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Omni[®] Hysteroscopic Grasper

Instructions for Use



1. Introduction

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

2. Indications for Use

The Hysteroscopic Grasper is intended to be used by trained gynecologists 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's MyoSure® Hysteroscopic Tissue Removal System or Omni® Hysteroscope.

3. Contraindications

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

4. Product Description

Product Name: Omni® Hysteroscopic Grasper

Product Model: OMNI-G-DSI-001, OMNI-G-DSI-003

The Omni® Hysteroscopic Grasper consists of a movable thumb ring, fixed ring, rotational knob, proximal marker and grasper jaws.



Figure 1. 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

5. 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 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 the Hysteroscopic Grasper is 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.

6. 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 the device if past the 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 a 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.

7. Technical Specifications

The device is sterile and single use.

Working Length: 330mm/13.1”

Outer diameter: 3.0mm/0.12”

Shelf life: 25 months

Omni-G-DSI-001 containing 1 device in outer package. Omni-G-DSI-003 containing 3 devices in outer package.

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

8. Disposal

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

9. Storage

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

10. Technical Support

Contact Acuvu Technical Support if the Hysteroscopic Grasper fails to operate as intended. If product is to be returned to Acuvu 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.

Report any complaints or problems in the quality, reliability, safety, or performance of this product to Acuvu. If the device has caused or added to patient injury, immediately report the incident to Acuvu and competent authority of the respective member state or country.













Contact information for Acuvu:







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11. Symbols and labels

	Catalogue number		Batch code
	Caution		Unique device identifier
	Consult instructions for use		Single sterile barrier system
	Does not contain the presence phthalates		Manufacturer
	Do not reuse		Sterilized using ethylene oxide
	Do not resterilize		Medical device

	Do not use if package is damaged	R_x Only	Prescription device
	Not made with natural rubber latex		Packaging unit
	Use by date		Keep away from heat
	Keep dry		



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Revision History

No.	Version #	Description	Originator	Release Date
1	A/0	Initial Release	Frank Huang	2025-12-31
2	A/1	Update Shelf life	Frank Huang	2026-04-02
3	A/2	Statement the copyright	Frank Huang	2026-05-21

Signature & Review

	Department	Name	Signature / Date
Authored By:	Product Manager	Frank Huang	
	R&D	Huang Fulai	
	R&D	Shu Jianwei	
	Quality	Zhang Liang	
	Regulatory	Wang Shulian	
Approved By:	Management Representative		