

SYMBOL DEFINITIONS



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



Federal (USA) law restricts the device to sale by or on the order of a physician



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



Serial Number (includes manufacturing date in format YYMMDD)



Defibrillation-Proof Type BF Applied Part



Class II Equipment



Manufacturer



Batch Code



Used by (+date)



Single Use Only



Ethylene Oxide Sterilized



Ingress Protection Marking



Direct current



Humidity limitation



Keep dry



Atmospheric pressure limitation



Temperature limit



INSTRUCTIONS FOR USE

HandX Needle Holder instrument IFU
 HandX Fenestrated Grasper instrument IFU
 HandX Self-Righting Needle Holder instrument IFU



Figure 1: Main HandX Components

INSTRUCTIONS FOR USE

HandX Needle Holder instrument IFU

HandX Fenestrated Grasper instrument IFU

HandX Self-Righting Needle Holder instrument IFU



Manufactured by Human Xtensions Ltd.
4 Meir Ariel St., Netanya, 4250574, Israel
Telephone: +(972) 9 766 9569

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US CUSTOMER SERVICE: cs-us@human-x.com

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 | 7. Shaft | 12. Finger Pads |
| 2. CI (Control Interface) | 8. Articulating Tip | 13. Power Adapter |
| 3. Finger Unit | 9. 5mm Needle Holder | 14. Sterile Power Cable |
| 4. Handpiece Body | 10. 5mm Fenestrated Grasper | 15. Protective Plug |
| 5. Gearbox | 11. 5mm Self-Righting Needle Holder | 16. Release Key |
| 6. Gearbox Cap | | |

INSTRUMENT

- Articulating Tips - 5 mm Fenestrated Grasper/5 mm Needle Holder/5 mm Self Righting Needle Holder
- Shaft
- Gearbox

INDICATION

The HandX is intended to assist in the control of Human Xtensions 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 RSTERILIZE. 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%