Instructions for Use
ActiLine Monopolar Electrodes
Single-use monopolar electrodes for HF surgery

PROMECON

Important
1. This product was designed, tested and manufactured for single patient use only.
2. Any attempt to reuse or reprocessing may lead to failure and potential patient injury.
3. Reprocessing and/or resterilisation of this product may give rise to patient infection through contamination.
4. Do not reuse, reprocess or resterilise this product!
5. These instructions for use do not replace the user manual of the electrosurgical unit used! Read the unser manual of the surgical unit.
6. The maximum electrical capacity is given on the sterile packaging of each instrument (KvP).

Indication
Monopolar electrodes are intended to cut and coagulate selected tissues by means of high frequency electrical current during an electrosurgical procedure. The shaft of the electrode is inserted into a handle. The handle is to be connected to a high frequency electrosurgical generator by means of the electrical cable and is used in conjunction with a patient grounding pad during an electro surgery. The product is not intended for use in direct contact with the central nervous system (brain, meninges and spinal cord).

Directions for use
1. Check that the package is not compromised or the content is not expired. Do not use the device if the sterility has been compromised. If before use the package is damaged, return the product to us.
2. Use aseptic techniques to open packaging and remove the electrode.
3. Before starting the procedure, verify compatibility of all instruments and accessories. Generators and electrical accessories complying to IEC60601-1 and IEC60601-2-2 standards are deemed to be compatible.
4. Inspect the product for overall condition and physical integrity. Do not use the product if a damage or defect is noted.
5. Check that the electrode is fully inserted into the handle, not loose, but firmly fixed to the steel noozle of the pencil.
6. To test the push buttons, first connect the pencil to a high frequency generator. Switch on the generator. Check that no activation is detected at the generator before depressing any of the CUT or COAG buttons. If pencil self activates, return the whole pencil to the manufacturer.
7. Activate the CUT and then COAG button one at a time. Each time verify that the generator gives the correct corresponding audible and visible light signals during each activation of the pencil buttons. If this preuse test fails, return the whole pencil to the manufacturer.
8. Connect the instrument to an appropriate electrosurgical generator with compatible cables intended for electro surgery. Turn the generator ON and set the power output to the lowest possible setting that provides the desired surgical effect.
9. Always refer to the instruction manuals of a high frequency generator and the general instructions of a surgical procedure.

Contraindications
Applying electrosurgery is **severely restricted** with patients who have cardiac pacemakers, implanted defibrilators or other active implanted devices. In worst cases, the pacemaker‘s function may be affected and ventricular fibrilation can possibly be caused. It is possible that the pacemaker suffers from irreparable damage. If electrosurgery is absolutely essential for the patient, the patient must be constantly monitored during the electrosurgical procedure. Before the electrosurgical procedure, it must be assured that the monitoring device is highfrequency safe. ECG devices of older construction types might perform highfrequency malfunctions in which cases a continuous palpartory pulse control becomes necessary. All essential devices for emergency heart therapy must be available (e.g. usable pacemaker, functioning defibrilator) and medical staff must be experienced in such emergency therapy. The rules of electrosurgery must particularly and restrictively be respected. It is important that a preferably low highfrequency power is applied. In every possible application, bipolar techniques should be preferably utilized over monpolar techniques.

Warnings and precautions
The device is provided sterile. Do not use the instrument if the sterility has been compromised or the packaging is damaged. Do not use device after its expiration date.This device is intended to be used by trained physicians familiar with electrosurgery. Only activate the instruments when touching the surgical field or instantly before that. Do not use device in the presence of inflammable or explosive materials. In order to prevent accidential burns, never leave the instrument out of sight. Place instrument away from patient when not in use. Never lay the product on the patient or close to him/her. A holster is recommended. Bevore activating the HF device, make sure that the monopolar tip does not touch any conductive accessories or non-insulated parts. Protect this product from any kind of mechanical damage. Do not throw! Do not use force! If there is a cable, and unless stated otherwise, do not kink it or wrap it around the accompanying product! Do not apply and exceed its rated accessory voltage which is indicated on the outer packaging. Avoid touching or grounding electrosurgical instruments to non-insulated instruments, scopes, trocar sleeves etc. All person using such devices should be knowledgeable in the use and handling of laparoscopic instruments, coagulation equipment, their accessories and other related equipment. Test all instruments, accessories and equipment before use. Coagulation should only be performed if the contact surface is visible. The monopolar tip must always be in full view before activating power. Apply power only when electrode tip is in full contact with the tissue selected for coagulation. Do not touch any other metallic instruments during coagulation. Electrosurgical instruments can pose a significant shock, burn or explosion hazard if used improperly, incorrectly or carelessly. 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. Fame Devices Corporation explicitly warns against making any changes to the device. Any such change will exempt Fame Devices Corporation from all liabilities.

Storage and handling
Temperature allowance: 5°C to 30°C, relative humidity 35% to 68%. Atmospheric pressure range: 700 hPA to 1060 hPA. Instrument must not be in contact with acids or other corrosive liquids. For disposal of used device please follow your local Health & Safety procedures.

Reference code structure:

M MM S XXX . LLL / WWW TT AAA / DDD

Tip Geometry

AAA Active tip length (needle, knife, spatula electrod)

DDD Diameter / Depth (wire loop, ball electrodes)
Suitable trocar diameter (laprascopic electodes MLE)
Canula diameter (athroscopic electrodes MAE)

Tip Material / Coating

S Standard / Stainless Steel

SN Titan Tip

Electrode Geometry

LLL Length of shaft (needle, knife, spatula, ball electrods)

WWW Width of wire loop (LEEP / LLETZ Electrodes)

Tip Style

needle, knife, spatula, wire loop, ball

Shaft Size

"blank" 2.4mm Shaft

4 4.0mm Shaft

Electrode Type

E Monopolar Electrode

LE Laprascopic Electode

AE Athroscopic Electrode

Monopolar Electrode ActiLine

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Explanation symbols used on labelling:

CE 1639

Consult instructions for use

Latex free

Manufacturer

STERILE EO Sterilised by ETO

Do not use if packaging is damaged

Used by/expiry date

For single use only

Keep away from sunlight

REF Catalogue No.

Quantity

LOT Batch code

Do not resterilise

Keep dry

Caution

EC REP European Representative

+30° +5° Temperature limitation