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

1

INSTRUCTION FOR USE (IFU)

Issue Date 01 July 2013
Revision 00

ELECTROSURGICAL
STERILE, SINGLE USE, BIPOLAR CABLE FOR HF SURGERY

Do Not Use If Package Damaged

CE
0120

2

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 Cable 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 Cable 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.

3

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 Bipolar Forceps
- ! Electrosurgical Generator; of any manufacturer Aesculop, ValeyLab, Berchtold, Conmed, Codman, Elmed, Kirwan; 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 3 Years.
- ∀ This device is for Single Use / Single Sterilization only.
- ∀ In case of any manufacturing fault manufacturer will provide replacement free of cost.

4

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
	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

EC REP

RB MEDIKAL INSTRUMENTS
SIE, Fateh Garh, Near Umer Town,
Sialkot (51310) – Pakistan
http://www.rbmedikal.com

Speciální Medicínská Technologie, s.r.o. Papírenská 114/5 160 00 Praha 6 Prague, Czech Republic
t:+420 233 325313 f: + 420 224318011
strausova@smt-praha.com
www.smt-praha.com