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18.02.2021

URGENT SAFETY INFORMATION

Action: Product Recall

Affected Product: implacross® PE insert 10° Ø 28/35mm

implantcast reference no.: FSCA_21001

Dear Sir or Madam,

by means of this urgent safety information we would like to advise you about a product recall. This has been voluntarily initiated by implantcast GmbH for the product listed below:

Affected Product	Reference Number
implacross® PE insert 10° Ø 28/35mm	02242835

The affected product is an inlay which is put into place within the EcoFit® EPORE®-system when using the EcoFit® hip cup EPORE® size 42/44mm.

Instead of the declared material of implacross® (a cross-linked UHMWPE¹) this item was made of conventional UHMWPE (acc. to ISO 5834-2). Therefore, the product does not match its material specification and must not be used.

According to our files you received one or more affected products and are therefore affected by this action.

The affected item was distributed between September 2016 and January 2021 (locally, the delivery period may vary). Attached you will find the reply form which lists the products dispatched to you including their LOT numbers.

¹ UHMWPE = Ultra-high-molecular-weight polyethylene

Risk Assessment / Patient Aftercare:

According to DIN EN ISO 21534: 2009-08, the employed UHMWPE (acc. to ISO 5834-2) is a suitable material for articulating surfaces. In other sizes of this product both UHMWPE and the implacross® variant are approved.

The use of UHMWPE instead of cross-linked UHMWPE (implacross®) may lead to different wear behaviour. Benchmarking tests of other sizes of this product, showed wear corresponding to the current state of the art both for UHMWPE as well as the implacross® variant. However, only the implacross® variant is approved for the size concerned, which is why no statements on a difference in wear behaviour are known for this particular case. Therefore, early wear and corresponding early indication of a revision surgery cannot be ruled out with the product concerned.

implantcast GmbH has not received any reports from the global post-marketing surveillance system regarding the defectively produced implacross® PE cup insert 10° Ø 28/35mm.

Hazardous Situations		
Description of the immediate health consequences that could result from the use of or exposure to the product in question.	Most likely consequence	Most serious consequence
	<i>None</i>	<i>None</i>
Description of the long-term health effects that could result from the use of or exposure to the product in question.	Most likely consequence	Most serious consequence
	<i>None</i>	<i>Earlier revision surgery</i>

Course of action to be conducted:

1. Please read this safety information carefully and make sure all relevant departments and officeholders are informed about its content.
2. Any **implacross® PE cup inserts 10° Ø 28/35mm (REF 02242835)** in your company must no longer be implanted with immediate effect.
3. We are recalling all affected **implacross® PE inserts 10° Ø 28/35mm (REF 02242835) of the lot numbers listed in the reply form.**
4. Please fill in the attached reply form and return it to implantcast GmbH within **five working days** via E-mail FSCA@implantcast.de or FAX +49 4161 744 201.

Should the product in question be no longer in your stock because it has been used in an operation, please complete the enclosed reply form all the same and return it to us.

The target date for completion of this action is **01. March 2021**. Your prompt response will enable us to meet this deadline and to ensure that all non-compliant products are removed from the market as soon as possible.

We confirm that the National Competent Authority of your country has been notified about this urgent safety information according to the guideline of market vigilance (MEDDEV Vigilance Guidance Document, Reference 2.12/1).

On behalf of implantcast GmbH we would like to sincerely thank you for your help and support with the implementation of this measure and apologize for any inconvenience caused.

We would like to assure you that implantcast GmbH does all in its power to ensure that only such products are on the market that comply with your and our high standards of quality.

Should any questions arise, please contact our product manager for the EcoFit® EPORE®-system or our director sales and marketing.

[Redacted signature]

[Redacted signature]

Yours sincerely,

implantcast

[Redacted signature]

Director Quality Management

[Redacted signature]

Safety Officer

Please return by e-mail to FSCA@implantcast.de
 or send to Fax-No. +49 4161 744 201

Reply form urgent safety information

implantcast Reference-no.: FSCA_21001

Affected Product: implacross® PE insert 10° Ø 28/35mm

REF	LOT	Product Description
		implacross® PE insert 10° Ø 28/35mm

BY SIGNING YOU CONFIRM:

- 1.) having received of the urgent safety information dated 18.02.2021 as well as having taken note of the received information.
- 2.) that all stocks have been checked and none of the affected products are on stock or that affected products were identified on stock and are sent back.

Please sign the reply form and return to e-mail: FSCA@implantcast.de
 or FAX: +49 4161 744 201.

Hospital and Address	
implantcast Customer Number	
Name of Contact Person	
Function of Contact Person	
Phone No. of Contact Person	
Date	Signature