HERizon™

Disposable Endoscopic Forceps

Instructions for Use

minerva®
The Uterine Health Company

Table of Contents

About this Manual

This manual provides information on how to operate the HERizon Disposable Endoscopic Forceps. It is essential to read and understand all the information in this manual before using the system. Pay attention to all warnings, contraindications, precautions and adverse events in this manual and other related materials. Failure to thoroughly understand and follow all instructions may result in harm to the patient or user of the system.

Reuse Warning

The HERizon Disposable Endoscopic Forceps is supplied STERILE using Ethylene Oxide. Do not use if sterile barrier is damaged. If damage is found, call your Minerva Surgical representative.

The HERizon Disposable Endoscopic Forceps are for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.

Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may result in patient injury, illness or death.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

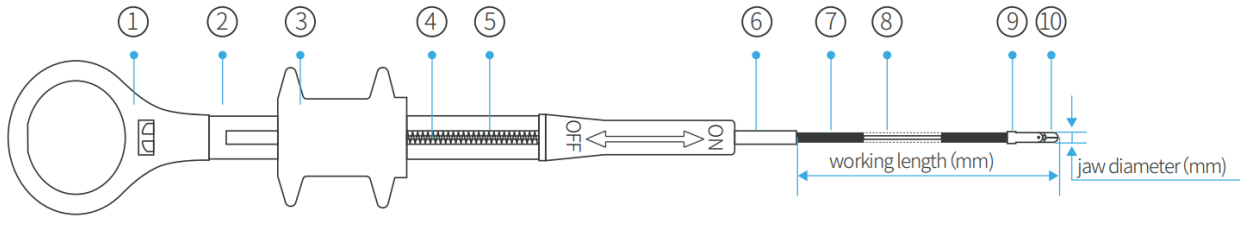
Device Description

The HERizon Disposable Endoscopic Forceps are available in five models and supplied sterile, sterilized by ethylene oxide, and single use only.

TABLE 1: ENDOSCOPIC FORCEPS MODELS

Model Name	Working Length	Catalog #
Disposable Endoscopic Forceps – Biopsy	350 mm	JY-PK-350-18-S
Disposable Endoscopic Forceps – Foreign Body Grasper	350 mm	JY-C-350-18-S
Disposable Endoscopic Forceps – Alligator	350 mm	JY-CC-350-18-S
Disposable Endoscopic Forceps – Alligator XL	450 mm	JY-CC-450-18-S
Disposable Endoscopic Forceps - Inverted Tooth	350 mm	JY-DC-350-18-S

The HERizon Disposable Endoscopic Forceps are composed of a bracelet, a core rod, a slip ring, a reset spring, a booster tube, a sheath tube, a sleeve, a cable, a jaw holder, and a jaw (Figure 1). All five models of forceps are identical with the exception of Jaw type and working length, as defined in Table 1.



Component Description			
1	Bracelet	6	Sheath Tube
2	Core Rod	7	Sleeve
3	Slip Ring	8	Cable
4	Reset Spring	9	Jaw Holder
5	Booster Tube	10	Jaw

FIGURE 1: DISPOSABLE ENDOSCOPIC FORCEPS

Intended Use/Indications for Use

The HERizon Disposable Endoscopic Forceps are intended for grasping tissue and foreign bodies during endoscopic procedures.

Contraindications

Hysteroscopy may be contraindicated by the following conditions, depending on their severity or extent:

- inability to distend the uterus
- cervical stenosis
- cervical/vaginal infection
- uterine bleeding or menses
- known pregnancy
- invasive carcinoma of the cervix
- recent uterine perforation
- medical contraindication or intolerance to anesthesia

Warnings/Precautions

- Do not attempt to disassemble the forceps.
- Handle the forceps with care.
- If the forceps do not function properly, replace it with another properly functioning forceps.
- Do not place the Disposable forceps in environments with high temperatures, humidity, dust, direct sunlight or corrosive gases.
- Only those personnel who have been trained or whose knowledge and practical experience are sufficient to ensure correct operation should operate and use this system.
- If this device is to be used with other equipment, the user should consult applicable IFUs and receive appropriate training on the use of the equipment and use it strictly in accordance with its IFU.
- This product is for prescription only.
- The disposable endoscopic forceps is ethylene oxide (EO) sterilized and for single use only.

Environmental Protection

Follow local governing ordinances and hospital practice regarding the disposal of the HERizon Disposable Endoscopic Forceps.

The Shelf Life of the Disposable Endoscopic Forceps is 3 years.

How Supplied

DO NOT USE IF PACKAGE IS OPENED OR DAMAGED. **DO NOT** USE IF LABELING IS INCOMPLETE OR ILLEGIBLE.

The Disposable Endoscopic Forceps is supplied sterile and is intended for single use. The shelf box contains:

- One (1) Disposable Endoscopic Forceps
- One (1) HERizon Disposable Endoscopic Forceps eIFU Insert

Forceps Operation

IMPORTANT: In addition to these instructions, follow the instruction manuals or IFUs of the products used in conjunction with this product. See *www.minervasurgical.com/IFU_Symbol-Glossary* for additional information. Refer to the HERizon Medical Image Processor System Operator's Manual for additional details and instructions on system set up and operation.

1. Introduce the forceps into the working channel of the Endoscope. The Forceps Jaw (Figure 1, ID 10) must be in the closed position.
2. Once inserted into the working channel of the endoscope, place the forceps Jaw (Figure 1, ID10) towards the target area.
3. Secure the Bracelet and Core Rod (Figure 1, ID 1 and 2) with one hand and push the Slip Ring (Figure 1, ID 3) forward to open the Jaws (Figure 1, ID 10) of the forceps.

4. Introduce the forceps into the target tissue, pull back the Slip Ring (Figure 1, ID 3) to close the forceps on the target tissue.
5. Hold the forceps Jaw (Figure 1, ID 10) in the closed position and slowly withdraw the entire device from the endoscope. If the size of the removed tissue is larger than initially intended, remove the device together with the endoscope.

Storage and Handling

The HERizon Disposable Endoscopic Forceps must be kept in a cool and dry environment.

Maintenance

Do not use after expirations date as specified on the device label. Single Use Items must not be repaired or reused.

Limited Warranty

Minerva Surgical warrants that the device(s) supplied is free from defects in materials or workmanship. The Disposable Endoscopic Forceps has a 3 year shelf life and is warranted throughout the intended shelf life, so long as the product has been maintained in accordance with procedures documented in the IFU.

The following circumstances are not covered by the warranty and will cause all liability statements to be invalid: faults caused by non-standard or improper use, incorrect treatment, and modification of device by technicians not authorized by Manufacturer. The packaging materials of devices and accessories sold by Minerva Surgical are all designed to protect them from damage.

Customer Service/Technical Support

Contact Minerva Surgical Customer Service for customer support.

Call +1 (855) 646-7874

Symbol Glossary

Symbol	Symbol Title	Standard	Description
	Contents	ISO 15223-1	Package content
	Unique device Identifier	ISO 15223-1	Indicates a carrier that contains unique device identifier information
	Manufacturer	ISO 15223-1	Indicates the medical device manufacturer
	Use-by date	ISO 15223-1	Indicates the date after which the medical device is not to be used
	Batch code	ISO 15223-1	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Catalog number	ISO 15223-1	Indicates the manufacturer's catalog number so that the medical device can be identified
	Do not resterilize	ISO 15223-1	Indicates a medical device that is not to be resterilized

	Do not use if package is damaged and consult instructions for use	ISO 15223-1	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Do not re-use	ISO 15223-1	Indicates a medical device that is intended for one single use only
	Consult instructions for use	ISO 15223-1	Indicates the need for the user to consult the instructions for use
	Date of manufacture	ISO 15223-1	Indicates the date when the medical device was manufactured
Rx only	U.S. Federal Law restricts this device to sale by or on the order of a licensed practitioner.	NA	Indicates this is a restricted device.
	Sterilized using ethylene oxide	ISO 15223-1	Indicates a medical device that has been sterilized using ethylene oxide.
	Keep away from sunlight	ISO 15223-1	Indicates a medical device that needs protection from light sources
	Keep dry	ISO 15223-1	Indicates a medical device that needs to be protected from moisture
	Temperature limit	ISO 15223-1	Indicates the temperature limits to which the medical device can be safely exposed
	Fragile, handle with care	ISO 15223-1	Indicates a medicaldevice that can bebroken or damaged if nothandled carefully.
	Stacking limit by six	ISO 7000：2018	To indicate that the items shall not be vertically stacked beyond the specified number
	Humidity limitation	ISO 15223-1	Indicates the range of humidity to which the medical device can be safely exposed

For Additional Product Information, Scan the QR Code

Product manufactured and packaged for Minerva Surgical, Inc.
by Jiangsu Jiyuan Medical Technology Co, Ltd.
4255 Burton Drive Santa Clara, CA 95054 USA
Customer Service: 855-464-7874
www.minervasurgical.com