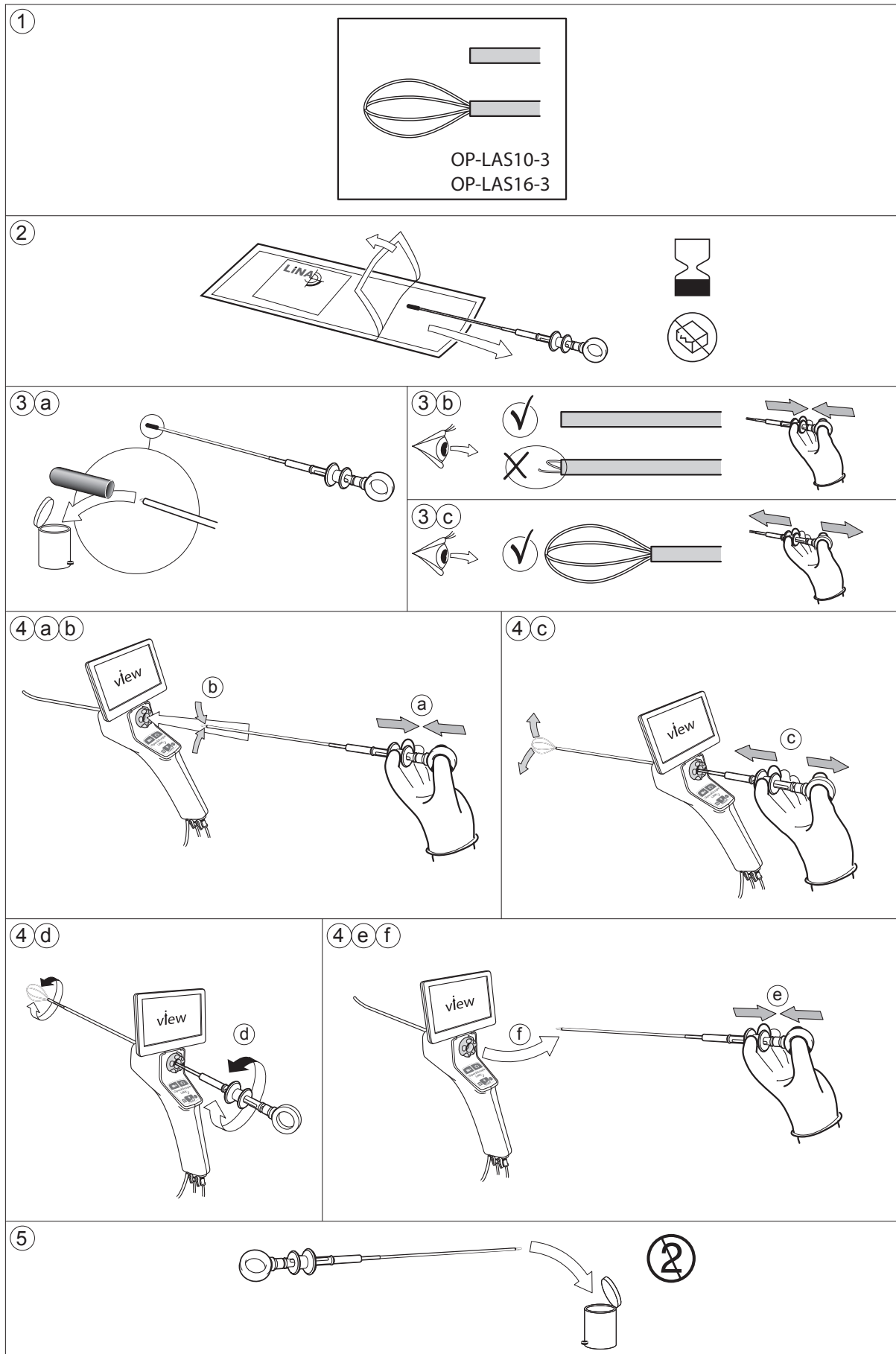


LiNA OperåScope™ Lasso

REF: OP-LAS10-3, OP-LAS16-3





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INTENDED USE

The LiNA OperåScope™ Lasso (Lasso) is intended for use in hysteroscopy procedures for retrieval of soft tissue such as polyps from the uterine cavity.

PATIENT POPULATION

Adolescents or older female patients.

PRODUCT DESCRIPTION

The Lasso is delivered as a sterile, single-use device. The Lasso is designed to be used specifically with the LiNA OperåScope™ hysteroscope to retrieve soft tissue endoscopically. 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 LiNA OperåScope™ Lasso is 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 Lasso 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 Lasso.
- Endoscopic polyp and soft tissue retrieval using the Lasso should ONLY be performed by medical professionals who have adequate training in hysteroscopy.
- The Lasso is 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 Lasso and replace with a new device.

INSTRUCTIONS FOR USE

The device consists of a handle, a shaft, and the basket (lasso) at the distal end.

Opening and closing the device is done by pushing or pulling the Handle Knob away from/towards the Finger Eyelet, 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 1b).
3. Using sterile technique, remove the device from the sterilized blister (Figure 2).
4. Remove the protection cap (Figure 3a).
5. Inspect the basket shaft and basket for any obvious damage.
6. Check the open/close function of the basket by actuating the handle (Figure 3b & 3c).
7. Close the basket (Figure 4a) before inserting the device into the LiNA OperåScope™ working channel (Figure 4b).
8. Slowly insert the basket into the LiNA OperåScope™ working channel until the basket is visualized on the LiNA OperåScope™ live camera image. Some resistance will be felt when the tip of the shaft passes through LiNA OperåScope's pre-curved tip. Take care not to bend the basket shaft.
9. Maneuver the basket towards the targeted site. Open the basket by activating the handle (Figure 4c). Advance the opened basket over to the targeted tissue, rotate the basket, if needed, (Figure 4d) and close the basket. Use only enough force to grasp the object. Over-exertion could cause the basket to fail.
10. Continue to apply gentle force on the handle (Figure 4e) as the basket is extracted from the working channel (Figure 4f). If the tissue is too large to be extracted through the operative channel, remove the Lasso and the LiNA OperåScope™ together.
11. Remove and prepare the tissue according to standard technique for histologic evaluation.
12. Steps 5 – 11 may be repeated if multiple retrievals 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