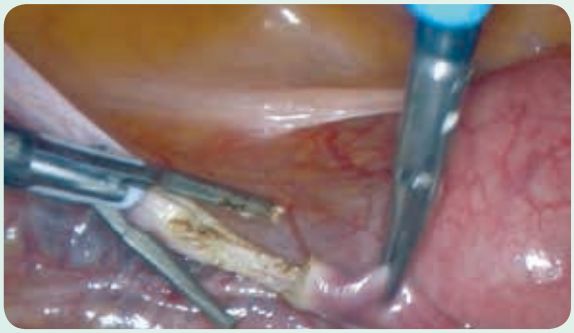
Bipolar dissection, cutting and coagulation.

Precise and anatomical surgery with the LAP BiSect Micro
No. 20195-204

The LAP BiSect enables laparoscopic surgery with a minimum need for equipment and instruments. Easier, quicker, more effective and more cost-efficient. For excellent dissection, cutting and coagulation, the LAP BiSect offers a wide range of functions and thus makes new operating techniques possible. Tissue is separated electrosurgically, so that it is not necessary to resharpen the blades as is required for mechanical cutting.

With its "multiple functions", the LAP BiSect minimizes the time required for changes between instruments, shortening operating times. The LAP BiSect is reusable and is thus clearly more cost-efficient than other dissection technologies. After just a few interventions. Together with the bipolar LAP forceps and the LAP BiClamp instruments, the new BiSect instruments open new avenues for surgical procedures.

The Erbe technology of the VIO system and the units of the ICC series supports the CUT and COAG effects with the appropriate optimized modes and setting.



The blue pedal of the footswitch is used for coagulation, the yellow pedal for dissection

01

Jaw of the LAP BiSect Macro

02

Jaw of the LAP BiSect Micro

THE ADVANTAGES OF THE LAP BISECT INSTRUMENTS

- ☑ Minimal need for changing instruments enables maximum focus on procedure and target tissue
- ☑ Excellent coagulation and cutting
- ☑ Available in two versions: Macro and Micro
- ☑ Saves costs (shorter operating times, instrument reusable)
- ☑ Easy to handle, both during surgery as well as reprocessing

... AND THE LAP BISECT MICRO

- ☑ Considerable freedom of movement during surgery due to the curved jaw shape
- ☑ Jaws allow precise and anatomical surgery
- ☑ as well as variable, individual surgery depending on the target tissue

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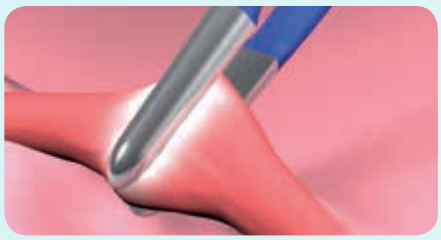
power your performance.
Bipolar PREMIUM forceps
Bipolar irrigation forceps
The Erbe forceps range with its
non-stick effect

Advantages of the non-stick effect



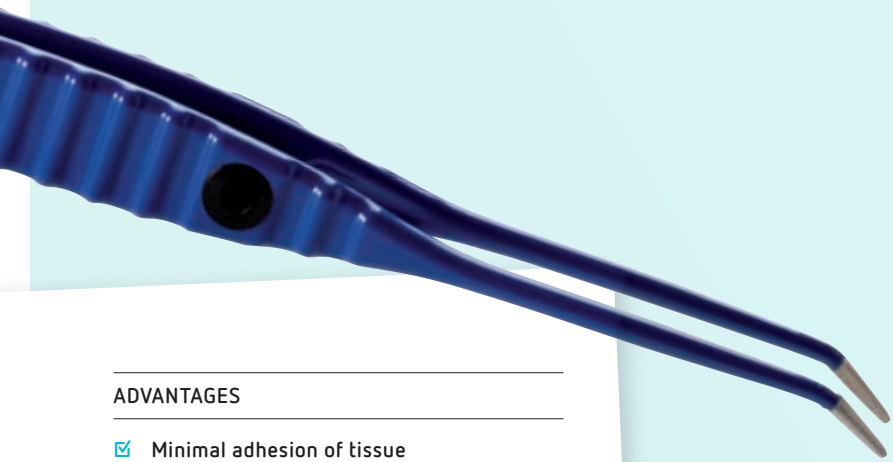
Coagulation of blood vessels

Superficial coagulation

During bipolar electrosurgical coagulation an unwanted sticking effect can occur when the forceps' tips adhere to the tissue. This carries a risk of inadvertent tearing open of coagulated vessels. In addition, tissue sticking to the forceps adversely affects the continued coagulation. Sticking is markedly reduced with the automatic power regulation provided by the Erbe VIO unit technology and the use of Soft Coagulation with AUTO STOP. The new PREMIUM forceps and irrigation forceps additionally reduce sticking.

The forceps are available in addition to the standard models (s. catalogue of electrosurgical accessories).

The Erbe bipolar forceps are available in various lengths and shapes for different surgical and anatomical requirements.



ADVANTAGES

- ☑ Minimal adhesion of tissue
- ☑ Minimal tearing of coagulated tissue
- ☑ Precise and safe operative procedure
- ☑ Maximum saving of time due to minimal time required for cleaning
- ☑ Safe coagulation due to consistent energy output

AREAS OF APPLICATION

- ☑ All surgical disciplines

SPECIAL BENEFITS IN

- ☑ Microsurgery
- ☑ ENT
- ☑ Oral and maxillofacial surgery
- ☑ Plastic surgery

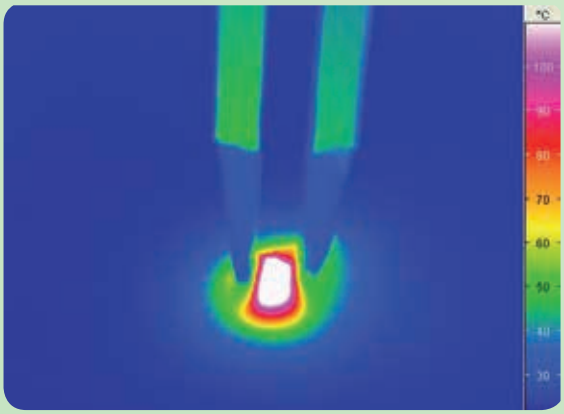
The forceps with the cool-down effect. Minimizes tissue adhesion to the branches.

The reusable PREMIUM forceps make it easy to coagulate tissue.
Sticking effects on the tips of the forceps are reduced to a minimum.

Pinpoint grasping with innovative tip geometry

The trick lies in a special alloy with high temperature conductivity to draw the heat away from the forcep tip and to prevent overheating. Heat accumulation and the resulting adhesion of coagulate is significantly reduced. The abraded and matt-finished surface of the forceps' tips allows tissue and vessels to be grasped safely. At the same time potential light reflections are reduced, improving the visibility at the operating site when working under a microscope.

The new forceps are available in all popular shapes and sizes and can be used in any surgical discipline.



Themography illustrates the low temperature level of the forceps' tips during coagulation

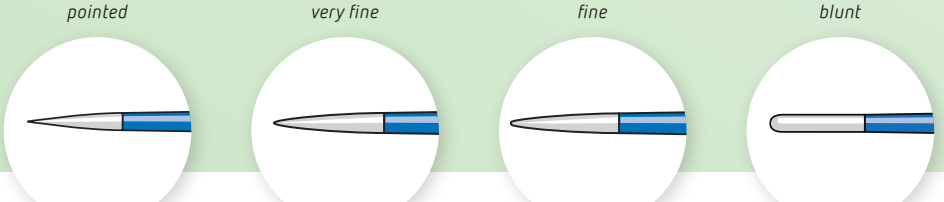
THE BENEFITS AT A GLANCE

- ☑ Limited tissue adhesion due to high temperature conductivity
- ☑ Long instrument life due to high-quality alloy
- ☑ Targeted precise coagulation due to precise design of the tips
- ☑ Firm grasping of tissue due to abraded gripping surface
- ☑ Less time required intraoperatively for cleaning
- ☑ Good visibility at the operating site due to reduced light reflections (e.g. during preparation under a microscope)

Overview of the PREMIUM forceps

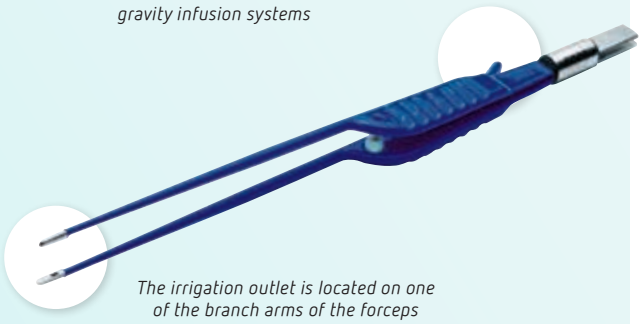
Bipolar forceps PREMIUM – straight		
20195-501	12 cm	pointed 0.2 mm
20195-502	12 cm	very fine 0.4 mm
20195-503	12 cm	fine 0.7 mm
20195-504	12 cm	fine 0.7 mm; angled
20195-505	18.5 cm	pointed 0.2 mm
20195-506	18.5 cm	very fine 0.4 mm
20195-507	18.5 cm	fine 0.7 mm
20195-508	18.5 cm	blunt 1.0 mm
20195-509	18.5 cm	blunt 1.0 mm; angled
20195-510	20 cm	pointed 0.2 mm
20195-511	20 cm	very fine 0.4 mm
20195-512	20 cm	blunt 1.0 mm
20195-513	20 cm	blunt 1.0 mm; angled
20195-514	20 cm	blunt 2.0 mm; angled
20195-515	23 cm	blunt 2.0 mm
20195-516	26 cm	blunt 1.0 mm; angled

Bipolar forceps PREMIUM – bayonet		
20195-531	15.5 cm	pointed 0.2 mm
20195-532	15.5 cm	very fine 0.4 mm
20195-533	15.5 cm	fine 0.7 mm
20195-534	17 cm	pointed 0.2 mm
20195-535	17 cm	blunt 1.0 mm
20195-536	20 cm	very fine 0.4 mm
20195-537	20 cm	fine 0.7 mm
20195-538	20 cm	blunt 1.0 mm
20195-539	20 cm	blunt 1.2 mm
20195-540	20 cm	blunt 2.0 mm
20195-541	20 cm	blunt 1.2 mm; angled downwards
20195-542	20 cm	blunt 1.2 mm; angled upwards
20195-543	23 cm	pointed 0.2 mm
20195-544	23 cm	very fine 0.4 mm
20195-545	23 cm	fine 0.7 mm
20195-546	23 cm	blunt 1.0 mm
20195-547	23 cm	blunt 1.2 mm
20195-548	23 cm	fine 0.7 mm; angled upwards
20195-549	23 cm	fine 1.2 mm; angled upwards
20195-550	23 cm	fine 0.7 mm; angled down-wards
20195-551	25 cm	pointed 0.2 mm
20195-552	25 cm	very fine 0.4 mm
20195-553	25 cm	fine 0.7 mm
20195-554	25 cm	blunt 1.0 mm
20195-555	25 cm	blunt 1.2 mm
20195-556	25 cm	fine 0.7 mm; angled upwards

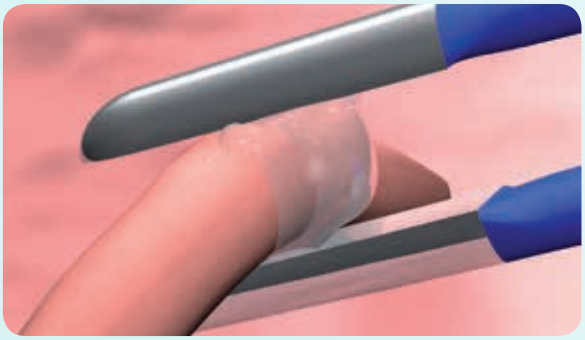


The function of the bipolar irrigation forceps

The external diameter of the irrigation connection is 3 mm. It can be connected to all convention gravity infusion systems



The irrigation outlet is located on one of the branch arms of the forceps



Irrigation during coagulation

The irrigation channel passes through the lower part of the forceps ending in an outlet in one of the branch arms. Irrigation with an NaCl solution has several positive effects:

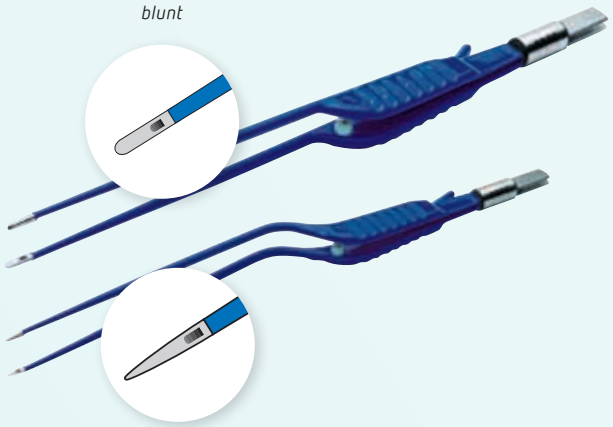
- ☑ **Effective coagulation**
- ☑ **No damage or tearing of the coagulated vessels after coagulation**
- ☑ **Even coagulation with constant power output**
- ☑ **NaCl solution optimizes the electrical contact**

Due to these advantages the surgical procedure can be carried out in a shorter period of time as the instrument rarely requires cleaning intraoperatively. The irrigation solution is connected to a standard infusion apparatus with an adjustable drip rate via the cylindrical clip.

The forceps can be disinfected in the thermodisinfector at a temperature of 95°C or in the autoclave at a temperature of 138°C.

Overview of irrigation forceps and connecting cables

blunt



fine

Bipolar irrigation forceps – straight		
20195-150	20 cm	blunt 1.5 mm

Bipolar irrigation forceps – bayonet		
20195-151	20 cm	fine 0.5 mm
20195-152	20 cm	blunt 1.0 mm
20195-153	23 cm	fine 0.5 mm
20195-154	23 cm	blunt 1.0 mm

Connecting cable for bipolar forceps

for VIO, ICC, ACC

Length 4 m	**No. 20196-045**
Length 5 m	**No. 20196-057**

for VIO, ICC, ACC, international

Length 4 m	**No. 20196-053**
Length 5 m	**No. 20196-061**

for Valleylab

Length 4 m	**No. 20196-055**

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