INNOTERE GmbH
Meissner Str. 191 · 01445 Radebeul · GERMANY

User,
Chief physician, Surgery management,
Clinical director,
Distributor

Date:
Radebeul, 9th September 2019

Important Safety Information
Product Recall
concerning
INNOTERE Paste-CPC, 3 cc
Lot number 232-023-IP

Dear *INNOTERE Paste-CPC user*,
Dear Sir or Madam,

With this letter, INNOTERE GmbH would like to inform you about a product recall of the above-mentioned lot of INNOTERE Paste-CPC.
INNOTERE is performing this recall as usability of Paste-CPC for minimally invasive application with the enclosed cannula cannot be guaranteed. A health risk for the patient or user does not exist.

Concerned medical device:

Product name	INNOTERE Paste-CPC, 3 cc
Description	Implant, Calcium phosphate paste in syringe
Article number (REF)	111VX2
Lot number	232-023-IP
Expiry date	02/2022

Problem description including the identified root cause:
INNOTERE has received feedback from a distributor concerning difficult injection of Paste-CPC out of the syringe through the enclosed cannula. According to the instruction of use INNOTERE Paste-CPC is a ready to use calcium phosphate paste which should be applicable either minimally invasive with cannula or in open surgery without cannula. However, in house tests have confirmed that minimally invasive application is not possible due to high viscosity of the Paste-CPC. Application without cannula was possible. INNOTERE is performing this recall as usability of Paste-CPC for minimally invasive

application with the enclosed cannula cannot be guaranteed. A health risk for the patient or user does not exist.

Measures for the user:

INNOTERE GmbH would like you to perform the following actions:

1. Please identify and separate all of the affected products of the lot in your institution. The article number and the production lot can be found on every individual product package.
2. Please fill in the attached response form and send it to the indicated fax number, Email address or postal address. 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.
3. As soon as we receive the response form and in case, that you still have affected product packages on stock, we will contact you to organize the return or exchange of the goods, respectively.
4. If you are a distributor and have sold the affected production lot, please carry out the recall with your customers according to your internal procedures.

Dissemination of the information described herein:

Please make sure that all users of the above-mentioned product lot and any other person, who needs to be informed in your institution, are notified of this Urgent Safety Information. Please retain this information at least until the recall is completed. The German Federal Institute for Drugs and Medical Devices (BfArM) has received a copy of this Urgent Safety Information.

Contact Person:

Dr. Sophie Rößler
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We apologize for any inconvenience this recall may cause and look forward to serving you in the future.

Yours sincerely,
INNOTERE GmbH

Dr. Sascha Heinemann,
Dr. Berthold Nies
Managing Director

Dr. Sophie Rößler
Safety Officer for Medical Products

Attachments: Response From

INNOTERE biomaterial

Response Form

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☐ We have identified the affected product in our stock; we have documented the quantity below. We retain a copy of this form for our files.

☐ We do not have any packages of the affected product lot left. We retain a copy of this form for our files.

ARTICLE TO BE RETURNED (including quantity) and/or COMMENTS:

Institution:

Name / Title:

Tel. Number:

Date / Signature:

Please return completed for via Fax, Email or mail to:

Fax Number: +49 351 2599 9429

E-Mail: sophie.roessler@innotere.de

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

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VAT-ID: DE 232 411 133