Urgent Field Safety Notice (FSN)

Manufacturer Information

Name		Single Registration Number (SRN)
EPflex Feinwerktechnik GmbH		DE-MF-000005425

Recipients of this Field Safety Notice:

All distributors who have received the affected products.

1. Information about the affected products	
1.1	**Product type(s)**
	The products are guidewires for peripheral applications. The products are supplied sterile.
1.2	**Product name**
	See product list in Annex I
1.3.	**Basic UDI-DI**
	42556056gwcIIaFP
1.4	**UDI-DI**
	See product list in the Attachment
1.5	**Intended purpose of the product**
	The guidewires are intended to facilitate the introduction and placement of diagnostic or therapeutic medical devices in peripheral blood vessels or hollow organs of the human body during endoscopic or interventional procedures.
1.6	**Catalogue number**
	See product list in Attachment I
1.7	**Affected LOTs**
	See product list in Attachment I

2. Reason for the Field Safety Corrective Action (FSCA)	
2.1	**Description of the product problem**
	The sterile packaging of the products failed the microbial barrier test after five years of real-time aging. Therefore, there is no evidence that the sterile packaging can maintain product sterility over a shelf life of five years.
2.2	**Hazard that triggered this FSCA**
	Sterile packaging must maintain a product's sterility throughout its entire shelf life. If it does not, there is a risk that a non-sterile product may be used. This may lead to infections in patients.
2.3.	**Probability of occurrence of the problem**
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3. Type of action to mitigate the risk			
3.1	**Actions to be taken by the user / customer** ☒Identify the affected products ☒Quarantine the affected products ☒Return the affected products ☒Complete the enclosed customer response form and return it within the specified period ☐Other		
3.2	**Is a response from the customer required?** The customer response form is enclosed.	☒Yes	☐No
3.3.	**Actions to be taken by the manufacturer**		
	Recall the affected products from the market.		

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4. General information	
4.1	FSN-Type
	☒Initial FSN ☐Follow-up FSN
4.2	For a follow-up FSN, provide the ID number and date of the previous FSN
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4.3.	Further information or information already expected in a follow-up FSN?
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4.4	The competent authority in your country has been informed of this customer notification.

Transmission of this Field Safety Notice (FSN)
This Field Safety Notice must be forwarded to all persons within your organization who need to be made aware of it, and to any organization to which the potentially affected products have been distributed. Please forward this notice to any other organization affected by this action. Please retain this notice and records of the actions taken for an appropriate period to ensure the effectiveness of the corrective action.

Contact person
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