
Urgent Field Safety Notice

Commercial name of the affected product: **FISTURA catheter**
FSCA-identifier : **FSCA-1**
Type of action : **Update of Instructions For Use**

Date: Wednesday 5th of April 2023

Details on affected devices: *FISTURA catheters type 6F, 7F, 8F, 9F (all batches)*

FISTURA catheters are sterile invasive radiofrequency ablation catheters used for treatment of anal fistula.

This field safety notice involves an update of the instructions for use to inform users of new warnings and potential side effects.

Description of the IFU update:

The 'warnings' chapter in the IFU has been expanded with the following information:

Substances used to clean the fistula tract must be removed as much as possible before starting the Fistura treatment. Alcohol based substances are forbidden, Natrium and Iodine based substances should be avoided as they can change the electric behaviour of the energy coming from the Fistura catheter. Abide the treatment protocol as applying excessive energy can lead to tissue necrosis.

The 'Possible side effects and complications' chapter in the IFU has been expanded with the following side effect: tissue necrosis

Advise on action to be taken by the user:

- *Read updated instructions for use (revision 06), see attachment.*
- *Remove the IFU of any unused Fistura catheters and replace it with the new revision (06)*
- *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*

<i>Address</i>	<i>F Care Systems Uitbreidingstraat 42-46 2600 Berchem</i>
<i>Phone</i>	<i>+32 (0)3 4515145</i>
<i>Email</i>	<i>steven.mertens@fcaresystems.com</i>

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 this FSN contact:

F Care Systems NV
Steven Mertens
Uitbreidingstraat 42-46
2600 Berchem – Belgium.
steven.mertens@fcaresystems.com

Sincerely,

(signature)

Rudi Devers,
(function within the company)

Acknowledgement Form

This Letter acknowledges receipt of the Field Safety Notice related to Fistura catheters

FSCA-identifier: FSCA-1

(Please check as appropriate)

- Yes, I have received the FSN
- Yes, I have/will replace the IFU in the affected devices
- I currently do not have any Fistura catheters in stock.

Name of customer: _____

Address: _____

Place and Postal Code: _____

Country: _____

Date and Signature: _____