



EndoLift

Instructions for Use

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NOTICE:

It is important that you read the entire manual before you use the EndoLift.

It is unsafe to use this device before you have read and are thoroughly familiar with this document.

SYMBOLS

Virtual Ports, Ltd.

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MANUFACTURER NAME

MANUFACTURER ADDRESS

MANUFACTURER LOGO

ATTENTION, SEE INSTRUCTIONS FOR USE

EXPIRATION DATE

REFERENCE NUMBER

LOT NUMBER

DATE OF MANUFACTURE

DO NOT REUSE

**STERILIZED BY GAMMA.
DO NOT USE IF PACKAGE IS OPENED OR DAMAGED.**

Caution: Federal law restricts this device to sale by or on the order of a physician.

**PRESCRIPTION USE STATEMENT
(Applicable for U.S.A. only)**

WHEN THE SYSTEM ARRIVES

As the box is unpacked, check the content of the box against the item listed on the packaging slip. If the content is incomplete, notify Virtual Ports. Check the content condition. If the content is damaged, notify Virtual Ports. Do not use if the package suffered any damage.

ILLUSTRATION

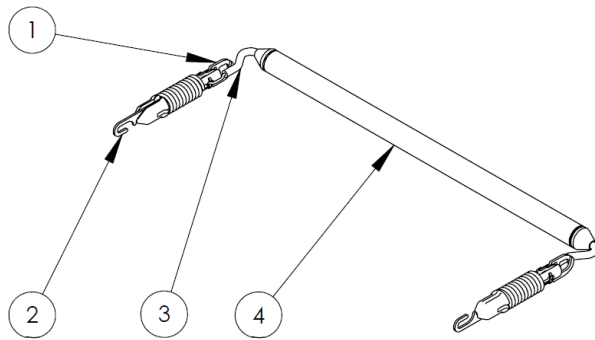


Figure 1 – EndoLift – Closed (default state)

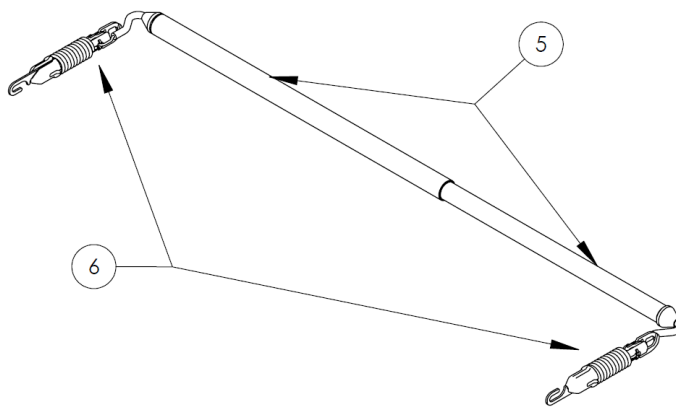


Figure 2 – EndoLift - Opened (telescopic tube extended)

EndoLift Parts

1. Anchoring clip jaws
2. Anchoring clip hook
3. Connecting wire (covered with plastic tube)
4. Telescopic Tube (Closed)
5. Telescopic Tube (Extended)
6. Anchoring clips

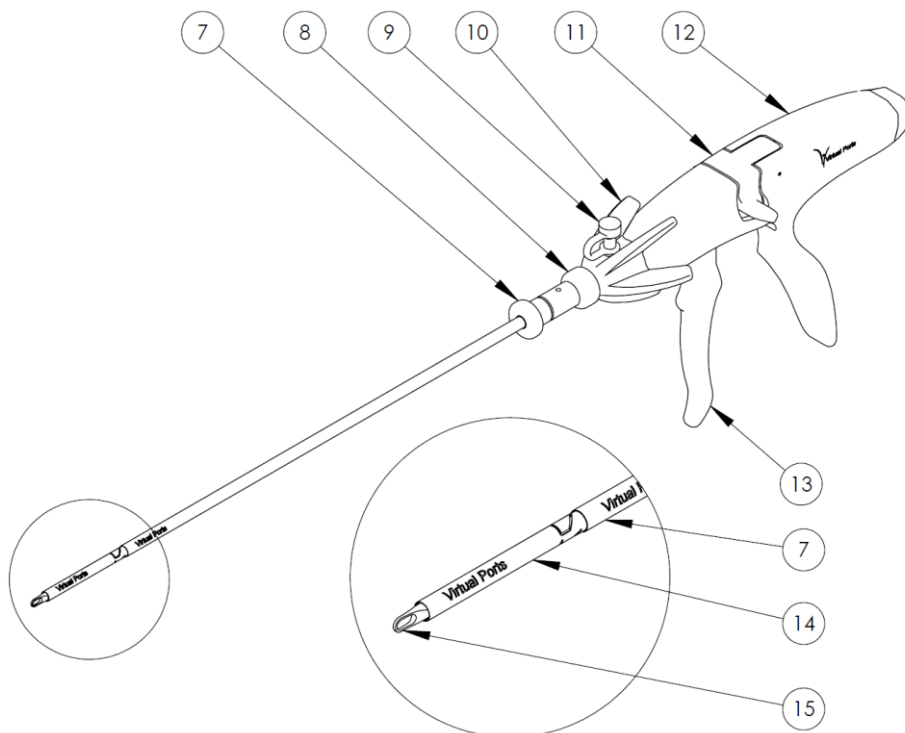


Figure 3 – Virtual Ports Applier

Applier Parts*

7. EndoLift Sleeve
8. Sleeve handle
9. Luer-Lock Connector (covered with cap)
10. Rotation knob
11. Release button
12. Handle
13. Trigger
14. Detachable tube
15. Applier loop

* See Applier User Manual for more information

DEVICE DESCRIPTION

The Virtual Ports EndoLift is an internally anchored, hands-free organ retracting device for use in minimally invasive surgery. The EndoLift is introduced into the internal operating cavity via a standard cannula (diameter of 5.0 – 5.5 mm) by means of the Virtual Ports Applier. The first anchoring clip is attached onto the internal operating cavity wall, on one side of the organ requiring retraction. The Applier is then connected to the second anchoring clip and maneuvered to place the telescopic tube underneath the organ to be retracted. Finally the second anchoring clip is attached onto the internal operating cavity wall on the other side of the organ, thereby achieving the desired retraction. The Applier is then removed and the port becomes available for use by other instruments. The EndoLift's position may be changed several times during the surgical procedure as needed. When the EndoLift is no longer required, it is removed from the internal operating cavity by means of the Applier and disposed of.

INDICATIONS

The EndoLift is indicated for internal organ retraction during minimally invasive surgery.

WARNINGS AND PRECAUTIONS

It is important for the EndoLift operator to be familiar with this manual, its precautions, procedures and safety issues. The following labels are used in this manual to identify important concerns:



Warnings

A Warning indicates a situation in which the user or the patient may be in danger of injury or death.



Precautions

Any special care to be exercised by a practitioner or patient for the safe and effective use of the device

NOTE

Emphasize important instructions.



WARNINGS

- Lack of familiarity with the device prior to use could result in damage to the device and serious injury.
- The EndoLift is provided **STERILE** and is intended for **SINGLE PATIENT USE ONLY**. **DO NOT RESTERILIZE**. Re-use of the EndoLift may lead to serious infections!
- The Virtual Ports Applier is a reusable instrument. It **MUST** be processed before each use according to the instructions in the User Manual supplied with the device.
- The accompanying instructions only describe the proper use of the EndoLift and are not recommending any surgical procedure. The EndoLift should only be used by persons with adequate training and experience in minimally invasive and general surgery.
- Do not attach the anchoring clips to tissues other than the internal operating cavity wall.
- Do not make contact between the EndoLift and an electrosurgery electrode. Accidental application of electrosurgery on the EndoLift could cause tissue damage and further complications.



PRECAUTIONS

- Do not attempt to operate the EndoLift with any instrument other than the Virtual Ports Applier. Doing so could damage the EndoLift and cause tissue injury.
- Make sure to use the EndoLift Sleeve (REF# AP164A) with the Applier. Use of a different sleeve could cause device malfunction.
- Handle the device with care to avoid both patient and personnel accidental injury when opening the anchoring clip's jaws.

STERILITY, CARE AND HANDLING

- Each EndoLift is packaged individually in sterile sealed pack.
- The EndoLift is disposable and should not be reused.
- Sterility of the EndoLift is ensured until the expiration date printed on the pack unless the sterile sealed pack has been damaged or previously opened.
- The EndoLift should be stored in a dry location.

SAFE OPERATION

• ***Load the EndoLift on the Virtual Ports Applier***

1. Make sure the EndoLift Sleeve (REF# AP164A) **7** is assembled on the Applier.
2. The Applier loop **15** should be visible at the distal end. If it is not, release the trigger **13** and press the release button **11** in order to bring it forward.
3. Engage the hook **2** of one of the anchoring clips **6** with the Applier loop.
4. Pull back gently on the trigger until the you hear a click, indicating the clip is fixed to the Applier detachable tube **14**.
5. Push the sleeve **7** forward encasing the telescopic tube **4**. Continue until the second clip of the EndoLift is also encased within the sleeve.

The EndoLift is now loaded and ready to be used.

• ***Insert the EndoLift into the internal operating cavity***

6. Insert the loaded Applier into the internal operating cavity through a 5mm or larger cannula.
7. Pull back on the sleeve to expose the EndoLift. Continue until the clip attached to the Applier is fully exposed.

• ***Retract an organ with the EndoLift***

8. Choose a first anchoring site on the internal cavity wall.
9. Approach the site with the anchoring clip and and pull the trigger to open the jaws **1** and pinch the tissue at the desired location.
10. **Release the Applier trigger** and gently pull back the handle **1** in order to close the jaws on the anchoring site.
NOTE: There is no need to apply excessive force onto the internal wall during the anchoring procedure.
11. Press the release button in order to separate the anchoring clip from the Applier.
12. Locate the second anchoring clip at the opposite end of the EndoLift and load it onto the Applier.
13. Maneuver the EndoLift telescopic tube under the organ to be retracted.
14. Attach the second anchoring clip onto the internal cavity wall to achieve the desired retraction.
15. Visually inspect the retraction before continuing with the surgical procedure.
16. If the retraction is satisfactory, remove the Applier from the internal operating cavity.

• ***Remove the EndoLift***

17. Insert the Applier through the cannula into the internal operating cavity.
18. Engage the hook of one of the anchoring clips with the Applier loop.
19. Pull the trigger to open the jaws and move the clip away from the internal cavity wall.
NOTE (1): Once the clip is removed from the internal cavity wall, release the trigger to close the jaws and avoid accidental tissue injury.
20. Press the release button **9** to release the anchoring clip from the Applier.
21. Engage the second anchoring clip with the Applier and remove it as well.
22. Push the sleeve **12** forward until the EndoLift is completely covered.
23. Remove the Applier with the EndoLift from the body.
24. Pull back on the sleeve **12** to expose the EndoLift.
25. Press the release button **9** in order to disconnect the EndoLift from the Applier.

TROUBLESHOOTING

- ☹(1) Problem: When the clip does not fit into the Applier detachable tube and gets stuck on its end.
☺ Corrective action:
1. Press the release button and disconnect the clip.
 2. Carefully re-engage the hook and pull back slightly to align the anchoring clip with the Applier tube (without pulling the trigger yet!!).
 3. Once the clip is aligned, pull the trigger until you hear a click and the anchoring clips fits into the tube.
- ☹(2) Problem: When pulling the trigger to activate the clips, nothing happens, i.e. the jaws don't open.
☺ Corrective action:
1. Press the release button to disconnect the clip.
 2. Carefully re-engage the hook with the Applier loop and pull back slightly to ensure the Applier loop is engaged at the curved (“J”) end on the hook.
 3. Pull the trigger to connect the clip and verify that the clip is activated.
- ☹(3) Problem: While approaching the desired anchoring site on the internal operating cavity wall (or when removing the clip from the cavity wall) , the connecting wire gets tangled between the anchoring clip jaws.
☺ Corrective action: Open the jaws and maneuver the anchoring clip to correct the situation. Use the rotation knob if necessary.

STORAGE AND SHELF LIFE

The EndoLift is a sterile device and intended for single use only. The EndoLift shelf life is 24 months. The product should be stored in a clean and dry place.

Environmental storage and use conditions:

Temperature range:	10°C to 60°C
Relative humidity range:	10% to 40% RH
Atmospheric pressure:	500 to 1060 hPa

CUSTOMER SERVICE INFORMATION

For technical support and service contact Virtual Ports at:

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