℞Only STERILE EO

LiNA OperåScope™ Rat Tooth Alligator Grasper

REF: OP-GRA-6

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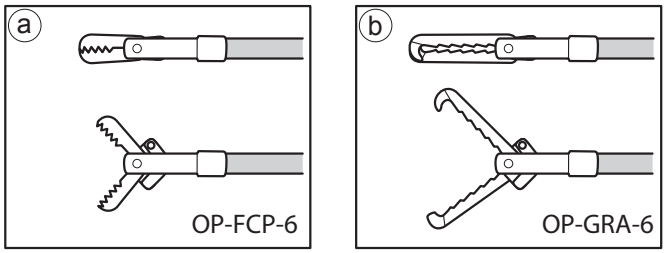

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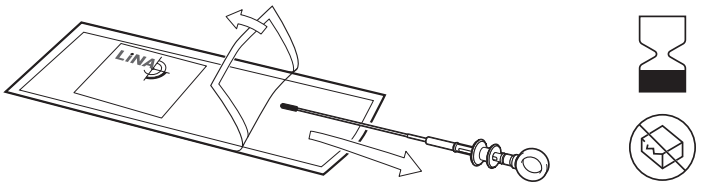

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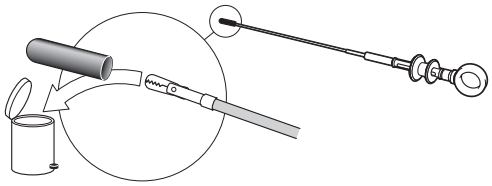

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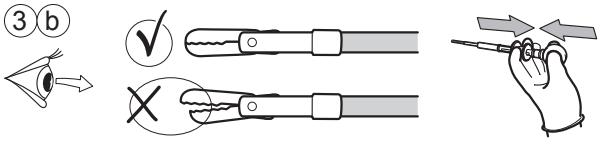

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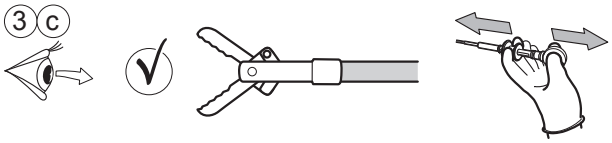

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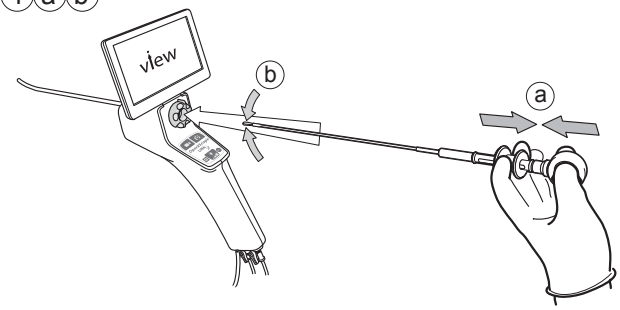

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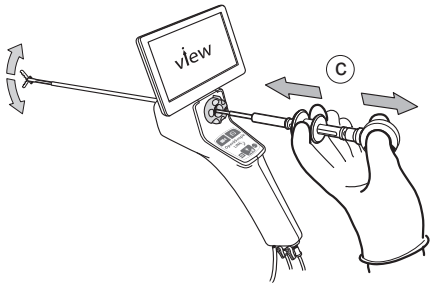

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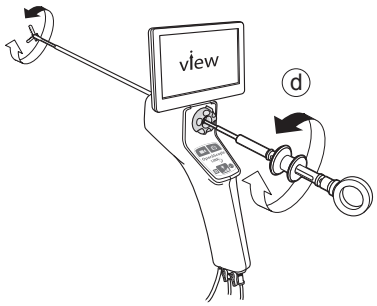

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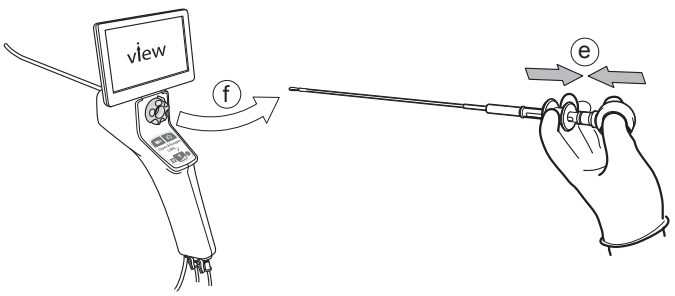

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LiNA OperåScope™ Rat Tooth Alligator Grasper

REF: OP-GRA-6

INTENDED USE

The LiNA OperåScope™ Rat Tooth Alligator Grasper is intended to be used in hysteroscopy procedures for retrieval of foreign bodies and polyps from the uterine cavity and in female cystoscopy procedures for retrieval of foreign bodies and bladder stones from the urinary bladder.

PATIENT POPULATION

Adolescent and adult females suited for hysteroscopy and cystoscopy.

PRODUCT DESCRIPTION

The LiNA OperåScope™ Rat Tooth Alligator Grasper (Grasper) is delivered as a sterile, single-use device designed to be used specifically with the LiNA OperåScope™ endoscope to retrieve foreign bodies and polyps from the uterine cavity and foreign bodies and bladder stones from the urinary bladder. The device consists of a handle, a shaft, and a jaw system (rat tooth alligator grasper) at the distal end.

Failure to follow all instructions or any warnings or precautions could result in serious patient injury. LiNA OperåScope™ Rat Tooth Alligator Grasper should not be used for any other purpose than the 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 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 or urinary bladder.
- 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 Grasper. 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 or cystoscopy.
- 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

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,
- Pain,
- Vasovagal episodes,
- Urethral trauma (Cystoscopy specific),
- 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 Grasper and replace with a new device.

INSTRUCTIONS FOR USE

Opening and closing the Grasper 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 1b**).
3. Using sterile technique, remove the device from the sterilized blister (**Figure 2**).
4. Remove the protection cap (**Figure 3a**).
5. nspect 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 the LiNA OperåScope™ 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**). If the object is too large to be extracted through the operative channel, remove the Grasper and the LiNA OperåScope™ simultaneously.
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**).

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.