

EN

Essentials Monopolar Laparoscopic Instruments



PS4551NS, PS4581NS, PS4552NS, PS4553NS, PS4556NS, PS4555NS, PS4554NS, PS4558NS, PS4587NS, PS4557NS, PS4559NS

The following should be read before using these Instruments.

Indications For Use & Product Characteristics

The instrument/s have application in a variety of endoscopic procedures to grasp and transect tissue, whilst providing the option of electrosurgical haemostasis. The instrument/s have a rotating 5mm diameter, 33cm long, insulated shaft and are designed for use through appropriate surgical trocars. The rotation wheel located on the handle rotates the shaft 360°. The instrument/s have a 4mm male monopolar diathermy connector extending from the top of the handle, and can be used for electrosurgery when properly attached to a monopolar cable and appropriate generator.

The Instrument jaws are activated by compression and release of the handles. On versions with Ratchet Mechanism, the ratchet automatically locks the jaws into the desired position, firmly grasping tissue; this ratchet is easily released by simply pushing the ratchet trigger.

How Supplied

Supplied in Non sterile format to Kit packer, for sterilisation as part of a kit prior to market release to intended user.

INDICATIONS FOR STERILISATION PROCESSING:

Method	Indicated	Contraindicated	Process limitations
ETO	x		Preconditioning – 60 +/- 15 % RH Maximum Temp – 55 °C Nominal gas concentration – 600 mg/L Minimum Exposure dwell time – 2 hrs Maximum Pressure - 50mbarA
Irradiation		x	Not Applicable - Unqualified
Steam / Other		x	Not Applicable - Unqualified

Note* It is the responsibility of the kit packer to validate the sterilisation process employed, with respect to the conditions of their presentation of the packaging system.

Electrosurgical Ratings

Instrument MAXIMUM rated voltage according to tests performed in accordance with IEC 60601-2-2 (High frequency and Mains frequency dielectric testing) is: 2,400V

Compatibility & Connectivity

- The instrument/s are designed for Monopolar use only.
- The instrument/s require connection to the electrosurgical generator via a monopolar cable with 4mm female plug to attach to the instrument, and appropriate connection pin size to accommodate the model of selected generator.
- The user should also review the *Instructions for Use* of all other accessories being used along with these instruments (generator, cable, patient return electrode ...) in addition to the instructions contained in this document.

Contraindications Of Use

- 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.
- DO NOT USE in the presence of flammable anesthetics 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.
- 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.
- DO NOT USE for conditions where minimally invasive techniques are contraindicated.
- Monopolar Scissors and Monopolar Maryland Dissecting Forceps are not intended for contraceptive coagulation of the fallopian tissue, but may be used to achieve haemostasis following transection of the fallopian tube(s).

Precautions / Warnings in Use

- DO NOT USE if sterile package is received opened or damaged.
- 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.
- Endoscopic and electrosurgical procedures should be performed only by physicians with adequate training and knowledge of these procedures. In addition, medical literature should be consulted regarding techniques, hazards, contraindications and complications prior to the performance of these procedures. Typical precautions are listed below:
 - The Monopolar Laparoscopic Instruments require use with a patient return electrode. The entire area of the patient return electrode should be reliably attached to a suitably prepared and appropriate area of the patient's body as defined by its manufacturer. It is recommended that a patient return electrode which has Contact Quality Monitoring (CQM) capabilities is used, so as to shut down or alarm if there is loss of safe contact between the electrode and the patient.
 - Refer to appropriate electrosurgical system user manual for indications and instructions to ensure that all safety precautions are followed.
 - Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of procedure.
 - 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.
 - INSPECT instruments and cables for damage prior to 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.

- 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.
- Always use caution when inserting or removing instruments through a cannula port. Lateral pressure on the instrument during insertion or removal can damage the working tip, shaft of the instrument and/or insulation. Do not introduce or withdraw the instrument with the blades/jaws open through a cannula port, as this could damage both instrument and cannula.
- The output power selected should be as low as is necessary to achieve the desired effect.
- Prior to increasing the intensity, check the adherence of the patient return electrode and its connections. Apparent low output, or failure of the instrument to function correctly at the normal operating settings may indicate faulty application of the patient return electrode or in its connections.
- DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling.
- When using electrocautery, ensure the blades/jaws are fully visible to avoid inadvertent tissue damage. Note that the surface of the active electrode may remain hot enough to cause burns after the electrocautery current is deactivated.
- Do NOT apply electrosurgical current directly to staples or clips.
- Damage to the instrument may occur if the cutting/grasping of staples or clips is attempted.
- Ring handled instruments are designed to be held with one finger and the thumb in the ring handles. DO NOT hold handle in a whole hand pistol grip which applies excessive force and may damage the instrument.
- 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.
- After removing the instrument, inspect the site for haemostasis (if desired). If haemostasis (when desired) is not present, use appropriate techniques to achieve haemostasis.
- When not using instruments, place them in a clean, dry, highly visible area that is not in contact with the patient. Inadvertent contact with the patient may result in burns.

Directions For Use

- Using sterile technique, remove the instrument from the package.
- The Instrument jaw has a protective cap, remove this cap before use.
- The instrument handle has a protective cover and the monopolar post has a protective cap, carefully remove and discard before use.
- Attach a suitable monopolar cable with 4mm female instrument fitting plug to the diathermy post on the instrument.
- Ensure a suitable Patient Return Electrode pad is applied to the patient.
- Connect the monopolar cable and Patient Return Electrode to the generator (in off condition)
- Select the correct and lowest necessary intensity Monopolar settings on the generator
- Insert instrument, with jaws closed, through 5mm or greater port under camera vision.
- Use the instrument in line with consideration to the indications, precautions and warnings in this document:
 - To rotate the shaft and active jaws, turn the rotation wheel to achieve desired position.
 - The Instrument jaws are activated by compression and release of the handles.
 - Keep the active jaws clean. Build-up of eschar may reduce the instruments effectiveness. Do not activate the instrument while cleaning the jaws, as injury to operating room personnel may result.
- Before removing the instrument through the port, ensure that the instrument is deactivated and that the jaws are in the **closed** position

Single Use Precautions











These instrument/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:

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

Disposal

After single patient use, the instrument/s are to be immediately disposed of as controlled medical waste according to national guidelines.

Labelling Symbology – Standard EN980 unless otherwise stated

 (Type BF Applied Part REF IEC 60601-1)	 (Do not use if package is damaged)	 (Do Not Reuse)
 1639 (CE Mark with notified body number)	 (Batch Code)	 (Manufacturer)
 (Catalogue number)	 (Consult Instructions for Use)	 (Keep dry)
 (Keep away from sunlight)		



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