HOLOGIC®

Omni™ Hysteroscopic Grasper
Instructions for Use

REF OMNI-G-001

Omni Hysteroscopic Grasper

Figure 1

Please read all information carefully.

Description

The sterile, single-use, hand actuated Hysteroscopic Grasper is used for traction of soft intrauterine tissue and are compatible with the MyoSure® and Omni® Hysteroscope.

Indications for Use

The Hysteroscopic Grasper is intended to be used by a trained gynecologist to provide soft intrauterine tissue traction (e.g., to grasp and remove polyps, adhesions, septum, and remove foreign bodies or severed tissue) and is intended to be used in conjunction with a Hologic MyoSure or Omni Operative Hysteroscope.

Contraindications

The Hysteroscopic Grasper should not be used with pregnant patients or patients exhibiting pelvic infection, cervical malignancies, or previously diagnosed uterine cancer.

Warnings and Precautions

Warnings

Before using the Hysteroscopic Grasper for the first time, review all available product labeling thoroughly. As with any surgical instrument, there are important health and safety considerations. These are as follows:

- Consider pre-operative imaging prior to the procedure to assess the patient for evidence of placental invasion of the myometrium. In the immediate postpartum phase, removal of retained products of conception (RPOC) in the setting of known or suspected placenta accreta, placenta increta or placenta percreta poses a risk of significant and potentially life-threatening bleeding.
- Do not use a device after its use-by date.
- Do not advance the device past the proximal guidance mark without confirming that there is clearance exiting the distal end of the hysteroscope. Doing so may cause patient injury, such as hematoma, hemorrhage, infection, perforation, or tissue damage.
- Once within the uterine cavity, always maneuver under direct visualization. Not doing so can cause hematoma, hemorrhage, infection, laceration, perforation, or tissue damage.
- Do not use the device to remove calcified tissue. Doing so may cause patient injury such as tissue damage, perforation, and infection.
- Content is supplied sterile using an ethylene oxide process. Do not use if sterile barrier is damaged. Doing so may cause patient infection.
- The device is for single-patient use only. Do not reuse, reprocess, or resterilize. Doing so may compromise the device and/or lead to device failure. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause the transmission of infectious disease(s) from one patient to another. Contamination or compromise of the device may lead to injury, illness, or death of the patient.

Precautions

- Caution: Federal law restricts this device to sale by or on the order of a physician.
- Opening the packaging with a sharp object may result in damage to the device.
- The user should inspect the single-use device for damage prior to use.
- Ensure that the Hysteroscopic Grasper are in a closed position while being inserted, advanced, and withdrawn through the working channel of the hysteroscope. Failure to do so may result in damage to equipment.
- If any malfunction should occur during use, stop the procedure immediately, and slowly withdraw the Hysteroscopic Grasper and replace with a new device.

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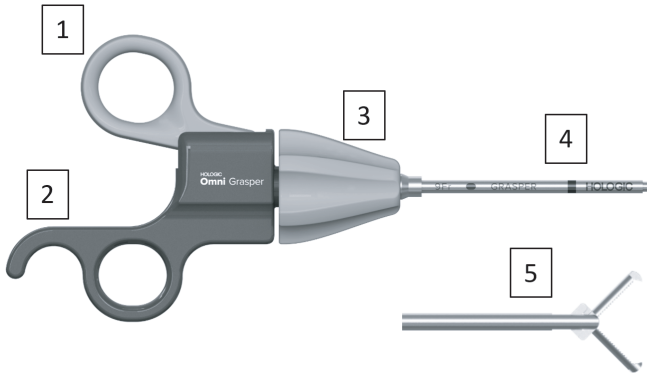

Figure 2. Omni Hysteroscopic Grasper

1.	**Movable Thumb Ring**	Actuates Hysteroscopic Grasper.
2.	**Fixed Ring**	Supports stationary fingers.
3.	**Rotational Knob**	Rotates Hysteroscopic Grasper.
4.	**Proximal Marker**	Indicates device position within hysteroscope.
5.	**Grasper Jaws**	Grasp targeted tissue.

Operation

Opening and closing the Hysteroscopic Grasper is completed by squeezing the Movable Thumb Ring.

1. Carefully inspect the packaging for any damage prior to use. Do not attempt to use the device if the sterile barrier is damaged. Do not use if past expiration date.
2. Inspect the device label to ensure that the correct device is chosen.
3. Open the pouch packaging and present the contents aseptically. While maintaining sterile technique, remove the device from the package and then remove the foam inserts and tip protector.
4. Check the open/close function of the Hysteroscopic Grasper by squeezing the Movable Thumb Ring.
5. Close the Hysteroscopic Grasper before inserting the device into the Hologic MyoSure or Omni Hysteroscope working channel.
6. Introduce the Hysteroscopic Grasper into the Hologic MyoSure or Omni Hysteroscope working channel.
7. Ensure the distal end of the hysteroscope is free from the uterine wall. Advance the Hysteroscopic Grasper until observed under direct visualization.
8. Position the Grasper Jaws using the rotational knob or the device handle. To grasp tissue, open and close the Grasper Jaws by squeezing the Movable Thumb Ring over the targeted pathology.
9. To ensure successful removal of pathology, maintain grip on the handle while withdrawing the Hysteroscopic Grasper. If the object is too large to be extracted through the operative channel, remove the Hysteroscopic Grasper and the Hologic MyoSure or Omni Hysteroscope simultaneously.
10. Steps 4-9 may be repeated if multiple retrievals are needed within a single procedure.

Disposal

Dispose of the Hysteroscopic Grasper as biohazardous waste or in accordance with any applicable hospital, administrative, and/or local government regulations.

Storage

The Hysteroscopic Grasper should be stored at room temperature, away from direct heat or moisture.

Technical Specifications

HYSTEROSCOPIC GRASPER: OMNI-G-001

Sterile, single-use device

Working Length: 13.1” / 33 cm

OD: 0.120” / 3.0 mm

Hysteroscopic Grasper Compatible Equipment	
MyoSure Hysteroscope	
40-250	MyoSure Hysteroscope w/Removable Outflow Channel
50-250XL	MyoSure XL Hysteroscope w/Removable Outflow Channel
Omni Hysteroscope	
60-250-1	Omni Hysteroscope Standard Kit
60-250-2	Omni Hysteroscope Light Kit
60-200	Omni Base Hysteroscope
60-202	Omni Operative Sheath (5.5 MM)
60-203	Omni Operative Sheath (6 MM)
60-200-30	Omni 30-Degree Base Hysteroscope
60-202-30	Omni 30-Degree, Operative Sheath (5.5 MM)
60-203-30	Omni 30-Degree, Operative Sheath (6 MM)
Hysteroscope Seals	
40-902	Rod Lens Hysteroscope Seals

Warranty, Service, and Repair

WARRANTY

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation (“Warranty Period”); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer’s warranties shall extend to Hologic’s customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products.

These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer’s refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or “as-is” basis.

Technical Support and Product Return Information

Contact Hologic Technical Support if the Hysteroscopic Grasper fail to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number. Return the Hysteroscopic Grasper according to the instructions provided by Technical Support. Used or opened product must be returned in accordance with the instructions included with the Hologic-supplied biohazard kit.

FOR MORE INFORMATION

For technical support or reorder information in the United States, please contact:

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
USA
Phone: 800-442-9892
www.hologic.com

Report any complaints or problems in the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to Hologic Authorized Representative and Competent authority of the respective member state or country. The Competent Authorities, for medical devices, are usually the individual Member States' Ministry of Health, or an agency within the Ministry of Health.

Symbols Glossary

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	EN ISO 15223-1, 5.1.5 ISO 7000, 2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	EN ISO 15223-1, 5.1.6 ISO 7000, 2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	EN ISO 15223-1, 5.4.4 ISO 7000, 0434A IEC 60601-1, Table D.1, 10	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	EN ISO 15223-1, 5.4.3 ISO 7000, 1641 IEC 60601-1, Table D.1, 11	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO/DIS 15223-1, 5.7.11 ISO 7000, 6049	Country of manufacture	To identify the country of manufacture of products.
	BS EN 15986 Annex B	Does not contain the presence phthalates	Indicates patient contact parts do not contain the presence of phthalates.
	EN ISO 15223-1, 5.2.6 ISO 7000, 2608	Do not resterilize	Indicates a medical device that is not to be resterilized.
	EN ISO 15223-1, 5.4.2 ISO 7000, 1051 IEC 60601-1, Table D.1, 28	Do not reuse	Indicates a medical device that is intended for single-use only.
	EN ISO 15223-1, 5.2.8 ISO 7000, 2606	Do not use if package is damaged	Indicates 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.

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	EN ISO 15223-1, 5.3.2 ISO 7000, 0624 ISO 780	Keep away from heat	Indicates a medical device that needs protection from heat sources.
	EN ISO 15223-1, 5.3.4 ISO 7000, 0626 ISO 780	Keep dry	Indicates a medical device that needs to be protected from moisture.
	EN ISO 15223-1, 5.1.1 ISO 7000, 3082	Manufacturer	Indicates the medical device manufacturer.
	ISO/DIS 15223-1, 5.7.7	Medical device	Indicates the item is a medical device
	EN ISO 15223-1, Annex B	Not made with natural rubber latex	Indicates no presence of dry natural rubber or natural rubber latex.
	ISO 7000, 2794	Packaging unit	To indicate the number of pieces in the package.
	FDA 21 CFR 801	Prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician.
	ISO/DIS 15223-1, 5.7.11 ISO 7000, 3707	Single sterile barrier system	Indicates a single sterile barrier system.
	EN ISO 15223-1, 5.2.3 ISO 7000, 2501	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO/DIS 15223-1, 5.7.10	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information
	EN ISO 15223-1, 5.1.4 ISO 7000, 2607	Use-by date	Indicates the date after which the medical device is not to be used.

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