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Instructions For Use (IFU)

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

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	Name	Signature	Date
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RB	Electrosurgical	QA	

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Sterile, Single Use, IFU (Page 1/1)

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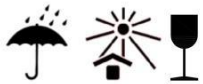
INSTRUCTION FOR USE (IFU)

Issue Date 01 July 2013
Revision 00

ELECTROSURGICAL
STERILE, SINGLE USE, BIPOLAR FORCEPS FOR HF SURGERY



Do Not Use If Package Damaged

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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 my 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 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.

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 anaesthetic gases). Organ perforation. Sudden massive haemorrhage.

CONTRAINDICATIONS:
Any use of this instrument for tasks other than for which is it 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 corrode 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 carton.

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 casing, buttons, cables & 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 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.

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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 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 & WARNINGS:
- ☐ 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.
- ☐ Press CUT/yellow 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, connectors 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 desire 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

COMPATIBLE ATTACHMENTS:
- Detachable Forceps of diameter 2.4 mm is suitable for this device.
- Electrosurgical Generator; of any manufacturer Aesculop, ValeyLab, Berchtold, Conmed, Codman, Elmed, Kirwan; 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 Extension; to extend the Forceps length can be used with this device.
- Forceps Adapters; to extend the Forceps 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.

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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.

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 device defect. Device 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 LOSS, DAMAGE, OR EXPENSE DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. MANUFACTURER DON'T ASSUME NOR AUTHORIZE ANY PERSON TO ASSUME FOR THEM ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

SYMBOLS USED ON LABELLING:

	Manufacturer
EC REP	Authorized Representative in European Community
REF	Catalogue Number
LOT	Lot Number
	See Instruction For Use
STERILE EO	Product is supplied Sterile by Ethylene Oxide
	Keep 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
CE 0120	Product Complies with requirements of directive 93/42/EEC for medical devices and harmonized standards BS EN AAMI ANSI IEC 60601-1 & BS EN AAMI ANSI IEC 60601-2-2

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INSTRUCTION FOR USE (IFU)

Issue Date 01 July 2013
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ELECTROSURGICAL
REUSABLE, BIPOLAR FORCEPS,

FOR HF SURGERY

REUSABLE
MAX. 20 CYCLES

CE
0120

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CAUTION:
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, ineffective 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.

HOW SUPPLIED:
FORCEPSS 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.

DESCRIPTION:
FORCEPS is intended for use in general surgical procedures. The use of an instrument for a task other than for which it is intended.

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

NOTE: Electrosurgical instruments should be used only by individuals who are trained and licensed to use such devices. Examples of such training and experience include: Training through qualified residency program, surgical skills workshops, surgical assistant training, etc.

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 anaesthetic gases). Organ perforation. Sudden massive haemorrhage.

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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.

Test All Instruments, Accessories And Equipment Prior To Each Use.
Written Standard Operating Procedures for the cleaning, sterilization, storage and inspection of the instruments, accessories and equipment are recommended. Do not use in presence of flammable liquids or anaesthetics. Electrosurgical generators used with these devices are designed to cause destruction of tissue and are inherently dangerous if operated improperly. Follow all safety precautions and instructions supplied by the manufacturer of the electrosurgical generator. The Forceps tip must always be in full view before activating power. Apply power only when Forceps tip is in full contact with the tissue selected for cut or coagulation. Forceps 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.

INITIAL USE OF INSTRUMENTS:
Every instrument must be cleaned and sterilized before it is used for the first time. The instrument was developed for sterilization by autoclave / ETO / Gamma Irradiation; and has shown good results using these methods.

INSPECTION & FUNCTIONAL CHECKS:
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 points & molded part. **Do Not Use Damaged Instrument.**
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 engineering department or return to manufacturer for repair.

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CLEANING:
FORCEPSS 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.
Forceps is intended for Max. 20 autoclave cycles Only. Check Forceps insulation, for cuts, voids, cracks, tears, abrasions, etc. **Do Not Use Damaged Forcepss.** 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.

After cleaning and rinsing, dry instruments completely and carefully with compressed air.

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, gauze or tubing if stored in drawers. Instruments and cables are intended for Single Use and meet AAMI 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:

Forcepss (Unwrapped) should be used in steam autoclave sterilization.

Sterilization Cycle	Temperature	Exposure Time	Min. Dry Time
Autoclave	270°F/132°C	3 minutes	- - -

Other time and steam temperature cycles may also be used. However, user must validate any deviation from the recommended time and temperature. There must be direct steam exposure to all surfaces of the instruments being sterilized. Allow instrument to air cool to room temperature before use. **NOTE:** Contact the manufacturer of your steam autoclave to confirm appropriate temperatures and sterilization times.

CAUTION: Autoclave temperatures should not exceed 279°F (137°C); casing, cable insulation or other non-metallic parts may be damaged. **Do not sterilize with hot air.**

METHOD-2:

Gamma Irradiation at 2.5 mega rad, follow validated process instructions.

NOTE: Contact the manufacturer of your Irradiator to confirm appropriate sterilization parameters.

METHOD-3:

Ethylene Oxide (ETO) Sterilization, follow validated process instructions

NOTE: Contact the manufacturer of your ETO sterilizer to confirm appropriate sterilization parameters.

HANDLING:

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:

- Product supplied is Non-Sterile, clean & sterilize prior to use.
- Check compatible attachments and connect.
- 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.

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- 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 desire results and effect.
- Keep HF output settings where below the maximum output voltage
- 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 equipments as far as possible from surgery zone.
- 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 extraction devices when using device

COMPATIBLE ATTACHMENTS:

- Electrosurgical Generator of any manufacturer Aesculop, ValeyLab, Berchtold, Conmed, Codman, Elmed, Kirwan; can be used with this Forcepss.

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 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 workmanship or 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 3 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.

7

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.

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SYMBOLS USED ON LABELLING:

	Manufacturer
EC REP	Authorized Representative in European Community
REF	Catalogue Number
LOT	Lot Number
	Fragile, Handle with Care
	See Instruction For Use
NON STERILE	Product is supplied Non-Sterile
	Keep dry
	Keep away from sunlight
CE 0120	Product Complies with requirements of directive 93/42/EEC for medical devices and harmonized standards BS EN AAMI ANSI IEC 60601-1 & BS EN AAMI ANSI IEC 60601-2-2
	Date of Manufacture
	Expiry Date

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