



DEVICE DESCRIPTION

The **FreeHold Duo™ Hands-Free Intracorporeal Retractor** and **FreeHold Trio™ Hands-Free Intracorporeal Retractor** are designed to provide hands-free tissue retraction during laparoscopic and robotic procedures.

These retractors enhance laparoscopic and robotic surgeries by providing hooks, sutures, and a pulley system to mobilize and suspend tissue away from the surgical field, enabling easier exposure and access to the tissue of interest. The retractors consist of hook assemblies (2 for the Duo, 3 for the Trio), and sutures. A mechanism within the hook assemblies (1 for the Duo, 2 for the Trio) prevents inadvertent lengthening of the sutures. The delivery/removal system consists of a 5 mm trocar-compatible Delivery/Removal Tube.

INDICATIONS FOR USE

The FreeHold Duo Retractor and FreeHold Trio Retractor are indicated for internal organ retraction during minimally invasive surgery. These products are intended for use by physicians trained and experienced in minimally invasive surgery techniques.

FreeHold Duo and FreeHold Trio Retractors are intended for one-time use only.

WARNINGS AND PRECAUTIONS

- Do not reuse, reprocess or re-sterilize.
- Do not use if the package is opened or damaged.
Do not use if seal is broken or compromised.
- FreeHold Duo and FreeHold Trio Retractors are not intended for the retraction of nerves or vessels.
- Care must be taken to avoid damage to blood vessels, nerves, and other anatomic structures that may be sensitive to puncture or injury. To minimize the risk of injury be sure to:
 - > Note important anatomical landmarks.
 - > Avoid use of excessive force, such as disproportionate tension on the sutures or hooks.
 - > Avoid placement of anchoring hooks into vascular structures or structures that may be injured by placement of hooks.
 - > Use caution when retracting heavy, friable structures.

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- These retractors are designed for intraoperative use only. Remove the device(s) from the patient before the end of the operation.
- After use, dispose of product and packaging in accordance with hospital administrative, and/or local government policy.

CAUTION: Federal law (USA) restricts this device to sale by, or on the order of, a physician.

STERILIZATION

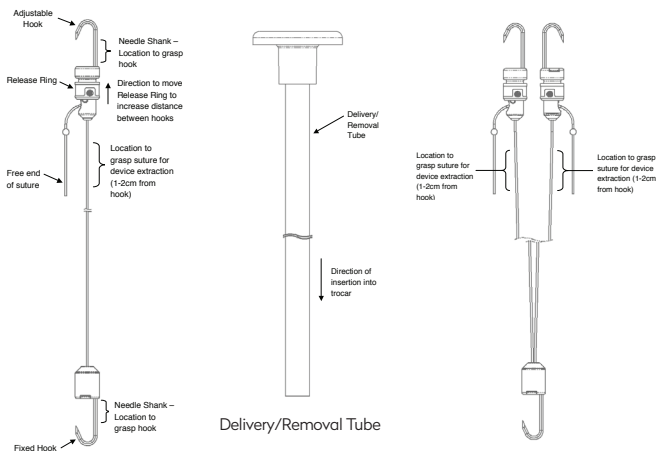
The FreeHold Duo and FreeHold Trio Retractors are sterile upon receipt. They are sterilized using irradiation as per ISO 11135 guidelines. The contents will remain sterile unless the package is opened or damaged outside a sterile field. Discard the device if it is rendered non-sterile prior to use.

STORAGE

- Store at controlled room temperature and avoid excessive heat.
- Expiration date of the product is indicated as year (4 digits) and month (2 digits). The product expires after the last day of the month.

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(1) FreeHold Duo Retractor or (1) FreeHold Trio Retractor are preloaded within a Delivery/Removal Tube packaged in mounting card.



INSTRUCTIONS FOR USE

Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive procedures.

The user should be familiar with the steps below prior to use.

1. Using sterile technique, remove the FreeHold Delivery/Removal Tube (preloaded with the FreeHold Duo or FreeHold Trio Retractor) from its packaging into the sterile field.
2. Inspect the Delivery/Removal Tube and device for damage. Do not use the device or Delivery/Removal Tube if damage is evident.
Note: During insertion or removal from trocar, the user should grab the tube, not the funnel, portion of the Delivery/Removal Tube.
3. Place the loaded Delivery/Removal Tube through any procedural trocar with a minimum 5mm internal diameter.
Note: Insertion of Delivery/Removal Tube and retractor must be done with adequate pneumoperitoneum and under direct visualization.
4. Insert a grasper through the Delivery/Removal Tube and push the FreeHold device into the surgical working space. Withdraw the grasper and Delivery/Removal Tube. Straighten the device prior to use.
Note: Keep Delivery/Removal Tube in the sterile field for future product removal.
5. Care should be taken when delivering, maneuvering or removing device from the surgical field in order to avoid inadvertently catching hooks on tissue.
6. Use a laparoscopic grasper or needle holder to grasp the Fixed Hook and to attach this hook to a desired anchor location for retraction or directly to the tissue to be retracted being careful to avoid sensitive structures.
7. Use a laparoscopic grasper or needle holder to grasp the needle shank on the Adjustable Hook (adjustable end with release ring). Attach this hook to a separate anchor location for retraction. If using the FreeHold Trio Retractor, repeat this step with the remaining Adjustable Hook assembly.
8. The amount of retraction can be adjusted by repositioning the hooks intraprocedurally or changing the length of suture between the hooks as needed:
 - **To decrease the distance** use a laparoscopic grasper or needle holder to pull on the free end of the suture until the desired length is achieved. One should always pull parallel to the taut suture when shortening the length between the hooks.
Note: The free end of the suture will be easiest to pull if the tissue to be retracted is supported while the suture is pulled. The force required to shorten the retraction suture can be decreased by lifting the release ring while simultaneously pulling on the free end of the suture.









- **To increase the distance** between the hooks, use a laparoscopic grasper or needle holder to move the release ring away from the taut suture. Simultaneously, with another laparoscopic grasper or needle holder, pull on the suture to decrease the amount of retraction.
Note: The release ring does not need to be continuously raised once the suture starts to move.

9. To remove the device when retraction is no longer needed:

- Before removing the hooks, use a laparoscopic grasper or needle holder to lengthen the distance between the hooks as much as possible.
- Insert the Delivery/Removal Tube through a procedural trocar (with a minimum 5 mm internal diameter).
- Insert a laparoscopic grasper through the Delivery/Removal Tube and grasp the suture connecting the hooks 1-2 cm from adjustable hook. Retrieve the device into the Delivery/Removal Tube.
Note: When retrieving the device after use in the abdominal space, advance the Delivery/Removal Tube as close as possible to the device. Do not drag the device towards the Delivery/Removal Tube.
- Prior to withdrawing the Delivery/Removal Tube into the trocar, ensure that the distal end of the device is fully inside the Delivery/Removal Tube to avoid unwanted exposure of hooks.
- Carefully withdraw the FreeHold device into the trocar. If resistance is encountered, gently push the laparoscopic grasper forward through the end of the Delivery/Removal Tube and try removing again.

10. Inspect the FreeHold Duo or FreeHold Trio Retractor after removal from the body to check for device integrity (tearing, pieces cut away, etc.).

11. Dispose of all FreeHold components in accordance with hospital, administrative, and/or local government policy.

DEFINITION	SYMBOL	DEFINITION	SYMBOL
Use By		Do Not Re-sterilize	
Do Not Re-Use		Manufactured For	
Lot or Batch Number		Consult Instructions for use	
Method of Sterilization		Catalogue Number	

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This product is covered by one or more of the following US patents: 8,251,889. Additional patents pending.