





# LiNA OperåScope™ Biopsy Forceps

REF: OP-FCP-6

## INTENDED USE

LiNA OperåScope™ Biopsy Forceps are intended for use in hysteroscopic and female cystoscopy procedures to obtain tissue samples for examination of tissue from the uterine cavity or urinary bladder.

## PATIENT POPULATION

Adolescent and adult females suited for hysteroscopy and cystoscopy.

## PRODUCT DESCRIPTION

The LiNA OperåScope™ Biopsy Forceps (Forceps) are delivered as a sterile, single-use device designed to be used specifically with the LiNA OperåScope™ endoscope to collect tissue endoscopically for histologic examinations. The device consists of a handle, a shaft, and a jaw system (forceps) at the distal end.

Failure to follow all instructions or any warnings or precautions could result in serious patient injury. LiNA OperåScope™ Biopsy Forceps should not be used for any other purpose than their intended function.

## CONTRAINDICATIONS

The device is contraindicated for use with the following conditions:

Hysteroscopy:

- Inability to distend the uterus,
- Cervical Stenosis,
- Cervical/Vaginal infection,
- Uterine bleeding or menses,
- Known Pregnancy,
- Invasive carcinoma of the cervix,
- Recent uterine perforation.

Cystoscopy:

- Acute/known Urinary Tract Infections,
- Severe Coagulopathy.

Hysteroscopy and Cystoscopy:

- Known Pelvic Inflammatory Disease (PID),
- Medical contraindication or intolerance to anesthesia.

## WARNINGS

- The Forceps 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 Forceps while viewing a LiNA OperåScope™ live camera image, allowing observation of the uterine cavity or urinary bladder.
- Do not advance the Forceps should resistance be experienced while in the patient.
- **For single use only.** Do NOT reuse, reprocess or re-sterilize the Forceps. 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 residual tissue in the Forceps.
- Endoscopic biopsy retrieval using the Forceps should ONLY be performed by medical professionals who have adequate training in hysteroscopy or cystoscopy.
- The Forceps are intended only as an adjunct in assessing patient condition. It must be used in conjunction with clinical signs and symptoms.

## POTENTIAL COMPLICATIONS

Continuous Flow hysteroscopic and cystoscopy procedures contain risks related to:

- Hyponatremia,
- Hypothermia,

- Uterine perforation/false passage resulting in possible injury to bowel, bladder, major blood vessels and ureter,
- Bladder perforation/false passage resulting in possible injury to bowel, uterus, major blood vessels and ureter,
- Pulmonary edema,
- Cerebral edema,
- Infection,
- Bleeding/hematuria,
- Peri- and post-procedural pain,
- Vasovagal episodes,
- Urethral trauma,
- Irritable bladder syndrome.

## 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 Forceps and replace with a new device.

## INSTRUCTIONS FOR USE

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

## REPORTING

Any serious incident that has occurred in relation to the device should be reported to the LiNA Medical ApS and the competent regulatory authority of the country in which the user and/or patient is established.

Country of origin: Poland.