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Field Safety Notice 07-2017-01

19th of July, 2017

Recall Nit-Occlud® Implantation Sheath

Dear Customer,

This letter is to inform you of a Field Safety Corrective Action initiated by pfm medical mepro gmbh, a wholly owned subsidiary of pfm medical ag.

Reason for Field Safety Notice

pfm medical ag has received feedback from the outside European community that in individual cases the atraumatic tip (Soft Tip) of the Nit-Occlud® Implantation Sheath detached during preparation and application under incorrect storage conditions (discoloration of the sterile packaging).

We have not received any information so far that the products have quality problems when properly stored and used. However, due to the high potential risk of detachment, we decided to recall the following batch numbers as a precaution in order to investigate them systematically.

List of affected batch numbers:

Product	REF	LOT
Implantation Sheath, 10F, 45°, 80cm	004580	1019089, 1019694, 1013727.01, 1015688, 1016084, 1018175, 1019897, 1020210, 1019435, 1014158.01, 1014604.01, 1018914, 1016125, 1018247, 1018118
Implantation Sheath, 12F, 45°, 80cm	204580	1018948
Implantation Sheath, 12F, 45°, 80cm	204580	1018119, 1015026.01, 1018173, 1018442, 1016846, 1016126, 1019837, 1018947, 1014281.01
Implantation Sheath, 14F, 45°, 80cm	404580	1019861, 1015043.01, 1019773, 1018174, 1018954, 1018120, 1012897.01, 1015909, 1016847
Implantation Sheath, 6F, 45°, 80cm	604580	1018170, 1020591, 1013884.01, 1016236, 1018121, 1018221, 1012896.01, 1018974, 1018980
Implantation Sheath, 8F, 45°, 80cm	804580	1018972, 1019325, 1018950, 1018220, 1018248, 1013729.01, 1014670.01, 1018951, 1020094, 1015907, 1016849, 1018440, 1018976, 1020593, 1018122, 1019866, 1016129
Implantation Sheath, 9F, 45°, 80cm	904580	1013730.01, 1013893.01, 1014358.01, 1018952, 1018215, 1018973, 1014605.01, 1016083, 1016466, 1018123, 1015908, 1020594, 1019326, 1018213, 1018214, 1018430, 1018977

Risk to Health

The sheaths are being used to get access to the vessel system. Particles from the tip of the sheath therefore might embolize in the vessel system and as a result impede or stop the blood flow. Particles in the venous system could cause a pulmonary embolism or thrombosis. Embolizing particles in the arterial system could possibly result in infarction on all organ systems with tissue death (necrosis) and could result in heart attack and stroke.

This can in the worst case lead to irreversible organ damage up to death.

Required actions for you and your Healthcare Facility

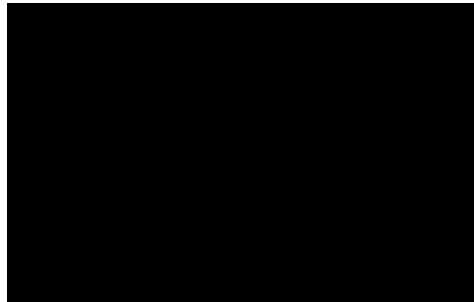
- Please check your stock for the specified product code(s) and lot number(s) of Nit-Occlud® Implantation Sheaths (see attached FSCA questionnaire). Please discontinue use, isolate, label and quarantine any stock to prevent continued use.
- Pass this Field Safety Notice to all clinical personnel involved with the use of Nit-Occlud® Implantation Sheaths.
- Ensure the contents of this Field Safety Notice are understood by the associated personnel.
- If you have distributed this product further, please immediately notify your customers and forward this Field Safety Note.
- Complete the attached [FSCA questionnaire](#) and fax or send per Email to:

pfm medical ag • Abteilung: Customer Solutions
Wankelstr. 60 • D-50996 Köln
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Note: It is extremely important that we receive the signed questionnaire.

Before sending back the goods please contact our customer solutions and pfm medical will arrange the return of the goods. pfm medical will contact you soon regarding the credit note and replacement.

We appreciate your cooperation and assistance in dealing with this matter and sincerely apologize for any inconvenience that may result from this action.



Attachments: - 1x Field Safety Corrective Action (FSCA) Questionnaire - pfm medical ag