FSN-22-001

Urgent Field Safety Notice

LiNA Librata™

Attention: All LiNA Librata™ Customers and Distributors

Date: 2022-12-14

Concerned device/documentation

Product name – LiNA Librata™

Product reference number – LIB-1

UDI-DI – (01)05708265013487

Product description – The LiNA Librata is a thermal balloon endometrial ablation device, intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding). The device consists of two major components, the control unit, and the tube with an inflatable balloon at the distal end. In the control unit fluid medium (glycerin) is heated before being forced into the catheter balloon under pressure to compress against the uterine wall and circulate within for homogenous heat distribution. This is a single use device.

Description of the problem

LiNA has become aware of a safety issue in relation to use of an obsolete version of an accompanying document. Use of an obsolete ***Customer Quick Reference Guide*** resulted in the incorrect interpretation of the device alarm pattern caused performed not adequate actions and in the consequences patient injury.

Risk section

The hazardous situation associated with this issue is that a user, by wrong interpretation of an alarm pattern, could perform inadequate actions to rule out any patient injury e.g uterine perforation and proceed to perform a repeat ablation leading to thermal tissue injury which may require additional surgery.

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DK-2600 Glostrup
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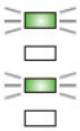
info@lina-medical.com
www.lina-medical.com
CVR: DK10054974
NIP: PL5262989150

Affected documentation

As per the device IFU, below is the correct alarm table to be used for reference and correct alarm pattern interpretation:

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.	1. Return the device for investigation and dispose of the battery. 2. Replace with a new device.

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

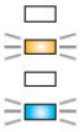
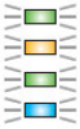
Light pattern	Description	Reason for error	User instruction
	The "FINALIZED" and "READY" lights are flashing during treatment.	The system has detected temperature or pressure levels outside the preset limits.	1. Wait 8 seconds to let the "ABORT" feature withdraw all the fluid from the balloon. 2. Perform a hysteroscopy to rule out any possible patient injury. 3. Return the device for investigation and dispose of the battery.
	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.	

Figure 1. Correct Alarm Pattern

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Actions required by customers and distributors

It is LiNA Medical's responsibility as the manufacturer to ensure that customers who use the ***Customer Quick Reference Guide*** receive this important communication. We therefore request that you read this notice carefully and complete the following actions:

1. Immediately check your internal reference materials to locate the documents listed on the attached business reply form, remove them from their point of use, and scrap to prevent accidental use.
2. Maintain awareness of this communication internally until all required actions have been completed within your facility.
3. Return the enclosed Business Reply Form by email to confirm receipt of this notification about *Customer Quick Reference Guide* segregation.
   - Response is required, even if you may not have physical inventory on-site anymore. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete it even if you no longer have any of the subject material in your physical inventory.
4. Please inform LiNA Medical of any adverse events concerning the use of the subject device and the *Customer Quick Reference Guide.* Please comply with any local laws or regulations concerning the notification of adverse events to your National Competent Authority

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Actions planned by LiNA

LiNA will change the way they distribute the *Customer Quick Reference Guide.* The guide will now be supplied inside the product box, so that the current version will be available at the time of each procedure.

In line with the recommendations of the MEDDEV Guidelines on a Medical Device Vigilance System rev 2.12-1 rev 8, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

We request that you respond to this notice within two weeks from the date of receipt. We appreciate your cooperation, and we recognize the inconvenience this may cause your facility.

If you need any support concerning this notice, please contact the below reference person:
Customer service:
Mail: infomails@lina-medical.com
Quality Improvement Coordinator – Monika Lewandowska:
Mail: mle@lina-medical.com

Business Reply Form

Exhibit A: Acknowledgement Form to FSN-22-001

Please complete and return this Business Reply Form no later than
27th of December 2022
Email the completed form to **mle@lina-medical.com**.

Re: Scrap *Customer Quick Reference Guide* concerned LiNA Librata™

We hereby confirm to having received LiNA Medical ApS's Field Safety Notice of November 28 2022, with instructions to remove the *Customer Quick Reference Guide* from their point of use, and scrap them accordingly.

Please mark "✓" below in ☐ when applicable:

☐ We did not have any Customer Quick Reference Guide in our facility

☐ We have scrapped the Customer Quick Reference Guide

Hospital name:	
Country:	
Street:	
City, State, Zip:	

Form completed by:

Date:	
Printed name:	
Title:	
Signature:	
Email:	