

# Customer Quick Reference Guide

## LiNA Librata™

Cordless Balloon Ablation Device



### Steps for the procedure

1. Remove the blister tray from the environmental pouch.
2. Carefully inspect the blister trays and Tyvek lids 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.
3.
  - a. Move the indicator ring backwards.
  - b. Open and remove the balloon cap.
4. Insert the battery into the device and place the device on the sterile field. The LiNA Librata is designed with 47 minutes of battery life, that covers one procedure only.

**NOTE:** Do not press the "ON"-button before all preparations have been made (as the heating process will then begin).
5. Conduct a pelvic examination to determine the position of the uterus. Particular attention should be made when sounding, dilating and inserting the device into uterus. Insert a speculum into the vagina and grasp with a tenaculum to bring the uterus to a mid-plane position.
  - Using a uterine sound, measure the length of the uterus from the external os to the fundus. Set the indicator ring on the catheter to the measurement obtained from the sounding. (Please note the markings on the Librata catheter are intentionally 0.5cm shorter than indicated. This allows a 0.5cm gap between the balloon and fundus once the catheter is inserted until the indicator ring reaches the cervix).

**NOTE:** Due to the small diameter of the LiNA Librata catheter, dilation of the cervix may not be required. In the event that the cervix needs to be dilated, dilate the cervix to 6mm.
6. Press the "ON" button. The device will make a short beep sound and the "HEATING" light will start flashing. The heating process takes approximately 10 min.

**NOTE:** During the heating process the device should remain on the sterile field and should not be hand-held or inserted into the patient.
7. Once the fluid is heated to the correct temperature, the "HEATING" light will stop flashing. The device will now make a short beep sound and the "READY" light will illuminate. The device is now ready and LiNA Librata treatment can be initiated.

**NOTE:** When the device is ready, the LiNA Librata treating process needs to be started within 30 minutes. If the treating process is not started within this time frame, the fluid can NOT be reheated and the procedure may therefore be aborted.

**NOTE:** Please note that the device will make a short beep sound every minute until the treatment is started.
8. Carefully insert the catheter into the uterus until the indicator ring touches the cervix. If resistance is felt before the indicator ring is touching the cervix, remove the catheter and take a second sounding of the uterus and adjust the indicator ring accordingly.

**NOTE:** Do not use excessive force when inserting the balloon catheter.
9. When the device has been inserted correctly into the uterus, the treating process may begin. Press and hold the "TREAT" button for 2 seconds and the "TREATING" light will then begin to flash.
10. The treating process takes approximately 2 minutes. During the treating process fluid will automatically be injected and withdrawn from the balloon a total of 5 times. Each cycle will take approx. 25 seconds.

**NOTE:** Prior the beginning of the treatment process, the device performs a short 5 second pressure test to indicate that the balloon has not passed outside the uterine cavity. If the device suspects that the balloon is outside the uterine cavity the device will abort the procedure. All lights on the device will flash simultaneously.

A hysteroscopy should then be performed to confirm that a perforation has not taken place. If no perforation is revealed during hysteroscopy, a second LiNA Librata device may be used.
11. When the treating process is done the "FINALIZED" light will illuminate and the device will make a short beep sound.
12. Remove the catheter slowly from the uterus.

**NOTE:** If unexpected resistance is felt during removal of the catheter pull the "EMERGENCY" strap on the back of the device until the word "STOP" appears. Wait 5 seconds and remove the catheter slowly from the uterus.
13. Dispose of the device. The battery and the device may now be safely disposed in accordance with local governing ordinances and recycling plans. If desired the battery can be removed from the device and disposed separately.



Innovation in Gynecology

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### DEVICE ALARMS:

#### During heat up (before the TREAT button is pushed):

| Light pattern | Description   | Reason for error   | User instruction  |
|---------------|---|--|---|
|               | The "FINALIZED" and "READY" lights are flashing during heat up. | Device failure for technical reasons only, no patient safety issue is suspected. | <ol style="list-style-type: none"> <li>1. Return the device for investigation and dispose of the battery.</li> <li>2. Replace with a new device.</li> </ol> |

#### During treatment (after the TREAT button has been pushed):

| Light pattern | Description   | Reason for error  | User instruction   |
|---------------|---|---|--|
|               | The "FINALIZED" and "READY" lights are flashing during treatment. | The system has detected temperature or pressure levels outside the preset limits.   | <ol style="list-style-type: none"> <li>1. Perform a hysteroscopy to rule out any possible patient injury.</li> <li>2. Return the device for investigation and dispose of the battery.</li> </ol> |
|               | The "TREATING" and "HEATING" lights are flashing.                 | The uterine cavity is too big to treat. The patient cannot be treated with the LiNA Librata device.                           |  |
|               | All lights are flashing.  | The balloon was unable to meet a minimal pressure before initiating treatment. The balloon may be outside the uterine cavity. |  |

### To abort the procedure:

1. Press the "ON" and "TREAT" buttons simultaneously ("ABORT").
2. Observe that the 'FINALIZED' light is flashing and that beeps are sounding.
3. Wait 8 seconds to let the "ABORT" feature withdraw all the fluid from the balloon. The 'FINALIZED' light will illuminate.
4. Remove the catheter slowly from the uterus.
5. In the unlikely event that the "ABORT" function does not work, or if unexpected resistance is felt during removal of the catheter, pull the "EMERGENCY" strap on the back of the device until the word "STOP" appears. This will drain the fluid from the balloon back into device.
6. Wait 5 seconds and remove the catheter slowly from the uterus.

**NOTE:** Please note that after using the "ABORT" feature, the treatment can NOT be resumed nor can the device be restarted.

This Customer Quick Reference Guide is designed to be used in conjunction with, but not replace, the LiNA Librata Instructions For Use. 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.