



Virtual Ports Applier

Instructions for Use

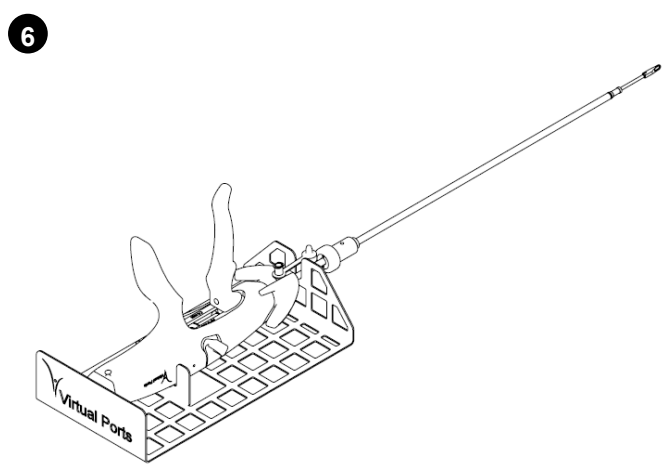
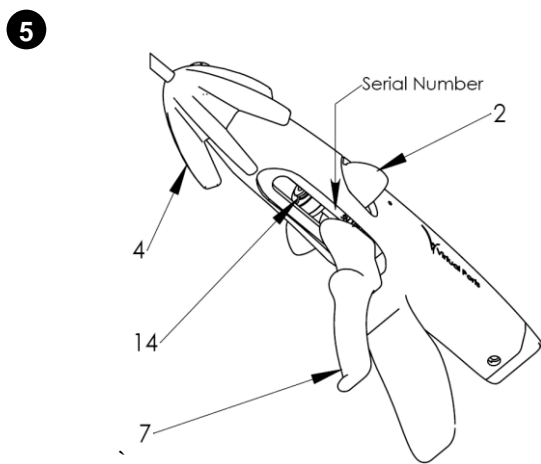
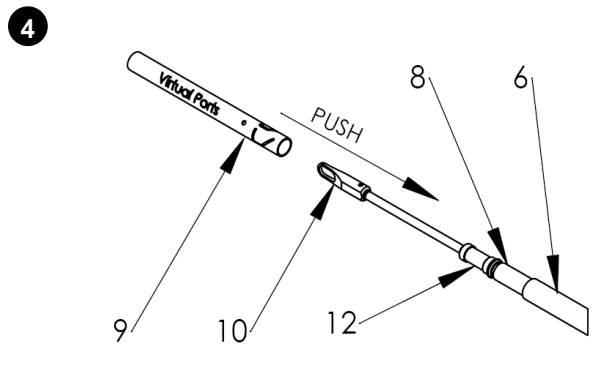
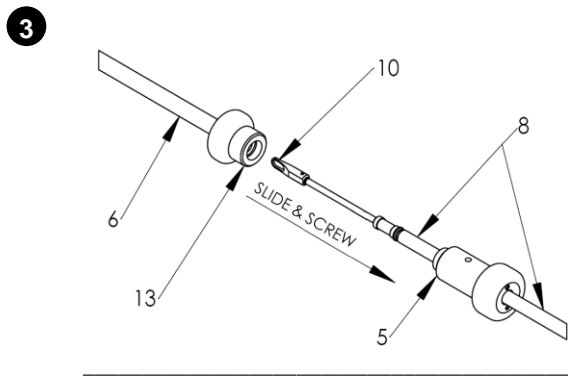
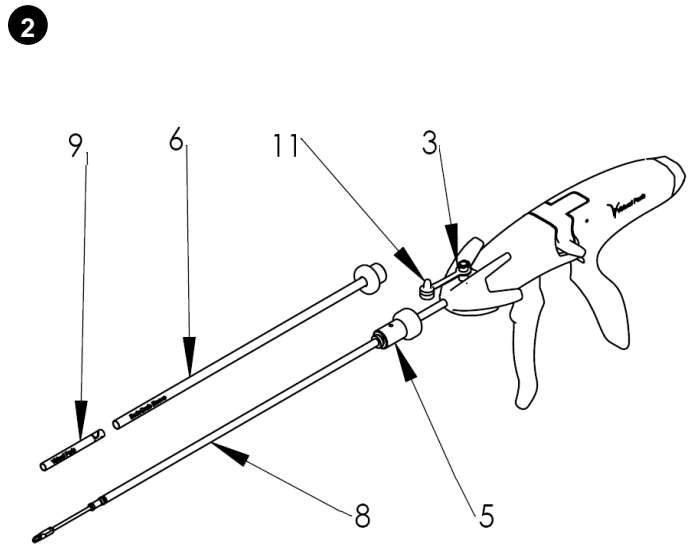
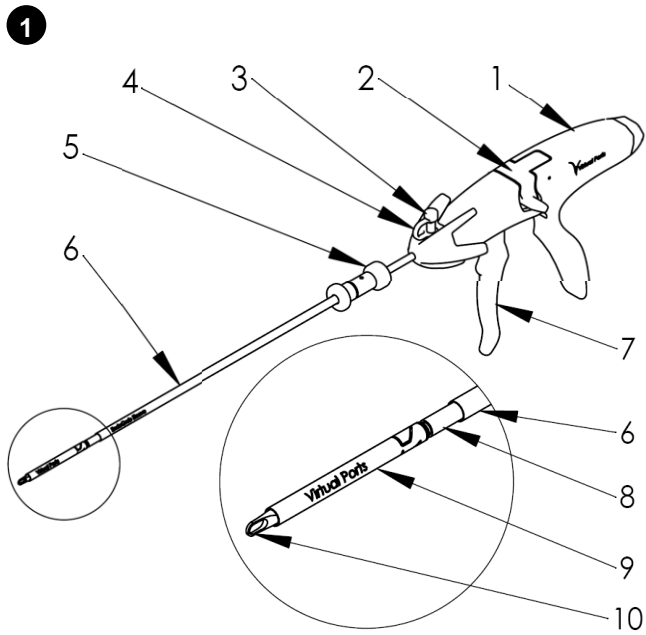


Table of Contents

SYMBOLS	4
WHEN THE SYSTEM ARRIVES	4
ILLUSTRATIONS	4
DEVICE DESCRIPTION	4
INDICATIONS	5
WARNINGS AND PRECAUTIONS	5
STERILITY, CARE AND HANDLING	5
Handling	5
<i>Disassembly</i>	5
<i>Assembly</i>	5
Processing	6
<i>After each use</i>	6
<i>Manual cleaning</i>	6
<i>Automatic cleaning</i>	6
<i>Control and treatment</i>	7
Packaging	7
<i>Sterilization method and parameters</i>	7
<i>Storage</i>	7
SAFE OPERATION	7
<i>General use</i>	7
TROUBLESHOOTING	7
STORAGE AND SHELF LIFE	8
CUSTOMER SERVICE INFORMATION	8

NOTICE:

It is important that you read the entire manual before you use the Virtual Ports Applier. It is unsafe to use this device before you have read and are thoroughly familiar with this document.

SYMBOLS

Virtual Ports, Ltd.

MANUFACTURER NAME

20 Alon HaTavor St.
Caesarea 38900, Israel

MANUFACTURER ADDRESS



MANUFACTURER LOGO



ATTENTION, SEE INSTRUCTIONS FOR USE



REFERENCE NUMBER



SERIAL NUMBER



DATE OF MANUFACTURE



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

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

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

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

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 Virtual Ports Applier

Figure 2 – The Applier disassembled

Figure 3 – Applier assembly (I): Inserting the Applier loop **10** into the sleeve handle attachment **13** to be screwed onto the sleeve handle **5**

Figure 4 – Applier assembly (II): Inserting the Applier loop **10** into detachable tube **9**; the detachable tube's clips will be fastened onto the groove **12**

Figure 5 – The Applier trigger **7** is pulled back to show the internal mechanism **14**; the engraved Serial Number is visible under the trigger

Figure 6 – The Applier placed on the Applier Washing Stand

DEVICE DESCRIPTION

The Virtual Ports System (the "System") is an internally anchored, hands-free device for use in minimally invasive surgery. The System comprises the Device tip (the "Device" which can be either the EndoGrab Retractor or the EndoClear Lens Cleaner) and the Virtual Ports Applier (the "Applier") as is described below.

The Device is introduced into the internal operating cavity via a standard cannula by means of the Virtual Ports Applier. It is applied and attached to the internal operating cavity wall. 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 Applier is indicated for minimally invasive surgery for use solely with Virtual Ports Devices EndoGrab and EndoClear.

WARNINGS AND PRECAUTIONS

It is important for the Virtual Ports Applier 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 Virtual Ports Applier is a reusable instrument. It **MUST** be processed according to this document before each use.
- 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 Virtual Ports Applier and are not recommending any surgical procedure. The Applier should only be used by persons with adequate training and experience in minimally invasive and general surgery.
- 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 use the Virtual Ports Applier to any means other than the instructed application of the Virtual Ports Devices.

STERILITY, CARE AND HANDLING

Handling

The Virtual Ports Applier is a reusable instrument.
It **MUST** be processed according to this document before each use.

- **Disassembly**
 1. Press the release button **2** to expose the Applier loop **10**.
 2. Pull and remove the detachable tube **9** while holding the shaft **8**.
 3. Unscrew the sleeve **6** from the sleeve handle **5**.
 4. Remove the sleeve **6**.
 5. Remove the sealing cap **3** from the Luer-Lock connector **11**.

(See Figure 2)

NOTE – “Sleeve” can be either the EndoGrab Sleeve or the EndoClear Sleeve.

- **Assembly**
 1. Press the release button **2** to release the trigger **7**.
 2. Carefully insert the Applier loop **10** into the sleeve at the handle attachment **13** and screw onto the sleeve handle **5** (see Figure 3).
 3. Carefully insert the Applier loop **10** into the detachable tube **9** (from the end with the clips) and push it onto the groove **12** at the end of the shaft **8** (see Figure 4).

4. Screw the sealing cap **3** onto the Luer-Lock connector **11**.

Processing

- **After each use**

1. Reprocess the contaminated Applier as soon as possible, no later than 4 hours after use.
2. Carry out non-fixating/NaCl-free pre-cleaning immediately after use with a pre-cleaner compatible with endoscopic or surgical instruments (such as EmPower® Foam by Metrex)
 - soak the Applier with the pre-cleaner agent
 - follow pre-cleaner manufacturer's instructions
3. Avoid fixating pre-cleaning temperatures of more than 45 °C and fixating disinfecting agents (active ingredient: aldehyde, alcohol).

Proceed to Manual OR Mechanical Cleaning as described below:

- **Manual cleaning**

1. Disassemble the Applier (see Disassembly section above).
2. Place the Applier and the disassembled parts in a suitable enzymatic detergent solution in such a way that all outer surfaces, interior surfaces, lumen, and openings are covered. Activate Applier (trigger **7**, release button **2** and rotation knob **4** and move the sleeve handle **5** along the shaft **8** to ensure cleaning of all moving parts, internal mechanism **14** and lumen. To avoid damaging the device, make sure to always
 - use only an enzymatic detergent compatible with endoscopic or surgical instruments (such as ENZOL® by J&J);
 - follow the detergent manufacturer's instructions regarding concentration, temperature and exposure time.
3. Remove encrusted materials with a soft nylon brush. Clean lumen and channels with a soft round nylon brush of the appropriate diameter where possible (i.e. detachable tube **9**, sleeve **6** and internal mechanism **14**). To avoid the risk of corrosion, DO NOT use a metal brush or other abrasives, which would damage the surfaces.
4. Rinse the Applier thoroughly in plenty of clear running water ensuring that water flows through every lumen and channel and all blind holes are repeatedly filled and drained. Activate Applier to ensure rinsing of all moving parts. Rinse for at least 30 seconds.
5. Flush the lumen and internal channels with a water filled syringe and by connecting a water supply to the Luer-Lock connector **11**. Flush for at least 20 seconds. Repeat as needed until the water comes out clean.
6. If ultrasound is needed as a mechanical supplement to manual cleaning, carry out according to the instructions provided by the manufacturer of the apparatus, running for 15 minutes with a suitable enzymatic detergent.
7. Visually inspect the Applier and its parts to verify successful cleaning. If not clean, repeat steps 2 – 6 as needed.
8. Carry out the final rinse in distilled or fully demineralized water. Rinse also via the Luer-Lock connector **11** to flush lumen and channels. Activate Applier to ensure rinsing of all moving parts. Rinse for at least 30 seconds.
9. Dry the Applier with an absorbent and lint-free cloth.
10. Dry lumen, blind holes and channels with a compressed-air gun and by attaching to the Luer-Lock connector **11**. Activate Applier to ensure drying of all moving parts. Apply compressed air for at least 30 seconds.
11. Assemble the Applier (see Assembly section above).

- **Mechanical cleaning**

1. Disassemble the Applier (see Disassembly section above).
2. Flush the lumen and internal channels with a water-pressure-gun or syringe by connecting it to the Luer-Lock connector **11**. Flush for at least 20 seconds. Repeat as needed until the water comes out clean.
3. Place the Applier in a washer in the Applier Washing Stand (see figure 6). Place Detachable Tube and Sleeve in appropriate trays/racks/baskets. If the washing machine has a special lumen cleaning rack or tray, attach the appropriate size port to the Applier Luer-Lock connector and place the Detachable Tube and Sleeve in appropriate adaptors.
4. Apply a washing cycle with the following parameters:
 - (1) **Rinse** with cold tap water (<16°C) for at least 2 minutes.
 - (2) **Enzyme Wash** with hot tap water (>43°C) for at least 1 minute.
Use an enzymatic detergent compatible with endoscopic or surgical instruments (such as Enzol® by J&J)
 - (3) **Rinse** with hot tap water (>43°C) for at least 15 seconds.
 - (4) **Pure Water Rinse** (66-82°C) for at least 10 seconds.
 - (5) **Dry** with heated air (115-120°C) for at least 7 minutes.

5. If the washer enables a lubricant (“instrument oil”) cycle it is highly recommended to apply it. In this case, step 2 below may be skipped.

- **Control and treatment**

1. Allow the Applier to cool down to room temperature.
2. Lightly lubricate moving parts with sterilizable, moisture-permeable and tissue-compatible maintenance oil. In particular lubricate the Applier loop **10**, the detachable tube **9**, the interior of the sleeve **6** and the internal mechanism **14**. Activate Applier to ensure adequate lubrication of all moving parts.
3. Inspect the Applier after each cleaning and disinfecting cycle to be sure it is clean, functioning properly, not damaged and does not have any loose, bent, broken, cracked, worn, or fractured components. Set aside the Applier if it is damaged.

Packaging

1. Press the release button **2** to make sure the Applier loop **10** is exposed before storing the device.
2. Pack the Applier in such a way that the packaging will prevent recontamination of the Applier in the period between reprocessing and reuse (i.e. sterile container, trays or sealed pack compatible with steam sterilization).

- **Sterilization method and parameters**

Sterilize with steam, taking note of the following:

The sterilization has to be done according to a validated steam sterilization procedure (e.g. in a sterilizer according to EN 285/ANSI/AAMI/ISO 11134-1993, ANSI/AAMI ST46-1993 and validated according to EN 554/ISO 13683). In the fractionated (pre)vacuum process, the sterilization using the 134 °C/2 bar program must be carried out with a minimum holding time of 5 minutes.

- **Storage**

Store reprocessed Applier under conditions as germ-free as possible, in a dry, dark, cool and dust-protected room.

SAFE OPERATION

- **General use**

1. The Applier can be held with either hand, placing the Applier handle **1** in the palm of the hand and four fingers on the trigger **7**.
2. Pulling the trigger **7** retracts the Applier loop **10**. This maneuver activates the Virtual Ports Devices.
3. Once the trigger **7** is pulled back fully and released, it will be stopped by the safety. In this position the Device (when engaged) is fixed at the distal end of the Applier and ready for use.
4. Pressing the release button **2**, with either the thumb or the index finger, releases the mechanism and the Applier loop **10** becomes visible again (thus releasing an engaged Device). The trigger **7** must be released in this step.
5. By means of the rotation knob **4** one can rotate the Applier loop **10**. The knob can be controlled with the index finger.
6. The sleeve **6** is used for enabling the passing of the Device through a cannula. Holding the sleeve handle **5**, one can easily slide it along the Applier tube **8**.

TROUBLESHOOTING

- ⊗ Problem: When engaging a Device and attempting to activate it, it does not fit into the Applier tube and gets stuck on the end of the shaft.
- ☺ Corrective action: The Device might not be aligned correctly.
 1. Press the release button **2** to release the Device.
 2. Carefully re-engage the hook of the Device and pull back slightly to align the Device with the Applier detachable tube **9** (without pulling the trigger **7** at this stage).
 3. Pull the trigger **7** until the safety clicks into position and the Device fits into the detachable tube **9**.
- ⊗ Problem: When pulling the trigger **7** to activate the Device clips, nothing happens – the Device does not respond.
- ☺ Corrective action: The Applier loop **10** might not be engaged correctly with the Device hook.
 1. Press the release button **2** to release the Device.
 2. Carefully re-engage the hook of the Device with the Applier loop **10** and pull back slightly to ensure the Applier loop **10** is engaged at the curved end on the hook.
 3. Pull the trigger **7** to verify the Device clip is activated.

- ⊗ 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 Device hook with the Applier loop **10**.
 2. Pull the trigger **7** until the safety clicks into position.
 3. Carefully move the Device away from the tissue where it lay to avoid accidental injury and proceed to remove the Device or re-apply.

STORAGE AND SHELF LIFE

The Virtual Ports Applier is a reusable device with a limited life span of 2 years or 2000 procedures. Shelf life of the Applier is 2 years from manufacture date. The product should be stored in 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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