Technical Specification for Combined High-End EV Surgical Station with UHD 4 K Laparoscopic Vision Platforms & Complete Energy Platform

Complete EV Surgical Station should comprise of following Energy & Vision Source

A) **RF Energy Platform** -Electro surgery unit with Thermo-fusion (Vessel Sealing)
B) **Argon Plasma Coagulation -** For management of bleeding and devitalization of tissue abnormalities
C) **Water Jet Tissue Dissection System with Suction Module -** 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.
D) **Smoke Evacuation Unit** – For taking care of surgical smoke
E) **UHD Camera Head & Camera Control Unit (CCU)**
F) **4K UHD Telescopes**
G) **4K UHD Medical Grade Monitor 32" (Twin)**
H) **LED Light Source with fiber optic Cable**
I) **X Light Source for NIR Imaging**
J) **Illuminator**
K) **CO2 Gas Insufflator**
L) **Suction - irrigation pump**
M) **ICG**

1. RF Energy Platform -Electro surgery unit with Thermo-fusion (Vessel Sealing)

* Radio Frequency Energy Platform High End Electro Surgical Generator unit with Vessel Sealing facility should be microprocessor controlled, US-FDA / European Certificate marked in accordance with the medical devices directive (93/42/EEC) & should comply with the requirement of the medical device directive of class I Equipment and electromagnetic compatibility.
* The Electro surgical generator should be 400-watt touch screen display with 15 digital signal processors.
* Unit should facilitate functions of monopolar, bipolar & vessel sealer with in-built regulated power supply adapter for bipolar resection.
* Special bipolar mode for coagulation of vascular tissue (Vessel Sealing) up to 7 mmwith Reusable / Single use Hand instrument for open as well laparoscopic surgeries & should have US- FDA approval for 7mm Vessel.
* Unit should have a Step guide suggesting appropriate setting configurations for every instrument and application.
* The system should make 25 million measurements / sec for better tissue effect and should measure tissue impedance through power peak system

Dr. Ankur Verma **HOD, Surgical Oncology**	Dr. Durgesh Kumar Pandey **Member**	Dr. Ashok Kumar Singh **Member**	Prof. Vijay Kumar **External Expert**	Prof. Akash Agarwal **External Expert**
Prof. Arvind Krishnamurthy **External Expert**	Mr. Rajni Kant Verma **Finance Officer/ Nominee**	Mr. Rajni Kant Verma **JD(MM)**		Prof. Akshay Anand **Director/Nominee of Director**

d) Reusable Bipolar forcep straight & Bayonet non sticky 02 each with mandatory minimum shelf life of 50- 100 Procedures

e) Reusable Thermo-fusion / Vessel Sealing hand instrument for Lap surgeries (for vasculatures up to 7mm) LAP forceps, Maryland, semi-deep ribbed, shaft @ 5 mm, non-adhesive coating, length 340 mm; with connecting cable 4 m and MF plug, complete instrument with mandatory minimum shelf life of 50 - 100Procedures - 2 Nos

f) Reusable Thermo-fusion / Vessel Sealing hand instrument for Open surgeries (for vasculatures up to 7mm) 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 with mandatory minimum shelf life of 50 - 100 Procedures - 4 Nos,

g) Single Use Tissue Navigation Instrument for Cutting & Sealing both Lap & Open Surgery 10 Pcs each

h) Reusable Bipolar Lap Scissor for Laparoscopic surgery with cable, shaft $ 5 mm, length 350 mm; complete instrument with mandatory minimum shelf life of 50 - 100 Procedures - 02 Nos

i) Single Use hand pencil with Monopolar Electrodes - disposable 100 Pcs to perform 100 procedures

j) Single Use Patient plate with equipotential ring - disposable 100 Pcs to perform 100 procedures

k) Workstation trolley with attached Suction unit from same OEM - 1Nos.

2. Argon Plasma Coagulation

For management of bleeding and devitalization of tissue abnormalities achieved by optimal coordination with RF generator

* Argon Plasma unit should be microprocessor controlled, US-FDA / European Certificate marked in accordance with the medical devices directive (93/42/EEC) & should comply with the requirement of the medical device directive of class I equipment and electromagnetic compatibility.
* The Argon Plasma Coagulation system should have automatic parameters setting for various types of instruments and automatic depth controlled plasma regulation.
* Should have t h r e e different APC modes suitable for different indicationsPrecise APC - adjustment made using the effect settings Pulsed APC - adjustment made using the parameter power settings Forced APC - adjustment made using the parameter power settings
* 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.
* Should have the facility to use Argon plasma coagulation and monopolar coagulation simultaneously

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4. Automatic Smoke Evacuation Unit

- The smoke plume evacuation system should be microprocessor controlled, US-FDA and / or European Certificate marked in accordance with the medical devices directive (93/42/EEC) & Electro Surgical Unit should comply with the requirement of the medical device directive of class I equipment and electromagnetic compatibility.
- The smoke plume evacuation system should be compatible with already installed VIO Surgical Workstation & Electrosurgical Units and should be fitted into same station trolley for smooth functioning and ergonomics.
- The smoke plume evacuation system should be able to extract and filter smoke and aerosol- laden air during surgical procedures & should be also able to filter COVID -19 like viruses and other microorganism present in surgical smoke generated during the procedure.
- The system should have a functional 5.7 inches touch screen display for better visibility& ease of control & display should be able to show settings, operating modes, filter run-time and information messages for the user.
- The System should have Bi-Turbo technology for effective filtration, should have ULPA-15 filter (5 stage filter protection) and active carbon filters & should also have ability to remove 99.9995% of all 0.1µm particles.
- The system filter should have maximum output of 730 l/min & have the ability to give a notification when volume flow of more than 300l/min is reached.
- The system should have ability to be used along with any electrosurgical unit, Laser and ultrasound devices & system should have automatic activation feature, no need of any additional footswitch for activation during monopolar electrosurgical applications.
- The system should display error if filter is not inserted to prevent damage & system should be able to use in vertical as well as horizontal way as per user needs.
- The system should have the ability to be fixed on the ceiling units (OT pendants) & should have the ability to be used with 2 instruments at the same time during any Surgical Procedures.
- The system should be able to used in open as well as lap surgical procedures with All required Accessories from same OEM only & system noise development at 100% evacuation should be ≤ 59 dB as must have sound insulation cladding, integrated ducts and airborne sound absorbers for noise insulations.
- The user should be able to set critical features like - suction efficiency, standby suction efficiency as well as standby suction time in both lap and open surgery modes & should have footswitch activation facility for laser and ultrasonic uses during procedure.
- The system should be provided with self-sealing water trap to protect the main filter cartridge from liquids & weight of system should be < 10kgs.
- Service life of the unit filter should be for

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* Dedicated Full UHD (3840*2160p) medical grade USB recording system for still images and video recording.
* Camera should have function to identify blood vessels using edge & spectral enhancement algorithms.
* Camera settings (e.g., white balance, zoom, gain, sharpness etc.) should be possible directly from the camera head buttons.
* The system should have **digital zoom** and **optional optical zoom** to enhance the quality of image size & cross specialty standardization of the camera system, regardless of the telescope used.

UHD IR Telescope 10mm (0 & 30 degree)

* 4K Optics for better contrast & color reproduction.
* Large field of view and depth of focus.
* Completely distortion free
* Laser welded, Sapphire tip and three tube design. Autoclavable type
* Telescope should have outstanding sharpness at periphery as well as at center of the image.

UHD IR Telescope 5 / 5.5mm (0 & 30 degree)

* HD/ Optics for better contrast & color reproduction.
* Large field of view and depth of focus.
* Laser welded, Sapphire tip a n d t h r e e t u b e design.
* Completely distortion free
* Autoclavable type and should be supplied with autoclavable tray.

ICG

- Should supply with Fluorescence Imaging technology for open procedure and Laproscopic procedure
- Video Processor and Illuminator
- The VPI shall be able to provide the VIS (visible) and NIR (near-infrared) illumination to the surgical endoscope via a flexible light guide simultaneously.
- The VIS light source shall be consisted of light emitting diode array.
- The NIR light source shall be consisted of NIR laser diode array.
- The VPI shall be able to generate simultaneous real-time UHD video color and ICG fluorescence images as an overlay in the same image.
- NIR light source shall be triggered by the button on the camera.
- It shall have an indicator in the monitor when NIR light source is on.
- Video output signals: 2 UHD-SDI, 1 DVI
- It shall be able to convert the video format between UHD-SDI and 3G-SDI.
- The device shall have features for easy use at the front panel for quick operation and setting purpose:

- Illumination button
- White balance button

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The system should come with an autoclavable fibre optic cable of 4.8 mm diameter, must be Autoclavable: High Resistance protection tube, reduced diameter with high fibre density, Small bending radius for comfortable use, min. 230 cm Length.

X-Light (source for NIR imaging):

- Light source with Near InfraRed/ICG technology
- Optional accessories Fiber optic light cable Ø3.5mm (no. 20820-000) Fiber optic light cable Ø4.8mm (no. 20821-000)
- Mains voltage 100–240 V
- Mains frequency 50–60 Hz
-
- Operating conditions Temperature: +10° C to +35° C
- Humidity: 5%–85% RH (without condensate) Atmospheric pressure: 70–106 kPa
- Transport and storage conditions Temperature: -10° C to +55° C
- Humidity: 5%–95% RH (without condensate) Atmospheric pressure: 50–106 kPa
- Manufacturer Erbe Vision GmbH, Eisenbahnstrasse 102, 78573 Wurmlingen, Germany E-mail: info@erbevision.com
- Distributor Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany Classification (according to MDR 2017/745) Class I
- Protection class CF

VIRON XO Illuminator

It should be applied along with working length 150mm.

LED Light Source with Fiber Optic Cable

- Color rendering index (CRI):
- Number of light outputs: min. 1
- Frequency: 50-60 Hz.
- Power consumption 220 VA.

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* Should have line voltage range of 170-260 volts.
* Should have frequency of 50Hz.
* Should have maximum power consumption up to 75VA.
* Should have CO2 medical grade (USP) insufflations medium.
* The LCD Display should show pressure, gas consumption settings and actual pressure.
* It should have pressure setting range between 1 to 25 mmHg.
* It should have a maximum of 30/40 L/min outlet for CO2 gas flow.
* It should have 3L/min fixed Veress CO2 flow.
* It should have 36-degree Celsius outlet of the trocar end for warmer (only for CO2)
* The unit should have operating environment range of 10 degree Celsius to 40 degree Celsius
* It should have dimensions of 160x330xx330mm
* It should have weight of at least 6 kg.

Suction - irrigation pump

* The suction irrigation pump should be a single unit.
* It should have a provision to customize/upgrade the user programs through software license keys.
* It should have Touch screen display for easy operation.
* It should have functions for distension, fluid aspiration and irrigation of body cavities.
* It should have monitoring of fluid deficit in laparoscopy.
* It should come with a pressure sensitive and wireless foot switch for easier operation.

Essential Criteria:

1. Demonstration Optional, Online or Physical or 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.
8. Equipment should have brand name / model number embossed/ etched on the equipment.

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Kalyan Singh Super Specialty Cancer Institute

कल्याण सिंह अति विशिष्ट कैंसर संस्थान

C.G. City ,Sultanpur Road, Lucknow-226002

सी०जी० सिटी, सुल्तानपुर रोड, लखनऊ- 226002

(An Autonomous Institute of the Govt. of Uttar Pradesh)

(उत्तर प्रदेश सरकार का स्वायत्तशासी संस्थान)

Email: procurement.kssscl@gmail.com

Proprietary Article Certificate (PAC) for Items/Goods

(High Freq Cu Surgical sthion)

(1) The indented goods are manufactured by M/s ERBE Elektromedizin GmbH.

(2) No other make or model is acceptable for the following reasons: (Integrated)

a) ERBE VIO (3)

b) ERBE JET 2

c) ERBE CRYO 2

IES, FSM 2 & VIRION X

along with various instruments as mentioned in corrigendum

(Dr Ankur Verma)
Associate Professor and Head
Department of Surgical Oncology
KSSSCI, Lucknow

(Signature of Indentor)

(Dr Ankur Verma)
Associate Professor and Head
Department of Surgical Oncology
KSSSCI, Lucknow

(Signature of HOD)

Technical Specification for Surgical WorkStation consists of Combined High-End Radio frequency, Energy, Water Jet, APC with Automatic Surgical Smoke Evacuation System

An integrated RF, with Argon and Kinetic energy surgical platform which can dissect, coagulate and seal the tissues during open and laparoscopic surgeries. System should comprise of below Type of Module Energies.

1. RF Energy Platform -Electro surgery unit with Thermo fusion (Vessel Sealing)

- Radio Frequency Energy Platform High End Electro Surgical Generator unit with Vessel Sealing facility should be microprocessor controlled, US-FDA & European Certificate marked in accordance with the medical devices directive (93/42/EEC) & should comply with the requirement of the medical device directive of class I equipment and electromagnetic compatibility.
- The Electro surgical generator should be **400-watt touch screen / touch pad display** with 15 digital signal processors.
- Unit should facilitate functions of monopolar, bipolar & vessel sealer with in-built regulated power supply adapter for bipolar resection.
- Special bipolar mode for coagulation of vascular tissue (Vessel Sealing) up to 7 mm with **Reusable / Single use Hand instrument** for open as well laparoscopic surgeries & should have US- FDA approval for 7mm Vessel.
- Unit should have a Step guide suggesting appropriate setting configurations for every instrument and application.
- The system should make **25 million measurements / sec** for better tissue effect and should measure tissue impedance through power peak system.
- System should have wifi compatibility for future OR integration.
- Unit should be plug & play with **4 or more** universal multi-functional sockets to accommodate any instrument.

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- Unit should support neutral electrode.
- **Following essential accessories to be supplied as a part of Radio Frequency Energy Platform High End Electro Surgical Generator unit with Vessel Sealing facility from Same Single OEM and Affidavit related to the 100% compliance of offered accessories as per nomenclature mentioned below – single or reusable along with mentioned qty and offered of same O.E.M should be provided, else bid will be rejected**

a) **Water resistant or 100% Washable (IPX8) Footswitch** Monopolar & Bipolar both with facility for swapping between programs with mandatary minimum shelf life of 500 Procedures – **1Nos.**

b) Reusable Monopolar cable for Endoscopic instruments with mandatary minimum shelf life of 100 Procedures – **2 Nos, if disposable** then **200 Pcs to perform 100 procedures** by each cable

c) Reusable Bipolar Cable for reusable bipolar forcep with mandatary minimum shelf life of 100 Procedures – **2 Nos, if disposable** then **200 Pcs to perform 100 procedures** by each cable

d) Reusable Bipolar forcep straight & Bayonet non sticky 01 each with mandatary minimum shelf life of 100 Procedures – **1 Nos, if disposable then 100 Pcs each of Straight & Bayonet non sticky Bipolar Forcep (200 Pcs) to perform 100 procedures by both forcep**

e) **Reusable / Single Use Thermo fusion / Vessel Sealing** hand instrument for **Lap surgeries** (for vasculatures up to 7mm) 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 with mandatary minimum shelf life of **100 Procedures – 1 Nos, if disposable** then **100 Pcs to perform 100 procedures**

f) **Reusable / Single Use Thermo fusion / Vessel Sealing** hand instrument for **Open**

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- The Argon Plasma Coagulation system should have automatic parameters setting for various types of instruments and automatic depth controlled plasma regulation.
- Should have three different APC modes suitable for different indications

  Precise APC – adjustment made using the effect settings

  Pulsed APC – adjustment made using the parameter power settings

  Forced APC – adjustment made using the parameter power settings
- 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.
- Should have the facility to use Argon plasma coagulation and monopolar coagulation simultaneously
- 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.
- Should give visual display of argon gas bottle content and should give Acoustic alarm when bottle content reaches a minimum.
- Should have facility for activation of unit by foot pedal of the Electro Surgical unit.
- Should have facility to use in double balloon endoscopy procedures.
- Should have facility for Argon supported cutting and coagulation.

- **Following essential accessories to be supplied as a part of Argon Plasma** from Same OEM only.
  a) Argon assisted cutting instrument for open surgery and laparoscopic surgery - 01 Nos each
  b) Imported Argon Cylinder with Pressure reducer – 02 Nos
  c) Imported Pressure reducer for argon cylinder – 01 Nos

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- The smoke plume evacuation system should be microprocessor controlled, US-FDA and / or European Certificate marked in accordance with the medical devices directive (93/42/EEC) & Electro Surgical Unit should comply with the requirement of the medical device directive of class I equipment and electromagnetic compatibility.
- The smoke plume evacuation system should be compatible with Electrosurgical Units for smooth functioning and ergonomics.
- The smoke plume evacuation system should be able to extract and filter smoke and aerosol- laden air during surgical procedures & should be also able to filter COVID - 19 like viruses and other microorganism present in surgical smoke generated during the procedure.
- The system should have a functional 5.7 inches touch screen display for better visibility& ease of control & display should be able to show settings, operating modes, filter run-time and information messages for the user.
- The System should have Bi-Turbo technology for effective filtration, should have ULPA-15 filter (5 stage filter protection) and active carbon filters & should also have ability to remove 99.9995% of all 0.1µm particles.
- The system filter should have maximum output of 730 l/min & have the ability to give a notification when volume flow of more than 300l/min is reached.
- The system should have ability to be used along with any electrosurgical unit, Laser and ultrasound devices & system should have automatic activation feature, no need of any additional footswitch for activation during monopolar electrosurgical applications.
- The system should display error if filter is not inserted to prevent damage & system should be able to used in vertical as well as horizontal way as per user needs.
- The system should have the ability to be fixed on the ceiling units (OT pendants) & should have the ability to be used with 2 instruments at the same time during any Surgical Procedures.
- The system should be able to used in open as well as lap surgical procedures & system noise development at 100% evacuation should be ≤ 59 dB as must have sound insulation cladding, integrated ducts and airborne sound absorbers for noise insulations.
- The user should be able to set critical features like - suction efficiency, standby suction efficiency as well as standby suction time in both lap and open surgery

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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. The installation process must be completed by the OEM/ Service provider within 30 days of supply.

The accessories/ consumables utilized during the period of installation process should be taken care FOC by OEM/ Service provider.

Main Equipment as well as offered accessories / consumables should have brand name / model number embossed/ etched on the front side.

Should have strong Installation base with latest Installation report (Not Older than 24 Months) of Surgical Workstation in various government reputed organization such as KGMU / DRRMLIMS / SGPGIMS / AIIMS Delhi/ AIIMS RISHIKESH / R.R Army Delhi.

CMC should be offered by O.E.M letterhead, Installation, training process should be performed by O.E.M trained service engineers at their cost.

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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

erbe

Erbe Elektromedizin GmbH
Waldhoernlestrasse 17
72072 Tuebingen, Germany

Date 2021-02-18

Natalie Zierhut, Business Manager Asia Pacific

Erbe Elektromedizin GmbH Waldhoernlestrasse 17 72072 Tuebingen Germany

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BIC: SOLADEST600

Kreissparkasse Tübingen
IBAN: DE54 6415 0020 0000 0001 41
BIC: SOLADES1TUB

Kalyan Singh Super Specialty Cancer Institute

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(An Autonomous Institute of the Govt. of Uttar Pradesh)

(उत्तर प्रदेश सरकार का स्वायत्तशासी संस्थान)

Email: procurement.kssscl@gmail.com

Proprietary Article Certificate (PAC) for Items/Goods

(Surgical work station)

(1) The indented goods are manufactured by M/s ERBE Elektromedizin GmbH.

(2) No other make or model is acceptable for the following reasons: (Integrated)

a) ERBE VIO 3 (VIO 3)

b) Argon Plasma Coagulation (APC 3)

c) Water Jet (ERBEJET 2)

Also Instruments as mentioned in property Catalogue

(Dr Ankur Verma)
Associate Professor and Head
Department of Surgical Oncology
KSSSCI, Lucknow

.....

(Signature of Indentor)

(Dr Ankur Verma)
Associate Professor and Head
Department of Surgical Oncology
KSSSCI, Lucknow

.....

(Signature of HOD)

erbe

Proprietary Certificate

To whom it may concern

Erbe Bipolar PREMIUM Forceps

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

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Proprietary Certificate

To whom it may concern

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

Article No.	Catalogue Description
20150-015	HybridAPC, ø 2.3 mm, length 1.9 m
20150-030	Applicator, straight, ø 6 mm, length 65 mm; with suction, e.g. for liver surgery
20150-031	Applicator, flexible tip, ø 6 mm, length 65 mm; with suction, e.g. for liver surgery
20150-036	Applicator, straight, with monopolar electrosurgical function, ø 6 mm, length 80 mm; with suction, e.g. for liver surgery
20150-038	Applicator, straight, ø 6 mm, length 306 mm; with suction, e.g. for TME
20150-039	Applicator, straight, ø 6 mm, length 180 mm; with suction, e.g. for TME
20150-060	HybridKnife, T-type, full-stream, ø 2.3 mm, length 1.9 m; with connecting plug international (3-Pin)
20150-061	HybridKnife, I-type, full-stream, ø 2.3 mm, length 1.9 m; with connecting plug international (3-Pin)
20150-062	HybridKnife, O-type, full-stream, ø 2.3 mm, length 1.9 m; with connecting plug international (3-Pin)
20150-100	ERBEJET 2 two-pedal foot switch with ReMode, AP & IP X8 equipment
20150-101	ERBEJET 2 one-pedal foot switch with ReMode, AP & IP X8 equipment
20150-301	Pump cartridge plus for ERBEJET 2

Date 2023-09-11

i.A. Manuel Neuburger

Manuel Neuburger, Product Specialist International Sales Support

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Proprietary Certificate

To whom it may concern

TriSect rapide®

- with VIO® 3 and thermoSECT mode

This is to certify that the below listed variations of TriSect rapide®, with our electrosurgical generator VIO® 3 and the thermoSECT mode, are proprietary products, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany. We are the only manufacturer of these products, and they are not manufactured by any other company elsewhere in the world.

- 21195-400 - TriSect rapide 140, single-use, bent 17 mm, shaft length 140 mm
- 21195-401 - TriSect rapide 200, single-use, bent 17 mm, shaft length 200 mm
- 21195-402 - TriSect rapide 350, single-use, bent 17 mm, shaft length 350 mm
- 21195-403 - TriSect rapide 450, single-use, bent 17 mm, shaft length 450 mm

The following technologies are proprietary to Erbes TriSect rapide® dissect and sealing instrument:

- unique **tripolar technology** enables a quick electrical cut without a blade
- **true single step:** grasp, seal and dissect vessels and tissue bundles in a single workflow
- **thermoSECT** mode for simultaneous dissection and sealing
- **softCOAG bipolar** mode for immediate hemostasis, with powerful initial coagulation
- **cooler impact:** reduced thermal spread with lateral spread lower than 1mm

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Erbe Elektromedizin GmbH
Waldhoernlestrasse 17
72072 Tuebingen, Germany

Date 2024-09-30

Natalie Zierhut, Business Manager Asia Pacific & Spain

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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.

2017/05/15

Axel Retzlaff, Director Regulatory Affairs

Erbe Elektromedizin GmbH Waldhoernlestraße 17 72072 Tuebingen Germany

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Proprietary Certificate

To whom it may concern

Erbe VIO® 3 & Instruments

This is to certify that the devices Erbe VIO® 3 in combination with the instruments listed below is a proprietary set of products, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany. We are the only manufacturer of this set of product and it is not manufactured by any other company elsewhere in the world.

10160-000	Erbe VIO® 3
20195-200	BiClamp® 210
20195-202	BiClamp® 201 T
20195-203	BiClamp® 271 T
20195-204	BiClamp® LAP BiSect Micro
20195-221	BiClamp® 150 C
20195-280	BiClamp® 280
20195-299	BiClamp® 260 C
20195-134	BiClamp® LAP forceps Maryland

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Erbe Elektromedizin GmbH
Waldhoernlestrasse 17
72072 Tuebingen, Germany

Date 2022-06-15

Natalie Zierhut, Business Manager APAC & Spain

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Proprietary Certificate

To whom it may concern

IES 3 - Smoke evacuation unit

This is to certify that the IES 3 Smoke evacuation unitis a proprietary product, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany. We are the only manufacturer of this product and this is not manufactured by any other company elsewhere in the world.

Erbe Elektromedizin GmbH
Waldhoernlestrasse 17
72072 Tuebingen, German

Date 2022-06-09

Natalie Zierhut, Business Manager APAC & Spain

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Proprietary Certificate

To whom it may concern

VIO® 3

This is to certify that the VIO® 3 is a proprietary product, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany. We are the only manufacturer of this product and this is not manufactured by any other company elsewhere in the world.

The preciseSECT mode is included and only available for the VIO® 3 system. Properties: fast, effective coagulation, with limited tissue-cutting property. Optimized exposure characteristics through dynamic adaptation of modulation.

Erbe Elektromedizin GmbH
Waldhoernlestrasse 17
72072 Tuebingen, Germany

Date 2023-10-09

Malik Luz, Product Specialist Global Sales Support

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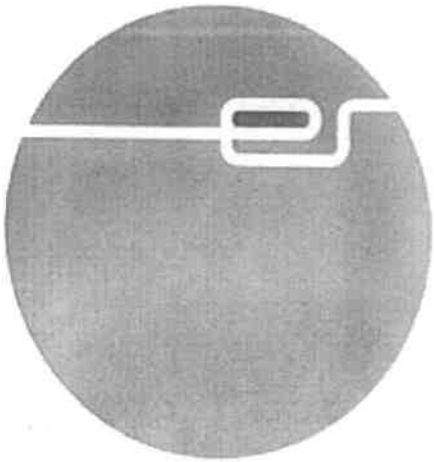
Proprietary Certificate

To whom it may concern

Erbe APC 3

This is to certify that the Erbe APC 3 is a proprietary product, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany. We are the only manufacturer of this product and this is not manufactured by any other company elsewhere in the world.



Erbe Elektromedizin GmbH
Waldhoernlestrasse 17
72072 Tuebingen, Germany

Date 2022-06-09

Natalie Zierhut, Business Manager APAC & Spain

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Proprietary Certificate

To whom it may concern

Erbe VIO® 3 and APC 3

This is to certify that the Erbe VIO® 3 with attached Argon Plasma Coagulation system (APC 3), that provides facility to change between programs by a ReMode button, specially designed Cut and Coag modes for different medical and surgical disciplines, like softCOAG®, preciseSECT and dryCUT® 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 2019-06-12

Axel Retzlaff, Manager Regulatory Affairs

Erbe Elektromedizin GmbH Waldhoernlestraße 17 72072 Tuebingen Germany

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Proprietary Certificate

To whom it may concern

Erbe VIO® 3, APC 3 and ERBEJET® 2

This is to certify that the electrosurgical device Erbe VIO® 3 with argon Plasma Coagulation system APC 3 and the hydrosurgery system ERBEJET® 2, built in one workstation are proprietary products, manufactured by Erbe Elektromedizin GmbH, Waldhoernlestrasse 17, 72072 Tuebingen, Germany and these products are not manufactured elsewhere.

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Erbe Elektromedizin GmbH
Waldhoernlestrasse 17
72072 Tuebingen, Germany

Date 2021-10-06

Natalie Zierhut, Business Manager Asia Pacific

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Proprietary Certificate

To whom it may concern

VIO®3, APC 3, ERBEJET® 2, ERBECRYO® 2, IES 3, ESM 2 & Viron X

This is to certify that the combination of above-mentioned products is a proprietary solution, manufactured by the Erbe Group with Headquarter at Waldhoernlestrasse 17, 72072 Tuebingen, Germany. We are the only manufacturer of these products, and they are not manufactured by any other company elsewhere in the world.

The following modes are proprietary for Erbe VIO®3:

preciseSECT	highCUT bipolar	thermoSEAL®
Optimized exposure as a result of dynamically adapting modulation. Medium coagulation	Smooth incisions, minimum to moderate hemostasis. For bipolar resection in a saline solution	Special COAG mode for sealing highly-vascularized tissue bundles and blood vessels with a diameter of up to 7 mm using appropriate Erbe instruments[1]

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Erbe Elektromedizin GmbH
Waldhoernlestrasse 17
72072 Tuebingen, German

Date 2024-09-12

Natalie Zierhut, Business Manager Asia Pacific & Sp