<<Facility>>
<<Department>>
<<Contact person>>
<<Street>>
<<Zipcode>> <<City>>

14.06.2016

URGENT PRODUCT SAFETY INFORMATION/PRODUCT RECALL

Products concerned: 2M implacross® E head

Unsere Referenz-Nr.: 20160613

Dear,<<customer>>

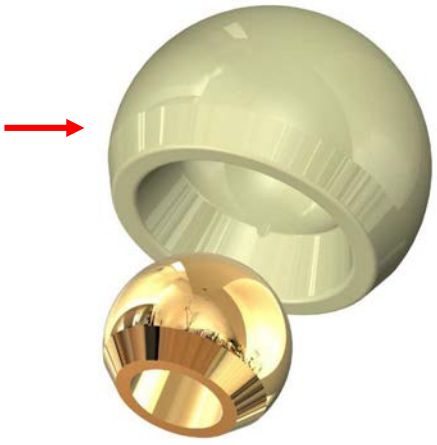
By means of this PRODUCT SAFETY INFORMATION we would like to notify you about an URGENT CORRECTIVE MEASURE WITH THE USERES OF MEDICAL DEVICES. This has been initiated by implantcast GmbH for all products listed below with the following LOT-/Serial-No.:

According to our files at least one of the involved products listed below was delivered to you and is therefore involved in this action.

REF-No.:

2M implacross® E head

REF 29052842	28/42 mm
REF 29052846	28/46 mm
REF 29053250	32/50 mm
REF 29053258	32/58 mm



LOT- / Serial-No.:

1528987xxx
15290LJxxx
15400ICxxx
15441HDxxx
15481I2xxx
160509Bxxx

The 2M implacross® E head is part of the tripolar hip system EcoFit® 2M. Hereby, the inner surface of the 2M head articulates with a conventional femoral head and its outer surface with a 2M hip cup and therefore facilitates combined movement.

Problem:

Within the market it has been reported on several occasions that within surgery a femoral head pressed into one of the concerned products was found to be moved only with difficulty.

The initiated investigation showed that it cannot be ruled out that further implant components from the above mentioned batches might be affected by a detected dimensional deviation.

Risk assessment:

A femoral head that has been pressed into a 2M implacross® E head during surgery might show an inadequate articulation within the concerned product.

At present and according to the current state of investigation an increased amount of wear cannot be ruled out in case of an implantation of an affected 2M head.

Course of Action:

1. With immediate effect all 2M heads of the named batches you might have with you may no longer be implanted.
2. We are calling back all concerned implant components according to the above mentioned LOT/Serial-No. for inspection with us.
3. Please fill in the attached fax-form and fax it to implantcast within five working days.
   FAX: +49 4161 744 201

Possibly these products are no longer on stock with you if they have been used up in operations.

Please return the filled-in customer´s reply form within five working days as from the date of receipt so we can update our files.

This way, you will not receive any further information about this subject unnecessarily. We appeal to you to fill in and return the form to us even if you presently have none of the above listed products on stock.

The envisaged deadline for this course of action is 22.06.2016. Your prompt response will render keeping this date possible and will ensure that all non-conform products are being removed from the market as soon as ever possible.

We confirm, that your National Competent Authority has been informed about this Field Safety Corrective Action according to the guideline for market vigilance (MEDDEV Vigilance Guidance Document), reference 2.12/1.

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

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

Should any questions arise, please contact your export manager:

Yours sincerely

implantcast

…… ……
…… ……

Please send to Fax-No. +49 4161 744 201

FAX-REPLY FORM

URGENT FIELD SAFETY CORRECTIVE ACTION

Products concerned: 2M implacross® E head

2M implacross® E head

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LOT- / Serial-No.: 1528987xxx
15290LJxxx
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15441HDxxx
15481I2xxx
160509Bxxx

implantcast Reference-No.: 20160613

PLEASE CHECK ALL THAT APPLY:

☐ WE STATE THAT ALL RELEVANT STOCK HAS BEEN CHECKED AND THAT NONE OF THE PRODUCTS CONCERNED ARE ON STOCK.

☐ WE STATE THAL ALL DEALERS AND HOSPITALS ARE INFORMED AND THAT ORDERS FOR THE CORRECTIVE ACTION HAVE BEEN GIVEN.

☐ WE STATE THAT ALL RELEVANT STOCK HAS BEEN CHECKED. WE HAVE IDENTIFIED SOME OF THE PRODUCTS CONCERNED ON OUR STOCK AND WOULD LIKE TO HAND BACK THE PRODUCTS LISTED BELOW FOR EXCHANGE.

Own stock / Dealer / Hospital	REF	Qty.	Own stock / Dealer / Hospital	REF	Qty.

In case of insufficient record space, please fill and send the required quantity of this form.

Please sign the form and send it back to us (FAX: +49 4161/744-201) in order to inform us as to the receipt of the notification of product safety.

Distributor	
Name of Contact Person	
Funktion Ansprechpartner :	
Tel. No of Contact Person	
Date:	**Signature:**