
Urgent Field Safety Notice
Concerning

Guidewire MR-Guide SFC-PTFET-150/14-035-klar-Platin-croco-steril
Guidewire MR-Guide SFC-PTFET-260/14-035-klar-Platin-croco-steril

28.06.2019

Sender:

EPflex Feinwerktechnik GmbH
Im Schwöllbogen 24
72581 Dettingen / Erms
Germany

Addressee:

Customers who received the identified guidewires

Identification of the affected medical devices:

REF: 47012190

LOT: 91703053

REF: 47012190

LOT: 91704795

REF: 47012202

LOT: 91800416

REF: 47012202

LOT: 91704794

Description of the problem including the determined cause:

EPflex Feinwerktechnik GmbH as a manufacturer of guidewires for various medical applications is aware of its responsibility for the safe and effective use of its products for the benefit of patients and users.

For this reason, we inform all customers who have received one of the product samples of MR-guidewires listed above about a missing instruction for use (IFU):

The delivered products of the above mentioned Lots do not contain instructions for use.

Which actions must be taken by the addressee?

- Read these safety instructions carefully.
- Please check your stock for these products and block all available products.
- Please return all products to EPflex Feinwerktechnik GmbH, which are still in your stock.
- Confirm receipt of this safety information and return the attached document to EPflex Feinwerktechnik GmbH.

Others actions (if applicable):

- Please send us an overview of all affected products delivered to end customers.
- Please inform the end customer of this safety information and arrange for the affected products to be returned from stock, if available.

Passing on the information given here:

Please make sure within your organization that all users of the above mentioned devices as well as any other personnel who must be informed have been made aware of this **Urgent Field Safety Notice**. In case you have provided these devices to third parties, please forward this Field Safety Notice also to them or inform the contact person stated below.

Please keep this notice at least until the action has been completed.

A copy of this "Urgent Field Safety Notice" has been provided to the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM).

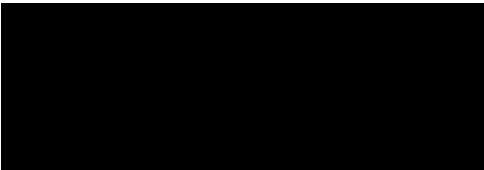
Contact person:

Dr. Wolfhard Pinkowski

Safety Officer

Tel.: +49 (0) 7123 9784 67

Mobile: +49 (0) 170 3424321



Dr. Wolfhard Pinkowski

Safety Officer according to § 30 MPG (German Medical Devices Act)

Reply Form

Herewith I confirm, that I received and understood the urgent Field Safety Notice about the missing IFU in the delivered product samples of MR-guidewires.

We have controlled our internal warehouse regarding the affected devices with the following result:

List of affected products

REF	LOT	Quantity	Delivery Date	Products available	Returned to EPflex	used/ scraped
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>
					<input type="checkbox"/>	<input type="checkbox"/>

Name: _____

Company/Organisation: _____

Date: _____

Signature of representative of company/hospital/applicant

Please return this form to EPflex:

Email: sicherheitsbeauftragter-mpg@epflex.com

Fax: +49 (0) 7123 9784-66

Please contact us before returning the quarantined goods. Tel.: +49 7123 9784 52