


Standard	FB	Field Safety Notice				
Number	0108	Revision Index	00	Effective date	2019-11-01	Page 1 / 4

FSN Ref: FSN-2026-01 Translation

Field Safety Notice (FSN)

Multi-Snare® of the manufacturer pfm medical mepro gmbh

Dear Customer,

This letter is to inform you of a field safety corrective action (reference no. FSN-2026-01), initiated by the manufacturer pfm medical mepro for the affected product Multi-Snare®.

The competent national authorities have been informed about the field safety corrective action.

All further 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 Notice.

2. Information on affected products

2.1. Product type(s)

Product type	Intended use
Multi-Snare®	The Multi-Snare® is intended to manipulate and retrieve foreign bodies or strip fibrin sheathing in the vascular system or hollow organs.

The products are packed individually in sterile packaging.

2.2. Manufacturer Information

Manufacturer of the affected products:

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

Standard	FB	Field Safety Notice				pfmmedical
Number	0108	Revision Index	00	Effective date	2019-11-01	Page 2 / 4

FSN Ref: FSN-2026-01 Translation

2.3. Primary clinical use of the product(s)

The Multi-Snare® is a medical device intended to manipulate and retrieve foreign bodies or strip fibrin sheathing in the vascular system or hollow organs.

Please note that manipulation includes but is not limited to the following:

- Removal of foreign objects
- Assistance in creating loops where cross-over technique is applied.
- Assistance in performing venipuncture to obtain access to central vein.
- Repositioning of indwelling venous catheters.
- Fibrin sheath stripping of an indwelling venous catheter.

The Multi-Snare® device is intended for transient use which means that they are normally intended for use for less than 60 minutes but generally in 30 minutes or less.

The Multi-Snare® medical device includes a retrieval snare, a snare catheter, an insertion aid to ease the guidance of the snare into the catheter and a torquer to ease the handling of the product (see figure 1 below).

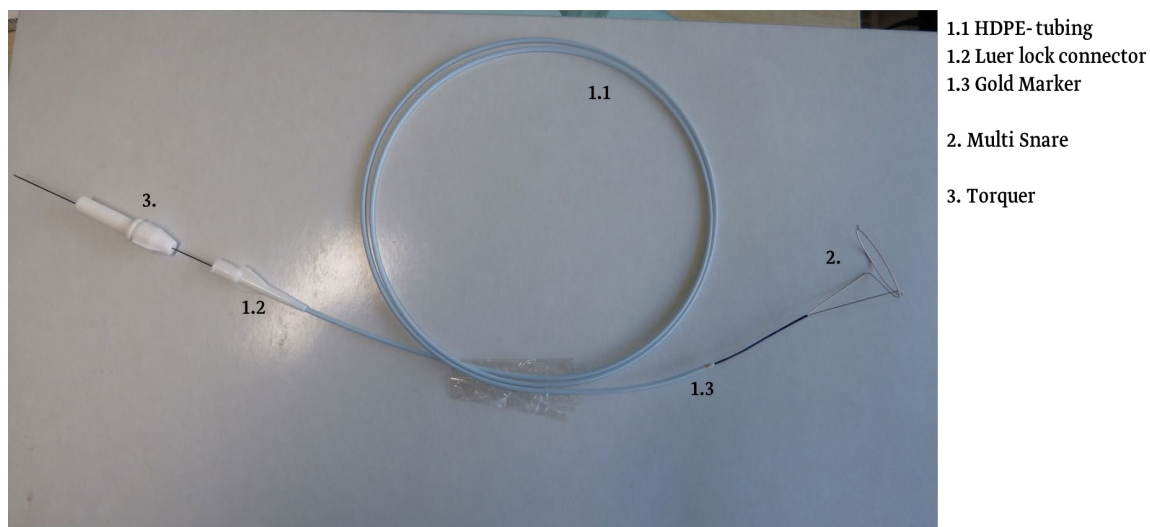



Figure 1. Photographic image of the complete Multi-Snare® product

The affected parts of the device are the snare catheter and the luer lock (1.1 and 1.2 in the image above). The catheter consists of a HDPE tubing with an atraumatic tip. At its proximal end, the snare catheter is provided with a Luer connector to which the insertion aid can be connected.

2.4. Affected products

The following articles and batches are affected by this safety measure.

REF	Product description	LOT Numbers
147305	Multi-Snare® 5 mm (5-8) 125 cm 4 F 105 cm	1050150, 1049868, 1050305
147310	Multi-Snare® 10 mm (10-15) 125 cm 4 F 105 cm	1049960, 1050205, 1049922
147320	Multi-Snare® 20 mm (20-30) 125 cm 6 F 105 cm	1050207
147330	Multi-Snare® 30 mm (30-40) 125 cm 6 F 105 cm	1050307

Standard	FB	Field Safety Notice				
Number	0108	Revision Index	00	Effective date	2019-11-01	Page 3 / 4

FSN Ref: FSN-2026-01 Translation

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

3.1. Description of product problem

During a biocompatibility assessment, it was determined that the Multi-Snare® catheter (catheter tubing with a Luer-Lock connector) does not meet the biocompatibility requirements for in vitro cytotoxicity for one of the tested laboratory parameters.

3.2. Background of the situation

The non-conformity was identified during a review of documentation. Specifically, in post-market specification testing, it has been determined that the snare catheter failed to meet one of the biocompatibility requirements; with laboratory results finding that one of the conducted test parameters failed to meet the requirements for in-vitro-cytotoxicity.

It should be noted that all of the other present biocompatibility test results for the snare catheter were within the requirements, i.e. the results for irritation or intracutaneous reactivity, coagulation and haemocompatibility were all within the acceptable parameters.

3.3. Risk for patient and or device user

Most interventional procedures requiring use of the Multi-Snare® device are completed in approximately 30 minutes, often within 15 minutes. This underscores the very brief period of potential patient exposure.

For the primary indication, “removal or manipulation of a foreign body in the vascular system,” the snare catheter is to be used within a guide catheter or introducer in accordance with the instructions for use. In such cases there is no direct contact with the patient’s vascular system and therefore presents no discernable risk to the patient.


Nonetheless, it is possible that the snare catheter can potentially be in direct contact with a patient’s vasculature when used without a guiding catheter; for example, in instances where fibrin stripping is necessary. In such cases, it is not known or anticipated that there have been or will be any discernable adverse impacts for a patient; however, it is not possible to definitively state that there is absolutely no potential of any adverse effects arising from brief vasculature exposure to the catheter component of the affected Multi-Snare® devices.

Therefore, treating physicians who have used the affected product during a procedure on a patient without a guide catheter or introducer should be informed of the potential safety risk associated with the snare catheter, which was found to be mildly cytotoxic in extensive laboratory testing to determine compliance with biocompatibility requirements.

3.4. Field actions to be taken

Please take the following actions immediately for the affected Multi-Snare® devices and return the attached FSN response form to pfm medical mepro gmbh within the specified time.

- Inform all customers (hospitals and clinics) and device users (physicians) who have received or used affected batches;
- Return devices from the affected batches to the local distributor or directly to pfm medical mepro gmbh (the manufacturer);
- Document the activities on the FSN Response Form and return it to pfm medical mepro gmbh, as soon as practicable.

Standard	FB	Field Safety Notice				
Number	0108	Revision Index	00	Effective date	2019-11-01	Page 4 / 4

FSN Ref: FSN-2026-01 Translation

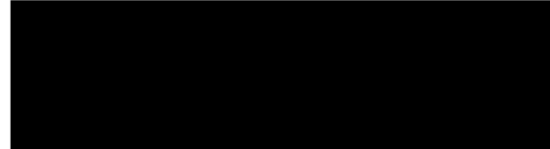
3.5. Actions taken by manufacturer

- The manufacturer has ceased production and distribution of the affected device and is undertaking actions to prevent a recurrence of this issue.
- Customers will receive a refund or a credit note for the affected products.

4. List of annexes/attachments

- FSN Response Form

Signature:



Date: 2026-04-14