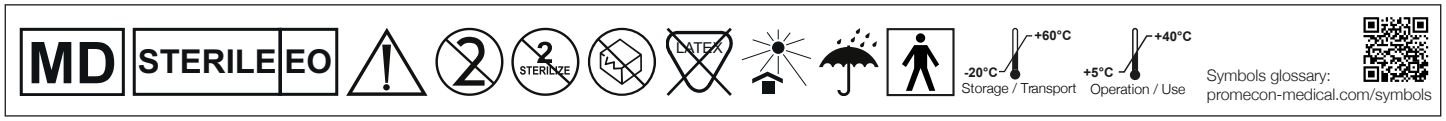
Actiline EcoGrip N

REF HF.12.500.100

PROMECON

EN Disposable Monopolar Electrosurgical Pencil
(with 2 Buttons and Blade Electrode)
5 Meter Cable and Standard 3-Prong Connector
(International)

DE Einmal Monopolar Elektrodengriff
(mit 2 Tasten und Spatelelektrode)
5 Meter Kabel und Standard 3-Pin-Stecker
(International)



Manufactured for Promecon GmbH

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EN ***Actiline*** EcoGrip N **- Disposable Electrosurgical Pencils Instructions for use**

Important Information

Please read the following information and instructions for use carefully and completely before applying. Failure to observe the instructions for use can endanger patient safety.

Device Description

The Disposable Monopolar Electrosurgical pencils are used for the cutting and coagulation of soft tissue and have a conductive cable which is designed for use with high frequency (HF) surgical generator (Electrosurgical unit).

⚠ The device is intended to be used with a neutral electrode.
The maximum applicable voltage of this product is 2.9kVp (5.8kVp-p).

Model Specifications (Type HT-N1-5):

- Description and Control ways: White colour, hand control with buttons
- Electrode Tip: Shape: 7cm blade / Exposed length: 4cm
- Cable length: 5m
- Connector / Plug: 3 pin (prong)

Intended Use

The Disposable Electrosurgical Active Electrodes are intended to use for cutting and coagulation to remove tissue and control bleeding by using high frequency (HF) current during electrosurgical surgery with a specified electrosurgical unit (ESU) generator. The device is disposable for single use and supplied as sterile with an electrode tip.

Indication

The applied products are indicated for use in tissue cutting and coagulating as required or encountered in General surgery, thoracic surgery, gynaecology surgery where the tip of the product can be easily access.

Contraindications

The applied products are contraindicated where patients with pacemakers as the use of the ESU may interfere with the pacemaker's circuitry.
The applied products are contraindicated in patients with automatic implantable cardioverter/ defibrillator (ACID). The applied products are contraindicated for use in tubal ligation procedure.

Precautions

1. Examine pencil and electrode for defects prior to use.
2. Apparent low output or failure of the HF surgical equipment to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections. In this case, the application of the neutral electrode and its connections should be checked before selecting a higher output power.
3. When more than one active electrode is plugged into same generator, be aware activation of one pencil may take the receptacle of all the other pencils "live". Read and understand the warnings and cautions given by the electrosurgical generator manufacturer.
4. Do not prep the operative site with flammable solution such as alcohol.
5. This device is for single patient use only. It is not intended for disinfection and subsequent reuse, which may result in device failure and/or create the risk of contamination.
6. This device has not been evaluated for reprocessing or re-sterilization. Reprocessing and/or resterilization may damage the device, rendering it unusable and/or may lead to device failure, which could result in patient illness, injury or death.
7. Visibly exposed metal of the active electrode shaft where it connects with the active handle.
8. The package shall be checked to be intact before using. If the primary package is damaged, do not use the product.
9. This product shall be used by qualified and experienced medical professionals only and any procedure must be conducted under strict sterile / aseptic conditions.

Instruction for Use / Application

1. ***Actiline*** EcoGrip N Electrosurgical Pencil is designed for use with electrosurgical generators equipped with the standard 3-prong receptacle. Prior to use, read the manufacturer instructions on how to operate the electrosurgical unit (ESU) and accessories.
2. Visually examine the package for damage before opening the package. Replace the pencil if the package or the pencil itself shows signs of damage.
3. Check the production and expiry date printed on the package. If the device using date exceed the expired date, it should be replaced by backup device within expire date.
4. Open the package using aseptic technique.
5. Uncoil the cable. Examine the pencil and cable for damage. Replace the pencil if damage found.
6. Remove and discard the electrode tip guard. Ensure that the electrode is securely seated in the pencil.
7. Plug the cable connector firmly into the correct receptacle on the electrosurgical generator.

8. Verify that the “CUT” control on the pencil works when the “CUT” button (yellow) is pressed. Repeat the same for “COAG” control (blue button).
9. Discard the pencil after use as a biohazard. Do not re-sterilize or reuse.

⚠ Warnings

1. Electrosurgery is dangerous. Careless use of any part or element in the electrosurgical system may result in serious patient burns. Read and understand all warnings, cautions, precautions and directions for use before attempt is made to operate any active electrode.
2. OPERATOR should ensure that connected ACCESSORIES are rated for at least the maximum peak output voltage of the HF SURGICAL EQUIPMENT set at the intended output control setting in the intended operating mode, with reference to the diagrams required.
3. The entire area of the Neutral Electrode should be reliably attached to the PATIENT’S body and as close to the operating field as possible.
4. The PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose.
5. Skin-to-skin contact (for example between the arms and body of the PATIENT) should be avoided, for example by insertion of dry gauze.
6. When HF SURGICAL EQUIPMENT and physiological monitoring EQUIPMENT are used simultaneously on the same PATIENT, any monitoring electrodes should be placed as far as possible from the surgical electrodes. Needle monitoring electrodes are not recommended.
7. The cables to the surgical electrodes should be positioned in such a way that contact with the PATIENT or other leads is avoided. Temporarily unused ACTIVE ELECTRODES should be stored so that they are isolated from the PATIENT.
8. For surgical procedures where the HF current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable in order to avoid unwanted coagulation.
9. The output power selected should be as low as possible for the intended purpose.
10. Apparent low output or failure of the HF SURGICAL EQUIPMENT to function correctly at the normal operating settings may indicate faulty application of the Neutral Electrode or poor contact in its connections. In this case, the application of the Neutral Electrode and its connections should be checked before selecting a higher output power.
11. The use of flammable anaesthetics or oxidizing gases such as nitrous oxide (N2O) and oxygen (O2) should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.
12. Non-flammable agents should be used for cleaning and disinfection wherever possible
13. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application of HF surgery. There is a risk of pooling of flammable solutions under the PATIENT or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluid pooled in these areas should be mopped up before HF SURGICAL EQUIPMENT is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in NORMAL USE of the HF SURGICAL EQUIPMENT.
14. For PATIENTS with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemaker may occur, or the pacemaker may be damaged. In case of doubt, approved qualified advice should be obtained.
15. Interference produced by the operation of HF SURGICAL EQUIPMENT may adversely influence the operation of other electronic EQUIPMENT.
16. Failure of the HF SURGICAL EQUIPMENT could result in an unintended increase of output power.
17. The qualified operator of the device should be a physician or medical workers under the supervision of the physician.
18. Keep active accessories away from patient when not in use never lay the pencil on the patient or the patient drape. Use a safety holster or place the pencil on the instrument tray when not in use.
19. Keep active accessories away from flammable objects, gases or vapours at all times when in use.
20. Keep desired voltage/power as low as possible to achieve the desired end effect in order to minimize the potential for capacitive coupling and inadvertent burning at high voltages.
21. The cable be positioned in such a way that contact with the patient or other cable is avoided. Temporarily unused active electrodes should be stored in a location that is isolated from the patient.
22. Accidental activation or use the equipment when the power supply exceeds the rated voltage, the patient, operator, or his assistant may get hurt, and the electrode may be damaged.
23. Prevent soaking the product or the contact with big amounts of liquid, product functionality may be affected.

Operation Environment

Ambient temperature: 5°C - 40°C
Relative humidity: ≤80 %RH
Atmospheric pressure: 860-1060 hPa

Storage Conditions:

Temperature requirement in warehouse: -20°C ~ 60°C degree.
Humidity requirement in warehouse: 10 ~90 %RH.
Atmospheric pressure requirement in warehouse: 500-1060 hPa

Disposal

Dispose the single-use product after use in conformity with the institution’s regulatory for contaminated devices and according to valid local / national regulations for such products.

Electromagnetic Compatibility (EMC) Declaration

This product should not be used adjacent to or stacked with other unit. If adjacent or stacked use is necessary, this product should be observed to verify normal operation in the configuration in which it will be used.
Further information on electromagnetic emissions and electromagnetic immunity in conjunction with the ESU can be shared on request by PROMECON.

eIFU

The instructions for use can be downloaded at www.promecon-medical.com

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