FSN Ref. FSN-DSP18-2024-manfufacturer
FSCA Ref: FSCA-DSP18-2024

Date: 16-JUL-2024

Urgent Field Safety Notice

iVascular sergeant 18

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 that affect to the product:

Peripheral support catheter *iVascular sergeant 18* **(ref. DSP18)**

Product issue

- Potential risk:

  Deterioration of the distal outer layer of the device could lead to the loss of small pieces of material.

- Potential situations of risk:

  When used multiple times during the procedure or when crossing heavily calcified lesions

- Potential risk for the patient:

  Loss of small pieces of material could result in distal embolization, although we have not been notified of any incidents

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Products affected:

COMERCIAL NAME	CATALOGUE NUMBER	UDI-DI
SERGEANT	DSPC18065001	08435387310619
SERGEANT	DSPC18090001	08435387310626
SERGEANT	DSPC18130001	08435387310633
SERGEANT	DSPC18150001	08435387310640
SERGEANT	DSPC18065002	08435387310732
SERGEANT	DSPC18090002	08435387310749
SERGEANT	DSPC18130002	08435387310756
SERGEANT	DSPC18150002	08435387310763

Lots manufactured before than: 2024-05-14 according to information on the label.

Description of the safety corrective action:

Product recall and substitution: Life Vascular Devices Biotech, S.L. or its distributor will be responsible for the removal and replacement of the affected products from the hospital. The product replacement will be done once the corrective measures will be implemented.

Actions to do by the impacted distributor / local branche:

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 30.09.2024 and we need your response in time to meet this objective.

vigilance@ivascular.global

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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 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,

Mª Eugenia Villanueva
PRRC – Vigilance System Manager