INSTRUCTIONS FOR USE

HANDX™

Monopolar Hook IFU

Doc No. 40-48-082-02 Rev 03

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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1. DESCRIPTION

The single use HandX™ Monopolar Hook instrument with monopolar activation is a laparoscopic handheld 5mm diameter instrument with articulation tip. The Monopolar Hook 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. INTENDED USE

The HandX™ device is intended to facilitate repair and / or removal of organs and soft tissues during laparoscopic procedures through tissue manipulation and mobilization, i.e., stitching and grasping cutting and / or coagulation using the HandX™ device.

3. INDICATIONS FOR USE

The HandX™ device is indicated for surgical treatment of tissue and organ inflammation, benign and / or malignant space occupying lesions, and anatomic deformations in the abdominal, thoracic, and pelvic cavities.

4. CONTRAINDICATIONS

1. The Monopolar Hook 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.

5. WARNING AND PRECAUTIONS

1. Monopolar Hook 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 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.
5. Do not place the Monopolar Hook 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.
6. The Monopolar Hook is provided sterile for single use only. Discard after use.
7. Do not reuse, reprocess or re-sterilize.
8. Used Monopolar Hook should be disposed according to biohazard disposal practices in accordance with the facility disposal procedure.
9. Do not use if the sterile package or device is damaged or has been dropped, as it could compromise the functionality and/or safety of the products.
10. Do not use the device past its expiry date.
11. Do not modify the Monopolar Hook.

12. Bipolar cables have a different type of plug that cannot be connected to a monopolar connection.

13. Prior to each use, visually inspect the Monopolar Hook for loose, bent, broken, cracked components. Do not use if any of these defects are observed on the device.

14. Verify that the Monopolar Hook insulation is intact and undamaged. Damaged insulation may result in burns or other injuries to the patient or user.

15. Do not activate high frequency (HF) in an open circuit condition. Activate the HF generator only when the working end (active electrode) is near or touching the target tissue.

16. Do not use hybrid or metal trocars that are composed of metal and plastic components. Capacitive coupling of HF current may cause unintended burns.

17. Do not activate HF while in contact with other instruments or accessories. Allowing the energized tips of this device to contact the uninsulated portion of other laparoscopic devices or accessories could result in patient or user injury.

18. 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.). the use of antistatic sheeting is recommended for this purpose.

19. Aspirate fluid from the area before activating the Monopolar Hook. 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.

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

21. The cable to the surgical electrode should be positioned in such a way that electrical contact with the patient or other leads is avoided. Temporarily unused Monopolar Hook and accessories should be stored in a location that is isolated from the patient.

6. ACCESSORIES COMPATIBILITY:

HF generator

- The HandX™ Monopolar Hook rated voltage is 4000Vpeak
- Use only with safety certified HF generators (IEC 60601-2-2)
- The HandX™ Monopolar Hook is compatible with standard electrosurgical generator generating a **MAXIMAL** high frequency voltage of 4000Vpeak at 45W power setting in any mode of operation.
- Refer to the HF generator IFU for operating instructions and warnings.

HF monopolar cable

- The HandX™ Monopolar Hook is outfitted with 4mm male plug. Use only HF monopolar cable with the following specification:
- 4mm compatible female plug
- **MINIMUM** rated voltage of 4000Vpeak
- 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.

7. SCHEMATIC VIEW

THE HANDX™ MONOPOLAR HOOK

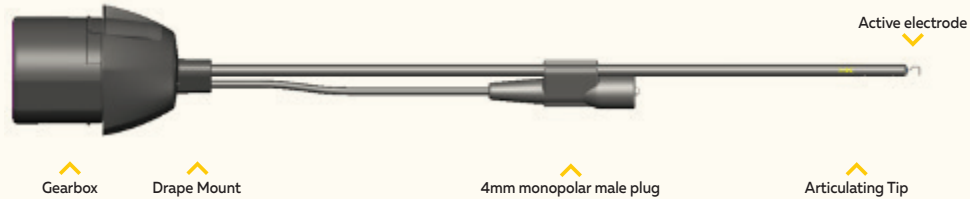

FIGURE 1: HANDX™ MONOPOLAR HOOK SCHEMATIC

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

8. INSTRUCTIONS FOR USE

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

   ⚠ **CAUTION:** For Monopolar Hook 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 Monopolar Hook 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. Connect the generator monopolar cable to the Monopolar Hook 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 personal.
   - 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.

   ⚠ **CAUTION:** In any case do not exceed **45W** in any mode of operation. Excessive power levels may result in Monopolar Hook malfunction and possible patient or user injury.

5. To avoid damage to the insulation and working end, carefully insert the Monopolar Hook though the cannula (Trocar).

6. Keep the Monopolar Hook's active electrode tip in the user's visual field whenever high frequency power is activated.

7. **WARNING:** When not in use, avoid all contact of the active electrode with the patient, users and ancillary equipment.

8. Keep the Monopolar Hook contact surfaces free of encrusted tissues residuals or body fluids, use a moistened swab. Use only non- flammable agents.

9. Switch off the automatic switch-on mode of the high- frequency device with endoscopic or laparoscopic accessories.

9. 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

Keep dry

Quantity

Date of manufacture

Keep dry

Batch Code

European Authorized Representative

Catalogue number

Unique Device Identification

Defibrillation-Proof Type BF Applied Part

Follow instructions for use

Humidity limitation

Temperature limit

10. TRANSPORT CONDITIONS

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

11. STORAGE CONDITIONS

Store in a cool dry place

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