

Instructions for Use

ActiLine EcoCeps - Single Use Bipolar Forceps



PROMECON

Important

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

Indication

Bipolar forceps are intended to grasp, dissect and coagulate selected tissues by means of high frequency electrical current during an electrosurgical procedure. The bipolar forceps are to be connected to a high frequency electrosurgical generator by means of the electrical cable. The forceps should be connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator. Bipolar forceps must only be used with bipolar coagulation current. Any use of this instrument for tasks other than for which it is indicated as well as improper, ineffective and insufficient maintenance will greatly reduce the life of an instrument and will invalidate the instrument's warranty. The product is not intended for use in direct contact with the central nervous system (brain, meninges, spinal cord and the heart).

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 device and packaging to us.
2. Use aseptic techniques to open packaging and remove the forceps.
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 device for overall condition and physical integrity. Check for breaks, cracks, damage or malfunctions before use. Do not use the device if a damage or defect is noted.
5. Take sterile forceps out of pouch, insert head into the cable socket (if not pre-connected) and plug cable into the electrosurgical unit whilst this is in „off“ or „standby“ mode.
6. Adjust the HF device to a setting appropriate to ensure that the maximum peak output voltage (500Vp) does not exceed the accessory voltage rating.
7. Single use bipolar forceps are operated via footswitch. Appropriate current should be set on electro-surgical generator prior to procedure taking place.
8. For irrigation models (-I suffix) connect to the side connector the irrigation tube and adjust flow with its own external control.
9. Always refer to the instruction manuals of a high frequency generator.

Contraindications

Applying electrosurgery is **severely restricted** with patients who have cardiac pacemakers, implanted defibrillators or other active implanted devices. In worst cases, the pacemaker's function may be affected and ventricular fibrillation 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 palpatory pulse control becomes necessary. All essential devices for emergency heart therapy must be available (e.g. usable pacemaker, functioning defibrillator) 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 monopolar techniques. Bipolar forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

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. Place instrument away from patient when not in use. In order to prevent accidental burns, never leave the instrument out of sight. Before activating the HF device, make sure that the tips of the forceps do not touch any conductive accessories or non-insulated parts. Never lay the product on the patient or close to him/her.

A holster is recommended.

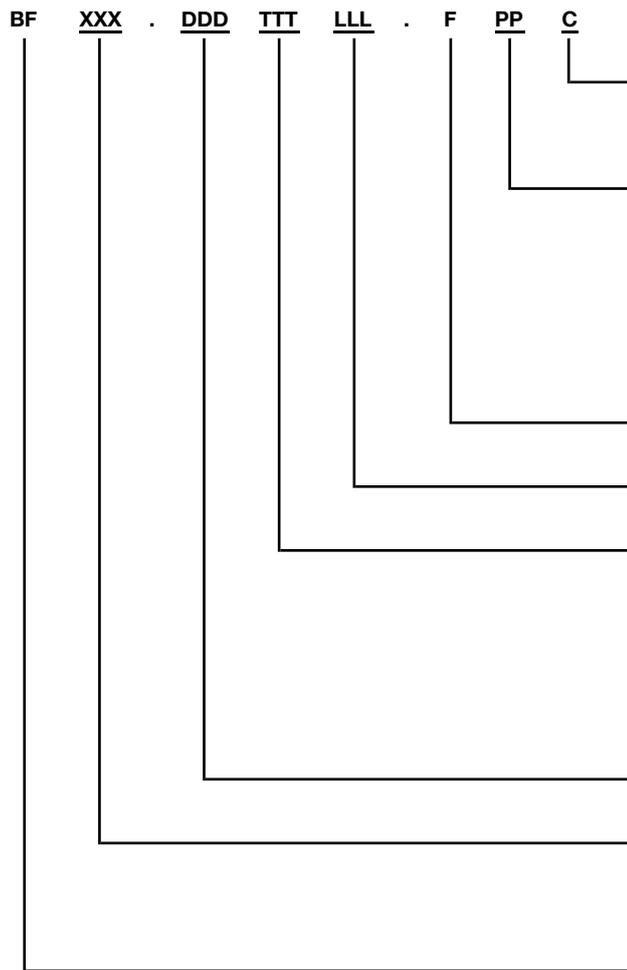
Protect this product from any kind of mechanical damage. Do not throw! Do not use force! If there is a cable, and unless stated otherwise, do not kink it or wrap it around the accompanying product! Do not apply and exceed its rated accessory voltage which is indicated on the outer packaging.

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 forceps 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. There are rare reports of sudden acute bleedings or organ perforations when using bipolar forceps. The surgeon should be prepared for such rare incidents before using bipolar forceps. 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:



Cable Length

3 / 4 / 5 meter

Plug Style

4M	Martin Standard	<i>2mm-pin protected plug</i>
3E	Erbe Standard	<i>4mm-pin protected plug</i>
2F	Valleylab (INT 28mm)	<i>two 4mm-pins fix plug</i>
1B	US Standard	<i>two-separated plugs</i>

With integrated Cable

Length of Forceps / Branches

Tip Material / Coating

S	Standard / Stainless Steel
ST	Tungsten Tip
SN	Titan Tip
SNS	Silver Tip

Diameter of Tip

Forceps Model

Branch Style, Tip Orientation, Plug Style (flat or US two pin plug), Xtreme, with Irrigation

Bipolar Forceps ActiLine EcoCeps



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eIFU

These instructions for use can be digitally downloaded under: www.promecon-medical.com



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Explanation symbols used on labelling:

CE 0120	Consult instructions for use	Latex free	Manufacturer	Quantity	Temperature limitation
Used by/expiry date	Non-sterile	Keep away from sunlight	REF Catalogue No.		
LOT Batch code	Do not use if packaging is damaged	Keep dry	Caution	EC REP European Representative	