



31.03.2021

URGENT SAFETY INFORMATION**Action:** Product Recall**Affected Product:** EcoFit® 2M head Ø 28/56mm, EcoFit® 2M head Ø 28/58mm**implantcast reference no.:** FSCA_21002

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 products listed below:

Affected Product	Reference Number
EcoFit® 2M head Ø 28/56mm	29062856
EcoFit® 2M head Ø 28/58mm	29062858

The affected products are femoral heads which are put into place within the EcoFit® 2M-system when using an EcoFit® 2M cup.

Instead of the declared material of UHMWPE¹ (acc. to ISO 5834-2) this item was made of a cross-linked UHMWPE (implacross®). 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. 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:

Testing of the approved EcoFit® 2M femoral heads made from implacross® E (a cross-linked UHMWPE doped with vitamin E) shows a better wear behaviour than the EcoFit® 2M femoral heads made from UHMWPE.

One would expect that the cross-linked UHMWPE (implacross®) used in this case will also show similar wear behaviour to implacross® E.

For this reason, we do not expect that using cross-linked UHMWPE (implacross®) instead of UHMWPE will result in any risk to the patient

implantcast GmbH has not received any reports from the global post-marketing surveillance system regarding the defectively produced EcoFit® 2M head Ø 28/56mm and EcoFit® 2M head Ø 28/58mm.

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>None</i>

Patient Aftercare:

An adjustment of the regular aftercare regime is not necessary.

The X-rays taken during the regular postoperative follow-up examinations of the patients concerned should be evaluated in the usual way.

No additional X-ray examinations deviating from the regular follow-up interval are indicated.

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 **EcoFit® 2M head Ø 28/56mm (REF 29062856)** and **EcoFit® 2M head Ø 28/58mm (REF 29062858)** of the LOT numbers listed in the reply form in your company must no longer be implanted with immediate effect.
3. We are recalling all affected **EcoFit® 2M head Ø 28/56mm (REF 29062856)** and **EcoFit® 2M head Ø 28/58mm (REF 29062858)** 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 **09. April 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® 2M-system or our director sales and marketing.

Product Manager

[Redacted signature]

Director Sales and Marketing

[Redacted signature]

Yours sincerely,

implantcast

[Redacted signature]

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_21002

Affected Product: EcoFit® 2M head Ø 28/56mm, EcoFit® 2M head Ø 28/58mm

REF	LOT	Product Description
		EcoFit® 2M head Ø 28/56mm
		EcoFit® 2M head Ø 28/58mm

BY SIGNING YOU CONFIRM:

- 1.) having received of the urgent safety information dated 31.03.2021 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