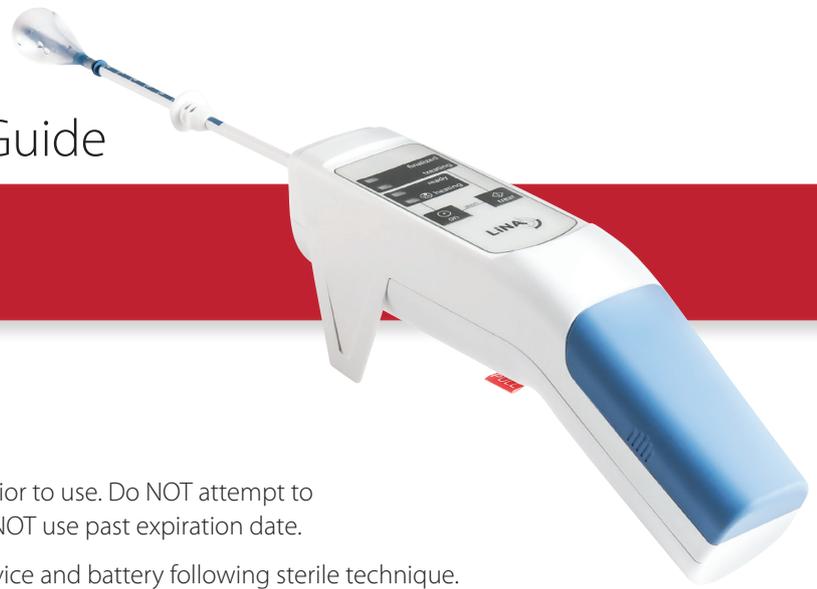


Customer Quick Reference Guide

LiNA Librata™

Cordless Balloon Ablation Device



Steps for the procedure

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. Peel back the lid on the packaging. Remove the device and battery following sterile technique.
3. Insert the battery into the device and place the device on the sterile field.
4. Conduct a pelvic examination to determine the position of the uterus. Particular attention should be made when sounding, dilating and inserting the device into the uterus.
5. 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.

NOTE: Due to the small diameter of the 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 Librata™ treatment can be initiated.

NOTE: When the device is ready, the 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.
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.
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 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 Pull" strap on the back of the device until the word "STOP" appears. Wait 5 seconds and remove the catheter slowly from the uterus.

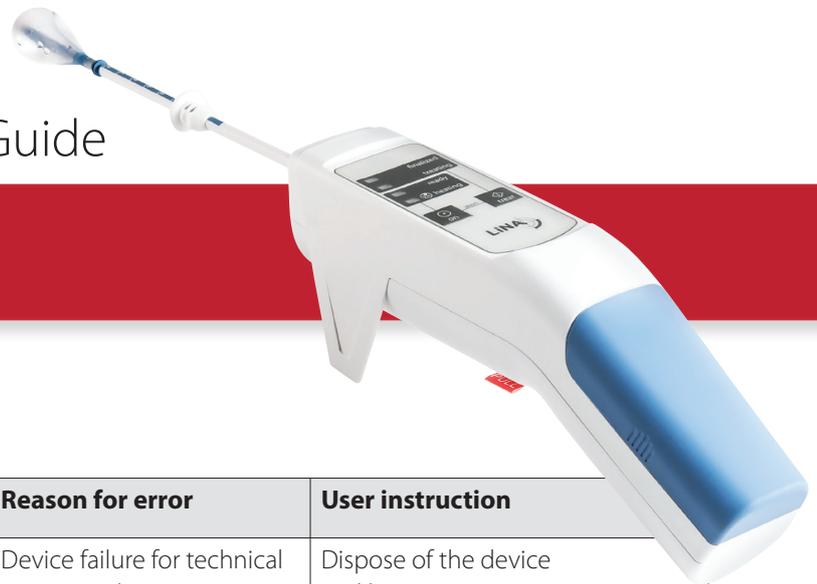


Innovation in Gynaecology

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Device Alarms

Light pattern	Description	Reason for error	User instruction
	The 2 green lights are flashing.	Device failure for technical reasons only, no patient safety issue is suspected.	Dispose of the device and battery. Replace with a new device if device failure occurs before the treatment has started.
	The 2 orange lights are flashing.	The uterine cavity is too big to treat. The patient cannot be treated with the Librata™ device.	Dispose the device and battery. A hysteroscopy might be considered at this point to confirm the size and shape of the uterus to determine alternate treatment choices.
	All lights are flashing.	The balloon was unable to meet a minimal pressure before initiating treatment. The balloon may be outside the uterine cavity.	Dispose the device and the battery. Perform a hysteroscopy to ensure that a perforation of the uterus has not occurred.

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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 Pull" strap on the back of the device until the word "STOP" appears. This will evacuate the fluid from the balloon.
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.