SYMBOL DEFINITIONS

Following are the graphical symbols and their descriptions used in the HandX™:

Rx	Federal (USA) law restricts the device to sale by or on the order of a physician	QTY	Quantity
	Do not use if package is damaged or open		Caution. There are specific precautions related to the device, refer to IFU
	Follow instructions for use	SN	Serial Number (includes manufacturing date in format YYMMDD)
	Defibrillation-Proof Type BF Applied Part		Class II Equipment
	Manufacturer	LOT	Batch Code
	Used by (+date)		Single Use Only
STERILE EO	Ethylene Oxide Sterilized	IPX1	Ingress Protection Marking
	Direct current		Humidity limitation
	Keep dry		Atmospheric pressure limitation
	Temperature limit		

HANDX™

INSTRUCTIONS FOR USE

HandX Needle Holder instrument IFU
HandX Fenestrated Grasper instrument IFU

Figure 1: Main HandX Components

EN

INSTRUCTIONS FOR USE

HandX Needle Holder instrument IFU
HandX Fenestrated Grasper instrument IFU

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⚠ **CAUTION:** U.S. Federal Law restricts this device to sale by or on the order of a physician

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HandX DESCRIPTION

The Human Xtensions HandX is a hand held powered laparoscopic device.

The HandX™ is electromechanically controlled it includes hardware and software and comprises two major parts, the Handpiece and the Instrument (Figure 1).

Main HandX Components as Illustrated in Figure 1

1. Arc & Spacer
2. CI (Control Interface)
3. Finger Unit
4. Handpiece Body
5. Gearbox
6. Gearbox Cap
7. Shaft
8. Articulating Tip
9. 5mm Needle Holder
10. 5mm Fenestrated Grasper
11. Finger Pads
12. Power Adapter
13. Sterile Power Cable
14. Protective Plug
15. Release Key

INSTRUMENT

- Articulating Tips - 5 mm Fenestrated Grasper/5 mm Needle Holder
- Shaft
- Gearbox
- Release Key

INDICATION

The HandX is intended to assist in the accurate control of HX laparoscopic Instruments including needle holder and grasper, for endoscopic manipulation of tissue, including grasping, approximation, ligation, suturing, during laparoscopic surgical procedures. It is intended to be used by trained physicians in an operating room environment in accordance with its Instructions For Use.

CONTRAINDICATIONS

Where laparoscopic surgery is contraindicated.

WARNINGS

1. The disposable components of the device are provided STERILE and are intended for use in a single procedure only. DISCARD AFTER USE DO NOT RESTERILIZE. Reuse reprocessing, or re-sterilization may compromise the structural integrity of the device and/or lead to device failure that in return may result in patient injury, illness or death.
2. Endoscopic procedures should be performed only by physicians having adequate training and familiarity with endoscopic techniques. A thorough understanding of the operating principles, risk versus benefits, and the hazards involved in an endoscopic approach is necessary to avoid possible injury to the user and/or patient.
3. HandX™ instrument cannot be used by itself and are intended to be used only with a HandX™ Handpiece.
4. Never use a HandX instruments if the device is damaged or the package is damaged or opened.
5. Do not use past the expiry date.
6. Used HandX instruments should be disposed according to bio-hazard disposal practices in accordance with the facility disposal procedure.
7. Do not connect wet accessories to the HandX Handpiece.
8. Never drop the equipment or subject it to severe impact, as it could compromise the functionality and/or safety of the equipment or system.
9. No modification of this device is allowed without authorization of the manufacturer.

NOTE: defibrillation was tested and in compliance with IEC 60601-1

USING THE DEVICE

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

TRANSPORT CONDITIONS:

HandX disposable instrument:

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

STORAGE CONDITIONS:

HandX disposable instrument:

- Temperature: 15°C to 30°C, 59°F to 86°F
- Humidity: 10%-85%