

INNOTERE GmbH
Meissner Str. 191 · 01445 Radebeul · GERMANY

Distributor and
Direct customers of INNOTERE

Date
Radebeul, 15th Januar 2020

Field Safety Notice (FSN)

- user information for a corrective measure in the field -

Sender: Dr. Sophie Rößler

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E-Mail: qualifiedperson@innotere.de

Address: All distributors and direct customers of INNOTERE who have received deliveries of the products concerned based on the traceability of sales data in the ERP system.

Identification of the medical devices concerned:

Product family: Paste-CPC
Product description: Self-setting synthetic bone graft substitute for filling of non-infected bone defects
Trade names: see table in the response form of this FSN
Product number (REF): see table in the response form of this FSN
Batch number (LOT): see table in the response form of this FSN

Dear users and customers,

we hereby inform you about an field safety notice on the dosage of Paste-CPC.

Due to new scientific findings on the excipient used in Paste-CPC, polyoxyl-35-castor oil, we recommend a dose limit for Paste-CPC.

New dose limit for Paste-CPC

The implanted amount of 6 g (3 ml) Paste-CPC must not be exceeded for a child during surgery.

The implanted amount of 42 g (21 ml) Paste-CPC must not be exceeded for an adult during surgery.

For polyoxyl-35-castor oil, very rare cases of allergic reactions and anaphylactic shock have been described in the literature. This information is already included in the instructions for use (IFU) of Paste-CPC. However, an expert opinion available to INNOTERE describes a possible dose-dependent reaction to this excipient. For this reason, the IFU will be extended by the indication of a corresponding dose limit for Paste-CPC.

Risks to patients, users and third parties when the product has already been used and/or during further use of the product, including risk assessment

Since local intolerances or anaphylactic reactions have not been observed from animal experiments or since the market launch 11/2014, the risk to the patient is considered very low.

In case of patients treated with an affected product immediately before receiving this safety information and who were treated with a dose above the recommended dose, the treating physician should be aware of the possible risks and should closely observe the patient immediately after surgery. There is no risk to patients already treated with any of the affected products and in whom no local intolerance or anaphylactic reactions have been observed. No special aftercare is necessary.

Provided that the field safety notice for the dose limitation of Paste-CPC is taken into account, the use of Paste-CPC is safe.

Measures:

If you are a user of Paste-CPC, INNOTERE would like you to perform the following actions:

1. Please check whether you are a user of one or more of the listed products using the table in the response form. Identify all products affected in your facility and ensure that all users have received and do consider the safety information. The article number and the production lot can be found on every product package.
2. Please fill in the enclosed response form and send it to the indicated fax number, Email address or postal address until 29.02.2020. We would like to ask you to answer us even if you do not have any affected products on stock. This allows us to make sure that you received this information.

If you are a distributor of Paste-CPC, INNOTERE would like you to perform the following actions:

1. Please check whether you distributed or are distributing one or more of the listed products using the table in the response form. Identify all products affected in your facility and ensure that all users have received and do consider the safety information. The article number and the production lot can be found on every product package.
2. Please confirm to INNOTERE that you have informed your customers about the field safety notice. Please also confirm that your customers have read and understood the field safety notice until 29.02.2020.

Dissemination of the information described herein:

Please make sure that all users of the above-mentioned product lots and any other person, who needs to be informed in your institution, are notified of this field safety notice. Please retain this information. The German Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this field safety notice.

Contact person:

Dr. Sophie Rößler
Tel.: +49 351 2599 9410
Mobil: +49 176 650 160 07
Fax: +49 351 2599 9429
E-Mail: qualifiedperson@innotere.de

We apologize for any inconvenience this recall may cause.

Yours sincerely,
INNOTERE GmbH

Annex: Response Form

Response Form

for the maintenance, knowledge and comprehensibility of the instructions for dose limitation of
 Paste-CPC

REF	Trade name	Size	LOT
LC1003	Calcifix	3ml	198-014-CX
111VX2	INNOTERE Paste-CPC	3ml	190-009-IP
111VX2	INNOTERE Paste-CPC	3ml	193-011-IP
111VX2	INNOTERE Paste-CPC	3ml	198-015-IP
111VX2	INNOTERE Paste-CPC	3ml	207-016-IP
111VX2	INNOTERE Paste-CPC	3ml	207-017-IP
111VX2	INNOTERE Paste-CPC	3ml	208-018-IP
111VX2	INNOTERE Paste-CPC	3ml	209-019-IP
111VX2	INNOTERE Paste-CPC	3ml	220-020-IP
111VX2	INNOTERE Paste-CPC	3ml	221-021-IP
111VX2	INNOTERE Paste-CPC	3ml	224-022-IP
111VX2	INNOTERE Paste-CPC	3ml	239-030-IP
111VX2	INNOTERE Paste-CPC	3ml	240-031-IP
111VX2	INNOTERE Paste-CPC	3ml	241-034-IP
211IP1	INNOTERE Paste-CPC	1ml	236-024-IP
211IP1	INNOTERE Paste-CPC	1ml	242-036-IP
231IP1	INNOTERE Paste-CPC	3x1ml	236-025-IP
231IP1	INNOTERE Paste-CPC	3x1ml	240-032-IP
231IP1	INNOTERE Paste-CPC	3x1ml	242-035-IP
211IP2	INNOTERE Paste-CPC	0,5ml	235-037-IP
311IP1	INNOTERE Paste-CPC	12ml	236-027-IP
311IP1	INNOTERE Paste-CPC	12ml	232-028-IP
311IP1	INNOTERE Paste-CPC	12ml	235-038-IP
311IP2	INNOTERE Paste-CPC	6ml	236-026-IP
311IP2	INNOTERE Paste-CPC	6ml	244-039-IP
111VX2	VELOX	3ml	189-008-VX
111VXE	VELOX	3ml	239-029-VX
111VXE	VELOX	3ml	242-033-VX
111VXE	VELOX	3ml	250-040-VX

With our signature we confirm the receipt, knowledge and comprehensibility of the field safety notice on dose limitation of Paste-CPC. We will keep a copy of this letter for our records.

We have no products of these batches in stock.

COMMENTS:

Distributor / Institution:

Name in print:

Tel. Number:

Date / Signature / Stamp:

Please return this signed response form by 29.02.2020 via Fax, Email or mail to:

Fax Number: +49 351 2599 9429

E-Mail: qualifiedperson@innotere.de

Postal Address: INNOTERE GmbH, Meissner Str. 191, 01445 Radebeul, Germany