
Urgent Field Safety Notice

Commercial name of the affected product: **HPR45i**
FSCA-identifier : **F CARE HPR45i**
Type of action : **Recall**

Date: Monday 29th of January 2018

Details on affected devices: *HPR45i probes (all batches)*

HPR45i probes are probes used for the treatment of internal hemorrhoids grade II, III and IV, together with the radio frequency generator EVRF.

This recall only concerns the HPR45i probes and not the radio frequency generator EVRF (which is CE1639 certified). All batches delivered in the past are affected by this recall.

Description of the problem:

The HPR45i probe has no valid CE certificate.

Currently we are not in the possession of a valid CE certificate for this device. The CE technical file has been submitted for approval by our Notified Body, the review process is ongoing.

We have not registered any serious adverse events with these probes. This recall is therefore not being performed due to safety issues but due to invalid CE labeling.

Advise on action to be taken by the user:

- *Identify all affected devices and cease use immediately.*
- *Return all identified devices to the contact indicated below using the F Care Systems account number:
TNT transportation company: 101756 (economy option),
UPS transportation company: W4F304 (standard option).*
- *Confirm receipt of this FSN by completing and returning the acknowledgement form attached to this letter within 48 hours after reception of this document.*
- *Contact details*

Address	F Care Systems Oosteveldlaan 99 2610 WILRIJK
Phone	+32 (0)3 4515145
Email	info@fcaresystems.com

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

For any enquiries about the F CARE HPR45i FSN contact:

F Care Systems NV
Rudi Devers
Oosterveldlaan 99
2610 Wilrijk – Belgium.
info@fcaresystems.com

Sincerely,

(signature)



Rudi Devers,
(function within the company)



Acknowledgement Form

This Letter acknowledges receipt of the Field Safety Notice related to HPR45i probes

Recall FSCA-identifier: F CARE HPR45i

(Please check as appropriate)

- ☐ Yes, I have received the FSN
- ☐ Yes, I have/will return the affected devices

Please list the Batch numbers and Quantities of affected devices to be returned:

Name of customer: _____

Address: _____

Place and Postal Code: _____

Country: _____

Date and Signature: _____