Instructions For Use (IFU)

Sterile, Single Use & Non-Sterile, Reusable; Electrosurgical Bipolar Forceps With & Without Cable

Doc. # TF-06/06
Rev. # 01
Date: 06 May 2015

Group: SB
Division: Electrosurgical
User: QA

Document Control Stamp

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<tr>
<td>Amir Shahzad</td>
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<td>06 May 2015</td>
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<td>Chief Executive</td>
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**INSTRUCTION FOR USE (IFU)**

**Sterile, Single Use & Non-Sterile, Reusable; Electrosurgical Bipolar Forceps**

**With & Without Cable**

### ElectroSurgical sterilE, simple use, bipolar forceps for HF Surgery

**CAUTION:**
Please read all of the following information and instructions prior to use. Federal law restricts this device to sale by or on the order of a physician.

**HOW SUPPLIED:**
This device is disposable, supplied sterile and intended for single use only. Prior to the expiration date, contents are sterile if the package has not been opened or damaged. Do not re-sterilize.

**DESCRIPTION:**
Device is intended for use in general surgical procedures. The use of an instrument for a task other than for which it is intended may cause damage to patient or user.

**INDICATIONS FOR USE:**
Device is designed to cut and coagulate selected tissue. It is to be connected with the bipolar output of an electrosurgical generator. Cut and Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit and activated by foot-control with ESU generator. Device must only be used with bipolar cut/coagulation current.

**NOTE:**
Only individuals who are trained and licensed to use such devices should use electrosurgical instruments. Examples of such training and experience include: Training through qualified residency program, surgical skills workshops, training programs offered by surgical assistant training.

**ADVERSE EVENTS:**
Adverse events reported while using electrosurgical devices include: Inadvertent activation with resultant tissue damage at the wrong site and/or equipment damage. Fires involving surgical drapes and other combustible materials have been reported. Alternate current pathways resulting in burns where the patient or physician or assistant is in contact with exposed metal. Explosions caused by electrosurgical sparking in a flammable gas environment (i.e., explosive anesthetic gases). Organ perforation. Sudden massive haemorrhage.

**CONTRAINdications:**
Any use of this instrument for tasks other than for which it is indicated, can lead to premature wear, result in a damage or can cause hazards to patients and users.

**HANDLING:**
Device must be handled with the greatest care when being transported, and stored. This is especially true for Forceps fine points and other sensitive areas. Working tip cords and their functions are impaired if they come into contact with abrasive materials. The instruments must not be exposed to acids or other abrasive cleaning agents.

**STORAGE:**
Instruments must be stored in a clean, dry, moisture free area. The instruments should be stored individually in their shipping container.

**SETUP & USE:**
It is very important to examine carefully each Forceps for breaks, cracks or malfunctions before use. It is especially essential to check areas such as Forceps working points & insulation, cables & plug. Do Not Use Damaged Instrument. Attach the sterile device cable to the IFU generator, ensuring that the contact pins are fully seated in the cable receptacles. Connect the cord to the generator only while it is in the ‘OFF’ or ‘STANDBY’ mode. Failure to do so may result in injury or electrical shock to the patient or operating room personnel.

**Use device at the lowest power setting; test the instrument connections by pressing the generator’s activating switch.**

If the generator fails to activate, check the fine connection with the cable. The working tip must always be in full view before activating power. Apply power only when working tip is in full contact with the tissue selected for cut or coagulation. Working tip must not come in contact with other metal instruments during use. Failure to observe these cautions and contraindications may result in injury, malfunction or other unanticipated occurrences or events for the operator, staff and/or the patient. Always review and follow generator manufacturer operating and use instructions.

**Cautions & Warning:**
- Product supplied is Sterile, ready for use. Do not re-sterilize.
- Check plug matching on generator base and device connector.
- Always check the device and the cables insulation under magnification before use.
- The device must be protected against mechanical damage.
- The cable must not be subjected to severe bending.
- Adjust current setting on generator according to patient & intended surgery.
- Do not lay device on the patient when not in use, nor use it in presence of gas or other flammable products.
- If any power increase is desired, check plate patient contact, clamps, connectors and active accessories.
- Place other equipment as far as possible away from surgery zone.
- Keep the voltage/power as low as possible to achieve the desired results and effects.
- Activation of an electrosurgical device when not in contact with target tissue or in position to deliver energy to target tissue (fulguration) may cause capacitive coupling.
- Use smoke-plume extraction when using device.

**COMPATIBLE ATTACHMENTS:**
- Detachable Forceps of diameter 2-4 mm is suitable for this device.
- Electrosurgical Generator; of any manufacturer Aesculap, ValleyLab, Berchtold, Conmed, Codman, Elmed, Kinvac can be used with this device.
- Cleaning Pad; to clean the working tip can be used with this device.
- Holster; can be used to place device when not in use with this device.
- Bipolar Forceps; to extend the Forceps length can be used with this device.
- Forceps Adapters; to extend the length can be used with this device.

**REPAIRS & MAINTENANCE:**
Never attempt to make repairs yourself. Any repairs made by the customer may void the warranty. Service and repairs should be referred to trained qualified persons only. Refer questions about repair to the manufacturer or the biomedical engineer or return to manufacturer.

**Disposal:**
Dispose-off used device according to hospital’s waste management protocol.

**Warranty:**
- Shelf life of this device is 5 Years.
- This device is for Single Use / Single Sterilization only.
- In case of any manufacturing fault manufacturer will provide replacement free of cost.

**return ed goods policy:**
Products must be returned in unopened packages with manufacturer’s seals intact to be accepted for replacement or credit excepted by damage, delay, or in the possession of the customer for more than 90 days.

**PRODUCT INFORMATION DISCLAIMER:**
MANUFACTURER DISCLAIMS ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MANUFACTURER SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. MANUFACTURER DOES NOT AUTHORIZE ANY PERSON TO ASSURE FOR THEM ANY OTHER OR ADDED LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

**Symbols on Labelling:**
- Manufacturer
- Authorized Representative in European Community
- Catalogue Number
- Lot Number
- Expiry Date
- Do Not Use If Package Damaged
- Product Complies with requirements of directive 93/42/EEC for medical devices and harmonized standards BS EN AAMI ANSI IEC 60601-1 & BS EN IEC 60601-1-2-2

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**Non-Sterile, Reusable, IFU (Page 1/2)**

### INSTRUCTION FOR USE (IFU)

**Sterile, Single Use & Non-Sterile, Reusable; Electrosurgical Bipolar Forceps**

**With & Without Cable**

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<tr>
<td>1</td>
<td><strong>CAUTION:</strong> Please read all information contained in this insert. The use of an instrument for a task other than that for which it is intended, as well as improper, reflective and insufficient maintenance can greatly reduce the life of an instrument and will invalidate the instrument’s warranty. Incorrect handling and care as well as misuse can lead to premature wear or can cause hazards to patients and users.</td>
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<td>2</td>
<td><strong>HOW SUPPLIED:</strong> Forceps are supplied NON-STERILE and must be cleaned and sterilized prior to use according to hospital protocol and the procedures outlined in this document. Failure to follow these procedures will invalidate the instrument’s warranty and can cause the instrument to fail.</td>
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<tr>
<td>3</td>
<td><strong>DESCRIPTION:</strong> Forceps is intended for use in general surgical procedures. The use of an instrument for a task other than for which it is intended.</td>
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<td>4</td>
<td><strong>INDICATIONS FOR USE:</strong> Forceps is designed to cut and coagulate selected tissue. It is to be connected with the bipolar output of an electrosurgical generator through Bipolar Cable. Cut and Coagulation is achieved using electrosurgical energy generated by the electrosurgical generator unit and activated by foot-control paddle with ESI generator. Forceps must only be used with bipolar cut / coagulation current.</td>
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### ELECTROSURGICAL REUSABLE, BIPOLAR FORCEPSS,

**FOR HF SURGERY**

**REUSABLE**

**Max. 20 Cycles**

### CAUTIONS & WARNINGS:

**Special safety precautions should be observed when using electrosurgical instruments. Electrosurgical instruments can pose a significant shock, burn or explosion hazard if used improperly, incorrectly or carelessly. Avoid touching or grounding electrosurgical instruments to non-insulated parts. Forceps, etc. All persons using such devices should be knowledgeable in the use and handling of electrosurgical instruments, cutting/coagulation equipment, their accessories and other related equipment.**

### CLEANING:

**FORCEPS should be disinfected and thoroughly cleaned prior to use. Proper cleaning and inspection will help ensure correct function of the Forceps. Clean, inspect and test each device carefully. To avoid Cross Contamination sterilize Forceps prior to use/surgery.**

### INDICATIONS FOR USE:

- Forceps is intended for Max. 20 autoclave cycles Only. Check Forceps insulation, for cuts, voids, cracks, tears, abrasions, etc. **Do Not Use**
- **Forceps, cleaning and rinsing must take place immediately after each use for best effect. Failure to clean properly may result in adherent particles that may resist cleaning and complicate or resist proper sterilization. Instruments must be completely cleaned and rinsed off of all foreign matter. Use warm water and a commercially available instrument pre-soak or cleaning agent. Enzymatic cleaners must be used to remove protein deposits. Follow the enzymatic cleaner’s instructions; rinse thoroughly.**
- **Do not use corrosive cleaning agents (i.e., bleach).**
- **Cleaning solutions and rinses at or near a neutral pH (7.0) are best.**
- **Do not use corrosive cleaning agents (i.e., bleach). Cleaning solutions and rinses at or near a neutral pH (7.0) are best.**
- **Do not use abrasive cleaners.**
- **Only a soft bristle brush should be used.**
- **Rinse thoroughly with distilled water.**
- **Prepare for storage and/or sterilization.**

### STORAGE & STERILIZATION:

**Instruments must be stored in a clean, dry, moisture free area. The instruments should be stored individually in their shipping carton or in a protective tray with partitions. Protect tips with cloth, gauge or tubing if stored in drawers. Instruments and cables are intended for Single Use and meet AAM standards for sterilization. Use following sterilization methods. Single Use Forceps is NOT intended for Re-Sterilization.**

**Thoroughly clean instruments of all foreign matter prior to sterilization. Follow the sterilizer manufacturer’s instructions for operation and loading.**
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**STANDARD STERILIZATION METHODS:**

**Method 1:**
- Forceps (Unwrapped) should be used in steam autoclave sterilization.
- Autoclave: 212°F (100°C), 3 min, Sterilized (Max. 20 cycles).
- Steam-Microbial temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature.
- Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature.
- Forceps must be protected against mechanical damage.
- The manufacturer's instructions concerning concentration of the disinfectant etc. must be strictly adhered.
- Adjust current setting on generator according to patient & intended surgery. Keep the voltage/power as low as possible to achieve the desired results and effect.
- Forceps should be used in steam autoclave to confirm appropriate sterilization and temperatures.
- Autoclave temperatures should not exceed 279°F (137°C); products must be protected against mechanical damage.
- Activation of an electrosurgical device when not in contact with target tissue or in position to deliver energy to target tissue (fulguration) may cause capacitive coupling.
- Do not lay device on the patient when not in use, nor use it in presence of gas or other flammable products.
- Do not sterilize with hot air.

**Method-2:**
- gamma Irradiation at 2°C/2°C/2°C: min. 32 kGy. 
- Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature.
- Forceps should be used in steam autoclave to confirm appropriate sterilization and temperatures.
- Autoclave temperatures should not exceed 279°F (137°C); products must be protected against mechanical damage.
- Activation of an electrosurgical device when not in contact with target tissue or in position to deliver energy to target tissue (fulguration) may cause capacitive coupling.
- Do not lay device on the patient when not in use, nor use it in presence of gas or other flammable products.
- Do not sterilize with hot air.

**Method-3:**
- Ethylene Oxide (ETO) Sterilization, follow validated process instructions.
- Always check the manufacturer of your ETO Sterilizer to confirm appropriate sterilization parameters.
- Forceps must be handled with the greatest care when being transported, cleaned, treated, sterilized and stored. This is especially true for Forceps fine points and other sensitive areas. Forceps corrode and their functions are impaired if they come into contact with aggressive materials. The instruments must not be exposed to acids or other aggressive cleaning agents.
- Important Notes:
  - Products supplied are Non-Sterile, clean & sterile prior to use.
  - Always check the device and the cable insulation under magnification before use.
  - The device & cable must be protected against mechanical damage.
  - The cable must not be subjected to severe bending.
  - The manufacturer's instructions concerning concentration of the disinfectant etc. must be strictly adhered.
  - Adjustment of the device and the cable insulation under magnification before use.

**RETURNED GOODS POLICY:**
- Products must be returned in unopened packages with manufacturer's seals intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Manufacturer will make determination of a product defect. Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.
- **PRODUCT INFORMATION DISCLOSURE:**
  - Manufacturer: Excludes all Warranties, Whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Manufacturer shall not be liable for any incidental or consequential losses, damage, or expense directly or indirectly arising from use of this product. Manufacturer does not assume nor authorize any person to assume for them any other or additional liability or responsibility in connection with these products.

**COMPATIBLE ATTACHMENTS:**
- Electrosurgical Generator of any manufacturer Aesculap, ValleyLab, Berchtold, Conmed, Elmed, Kirkland, can be used with this Forceps.

**REPAIRS & MAINTENANCE:**
- Should your instruments require repair or maintenance, contact manufacturer for return authorization and address. Instruments returned to manufacturer for repair must have a statement testifying that each instrument has been thoroughly cleaned and sterilized. Failure to supply evidence of cleaning and disinfection will result in delayed processing of your instrument repair. Products repaired by manufacturer are guaranteed to be free of defects in workmanship and parts when used normally for their intended surgical purpose. Any warranty on parts proving to be defective will be replaced or repaired at manufacturer discretion, at no charge to the customer.

**DISPOSAL:**
- Dispose-off used device according to hospital’s waste management protocol.

**WARRANTY:**
- Shelf life of our device is 5 Years, if stored in proper storage conditions.
- This reusable device is for Max. 20 autoclave cycles only.
- In case of any manufacturing fault manufacturer will provide replacement free of cost.