

**Urgent Field Safety Notice –
Address**

Sales Division
Sales Division

Lohmann & Rauscher GmbH & Co.KG
Westerwaldstr. 4 · D-56579 Rengsdorf
Kurzz. Tel.: 99-XXXX/ Fax: 99-XXXX
Email: xxx.xxxx@de.LRmed.com

Date

**Urgent Field Safety Notice
due to defective Redon Bottle of pfm medical mepro (in Kitpack procedure packs)**

Dear Sir or Madam,

Today we would like to inform you about the precautionary product recall of defective Redon Bottle of pfm medical mepro (in Kitpack procedure packs) based on a recall of pfm with its products. (see enclosure: FSN of pfm medical mepro)

The products and batches affected by this defect were immediately quarantined in our warehouse.

If the Redon bottles do not work properly without being noticed, the patient may experience secondary symptoms such as pressure pain or shortness of breath.

Since the pfm products are part of the Kitpack procedure packs delivered to you, the following measures must be taken in the interest of patient safety:

Please do not use the affected pfm products from the Kitpack procedure packs and please discard these products before use in the operating theatre.

In order not to endanger the operation and to maintain direct patient care, we will label the Kitpack procedure packs still in stock with the following additional information:

"Attention: Please do not use the included Redon bottle. Please discard."

The other components of the respective Kitpack procedure packs are not affected by this recall and can be used as usual.

The products will, of course, be exchanged free of charge or credited on request.

Please ensure in your organisation that all users of the products listed below and other persons to be informed are aware of this Urgent Field Safety Notice and return the enclosed confirmation to us completed.

If you have passed on the products to third parties, please forward a copy of this information to them.

We thank you in advance for your cooperation and apologize for any inconvenience.

With best regards,

Lohmann & Rauscher GmbH & Co KG

i.V. / On behalf of

i.V. / On behalf of

XXXXYY
Sales department

XXXXYY
Regional Vigilance Officer

Attachment:

- 1) Urgent Field Safety Notice due to defective Redon Bottle of pfm medical mepro (in Kit-pack procedure packs)
- 2) FSN of pfm medical mepro

Enclosure 1

Urgent Field Safety Notice!

Date

due to defective Redon Bottle of pfm medical mepro (in Kitpack procedure packs)

(via Fax to 02634 - 99 xxxx)

Sender: Lohmann & Rauscher GmbH & Co. KG
Westerwaldstr.4
D-56579 Rengsdorf

Addressee: Adresse
Xxx
xxx
& all users who use the below mentioned products.

Description: Field Safety Notice due to defective Redon Bottle of pfm medical mepro (in Kitpack procedure packs)

Table should be adapted to the respective customer

If necessary, name sales contact person

Corrective Actions:

Please do not use the affected products in the Kitpack procedure packs anymore.

Please inform all employees who use the products about this Field Safety Notice and confirm that you are not using the affected products

The undersigned confirms (please tick as appropriate)

- that they will not use the affected products from the Kitpacks,
- that they have informed all persons involved about this important information,
- that they no longer possess the mentioned products,
- that they have not sold the mentioned products to third parties,
- that they have informed third parties, if they have received the mentioned products from them, of the Field Safety Notice and non-use of the affected products from the Kitpack procedure packs.

Please name a contact person in your company:

Contact Person for Lohmann & Rauscher within your facility:

Name	Function
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Telephone number	Email
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*Lohmann & Rauscher will get in touch with the named contact person

Adaption on the customer orders

Please enter the products with quantity in the following table:

REF	Product	Lot number (batch)	Quantity
XXX	Kitpack procedure packs		

Customer address data, signature

Date / Signature : _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____