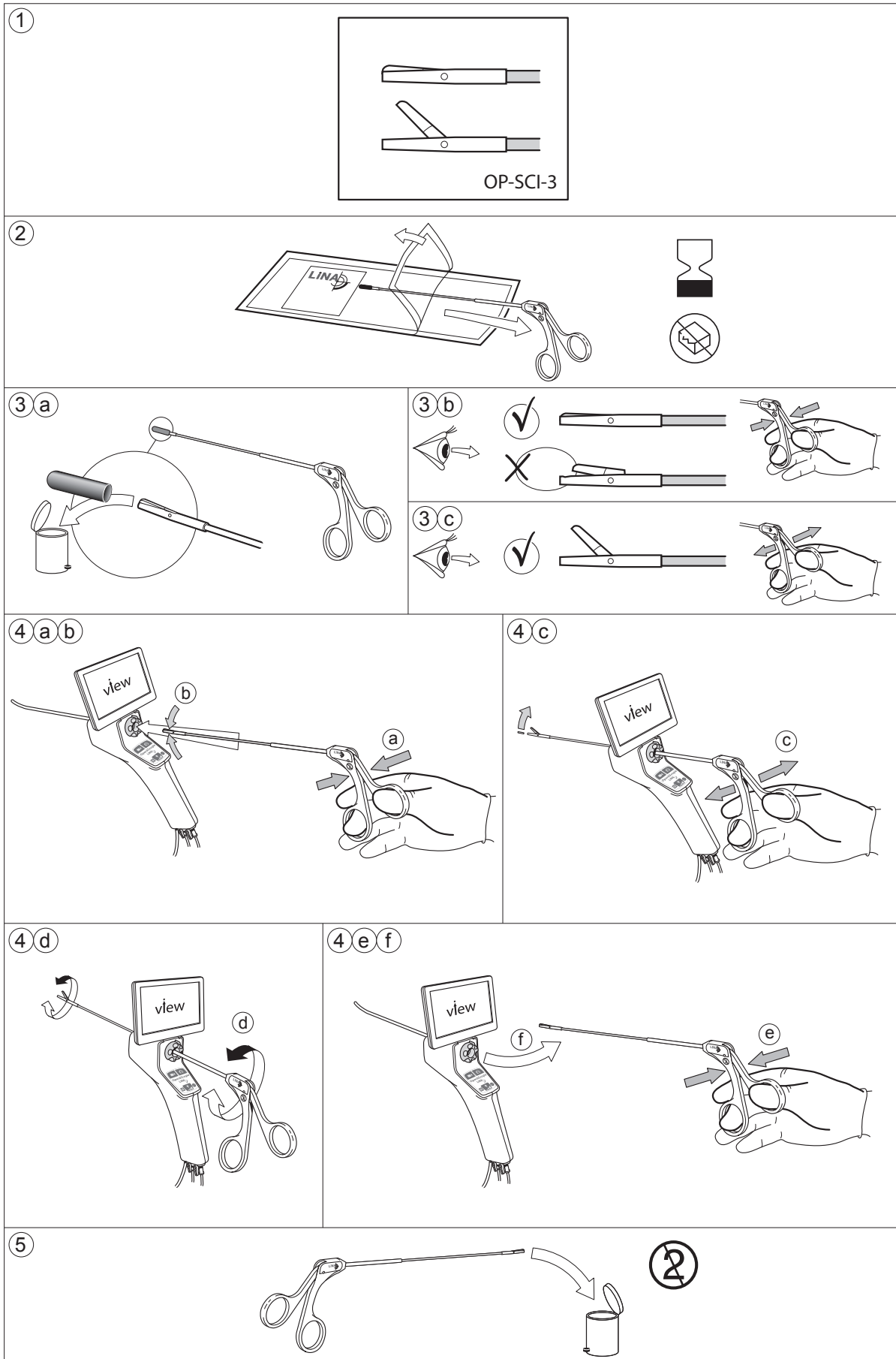


# LiNA OperàScope™ Scissors

REF: OP-SCI-3





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## **INTENDED USE**

The LiNA OperåScope™ Scissors (Scissors) are intended for use in hysteroscopy procedures for cutting of soft tissue such as polyps from the uterine cavity.

## **PATIENT POPULATION**

Adolescents or older female patients.

## **PRODUCT DESCRIPTION**

The Scissors are delivered as a sterile, single-use device. The Scissors are designed to be used with the LiNA OperåScope™ hysteroscope to cut soft tissue such as polyps. The Scissors are compatible with hysteroscopes with a straight working channel of min Ø1.87mm (5.6Fr) diameter and a max length of 310mm. The device should not be used for any other purpose than the intended function.

## **CONTRAINDICATIONS**

The device is contraindicated for use with the following conditions:

- Inability to distend the uterus
- Cervical Stenosis
- Cervical/Vaginal infection
- Uterine bleeding or menses
- Known Pregnancy
- Invasive carcinoma of the cervix
- Recent uterine perforation
- Known Pelvic Inflammatory Disease (PID)
- Medical contraindication or intolerance to anesthesia

## **WARNINGS**

Failure to follow all instructions or any warnings or precautions could result in serious patient injury.

- The Scissors are provided STERILE via ethylene oxide sterilization. Carefully inspect the packaging for any damage prior to use. Do NOT use the device if the sterile barrier is damaged.
- Do NOT use the device if exposed to non-sterile surfaces before procedure.
- Do NOT use if past expiration date or if missing expiry date.
- To mitigate the risk of perforation, only advance or manipulate the Scissors while viewing a LiNA OperåScope™ live camera image, allowing observation of the uterine cavity.
- Do not advance the device should resistance be experienced while in the patient.
- For single use only. Do NOT reuse, reprocess or re-sterilize the device. Any reprocessing may impede the functions of this device. Reusing single use devices may also increase the risk of cross contamination. Attempts to clean the device results in risk of device malfunction and/or erroneous pathology specimen collection due to residuals in the Scissors.
- Endoscopic soft tissue cutting using the Scissors should ONLY be performed by medical professionals who have adequate training in hysteroscopy.
- The Scissors are intended only as an adjunct in assessing patient condition. It must be used in conjunction with clinical signs and symptoms.

## **POTENTIAL COMPLICATIONS**

Hysteroscopic procedures contain risks related to perforation/false passage, cervical laceration, hemorrhage, vasovagal episodes, pain and fluid related complications.

## **PRECAUTIONS**

Always have a backup device readily available for immediate use. If any malfunction should occur during use, stop the procedure immediately, and slowly withdraw the Scissors and replace with a new device.

## **INSTRUCTIONS FOR USE**

The device consists of handles, a shaft, and the blade system (scissors) at the distal end.

Opening and closing the device is done by pushing or pulling the Handles away from/towards each other, see figure 3b and 3c.

### **Read the instructions for use prior to using this device!**

1. Carefully inspect the packaging for any damages prior to use. Do NOT attempt to use the device if the sterile barrier is damaged. Do NOT use if past expiration date.
2. Inspect the label to ensure that the correct device is chosen (Figure 2).
3. Using sterile technique, remove the device from the sterilized blister (Figure 2).
4. Remove the protection cap (Figure 3a).
5. Inspect the Scissor blades for any obvious damage.
6. Check the open/close function of the Scissors by actuating the handle (Figure 3b & 3c).
7. Close the Scissors (Figure 4a) before inserting the device into the LiNA OperåScope™ working channel (Figure 4b).
8. Slowly insert the Scissors into the LiNA OperåScope™ working channel until the blades are visualized on the LiNA OperåScope™ live camera image. Some resistance will be felt when blades system passes through LiNA OperåScope™s pre-curved tip. Take care not to bend the Scissors shaft.
9. Maneuver the Scissors towards the targeted site. Open the Scissors by activating the handles (Figure 4c). Advance the opened Scissors over to the targeted site, rotate the Scissors, if needed, (Figure 4d) and close the Scissors. Use only enough force to cut the tissue. Over-exertion could cause the Scissors to fail.
10. Continue to apply gentle force on the handles (Figure 4e) as the Scissors are extracted from the working channel (Figure 4f).
11. Steps 5 – 10 may be repeated if multiple cuts are needed within a single procedure.

## **DISPOSAL**

After use, the product may be a potential biohazard. Handle and dispose the device in accordance with local, state and federal laws and regulations (Figure 5).

Country of origin: Poland