

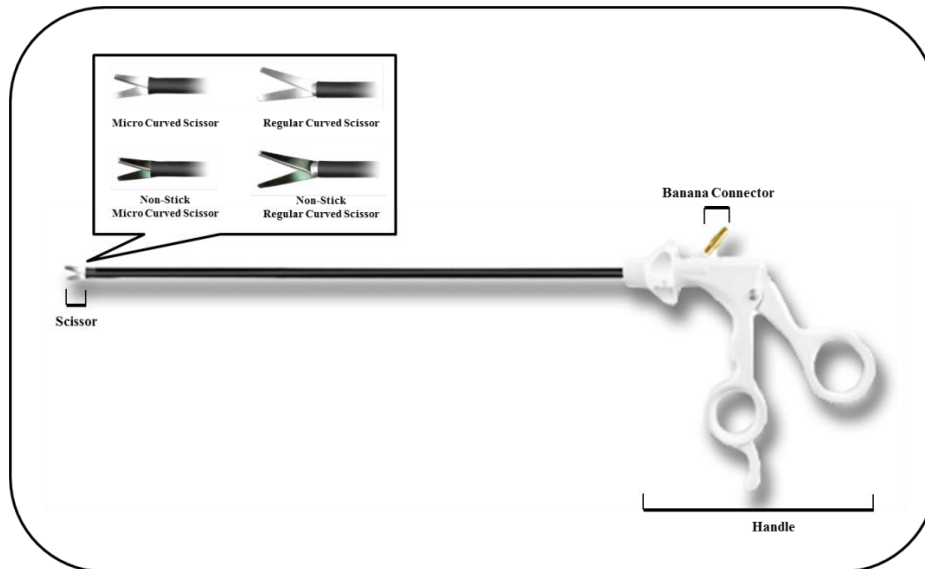
Instruction for Use

Product: Monopolar Scissors

The Following information should be read before using this device.

Description:

The Monopolar Scissors is provided with long metzenbaum blades with unipolar electro-surgical capacity. The product does not contain latex.



Contraindications:

This device is not intended for contraceptive coagulation on fallopian tissue. It may be used to achieve hemostasis following transaction of the fallopian tube.

Recommended Use:

The Monopolar Scissors is to be used in a variety of laparoscopic procedures to coagulate, transect and dissect tissue.

Preparation:

1. Insert the sleeve through the desired 5mm trocar sheath. Please note the blades must be closed prior to insertion into or removal from the sheath.
2. The lap instrument as scissors are closed and opened to dissect tissue by closing and operation of the ring handles.
3. The device is equipped with a standard 4mm male plug connector. To operate the unipolar electro-surgical feature, please follow instructions provide by electro-surgical generator manufacturer.

Cautions/Warnings:

1. Federal (U.S.A) law restricts this device to sale, distribution, and use by, or on the order of a physician.
2. Contents sterile unless enclosed package has been opened or damaged.
3. This device was designed, tested and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure and subsequent patient injury. Reprocessing and/or re-sterilization of this device may create the risk of contamination and patient infection. Do not reuse, reprocess or re-sterilize this device.
4. Endoscopic 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.
5. Before endoscopic instruments and accessories from different manufacture are utilize together in a procedure, verify compatibility and ensure that electrical isolation of grounding is not compromised.

6. These instruments are used in conjunction with HF device and suitable HF cables such as an 8mm/4mm male plug with 4mm female monopolar cable between this instrument and electrosurgical generators.

7. Setting parameters:

	Voltage (Vp-p)	Power (Watts)	Frequency (kHz)
Monopolar Instrument	100 ~ 700	80 ~ 300	200 ~ 500

8. Adjust the HF device in such a way that the maximum peak output voltage is equal or lower than the maximum peak rated voltage indicated for the instrument.

9. A thorough understanding of techniques and principals involved in electrosurgical procedures is necessary to avoid burn or shock hazard to patient and/or operator.

10. Test all instruments, accessories and equipment prior to each use.

11. Keep the voltage power as low as possible to achieve the desired end effect, refer to use instructions provided by the electrosurgical generator to ensure that all safety precautions are followed.

12. Using a metal trocar sheath in conjunction with a plastic site stability device creates a potential hazard when using electrosurgical instruments.

13. Do not use electrosurgical instruments on patients with pacemakers. Do not use in presence of flammable liquids or anesthetics.

14. Electrosurgical generators used with these devices are designed to cause destruction of tissue and are inherently dangerous if operated improperly. Follow all safety precautions and instructions supplied by the manufacture of the electrosurgical generator.

15. The electrode 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. Electrode tip must not come in contact with the laparoscope or other metal instruments during use.

16. Dispose used product following local state or federal guidelines.



Caution



Sterilized using Ethylene Oxide



Consult instructions for use



Do not use if package is damaged



Batch code



Do not reuse



Keep away from sunlight



Date of manufacture



Keep dry



Do not re-sterilize



Use by



Temperature limitation: 15°C~25°C



Catalogue number



Manufacturer



Authorised representative in the European community



Notified body: DNV GL Presafe AS, with CE2460

If further information is required, please contact:



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