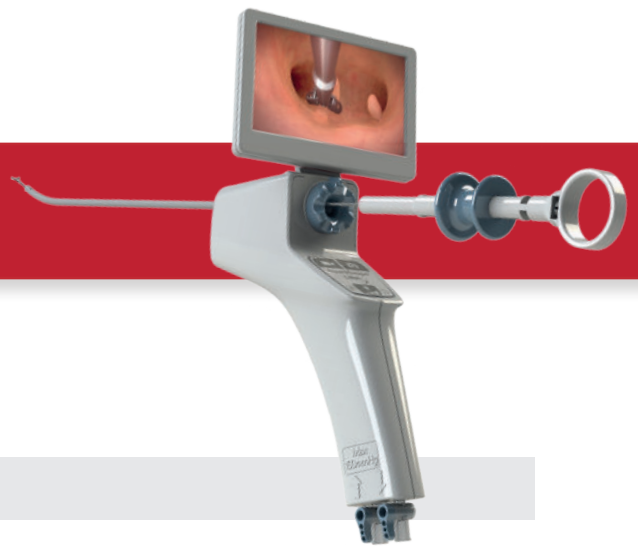


LiNA OperåScope®

Single-Use Operative Hysteroscopy System



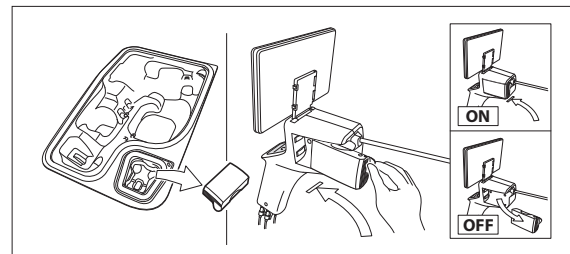
Setup Checklist

Supplies

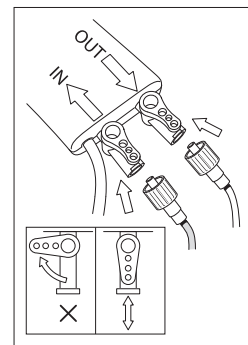
- LiNA OperåScope® with HDMI cable & LCD (sterile, single use)
- LiNA OperåScope® Instrument (sterile, single use)
- LiNA OperåScope® Tubing & Drape Kit (sterile, single use)
- Saline (hanging bag with pressure cuff)
- IV pole
- Speculum (open-sided speculum preferred)
- Set of dilators up to Hegar 5/Pratt 15
- Vaginal prep – povidone/iodine
- Half-drape
- Alcohol swab(s)
- Hand towels
- Sterile gloves
- LiNA OperåScope® Recording Module (optional)
- Tenaculum (optional)
- Sound (optional)
- Sterile pick-ups/tweezers (optional)
- EMB collection container (optional)
- Paracervical block (optional)

Setup Steps

1. Using sterile technique, remove the LiNA OperåScope® from the sterilized blister.
2. Remove the battery from the sterilized blister and insert the battery into the LiNA OperåScope® Handle.
3. The light source at the distal tip of the cannula will illuminate and the camera image should be visible on the onboard LCD.

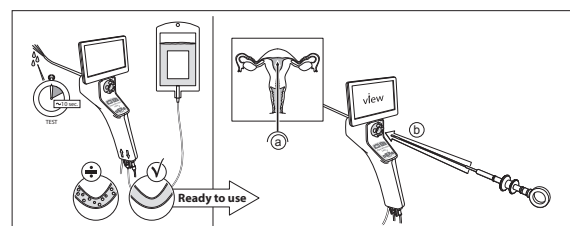


4. Close the LiNA OperåScope® inflow/outflow stopcocks. Attach the outflow fluid tubing to the outflow port and the inflow fluid tubing to the inflow port. The LiNA OperåScope® tubing set has Luer Lock connectors, which can assist with ease of connecting the tubing to the ports. Then spike fluid.
5. The LiNA OperåScope® can be connected via HDMI cable to an external monitor or the LiNA OperåScope® Recording Module.



Note: Prior to using the LiNA OperåScope® Recording Module, ensure the unit is plugged in and green power light is illuminated.

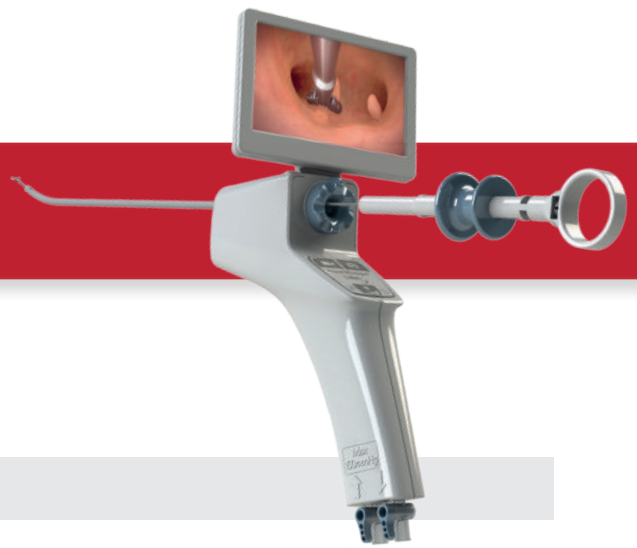
6. Flush the fluid through the cannula until all air bubbles have cleared from the tubing. Leave outflow stopcock closed until or unless the cavity needs to be flushed.
7. The LiNA OperåScope® is now ready for use.



Innovation in Gynecology

LiNA OperåScope®

Single-Use Operative Hysteroscopy System



Setup Checklist

Additional Guidance

- If using a paracervical block, the anesthetic should be injected prior to Setup Steps 1-7. This will give time for the block to take effect.
- If the LiNA OperåScope® does not have power, confirm the batteries are correctly positioned in the battery pack and the battery pack has been properly inserted at a slight angle into the LiNA OperåScope®.
- If distension is not achieved, ensure that the inflow stopcock is fully open and the outflow stopcock is closed; check for leakage around the cervix; adjust bag height or cuff pressure. When introducing an instrument, inflow may be restricted until the instrument fully transits the operative channel.
- Resistance will be felt prior to the instrument coming into view. Ensure the LiNA OperåScope® is at or near the internal os and distension is adequate. The instrument will come into view at the 12 o'clock area of the LCD screen.
- Rotating the thumb wheel to steer the catheter tip may also aid in directing the instrument towards target tissue or IUD.
- When removing an IUD or large specimen, close the inflow stopcock and withdraw the LiNA OperåScope® and Instrument together. If the specimen is small enough to fit through the instrument channel, closing the inflow is not necessary.
- Be sure to remove batteries prior to disposing of the LiNA OperåScope®.

This LiNA OperåScope® Checklist is designed to be used in conjunction with, but not replace, the LiNA OperåScope® Instructions For Use. If a discrepancy is identified, the Instructions For Use supersedes this Checklist.

Prior to performing the procedure, the physician must review, and be familiar with, the full Instructions For Use, as well as any warnings, contraindications and safety information.

©2019 LiNA Medical ApS. All rights reserved.

LiNA is a registered trademark of LiNA Medical ApS in the EU, US and CN.



LiNA Medical ApS
Formervangen 5
DK-2600 Glostrup, Denmark
Tel.: +45 43 29 66 66

Fax: +45 43 29 66 99
info@lina-medical.com
www.lina-medical.com
CVR: 10054974

Distributor:
LiNA Medical USA
Norcross, GA 30093, USA

Tel: +1 (855) 546-2633
Fax: +1 (678) 380-0500
info@linamed.com
www.linamed.com