



Diathermy Handpencils & Electrode Accessories

Models:

Handpencils – (PS5555 & PS5557)

Solid Electrodes - (PS5003, PS5004, PS5005, PS5006, PS5007, PS9170,)

EN

DIRECTIONS FOR USE

The following information should be read before using this device.

Indications:

The Purple Surgical single use diathermy hand pencils allow the surgeon to utilise cut, coagulation or blend activation of monopolar diathermy via either the ergonomic, finger switch activated hand held instrument model, or foot switch controlled model.

A range of 2.4mm \varnothing electrode accessories to suit different surgical procedures, can be used with the Purple Surgical Diathermy Hand pencils; these may also be used with compatible hand pencils from other manufacturers

Contraindications:

-The device is not intended for use when monopolar diathermy is contraindicated.

- DO NOT USE on patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

Device Description:

The Purple Surgical single use handpencil consists of a tough, plastic handpiece with 3 Metre long incorporated cable.

The **Hand switching** pencil version cable attaches directly to the Electrosurgical Unit by means of a universal three pin 4.0mm banana plug connector.

The **Foot switching** pencil version cable attaches indirectly to the Electrosurgical Unit via connection to a foot switch accessory (not provided with the product) by means of a universal single pin 4.0mm banana plug connector

Directions For Use:

- Using sterile technique, remove the device from the packaging. To avoid damage to instruments on the sterile table, do not flip the device into the sterile field.
- A non-sterile technician should then attach the cable to the Electrosurgery Unit via the universal three pin connector for hand switching version, or to the Foot control pedal via the universal single pin connector for foot switching version.
- Activation of the 'cut' and/or 'coag' functions on the hand pencils should be performed when the tip of the electrode is advanced towards, but not directly touching, the site of the desired tissue effect.
- A number of different electrodes are available to be placed in the handpiece to facilitate more flexibility in application. The electrodes may be removed by pulling away from the handpiece by gripping the plastic sheath on the electrode.

Precautions/Warnings:

- These devices are designed for single use only and are not to be re-used or re-sterilized. Do not use if package is opened or damaged.
- As monopolar diathermy is being utilised, standard checks to ensure electrical grounding is not compromised must be undertaken.
- Do not immerse electrosurgical instruments in liquid, unless the instruments are designed and labelled to be immersed.
- A thorough understanding of techniques and principles involved in electrosurgical procedures is necessary to avoid burn or shock hazard to patient and/or operator.
- Refer to appropriate electrosurgical system user manual for indications and instructions to ensure that all safety precautions are followed.
- When using electrocautery, ensure the electrode(s) is/are fully visible to avoid inadvertent tissue damage.
- Do not use instruments with monopolar cautery as bipolar cautery instruments.
- Do not apply electrosurgical current directly to staples or clips.
- When not being activated use a holster or quiver to house the electrosurgical handpencil safely away from operating room personnel, surgical drapes and the patient.
- Ensure that the electrosurgery handpencil connectors are housed securely in the electrosurgical generator.
- Always use the lowest electrosurgery power settings to achieve the desired tissue effect.
- Due to concerns about the carcinogenic and infectious potential of electrosurgical by-products (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.

Single Use Precaution:

These device(s) are designed and sold for single use only. Re-processing and, or, re-sterilisation is not permitted.

The effects of any unauthorised reprocessing or re sterilisation can result in the following complications:

1. Cross contamination due to ineffective re processing/re sterilisation.
2. Mechanical fatigue, and associated failure, due to the effects of the reprocessing / re sterilisation method.

After single patient use, the device is to be immediately disposed of as controlled medical waste.

How Supplied

The Purple Surgical electrosurgical handpencil and electrode accessories are supplied sterile for single patient use.

Shelf Life:

4 years from date of sterilisation – use by date as denoted on labelling in format YYYY-MM.

purple surgical



Purple Surgical Holdings Limited

also known as:

Purple Surgical International Limited,

Purple Surgical UK Limited,

Purple Surgical Manufacturing Limited,

2 Chestnut House, Farm Close, Shenley, Herts, WD7 9AD, UK

T: +44 (0)1923 839333 F: +44 (0)1923 839444

E: mail@puplesurgical.com W: www.puplesurgical.com

CE 1639

STERILE EO

STERILE R

LOT



EC REP