INSTRUCTION FOR USE (IFU)

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

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Issue Date 01 July 2013
Revision 00

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ELECTROSURGICAL
STERILE, SINGLE JSE, BIPOLAR FORCEPS
FOR HF SURGERY

STERILE EO

Do Not Use | Package Damaged

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1. 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.

2. NON-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.

3. 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.

4. 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 push buttons on device. 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.

5. ADVERSE EVENTS:

Adverse events reported while using electrosurgical devices include (but are not limited to) 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 when the patient or physician is in contact with an exposed metal. Burns caused by electrosurgical sparking in a flammable gas environment (e.g., explosive anesthetic gases). Organ perforation. Sudden massive hemorrhage.

6. 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.

7. HANDLING:

Device must be handled with the greatest care when being transported, stored, used. It is especially true for Forceps fine parts and other sensitive areas. Working tip corrosion 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.

8. STORAGE:

Instruments must be stored in a clean, dry, moisture free area. The instruments should be stored individually in their shipping carton.

9. SETUP & USE:

It is very important to examine carefully each Pencil for breaks, cracks or malfunctions before use. It is especially essential to check areas such as Forceps points, pencil saving, buttons, cable & plug. Do Not Use Damaged Instrument. Attach the sterile device cable to the HF generator, ensuring that the contact pins are fully seated in the cable receptacle. 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.

10. 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 line connection with the cable. The working tip must always be in full view before activating power. Apply power only when the 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.

11. CAUTIONS & WARNINGS:

- Product supplied as 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.
- Press CUT/BLUE button for cutting and COAG/blue button for coagulation.
- 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, connections and active accessories.
- Place other equipments as far as possible away from surgery zone.
- Keep the voltage/power as low as possible to achieve the desired results and effect.
- 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.

12. 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, Kinvar can be used with this device.
- Cleaning Pad, to clean the working tip can be used with thin devices.
- Holder, can be used to place device when not in use with this device.
- Bipolar Forceps Extender, to extend the Forceps length can be used with this device.
- Forceps Adapters, to extend the Forceps length can be used with this device.

13. WARRANTY:

- Shelf life of this device is 3 years.
- This device is for Single Use / Single Sterilization only.
- In case of any manufacturing fault manufacturer will provide replacement free of cost.

14. 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 for product defect. Manufacturer will make determination of a device defect. Device will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

15. 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 LOSS, DAMAGE, OR EXPENSE DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. MANUFACTURER DOESN'T AUTHORIZE ANY PERSON TO ASSUME FOR THEM ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THEIR PRODUCTS.

16. SYMBOLS USED ON LABELING:

- Manufacturer
- Authorized Representative in European Community
- Catalogue Number
- Lot Number
- Saw Instruction For Use
- Product is supplied sterile by Ethylene Oxide
- Cater Dry
- Keep away from sunlight
- Fragile, Handle with Care
- Do not reuse
- Do not re-sterilize
- Date of Manufacture
- Expiry Date
- Do Not Use If Package Damaged
- Product Complies with requirements of directive 93/42/EEC for medical devices and harmonized standards IS EN AAMI AN12 IEC 60601-1 & IS EN AAMI AN12 IEC 60601-2-2

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