[redacted]

05.04.2018

URGENT PRODUCT SAFETY INFORMATION / PRODUCT RECALL

Products concerned: MUTARS® HD Coupling C-O-M

Our reference no.: FSCA_18001

Dear [redacted],

By means of this PRODUCT SAFETY INFORMATION we would like to advise you about an URGENT CORRECTIVE MEASURE FOR THE USERS OF MEDICAL DEVICES. This has been initiated by implantcast GmbH for the products with the respective REF numbers listed below:

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

Item Description	REF-Number
MUTARS® HD coupling C-O-M 12,5mm	57201230
MUTARS® HD coupling C-O-M 12,5mm peg TiN	57201230N
MUTARS® HD coupling C-O-M 15mm	57201232
MUTARS® HD coupling C-O-M 15mm TiN	57201232N

Issue:

As part of the internal surveillance and reporting system two incidents were registered in which the MUTARS® HD Coupling C-O-M failed.

Risk Assessment:

In the case of an affected MUTARS® HD Coupling C-O-M having been implanted, an implant failure cannot be ruled out according to the current state of the examination.

Information concerning follow-up measures for patients who have already been provided with a MUTARS® HD coupling C-O-M:

If instability occurs, there may be an indication for a revision operation.

Course of Action:

1. With immediate effect all MUTARS® HD Coupling C-O-M you might have on stock may no longer be implanted.

2. We are recalling all concerned implant components of the REF-numbers listed above for inspection by us.

3. Please fill in the attached form and return the form to implantcast within five working days. FAX: +49 4161 744 201 or E-Mail: MDVS@implantcast.de

Please return the filled-in customer reply form within five working days as from the date of receipt so we can update our files. This way, you will also avoid to 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 as they might have been used up in an operation.

The envisaged deadline for completion of this course of action is 12.04.2018. Your prompt response will enable us to meet this deadline and will ensure that all non-conform products are being removed from the market as soon as possible.

We confirm, that the National Competent Authority of your country 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 our Product Manager for the MUTARS®-System or our Director Sales and Marketing:

Product Manager

[redacted]

Director Sales and Marketing

[redacted]

Yours sincerely

implantcast

[redacted]

Director of Quality Management

[redacted]

Safety Officer

Please send to Fax-No. +49 4161 744 201 or mail to: MDVS@implantcast.de

REPLY FORM

URGENT FIELD SAFETY CORRECTIVE ACTION

implantcast reference no.: FSCA_18001

Products concerned: MUTARS® HD Coupling C-O-M

BY SIGNING YOU DECLARE:

THE RECEIPT OF THE FSN DATED 05.04.2018 AS WELL AS TO HAVE TAKEN NOTE OF THE INFORMATION IN THE FSN

THAT ALL RELEVANT STOCK HAS BEEN CHECKED AND THAT NONE OF THE AFFECTED PRODUCTS ARE ON STOCK OR THAT AFFECTED PRODUCTS WERE IDENTIFIED AND RETURNED RESPECTIVELY

Please sign the form and send it back to us (FAX: +49 4161 744 201 or E-mail to: MDVS@implantcast.de) in order to inform us about the receipt of the product safety information.

Hospital and Address:	
Name of Contact Person:	
Function of Contact Person:	
Phone No. of Contact Person:	
Date:	**Signature:**