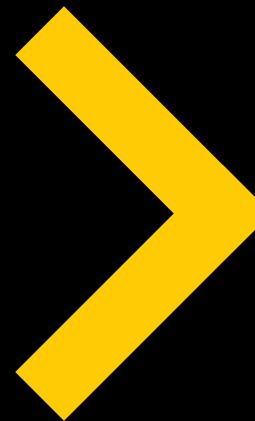


INSTRUCTIONS FOR USE



Monopolar Scissors IFU



Before using the product, read the IFU thoroughly

IMPORTANT!

This Instructions for Use is designed to assist in using this product. It is not a reference to surgical techniques.



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Rx Only

 **CAUTION:** Federal law restricts this device to sale by or on the order of a physician

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1. DESCRIPTION

The single use HandX™ Monopolar Scissors instrument with monopolar activation is a laparoscopic handheld 5mm diameter instrument with articulation tip. The Monopolar Scissors is designed to be used with a HandX™ Handpiece only and is designed for introduction and use through all compatible sized trocar sleeves. For general limitations on use, contraindications, warnings, precautions, instructions for use, cleaning and disinfection, refer to the HandX™ Instructions for Use provided with the HandX™ Handpiece.

2. INDICATIONS FOR USE

The HandX is intended to assist in the control of Human Xtensions™ laparoscopic instruments including needle holder, grasper and monopolar instruments, for endoscopic manipulation of tissue, including grasping, approximation, ligation, suturing, cutting and/or coagulation, during laparoscopic surgical procedures. The HandX monopolar instruments are connected by a standard cable to a standard electrosurgical power source. It is intended to be used by trained physicians in an operating room environment in accordance with its Instructions for Use.

3. CONTRAINDICATIONS

1. The HandXTM Monopolar Scissors with monopolar activation is NOT intended for contraceptive coagulation of fallopian tissue but may be used to achieve hemostasis following transection of the fallopian tube.
2. This device is intended for use only as indicated.

4. WARNING AND PRECAUTIONS

1. The HandX™ Monopolar Scissors cannot be used by itself and is intended to be used only with a HandX™ Handpiece.
2. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. Consult the medical literature relative to techniques, complications, and hazards prior to performing endoscopic procedures.
3. 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.
4. Do not activate the HandX™ Monopolar Scissors in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N₂O) and oxygen) or near solvents (such as ether or alcohol), as explosion may occur.
5. Do not place the HandX™ Monopolar Scissors near or in contact with flammable materials (such as gauze or surgical drapes). Monopolar instruments that are activated or hot from use may cause a fire.
6. The HandX™ Monopolar Scissors is provided sterile for single use only, discard after use and do not reuse, reprocess, or re-sterilize.
7. Used HandX™ Monopolar Scissors should be disposed according to bio-hazard disposal practices in accordance with the facility disposal procedure.
8. Prior to use, visually inspect the packaging/pouch/blister for breaches of packaging integrity. Do not use the HandX Handpiece, instruments, or HandX disposables if the device or package is damaged/opened/dropped, as it could compromise the safety, functionality, and sterile barrier of the HandX system.
9. Do not use the device past its expiry date.
10. Do not modify the Monopolar HandX™ instrument in any way. Danger of burns or other injuries to the patient or user.
11. Bipolar cables have a different type of plug that cannot be connected to a monopolar connection.
12. Prior to each use, visually inspect the HandX™ Monopolar Scissors for loose, bent, broken, cracked components. Do not use if any of these defects are observed on the device.



13. Verify that the HandX™ Monopolar Scissors insulation is intact and undamaged. Damaged insulation may result in burns or other injuries to the patient or user.
14. Do not activate high frequency (HF) in an open circuit condition. Activate the HF generator only when the working end effector (active electrode) of the monopolar instrument is touching the target tissue.
15. Do not use with hybrid trocars that are composed of metal and plastic components. Capacitive coupling of HF current may cause unintended burns. Use only all metal or all plastic trocar systems.
16. Do not activate HF while in contact with other instruments or accessories. Allowing the energized end effector of this device to contact the uninsulated portion of other laparoscopic devices or accessories could result in patient or user injury.
17. The patient shouldn't come in 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.
18. Aspirate fluid from the area before activating the Monopolar HandX™ instrument. Conductive fluids (e.g., blood or saline) in direct contact with or near an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
19. The surface of the active electrode may remain hot enough to cause burns after the HF current is deactivated.
20. The cable to the surgical electrode should be positioned in such a way that electrical contact with the patient or other conductors is avoided. Temporarily unused Monopolar HandX™ instrument and accessories should be stored in a location that is isolated from the patient.
21. The HandX™ Monopolar Scissors is compatible with high frequency power up to 3000 Vpeak.
22. The HandX™ Monopolar Scissors are insulated up to the blades. In case of insulation folding, do not use the monopolar instrument. Using HandX™ Monopolar Scissors with folded insulation might cause unpredicted energy burst.

5. ACCESSORIES COMPATIBILITY:

- Use only with safety certified HF generators (IEC 60601-2-2).
- Refer to the HF generator IFU for operating instructions and warnings.

HF monopolar cable

- The HandX™ Monopolar Scissors is outfitted with 4mm male plug.
- Use only HF monopolar cable with the following specification:
 1. 4mm compatible female plug
 2. **MINIMUM** rated voltage of 3000Vpeak.
 3. Total Length of **MAXIMUM** 3 meter
- Refer to HF monopolar cable IFU to verify compatibility.

HF neutral pad electrode

- Refer to the HF generator IFU for selection of neutral pad electrode consistent with 4000 Vpeak rating.

6. SCHEMATIC VIEW

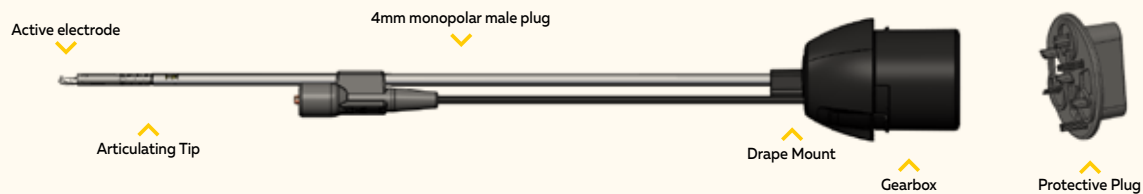


FIGURE 1: HANDX™ MONOPOLAR SCISSORS

NOTE: THE HANDX™ WITH THE HANDX™ MONOPOLAR SCISSORS IS COMPLIANT WITH IEC 60601-1, IEC 60601-1-2, AND IEC 60601-2-2.

7. INSTRUCTIONS FOR USE

1. Follow **Pre-operative assembly** per HandX™ Instructions for Use

⚠ **CAUTION:** For Monopolar HandX™ instrument, prior to carefully sliding the instrument into the sterile cover opening make sure that the 4mm monopolar male plug is clipped on the shaft.

⚠ **CAUTION:** Secure the distal end of the sterile cover around the HandX™ Monopolar Scissors drape mount using standard sterile OR tape, or the sterile tape provided with the sterile cover and unclip the 4mm monopolar male plug from the shaft.

2. **WARNING:** Connect the generator monopolar cable to the HandX™ Monopolar Scissors 4mm male plug.
 - Verify that the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.
 - Verify that the plug connection is secure. Poor or insufficient contact may lead to voltage flashovers, which can result in possible patient or user injury.
3. Adjust the high- frequency output to the operation. Take into account clinical experience and reports in the professional literature.
4. Select the lowest possible power output for the high- frequency device that achieves the desired surgical effect.
5. The HandX™ Monopolar Scissors is compatible with high frequency voltage of 3000Vpeak.
6. ⚠ **CAUTION:** In any case do not exceed the power high frequency power up to 3000Vpeak. In any mode of operation. Excessive power levels may result in HandX™ Monopolar malfunction and possible patient or user injury.
7. To avoid damage to the insulation and working end, carefully insert the Monopolar HandX™ instrument through the cannula (Trocars).

8. Keep the Monopolar HandX™ instrument active electrode in the user's visual field whenever high frequency power is activated.
9. **WARNING:** When not in use, avoid all contact of the active electrode with the patient, users and ancillary equipment.
10. Keep the Monopolar HandX™ instrument contact surfaces free of encrusted tissues residuals or body fluids, use a moistened swab. Use only non- flammable agents.
11. Switch off the automatic switch-on mode of the high- frequency device with endoscopic or laparoscopic accessories.

8. SYMBOL DEFINITIONS



Caution. There are specific precautions related to the device, refer to IFU



Do not use if package is damaged



Manufacturer



Use-by date



Do not re-use



Sterilized using ethylene oxide

Rx Only

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Keep dry



Quantity



Date of manufacture



Batch Code



Catalogue number



Unique Device Identification



Defibrillation-Proof Type BF Applied Part



Medical device



Sterile packaging



Non-sterile protective packaging with a sterile barrier system inside



Follow instructions for use



Humidity limitation



Temperature limit

9. TRANSPORT CONDITIONS

- Temperature: -10°C to 50°C (14°F to 122°F)
- Humidity: 10% - 85%

10. STORAGE CONDITIONS

- Temperature: 15°C to 30°C
- Humidity: 10% - 85%



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