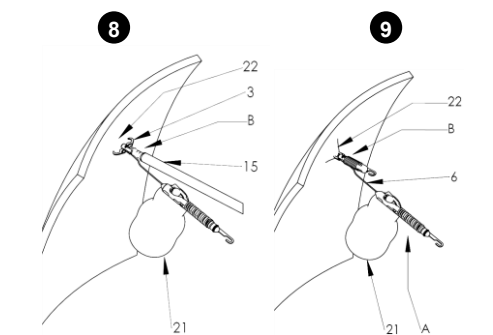
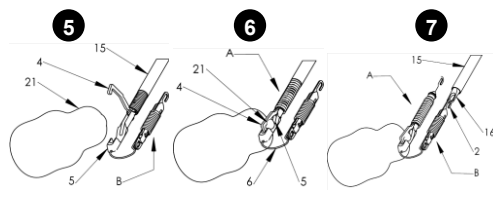
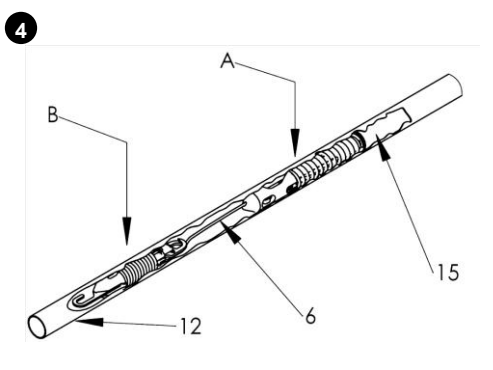
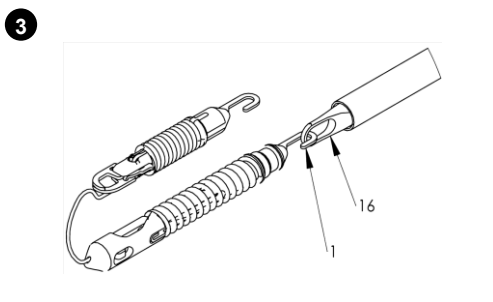
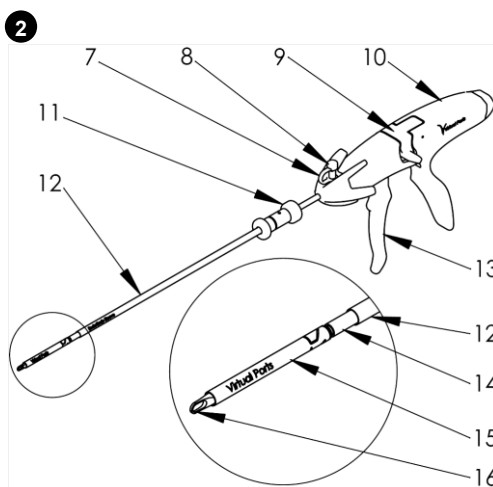
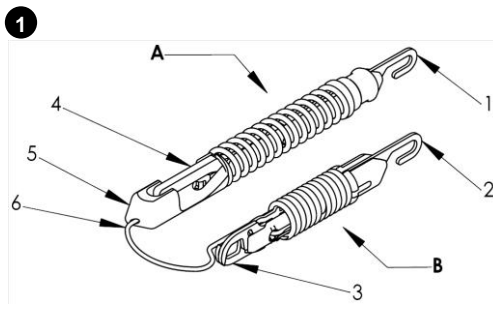


Laparoscopic Retractor



CONTACT

Israel Corporate Office
Virtual Ports, Ltd.
20 Alon HaTavor St.
Caesarea 38900, Israel
Phone: +972-4-6277506
Fax: +972-4-6275390
e-mail: info@virtual-ports.com

U.S.A. Corporate Office
Virtual Ports, Inc.
Virginia Biotechnology Research Park
800 East Leigh Street
Richmond, VA 23219
Phone: 1-877-226-9704

ENGLISH

INSTRUCTIONS FOR USE

NOTICE:
It is important that you read these instructions for use before you use the EndoGrab™ System. It is unsafe to use this device before you have read and are thoroughly familiar with this document.

SYMBOLS

Virtual Ports, Ltd.
20 Alon HaTavor St.
Caesarea 38900, Israel

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.
This device complies with applicable requirements of the Council Directive 93/42/EEC

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

Mr. Alfred Eckert
Zum Klosterbruehl 32,
D-66636 Tholey, Germany

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

AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY

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.

ILLUSTRATIONS

- Figure 1 – The EndoGrab Retractor consists of Organ Clip A and Anchoring Clip B
- Figure 2 – Engaging the organ clip hook 1 with the Applier loop 16
- Figure 3 – Encasing the Device (both clips A and B) within the EndoGrab Sleeve 12
- Figure 4 – Approaching an organ 21 with the organ clip body 5 and the flap 4 opened
- Figure 5 – Grabbing an organ 21 with the organ clip A
- Figure 6 – Switching to the anchoring clip B by engaging anchoring clip hook 2 with Applier loop 16
- Figure 7 – Approaching the anchoring site on the internal operating cavity wall 22 with the jaws 3 of the anchoring clip B opened to attach onto the anchoring site
- Figure 8 – Completed retraction: The organ clip A is holding the retracted organ 21 while the anchoring clip B is attached to the internal operating cavity wall 22
- Figure 9 – The Virtual Ports Applier

DEVICE DESCRIPTION

The Virtual Ports EndoGrab™ Laparoscopic System (the "System") is an internally anchored, hands-free organ retracting device for use in minimally invasive surgery. The System comprises the EndoGrab Retractor (the "Device") and the Virtual Ports Applier (the "Applier") as is described below.
The EndoGrab Retractor is introduced into the internal operating cavity via a standard cannula (diameter of 5 – 5.5 mm) by means of the Virtual Ports Applier. It is attached to the organ requiring retraction with the "organ clip" and then to the internal operating cavity wall with the "anchoring clip", thereby exposing the operative field. The Applier is then removed and the port is available for use by other instruments. When the Device is no longer required, it is removed from the internal operating cavity by means of the Applier.

INDICATIONS

The Virtual Ports EndoGrab System is indicated for internal organ retraction during minimally invasive surgery.

WARNINGS AND PRECAUTIONS

It is important for the EndoGrab System 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 EndoGrab Retractor is provided STERILE and is intended for SINGLE PATIENT USE ONLY. DO NOT RESTERILIZE. Re-use of the EndoGrab Retractor 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.
- Inspect the Applier after each cleaning and sterilization cycle to be sure it is clean, functioning properly, not damaged and does not have any loose, bent, broken, cracked, worn, or fractured components.
- The accompanying instructions only describe the proper use of the EndoGrab System and are not recommending any surgical procedure. The System should only be used by persons with adequate training and experience in minimally invasive and general surgery.
- Do not use the EndoGrab for the retraction of the liver.
- Do not attach the anchoring clip B to anchor the retraction to tissues other than the internal operating cavity wall (the peritoneum).
- Do not make contact between the Device and an electrosurgery electrode. Accidental application of electrosurgery on the Device could cause tissue damage and further complications.

Precautions

- Do not attempt to operate the EndoGrab Retractor with any instrument other than the Virtual Ports Applier. Doing so could damage the product and cause tissue injury.
- Do not attempt to use the Virtual Ports Applier to any means other than the instructed application of the EndoClear Lens Cleaner or other Virtual Ports devices.

STERILITY, CARE AND HANDLING

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

SAFE OPERATION

- Load the EndoGrab Retractor on the Virtual Ports Applier**
 1. The Applier loop 16 should be visible at the distal end. If it is not, release the trigger 13 and press the release button 9.
 2. Engage the hook 1 of the organ clip A with the Applier loop 16 (see Figure 2).
 3. Pull back gently on the Applier trigger 13 until the safety clicks into position.
 4. Push the EndoGrab sleeve 12 forward until both clips of the Device are encased within the sleeve (see Figure 3).

The EndoGrab Retractor is now loaded and ready to be used.
- Insert the EndoGrab into the internal operating cavity**
 5. Insert the loaded Applier into the internal operating cavity through a 5mm or larger cannula.
 6. Pull back on the EndoGrab sleeve 12 to expose the Device. Continue until both clips are fully exposed.
- Retract an organ with the EndoGrab**
 7. When the desired organ for retraction 21 is reached, pull the trigger 13 to open the flap 4 of the organ clip A (see Figure 4).
 8. Grab the desired organ 21 in between the organ clip's flap 4 and body 5 and release the trigger 13 to attach the clip to the organ (see Figure 5).
 9. Press the release button 9 in order to release the organ clip A from the Applier.
 10. Engage the hook of the anchoring clip 2 with the Applier loop 16 (see Figure 6).
 11. Pull back gently on the Applier trigger 13 until the safety clicks into position.
 12. When the desired anchoring site on the internal cavity wall 22 is reached, pull the trigger 13 to open the jaws 3 of the anchoring clip B (see Figure 7).
 13. Release the Applier trigger 13 and pull back slightly in order to close the jaws 3 of the anchoring clip B on the anchoring site 22. There is no need to apply excessive force onto the internal wall during the anchoring procedure.
 14. Press the release button 9 in order to release the anchoring clip B from the Applier (see Figure 8).
 15. Visually inspect the retraction before continuing with the surgical procedure. The connecting wire 6 may stretch and change shape during the retraction.
 16. If the retraction is satisfactory, remove the Applier from the internal operating cavity. If not, see step 21 below.
- Adjust the retraction or remove the EndoGrab**
 17. Insert the Applier through the cannula into the internal operating cavity.
 18. Engage the hook 2 of the anchoring clip B with the Applier loop 16.
 19. Pull the trigger 13 to open the jaws 3 of the anchoring clip B and move it away from the internal cavity wall.
 20. Release the trigger 13 to close the jaws 3.
 21. Proceed with one of the following options:
 - a. **Adjust retraction by repositioning the anchoring clip B on the internal cavity wall:**
 22. Follow steps 12 – 16.
 - b. **Adjust retraction by attaching the organ clip A at a different position on the same organ OR perform retraction of a different organ:**
 23. Press the release button 9 in order to release the anchoring clip B from the Applier.
 24. Engage the hook 1 of the organ clip A with the Applier loop 16.
 25. Pull the trigger 13 all the way in order to open the flap 4 of the organ clip A and move it away from the organ.
 26. Follow steps 7 – 16.
 22. **Remove the EndoGrab Retractor from the internal operating cavity:**
 27. Follow steps 23 – 25.
 28. Release the trigger 13 to close the flap 4.
 29. Push the sleeve 12 forward until both clips are completely covered.
 30. Remove the Applier with the Device from the internal operating cavity.
 31. Pull back on the Applier sleeve 12 to expose the Device.
 32. Press the release button 9 in order to release the Device from the Applier.

TROUBLESHOOTING

- Problem:** When engaging either one of the Device clips and attempting to activate it, it does not fit into the Applier detachable tube and gets stuck on the end of the tube detachable.
 - Corrective action:** The Device clip might not be aligned correctly.
 1. Press the release button 9 to release the Device.
 2. Carefully re-engage the hook 1 or 2 of the Device and pull back slightly to align the Device with the Applier detachable tube 15 (without pulling the trigger 13).
 3. Pull the trigger 13 until the safety clicks into position and the Device fits into the detachable tube 15.
- Problem:** When pulling the trigger 13 to activate either one of the Device clips, nothing happens, i.e. the flap 4 or jaws 3 do not open.
 - Corrective action:** The Applier loop 16 might not be engaged correctly with the clip hook 1 or 2.
 1. Press the release button 9 to release the Device.
 2. Carefully re-engage the hook 1 or 2 of the Device with the Applier loop 16 and pull back slightly to ensure the Applier loop 16 is engaged at the curved end on the hook 23.
 3. Pull the trigger 13 to verify the Device clip is activated.
- Problem:** While approaching the desired anchoring site on the internal operating cavity wall, the connecting wire 6 gets tangled between the anchoring clip jaws 3.
 - Corrective action:** The open the jaws 3 and maneuver the anchoring clip to correct the situation.
- Problem:** When removing the Device from the internal operating cavity, the anchoring clip B does not fit into the EndoGrab sleeve 12 after the organ clip A.
 - Corrective action:** Release the organ clip A and engage the anchoring clip B, and proceed to encase the anchoring clip first and then the organ clip.
- Problem:** The Device is accidentally released and dropped within the internal operating cavity.
 - Corrective action:** Take action as soon as possible.
 1. Find and engage the hook of either one of the Device's clips (1 or 2) with the Applier loop 16.
 2. Pull the trigger 13 until the safety clicks into position.
 3. Carefully move the Device away from the tissue where it lay to avoid accidental injury.
 4. If the organ clip A is now fixed on the Applier, proceed from step 7 (retraction) or 29 (removal).
 5. If the anchoring clip B is now fixed on the Applier, proceed from step 29 (removal) and then start over from step 1 if needed.

STORAGE AND SHELF LIFE

The EndoGrab Retractor is a sterile device and intended for single use only. The EndoGrab Retractor's 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