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implantcast GmbH
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21614 Buxtehude
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E-Mail: info@implantcast.de
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13. Dezember 2022

URGENT SAFETY INFORMATION

Measure: Product Recall

Affected device: MUTARS® HD coupling

Our Reference No.: FSCA_22002

Dear Sir or Madam,

by means of this safety notice we would like to inform you about a voluntary product recall by implantcast GmbH for the following MUTARS® HD couplings:

Affected Products	Reference Number
MUTARS® HD coupling C-O-M 12,5mm TiN	57201230N
MUTARS® HD coupling C-O-M 15mm TiN	57201232N
MUTARS® HD coupling M-O-M 12,5mm TiNbN	57201233N

The reason for this product recall is that four serious incidents were fed back to us in which the MUTARS® HD coupling failed.

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

Sparkasse Harburg-Buxtehude
BLZ: 207 500 00 • Konto-Nr.: 50044866
IBAN: DE51 2075 0000 0050 0448 66
SWIFT-BIC: NOLADE21HAM

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Risk Assessment / Patient Aftercare:

According to the current state of investigation a failure cannot be ruled out in case an affected MUTARS® HD coupling has been implanted.

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**
	None	Revision
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**
	None	Revision

Information on follow-up measures for patients who have been treated with a MUTARS® HD coupling:

If increased instability or blockade occurs there may be an indication for a revision surgery.

No special follow-up measures are necessary beyond the routine follow-up examinations.

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. With immediate effect, any **products you might have on stock** at your organisation **must not** be implanted
3. We are recalling all **MUTARS® HD couplings** of the REF numbers listed in the table below.
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 products in question be no longer in your stock because they have 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 **30.12.2022**. 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 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 MUTARS®-system or our director sales and marketing.

[redacted] [redacted]

Sincerely yours

implantcast

[redacted]
Director Sales and Marketing

[redacted]
Person responsible according to Article 15 MDR EU 2017/745

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_22002

Affected products: MUTARS® HD couplings

REF	LOT	Product Description
57201230N		MUTARS® HD coupling C-O-M 12,5mm TiN
57201232N		MUTARS® HD coupling C-O-M 15mm TiN
57201233N		MUTARS® HD coupling M-O-M 12,5mm TiNbN

BY SIGNING YOU CONFIRM:

1) having received the urgent safety information dated 13.12.2022 as well as having taken note of the received information.

2) that all stocks have been checked by you and affected products on stock that have not been implanted are sent back to the following address:

   implantcast GmbH
   AWS-Eingang
   FSCA_22002
   Alter Postweg 10b
   21614 Buxtehude

Bitte unterschreiben Sie das Antwortformular und senden Sie es zurück per E-Mail an: FSCA@implantcast.de oder per FAX an: +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