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URGENT FIELD SAFETY NOTICE

Liposuction system EVA SP7

EVA SP7
FSCA-14032018
Device modification

March 14th, 2018

Dear Distributor of EUROMI products or surgeons,

The purpose of this letter is to inform you that EUROMI is sending new fuses for EVA SP7 liposuction system devices.

Details on affected devices:

Device: EVA SP7

Serial number:

SP71702011

SP71701006

SP71603004

SP71602003

Description of the problem and potential risks:

This safety corrective action is initiated due to insufficient fuse power, which could cause the shutdown of the device and liposuction cannot be performed.

The device EVA SP7 does not have sufficient power to achieve proper suction after 30 minutes of intensive use. An error message can appear during liposuction (ERROR 205) and the device cannot be used anymore. If the device stops the surgeon can still perform a manual liposuction.

Advise on action to be taken by the user:

1. The new fuse will be sent to users (or distributors). After receiving the fuse, please make sure that it is not damaged.
2. Carefully read this notification and make sure that the technician who will make the change is well trained (whether by EUROMI company or recognised in the medical device field).
3. Change the fuse according to the method below (please check appendix 2)
4. Complete the form attached in the appendix 1 to acknowledge that the change has been made. Return a scanned copy to materiovigilance@euromi.com
5. Dispose of the old fuse.

Please ensure that all persons within your organization who use the above-mentioned devices and anybody else who needs to know receive this field safety notice.

Please keep this notice at least until the corrective action has been completed.



Contact reference person:

Mélanie KORDAS – EUROMI
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The undersign confirms that this notice has been notified the appropriate Regulatory Agency
We thank you in advance for your complete voluntary collaboration and please accept our apologies for the extra work involved.

If you have any questions, do not hesitate to contact EUROMI.

Best regards,

Mélanie KORDAS
Vigilance manager



APPENDIX 1 ACKNOWLEDGMENT FORM

FSN-14-03-2018

By signing below, I acknowledge that the required actions have been taken in accordance with the Urgent Safety Notice.

Hospital Surgeon Distributor (please check the applicable mention)

Name (in capital letters): _____

Function: _____ Phone: _____

Date: ___/___/_____

Name of Institution: _____

Address of Institution: _____

City: _____

Country: _____

Post Code: _____

Signature :

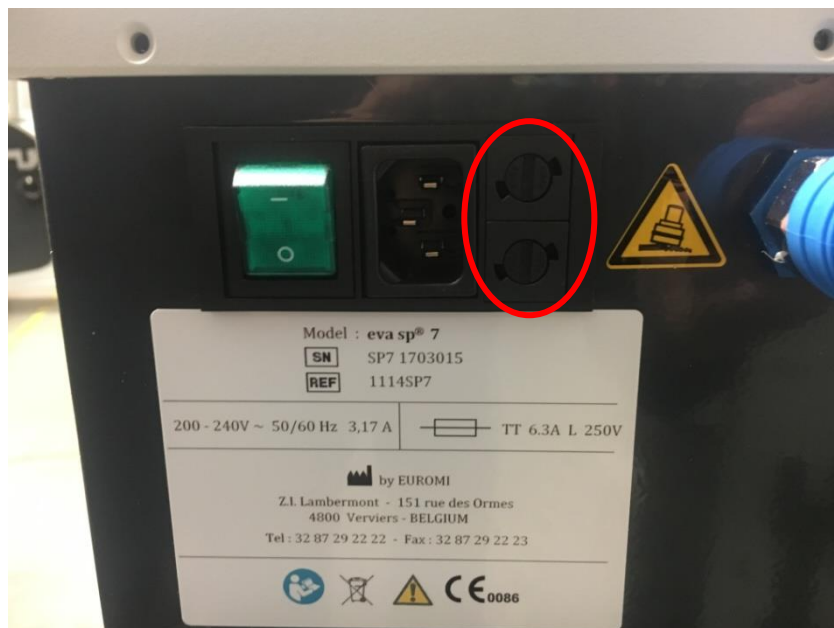
Note: This form must be returned to EUROMI so that we can close this action. It is important that you complete this form and return it to us by e-mail to: materiovigilance@euromi.com

APPENDIX 2 PROCEDURE FOR FUSES CHANGE

You have received a set of 3 fuses:

- 2 fuses of 6.3 Ampere (for the ON/OFF button)
- 1 fuse of 8 Ampere (for the pump)

To replace the fuse for the ON/OFF button, they are directly located at the right of the ON/OFF button, please open the plastic cover and put the fuse of 6.3 Ampere (Total: 2 fuses to be changed).



To replace the fuse for the pump, please open the door located at the back of the device, the fuse holder is located next to the pump under the metal plate. You can directly change the fuse and put the fuse of 8 Ampere (Total: 1 fuse to be changed).

