FSN Ref: **FSN-2023-03** Date: 02.11.2023

Field Safety Notice

Nit-Occlud® Lê VSD from the manufacturer pfm medical mepro

Dear Customer,

This letter is to inform you of a field safety corrective action (reference no. **FSN-2023-03**), initiated by the manufacturer pfm medical mepro for the affected products: **Nit-Occlud® Lê VSD**.
The competent national authorities have been informed about the field safety corrective action.

All information on the affected reference numbers and lots can be found in this FSN.

Mailing of this Field Safety Notice

Please forward this notice to all users of the affected products and inform all customers who have received affected products.

1. FSN Type

This is a newly issued field safety corrective action.

2. Information on affected products

2.1. Product Type(s)

Product type	Intended use
Nit-Occlud® Lê VSD	Interventional closure of hemodynamically significant ventricular septal defects using catheter techniques. Ventricular septal defects are considered hemodynamically significant if transthoracic echocardiography shows enlargement of the left heart chambers.

The products are packed individually in sterile packaging.

2.2. Manufacturer Information

Manufacturer of affected products:

pfm medical mepro gmbh
Am Söterberg 4
66620 Nonnweiler-Otzenhausen
https://www.pfmmedical.com

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2.3. Primary clinical use of the product(s)

The Nit-Occlud® Lê VSD is intended for closure of ventricular septal defects. It is a permanent implant, introduced into the ventricles by means of minimally invasive catheter technology. The coil is made of nitinol, a material with shape memory characteristics, and in its relaxed state it adopts to the form of a cone. To accelerate clotting and reduce the closure time, polyester threads are tied to the distal coil surface, with the largest windings. The Nit-Occlud® Lê VSD coil is available in different sizes to provide optimum closure for a wide range of VSDs. The appropriate patient population is determined by the treating physician, taking into account the contraindications. The Nit-Occlud® Lê VSD coil system consists of two main components: the coil itself and a delivery system with a single-use handle including implantation catheters.

2.4. Affected Articles

The following articles and batches are affected by the safety measure. The affected batches were delivered to you starting in July 2022.

REF	Product description	LOT(s)	Serial number(s)
149086V1	Nit-Occlud® Lê VSD	1038137	68, 70, 71, 72, 67, 66, 65
149106V1	Nit-Occlud® Lê VSD	1036484	74, 75, 81, 79
149128V1	Nit-Occlud® Lê VSD	1036286	48, 46, 52, 53

3. Reason for the field safety corrective action (FSCA)

3.1. Description of product problem

The manufacturer pfm medical mepro has identified a material problem in the handle of a currently manufactured VSD batch, which is being investigated more closely from a risk perspective. Due to a defective component in the handle, the release mechanism may be impaired.

3.2. Background of the situation

During the production of a currently manufactured VSD batch, a material problem was detected in a component involved in the release mechanism. This component was subsequently investigated, and it was confirmed that this component does not achieve the required tensile strength in some cases.
The component is partly responsible for the connection between the release mechanism on the implant and components in the handle. In the release mechanism, this component is responsible for retracting the wire to which the implant is attached, allowing the implant to be released.
If the component is damaged, the user can still operate the release mechanism, but the required connection to the implant is missing.

3.3. Risk for patient/user or third person

Due to the fact that the system may not work properly, problems with the release of the coils may occur during implantation. Premature uncontrolled release due to the damaged component is not possible because of safety precautions in the system (safety pin, general design of the product).

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During the release process with a damaged component, the implant may detach during retrieval or may not be released at all.
There is no risk for products that have already been implanted as the fault only affects the release process.
So far, no incident has occurred regarding this problem.

3.4. Measures taken by health organisation

Please take the following actions immediately for the affected products and return the attached FSN response form to us within the specified time.

- Inform all users and customers who have received affected batches;
- Return the products from the affected batches to us;
- Document the activities on the FSN Response Form and return it to us.

3.5. Measures taken by manufacturer

The manufacturer has taken measures to prevent a recurrence of the defect.
You will receive replacement goods for the returned products.

4. List of annexes/attachments

- FSN Response Form

Signature:

02.11.2023 09:17:58
i.V. Katja Richter
Regulatory Affairs Manager (PRRC)

02.11.2023 09:25:45
i.V. Hartmut Simon
Head of Quality Management