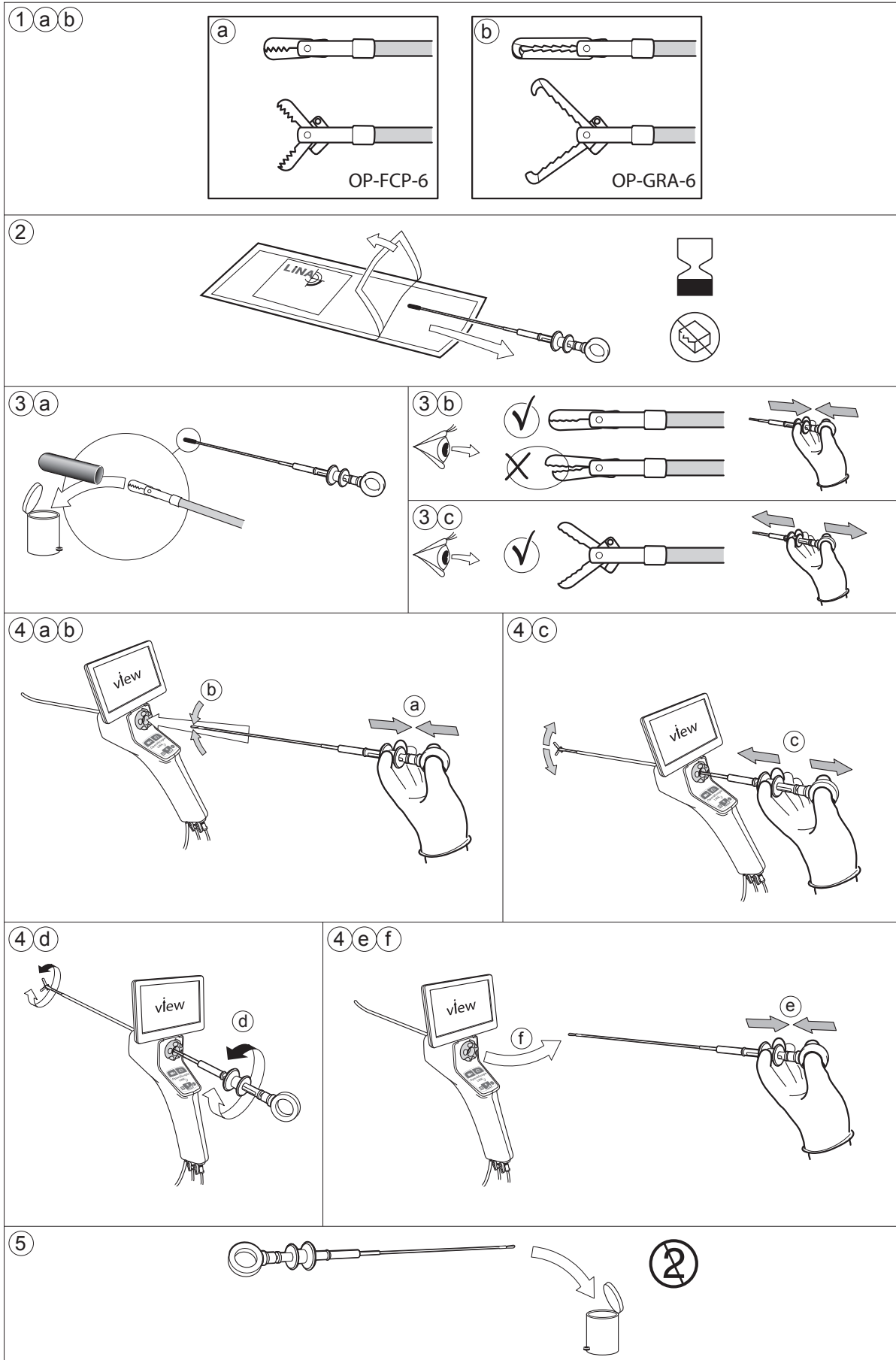




# LiNA OperåScope™ Rat Tooth Alligator Grasper

REF: OP-GRA-6





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## **INTENDED USE**

The LiNA OperåScope™ Rat Tooth Alligator Grasper (Grasper) is intended for use in hysteroscopy procedures for polyp and foreign body retrieval from the uterine cavity.

## **PATIENT POPULATION**

Adolescents or older female patients.

## **PRODUCT DESCRIPTION**

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

## **INSTRUCTIONS FOR USE**

The device consists of a handle, a shaft, and the jaw system (grasper) 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 Grasper shaft and jaws for any obvious damage.
6. Check the open/close function of the Grasper by actuating the handle (Figure 3b & 3c).
7. Close the Grasper (Figure 4a) before inserting the device into the LiNA OperåScope™ working channel (Figure 4b).
8. Slowly insert the Grasper 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 LiNA OperåScope's pre-curved tip. Take care not to bend the Grasper shaft.
9. Maneuver the Grasper towards the targeted site. Open the Grasper by activating the handle (Figure 4c). Advance the opened Grasper over to the targeted site, rotate the Grasper, if needed, (Figure 4d) and close the Grasper. Use only enough force to grasp the polyp or object. Over-exertion could cause the Grasper to fail.
10. Continue to apply gentle force on the handle (Figure 4e) as the Grasper is extracted from the working channel (Figure 4f).
11. Remove and prepare the object according to standard technique for histologic evaluation and/or foreign body retrieval.
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