FSN Ref. FSN-MCC-2026
FSCA Ref: FSCA-MCC-2026

Date: 2026-03-05

Urgent Field Safety Notice

For Attention of*: name of distributor or local branch

Contact details of local representative (name, e-mail, telephone, address etc.)
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

The purpose of this Field Safety Notice is to communicate that Life Vascular Devices Biotech, S.L. has decided to implement a voluntary Field Safety Corrective Action in order to assure the safety of the patients.

We have detected a potential risk affecting the product:

Microcatéter coronario iVascular navitian

Product issue

- Potential risk:

  Deterioration of the outer layer of the thinnest distal segment of the device, which could lead to the loss of small fragments of material.

- Potential risk situations:

  Extremely calcified lesions

- Potential risk to the patient:

  The loss of small fragments of material could cause distal embolization, although no incidents have been reported to us.

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Products affected:

COMERCIAL NAME	CATALOGUE NUMBER	UDI-DI
NAVITIAN	MCCC14135001	08435387311012
NAVITIAN	MCCC14150001	08435387311029

All lots currently on the market.

Description of the safety corrective action:

Recall: *Life Vascular Devices Biotech, S.L*. or its distributor will be responsible for the removal of the affected products from the hospital.

Actions to do by the impacted distributor / local branch:

1. Immediately check your internal inventory for affected devices.
2. Segregate the affected devices in a secure location for return to Life Vascular Devices Biotech S.L.
3. Read this notice carefully and provide it to any relevant person in your organization
4. Send this Field Safety Notice to all health centres where any of the subject devices have been distributed.
5. Return the attached completed response form.

Response form

To complete the security corrective action, we need your cooperation. Please complete the attached form with the requested information and send it to the following e-mail address within 10 calendar days of receipt. Our aim is to complete the removal by 30.03.2026 and we need your response in time to meet this objective.

vigilance@ivascular.global

In line with the requirement of the Regulation (EU) 2017 /745 on medical devices (MDR), we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

We want to thank you for your cooperation in completing this action and regret any inconvenience that it may cause. If you have any questions or would like assistance regarding the content of this letter, please contact your usual representative of the company that supplies you with the devices concerned in your institution.

Yours sincerely,

M. Eugenia Villanueva
PRRC – Vigilance System Manager

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CUSTOMER REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number*	
FSN Date*	
Product/ Device name*	
Product Code(s)	
Batch/Serial Number (s)	

2. Customer Details	
Healthcare Organisation Name*	
Department/Unit	
Address	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Comments:
☐	I performed all actions requested by the FSN.	Comments:
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Comments:
☐	I have returned affected devices - enter number of devices returned and date complete.	Comments:
☐	No affected devices are available for return/ destruction	Comments:
☐	Other Action (Define):	Comments:
☐	I do not have any affected devices.	
☐	I have a query please contact me (e.g. need for replacement of the product).	Comments:
Print Name*		
Signature*		
Date*		

4. Return acknowledgement to the sender	
Email	
Customer Helpline	
Deadline for returning the customer reply form*	

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.