Prior to increasing the intensity, check the adherence of the neutral electrode and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections.

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). Skin to skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.

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.

In all cases, monitoring systems incorporating HIGH FREQUENCY current limiting devices are recommended.

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 tissue damage.

Interference produced by the operation of HF SURGICAL EQUIPMENT may adversely influence the operation of other electronic equipment.

This device is intended for an individual patient, during a single procedure and should be discarded after use. Potential of cross contamination if re-used.

The intensity should be set as low as is necessary to achieve the desired effect. Keep the active electrodes clean. Build-up of eschar may reduce the instrument’s effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.

For use with a max peak voltage of 3000V.

For use with standard Operating Room Suction, connected via a suction connection tube.

These Electro Surgery Accessories can be used with Operating Theatre generators with a suitable voltage, operating in monopolar mode.

Connection is to a lead having a 4mm female connector (suctions have a 4mm male connector).
Indications for Use

Electrosurgical Accessory: Disposable electro surgery suction intended to remove tissue and control bleeding by use of high-frequency electrical current.

The single use Diathermy Suction Instruments are indicated for use in the same procedures as current re-useable Diathermy Suction Instruments. The suction tubes can be used during surgery to remove fluids or tissue from the operative site. The tube can also be used as a probe to move objects for better visibility. The diathermy is also indicated for use in localised cutting and/or coagulation of the tissue. The geometry and end finish of the single use device is similar to the reusable one, and the strength of the tube / handle joint is comparable. They connect to leads, in turn connected to electrosurgical generators. They also connect to suction equipment.

Manufacturer
Single Use Surgical is a trading name of Pelican Feminine Healthcare Ltd, Greypoint, Cardiff Business Park, Cardiff, CF14 5WF

Product conforms with the essential requirements of applicable EC directives

Do not resterilise
Do not reuse

Method of sterilisation using ethylene oxide
Do not use if packaging damaged

Keep away from direct sunlight
Protect from heat and radioactive sources

Latex free

Warnings

A. This product is Single Use, it cannot be adequately cleaned and sterilised by the user in order to facilitate safe reuse. Attempts to clean or sterilise these devices may result in bio incompatibility, or infection risks to the patient.

B. Please see user manuals for generator and neutral electrode for additional instructions. The hand piece is a monopolar device, and a dispersive electrode should be used with the generator to prevent burns/injury to the patient.

C. The Operator should avoid HF output settings where the Maximum Output Voltage exceeds the Maximum Peak voltage rating of this Accessory of 3000V

D. DO NOT USE in 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.

E. DO NOT USE in the presence of flammable anaesthetics or oxidizing gases (such as nitrous oxide (N2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.

F. DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.

G. When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

H. DO NOT USE with hybrid trocar systems, i.e., a combination of metal and plastic. This may result in alternate site burns due to capacitive coupling. Use only all-metal or all-plastic trocar systems.

I. INSPECT instruments and cables for damage prior to each use, especially the insulation of laparoscopic/endoscopic instruments. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.

J. ASPIRATE fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.

K. DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling.

L. The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.

M. 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.

N. Connect adaptors and accessories to the electrosurgical unit only when the unit is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.