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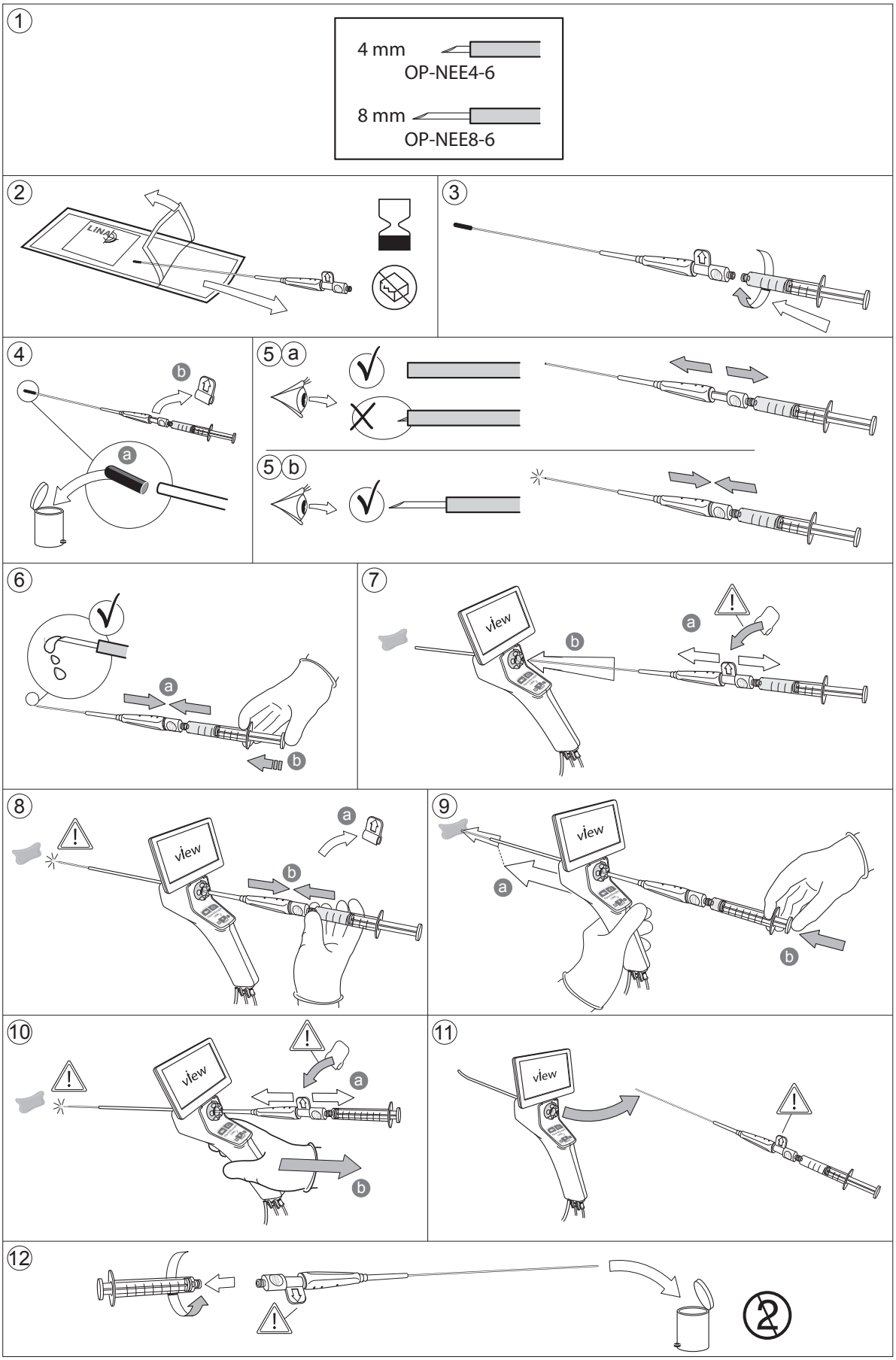
LiNA OperåScope™ Needle

REF: OP-NEE4-6, OP-NEE8-6

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO BE SALE BY OR ON THE ORDER OF A PHYSICIAN.



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INDICATIONS FOR USE

The LiNA OperåScope™ Needle is intended for hysteroscopic injection into the uterine wall as well as for cystoscopic injection in the urinary bladder wall.

PATIENT POPULATION

Females suited for hysteroscopy and cystoscopy.

PRODUCT DESCRIPTION

The LiNA OperåScope™ Needle (Needle) is delivered as a sterile, single-use device designed to be used specifically with the LiNA OperåScope™ for hysteroscopic and cystoscopic injections. The device consists of a handle, a shaft, and an injection needle tip, which is pointed at the distal end and has a luer-lock connection at the proximal end.

Failure to follow all instructions or any warnings or precautions could result in serious patient injury. The LiNA OperåScope™ Needle 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,
- Any contraindication related to hysteroscopy.

Cystoscopy:

- Acute/known Urinary Tract Infections,
- Severe Coagulopathy,
- Any contraindication related to cystoscopy.

Hysteroscopy and Cystoscopy:

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

WARNINGS

- 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 Needle while viewing a LiNA OperåScope™ live camera image, allowing observation of the uterine cavity or urinary bladder.
- Do not advance the Needle if resistance is experienced while in the patient.
- **For single use only**. Do NOT reuse, reprocess or re-sterilize the Needle. 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. Endoscopic injection using the Needle should ONLY be performed by medical professionals who have adequate training in hysteroscopy or cystoscopy. The Needle 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,
- Perforation of urethra,
- Pulmonary edema,
- Cerebral edema,
- Infection,
- Bleeding/hematuria,
- Peri- and post-procedural pain,
- Vasovagal episodes,
- Urethral trauma,
- Irritable bladder syndrome,
- Urethral erosion,
- Cervical trauma,
- Vascular occlusion,
- Fluid related complications,
- Inadvertent injection of the therapeutic agent,
- Voiding dysfunction.

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 Needle and replace with a new device.

INSTRUCTIONS FOR USE

The preparation of the injectable material should be done according to the instructions for use of the injectable material.

Exposing and retracting the device is done by pushing or pulling the rear handle after removing the limit buckle **(Figure 5a & 5b)**.

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 1)**.
3. Using sterile technique, remove the device from the sterilized blister **(Figure 2)**.
4. Inspect the Needle for any obvious damage.
5. Attach a pre-filled syringe to the luer lock fitting on proximal end of the Needle **(Figure 3)**.
6. Remove the protection cap **(Figure 4a)**.
7. Remove limit buckle **(Figure 4b)**.
8. Check the extend/retract function of the LiNA OperåScope™ Needle by actuating the rear handle. The Needle must be retracted in the shaft **(Figure 5a & 5b)**.
9. Prime and remove air bubbles while the needle tip is extended **(Figure 6)**.
10. Retract needle tip and re-attach the limit buckle **(Figure 7a)**.
11. Slowly insert the Needle into the LiNA OperåScope™ working channel until the Needle is visualized on the LiNA OperåScope™ live camera image **(Figure 7b)**. Some resistance will be felt when the Needle passes through the LiNA OperåScope™ pre-curved tip. Take care not to bend the Needle shaft.
12. Maneuver the Needle towards the targeted injection site.
13. Remove limit buckle **(Figure 8a)**.
14. Expose needle tip **(Figure 8b)**.
15. Insert the Needle into intended tissue by pushing the LiNA OperåScope™ forward **(Figure 9a)**.
16. Perform desired amount of injection according to procedure. Push press to inject medicine. **(Figure 9b)**.
17. Carefully remove from the tissue by pulling the LiNA OperåScope™ backward. **(Figure 10)**.
18. Steps 15 – 17 may be repeated multiple times within a single procedure.
19. Extract the Needle from the LiNA OperåScope™ working channel and retract needle tip **(Figure 11)**.
20. Re-attach limit buckle and safely transfer the Needle to disposable waste bin **(Figure 12)**.

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 12)**.

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.

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