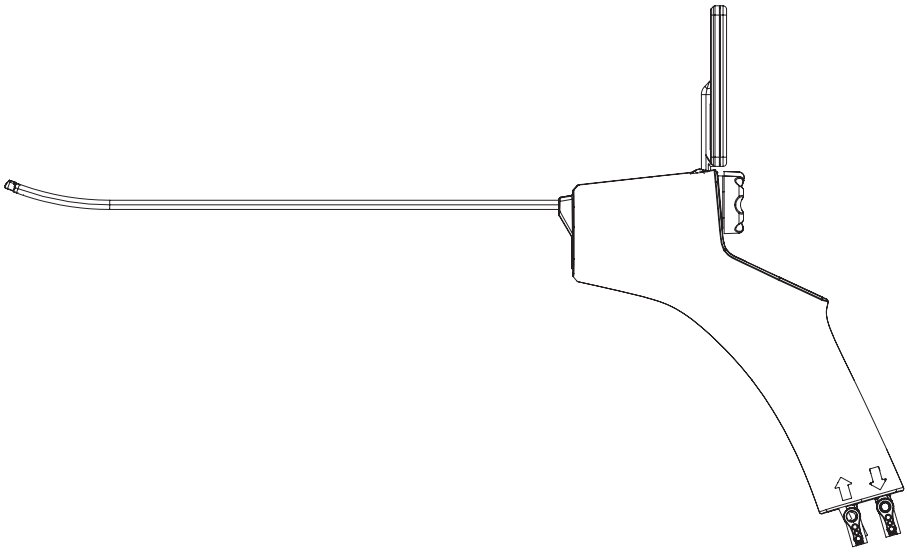
LiNA
OperåScope™



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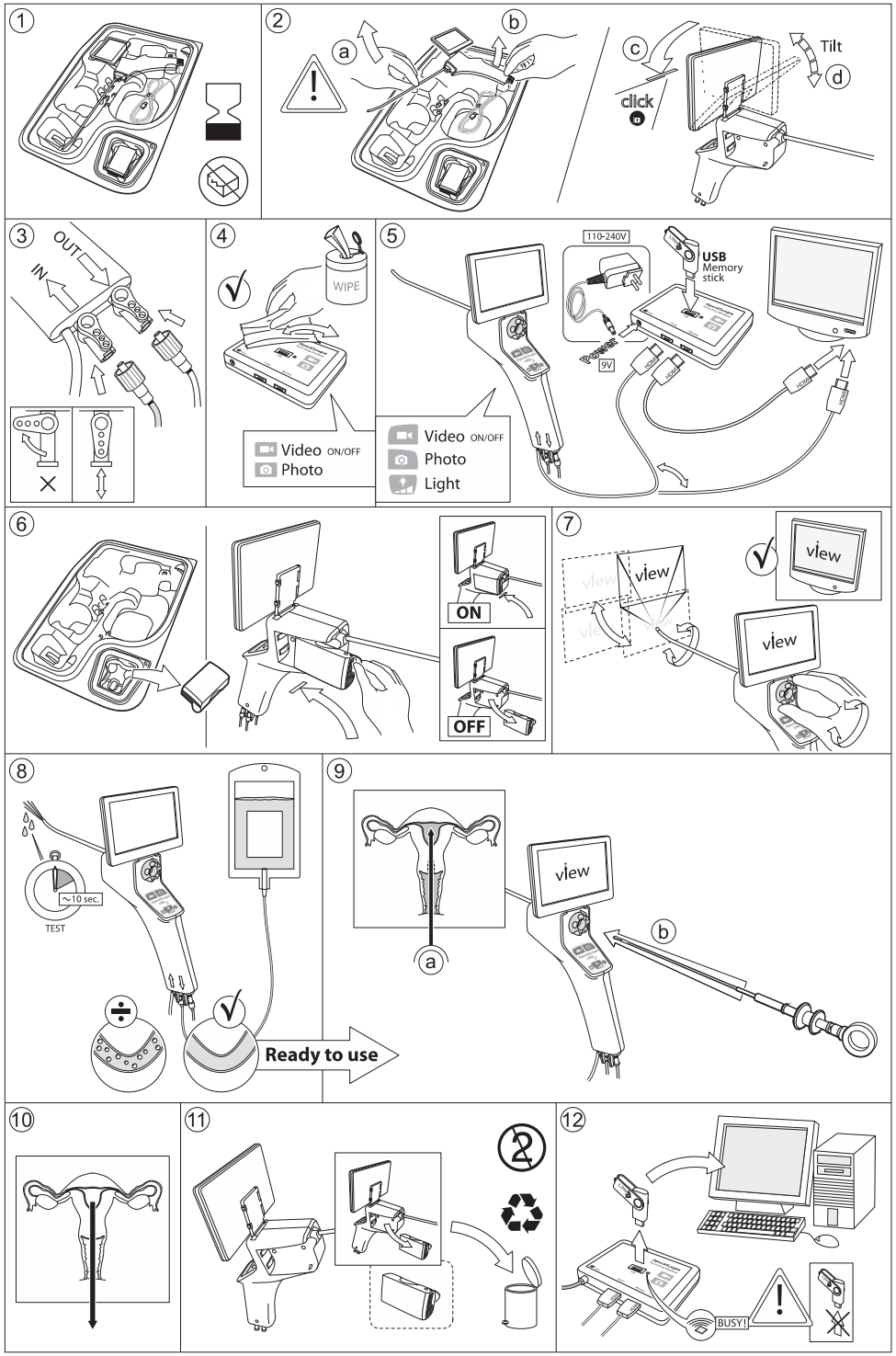

LiNA OperåScope™
Instructions for Use

INTENDED USE AND PRODUCT DESCRIPTION

The LiNA OperåScope™ is intended for use in visualization of the cervical canal and uterine cavity during diagnostic and therapeutic gynecological procedures.

The LiNA OperåScope™ is a single-use battery operated hysteroscope with a cannula and LCD display with a 3m HDMI cable attached to the handle. The LiNA OperåScope™ is provided sterile via ethylene oxide and the battery pack is provided sterile via radiation.

The 4.2 mm (nominal) diameter cannula contains a miniature camera and LED illumination at the distal tip, and a pre-curved tip section of the cannula is rotated by a turning knob **(Figure 7)** on the handle. The center of this turning knob is the insertion channel for introduction of Hysteroscopic instruments/accessories up to 1.86 mm (5.5 Fr) nominal in diameter; and 310mm minimum working length. Distention and flushing of the uterine cavity with distention medium is facilitated with separate in-flow and out-flow luer lock stopcocks at the bottom of the handle. The HDMI cable at the bottom of the handle can be connected to an external monitor with HDMI input, or alternatively connected to the LiNA OperåScope™ Recording Module™ for recording of video or pictures to a standard USB drive.

During operation, visualization can be optimized by adjusting the brightness (illumination). The brightness is controlled by brightness button **(Figure 5)** located on the handle.

In addition to the LiNA OperåScope™, the LiNA OperåScope™ Recording Module (Figure 4) is available to capture both still and video images for later viewing, The LiNA OperåScope™ Recording Module is provided nonsterile and designed to be connected to the LiNA OperåScope™ HDMI cable. The LiNA OperåScope™ Recording Module is not intended to come in contact with the sterile field or the patient.

The target group is patients with diagnostic and therapeutic gynecological procedures that require visualization of the cervical canal and uterine cavity.

Caution: Federal Law (USA) restricts the device to sale by or on the order of a physician.

The LiNA OperåScope™ is designed with 60 minutes of battery life.

The LiNA OperåScope™ and Recording Module are to be used under ambient conditions and stored under room temperature and dry conditions (recommended storage conditions: 0°C – 55°C and 10% - 90% humidity).

ACCESSORIES

The following accessories can be used with LiNA OperåScope™:

- LiNA OperåScope™ Recording Module;
- Commercially available fluid management tubing with a male luer lock;
- Commercially available instruments/accessories for diagnostic/therapeutic use.

The types of procedures where the LiNA OperåScope™ could offer visualization include:

- Assessment of abnormal bleeding, pelvic pain, amenorrhea and abnormal findings from hysterosalpingogram;
- Assessment of infertility and pregnancy wastage;
- Confirmation of the presence of intrauterine foreign body;
- Assist in locating submucosal fibroids and polyps targeted for removal;
- Provide visual guidance during directed biopsy, submucosal myomectomy, transection of intrauterine adhesions and septa.

CONTRAINDICATIONS:

The device is contraindicated for use in:

- Inability to distend the uterus
- Cervical Stenosis
- Cervical/Vaginal infection

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- Uterine bleeding or menses
- Known Pregnancy
- Known carcinoma of the cervix and/or the uterus
- 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 LiNA OperåScope™ is provided STERILE via ethylene oxide (LiNA OperåScope™) and radiation sterilization (Battery). Carefully inspect the packaging for any damage prior to use. Do NOT attempt to use the device if sterile barrier is damaged. Do NOT use past expiration date. Do NOT use if the device is exposed to non-sterile surfaces before procedure.
- To mitigate the risk of perforation, only advance/manipulate the LiNA OperåScope™ while viewing a live camera image and illumination, allowing observation of the cervical and endometrial cavity.
- Low light intensity at the lowest available setting may limit visualization and be unsuitable for surgical procedures. Device operators should check that the light intensity range is suitable for the planned procedure prior to use
- Do not advance the LiNA OperåScope™ should resistance be experienced while in the patient.

WARNINGS:

- Do not attempt to alter the shape of the distal cannula.
- For single use only. Do NOT reuse, reprocess or re-sterilize the LiNA OperåScope™. 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 residual tissue in the LiNA OperåScope™.
- Hysteroscopy procedures using the LiNA OperåScope™ should be performed only by medical professional who have adequate training in hysteroscopy.
- Do not remove the battery during the treatment process.
- Always have a backup device readily available for immediate use.
- For use only with the batteries provided with each LiNA OperåScope™ device – batteries are identified as AA Energizer alkaline batteries in a dedicated battery pack for the LiNA OperåScope™.
- LiNA OperåScope™ is designed with 60 minutes of battery life.
- If any malfunction should occur during use or battery life expires, stop the procedure immediately, and slowly withdraw the LiNA OperåScope™ and replace with a new LiNA OperåScope™.
- 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.
- Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used within 30 cm (12 inches) of the LiNA OperåScope™, as degradation of LiNA OperåScope™ performance could result.
- Use of accessories, transducers and cables other than those specified could result in a change in electromagnetic properties resulting in potential improper operation.
- Use of the LiNA OperåScope™ equipment adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Avoid submersing the LiNA OperåScope™ handle, battery, HDMI port and/or LCD screen in a fluid bath. Should the LiNA OperåScope™ be submerged, ensure the LiNA OperåScope™ is dried off and remains operational before clinical use. If the LiNA OperåScope™ is nonoperational, replace with a new device.

US specific warnings:

- The LiNA OperåScope™ is intended only as an adjunct in assessing patient condition. It must be used in conjunction with clinical signs and symptoms.

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PRECAUTIONS:

Potential complications of Continuous Flow Hysteroscopy:

- Hyponatremia
- Hypothermia
- Uterine perforation resulting in possible injury to bowel, bladder, major blood vessels and ureter.
- Pulmonary edema
- Cerebral edema
- Infection
- Bleeding
- Pain

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 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.

Before each use or after a change of LiNA OperåScope™ settings, check to ensure LiNA OperåScope™ view provides a live image (rather than a stored one) and has the correct image orientation.

If a continuous flush/irrigation during LiNA OperåScope™ operation is not maintained, the distal tip operating temperature may exceed 41oC (105.8oF).

While the LiNA OperåScope™ Recording Module is connected to the LiNA OperåScope™, ensure that the power supply unit is easily accessible if power should need to be disconnected.

Ensure the LiNA OperåScope™ Recording Module and monitor are outside of the patient's reach.

INSTRUCTION FOR USE:

Read the instruction 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 past expiration date.
2. Using sterile technique, remove the hysteroscope from the sterilized blister **(Figure 2)**.
3. Attach the inflow fluid tubing to the inflow port and the out flow tubing to the outflow port **(Figure 3)**.
4. LiNA OperåScope™ can be connected via HDMI cable to an external monitor or the Recording Module.
   Note: Prior to using the Recording Module, ensure the unit is plugged in and green power light is illuminated.
5. Remove the battery from the sterilized blister and insert the battery into the LiNA OperåScope™ Handle **(Figure 6)**.
6. The light source at the distal tip of the cannula will illuminate and the camera image should be visible on the onboard LCD. If illumination or camera image is not functional, discontinue setup and open a new LiNA OperåScope™ **(Figure 7)**.
7. Flush the fluid through the cannula until all air bubbles have cleared from the tubing **(Figure 8)**.
8. The hysteroscope is now ready for use.
9. With fluid flowing, the cannula is inserted through the cervical canal while viewing the image, as is standard procedure for introduction of a hysteroscope **(Figure 9)**.
10. If picture or video recording is desired, insert a USB memory stick into the Recording Module and make sure the HDMI cable is connected from the LiNA OperåScope™. Both the LiNA OperåScope™ handle and Recording Module have picture and video capture buttons. Press and release the picture button to capture a still image. Press and release video button to start recording; press and release the video button again to stop recording **(Figure 13)**.
11. The LiNA OperåScope™ has central lumen located within the turning knob of the Handle **(Figure 9)** and provides a conduit to delivery diagnostic and therapeutic instruments/accessories to uterine cavity.

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Instruments/accessories within the following dimensions are compatible with the LiNA OperåScope™ central lumen:

- Maximum outer diameter: 1.86 mm (5.5 Fr)
- Minimum useable length: 310 mm

12. After the procedure is completed, remove the hysteroscope **(Figure 10)**.
13. Remove the battery pack and dispose of the battery. The device may now be safely disposed in accordance with local governing ordinances **(Figure 12)**.
14. Remove USB stick from Recording Module and transfer the recordings to a computer using a USB port.

Technical specification for LiNA OperåScope™

Nominal input voltage:	3V DC ±10%
Nominal Current:	330mA ±20%
Battery type:	2pcs AA 1.5V Energizer Alkaline (Non-rechargeable)
Operating time:	≥60 minutes
Camera resolution:	400x400 pixels
Diagonal size of LCD display:	4.3 Inch
Minimum usable length:	240mm
Pre-fixed tip angle:	20° ±5°

Shelf Life Conditions

The shelf life for LiNA OperåScope™ is 12 months. The test units were then subjected to simulated shipment conditions per ASTM D4169, Cycle 13, assurance level 1. All units were inspected and subjected to design verification testing and met all acceptance criteria.

LiNA OperåScope™ RECORDING MODULE (OP-RM-1)

Download of Video/Still Imagery Files Post Procedure

Video and still imagery can be downloaded from the LiNA OperåScope™ via the LiNA OperåScope™ Recording Module USB and imported into the patient's medical record. Since there is no patient identifying information on the video/still imagery file, the downloaded file should be uploaded and saved to the patient's medical record immediately post procedure ensuring the proper link between the file and the patient.

Playback of recorded Video/Still images on computer

Step 1
Insert the USB-stick into the computer USB port
Step 2
Download and install some supplement codec software for Windows Media Player such as Media Player Codec Pack.
Step 3
Click "Start" in Windows and select the folder in which your H.264 file is located, such as My Videos or My Downloads.
Step 4
Right-click on the video and select "Open With." Choose "Windows Media Player" from the available options to begin playing your video/Images.

Post Procedure Cleaning

The LiNA OperåScope™ Recording Module is intended to be used outside the sterile field and away from the patient. While the LiNA OperåScope™ Recording Module is not intended to come in direct contact with patient, the device can be exposed to body fluids and/or blood as it is used in the operating room during patient treatment.

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After each patient use, the following cleaning/disinfecting instructions to ensure proper cleaning of the external components

DO NOT SUBMERGE LiNA OperåScope™ RECORDING MODULE

DURING CLEANING/DISINFECTING, ORIENT THE LiNA OperåScope™ RECORDING MODULE POSITION TO MINIMIZE LIQUID FROM COMING IN CONTACT WITH THE POWER, USB, SCOPE AND MONITOR CONNECTORS

LiNA OperåScope™ RECORDING MODULE CASE SHOULD NOT BE OPENED FOR CLEANING/ DISINFECTING

WARNING: NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

1. Power off and unplug the LiNA OperåScope™ Recording Module
2. Place the LiNA OperåScope™ Recording Module and power cord on a clean, dry surface
3. Using a cleaning/disinfecting wipe, completely wipe the top, bottom and all 4 sides of the LiNA OperåScope™ Recording Module.
4. After wiping, visually inspect the exterior for residual bodily fluids or dirt and repeat wipe.
5. Let the LiNA OperåScope™ Recording Module sit for at least 3 minutes.
6. Using a 70% Isopropyl swab, thoroughly wipe the seams of the Module ensuring the Module is free of bodily fluid.
7. Once the Module is visually clean, place the device in a storage area for future use.

LiNA OperåScope™ Recording Module Battery 7-year Shelf Life:

The LiNA OperåScope™ Recording Module battery has an operating life of 7 years from the date of manufacture and will be replaced prior to the anticipated shelf life expiration.

Nominal input voltage:	100-240V AC ±10%	**Nominal input frequency:**	50-60Hz
Nominal input current:	0.16-0.08Arms @ max load	**Nominal output voltage:**	Uout: 9V DC +5% / -5%
Nominal output current Iout:	800mA	**AC adapter provided:**	Friwo Fox 9VDC/800mA

General Information

The LiNA OperåScope™ device and Recording Module complies with EN 60601-1-2: 2015 for EMC.

- Note: the emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals/ clinics (CISPR 11 Class A). The equipment is not indicated for use outside a hospital or clinic setting.
- Immunity according to Professional healthcare facility environment

REF	Catalog Number		Consult Instructions for Use
LOT	Lot Number		Do Not Use Device If Package Is Damaged
	Manufacturer		Keep Dry
	Temperature Limit		Humidity Limitaion
NON STERILE	Non-sterile	STERILE EO	Sterilized Using Ethylene Oxide
	Use-by Date	STERILE R	Sterilised Using Irradiation

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Rx Only	Caution: Federal Law restricts this device to sale by or on the order of a physician.		Do Not Resterilize
	Do Not Reuse		Caution

Open Source Software used in LiNA OperåScope™ Recording Module

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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.