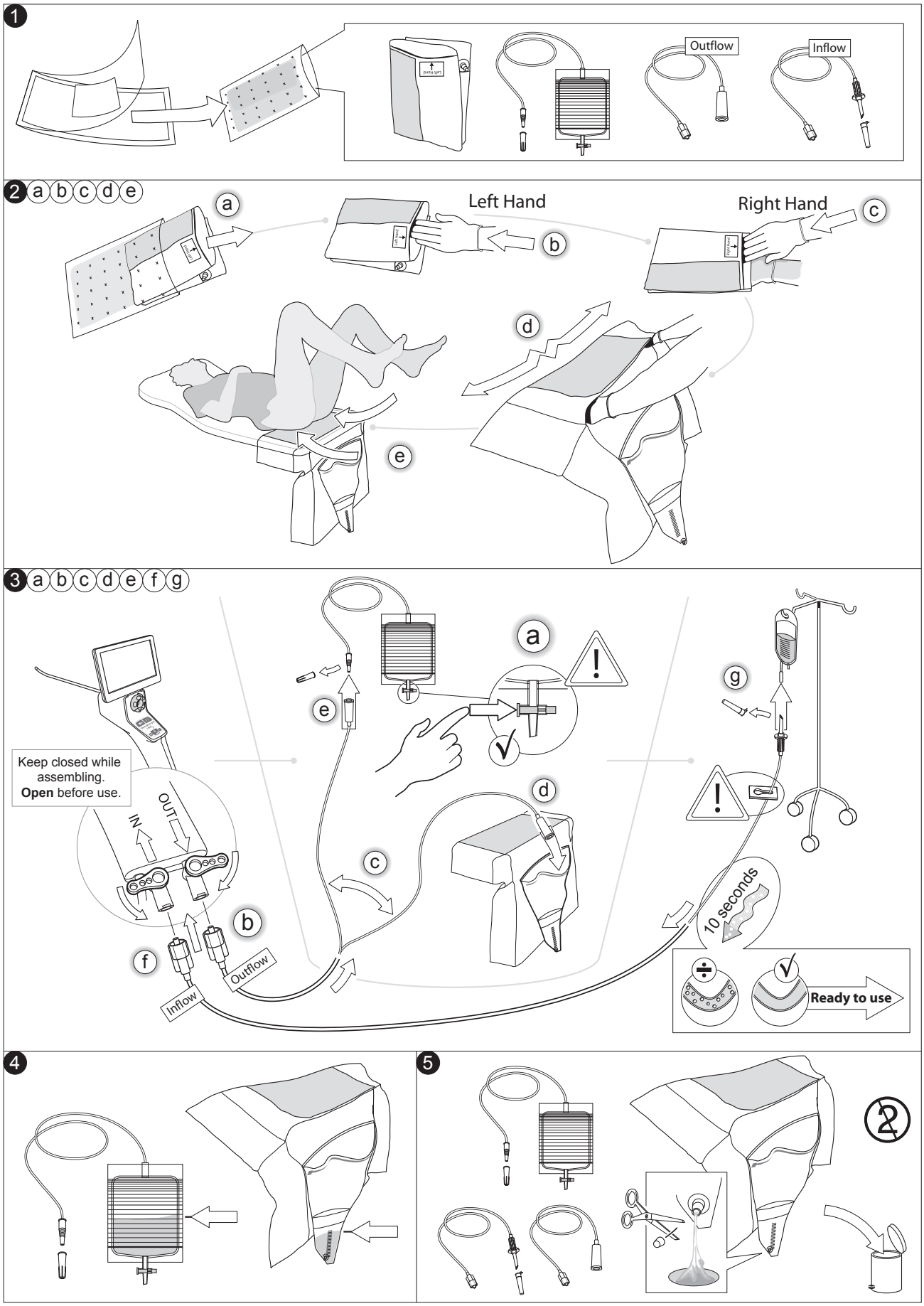
℞Only STERILE EO

LiNA OperåScope™ Tubing & Drape Kit

REF: OP-TDK-6



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INTENDED USE
The LiNA OperåScope™ Tubing & Drape Kit is intended for all hysteroscopic and female cystoscopy diagnostic and/or operative procedures, to manage the fluids used for distending of the uterine cavity or urinary bladder.

PATIENT POPULATION
Adolescent and adult females suited for hysteroscopy and cystoscopy.

PRODUCT DESCRIPTION
The LiNA OperåScope™ Tubing & Drape Kit (Tubing & Drape Kit) is delivered as a sterile, single-use procedure kit designed to be used specifically with the LiNA OperåScope™ endoscope. The device consists of a drape with pouch, an inflow tubing, an outflow tubing and a collection bag.

Failure to follow all instructions or any warnings or precautions could result in serious patient injury. LiNA OperåScope™ Tubing and Drape Kit should not be used for any other purpose than its 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 Tubing & Drape Kit 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.
- **For single use only.** Do NOT reuse, reprocess or re-sterilize the components. 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 cross contamination to residual tissue in the tubing or drape.
- A liquid distension medium is used and strict fluid intake and output surveillance should be maintained. Intrauterine instillation exceeding 1 liter should be followed with great care to reduce the possibility of fluid overload.
- Hysteroscopic and cystoscopic diagnostic and/or operative procedures should ONLY be performed by medical professionals who have adequate training in hysteroscopy or cystoscopy.

POTENTIAL COMPLICATIONS
Continuous Flow hysteroscopy 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. The use of normal saline as a distending medium and limiting the infused volume to less than 1000 ml is recommended to decrease the risk of the above complications. Intrauterine and bladder distension can usually be accomplished with pressures in the range of 35 - 75 mmHg. Unless the systemic blood pressure is excessive, it is seldom necessary to use pressures greater than 75-80 mmHg.

REQUIRED ACCESSORIES
- Infusion bag stand with optional pressure cuff or fluid management pump,
- Saline bag (distending medium),
- Gynecological bench (examination bench).

INSTRUCTIONS FOR USE
The device consists of a drape with a pouch, an inflow tubing, an outflow tubing, and a fluid collection bag.

Read the instructions for use prior to using this device!

1. Throughout the procedure, use sterile techniques to avoid contaminations.
2. Prior to opening the sterile pouch, hang the saline bag in the stand/ pressure cuff or connect to the pump.
3. Prepare the LiNA OperåScope™ for use by closing both Luers. Refer to the LiNA OperåScope™ manual for details.
4. 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.
5. Remove the inner pouch from the sterilized blister (**Figure 1**).
6. Remove the drape from the inner pouch (**Figure 2a**).
7. Inspect the drape for labels for left & right hand. Unfold the drape by inserting the left & right hand at the labels and pull them away from each other (**Figure 2b-2d**).
8. Place the drape between the bench and the patient's buttock. Let the pouch hang down towards the floor (**Figure 2e**).
9. Remove the collection bag from the inner pouch. Close the drain valve at the bottom and remove the protection cap from the inlet (**Figure 3a**).
10. Remove the OUTflow tubing from the inner pouch. Connect the Luer to the OUT connector on the LiNA OperåScope™ and connect the other end to the collection bag or put it into the drape pouch (**Figure 3b – 3e**).
11. Remove the INflow tubing from the inner pouch. Connect the Luer to the IN connector on the LiNA OperåScope™ (**Figure 3f**).
12. Remove the protection cap from the spike and insert the spike into the saline bag (**Figure 3g**). The slide clamp may be used to temporarily stop the flow from the saline bag, if needed.
13. Carefully inspect the saline bag for material fragments.
14. Apply light pressure to the saline bag using the pressure cuff.
15. Open the inlet Luer on the LiNA OperåScope™ and flush fluid through the tubing and the LiNA OperåScope™ until all air bubbles have cleared from the tubing. Open the outlet Luer.
16. Insert the LiNA OperåScope™ into the patient and perform the procedure.
17. Adjust the pressure on the saline bag and outlet cock position to distend the uterus or urinary bladder.
18. Throughout the procedure, monitor the fluid deficit to avoid fluid overflow (**Figure 4**).
19. When the procedure is complete, remove the LiNA OperåScope™ from the patient and close the inlet Luer, remove the pressure from the saline bag. Disconnect the tubings from the LiNA OperåScope™, saline bag and collection pouch.
20. Dispose of the fluids from the saline bag, the collection bag, and the drape pouch. If needed, cut the drain plug on the pouch (**Figure 5**).

DISPOSAL
After use, the product may be a potential biohazard. Handle and dispose the fluids, drape, tubings and collection bag 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.

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