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[redacted]

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URGENT PRODUCT SAFETY INFORMATION / PRODUCT RECALL

Products concerned:

2M insert 15° for MUTARS® RS cup and LUMiC® TiN

Our Reference No.: FSCA_17002

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
2M insert 15° for MUTARS® RS cup and LUMiC® TiN Ø38/39mm	02423839
2M insert 15° for MUTARS® RS cup and LUMiC® TiN Ø42/44mm	02424244
2M insert 15° for MUTARS® RS cup and LUMiC® TiN Ø44/48mm	02424448
2M insert 15° for MUTARS® RS cup and LUMiC® TiN Ø46/52mm	02424652

In a separate letter, you will receive information about the affected serial numbers in the next few days.

Issue:

During a user training with sterile packaged original parts, it came to light that the retaining ring in a 2M inlay 15 ° for MUTARS® RS Cup and LUMiC® TiN Ø 38/39 mm had been incorrectly mounted into the groove of the inlay. It cannot be ruled out that this assembly error has also occurred with other sizes.

Explanation:

The PE retaining ring has a top and a bottom side to it. If the ring is mounted correctly, a snap-on lip snaps into a notch in the hip cup to ensure correct and secure positioning of the inlay in the hip cup (see Fig. 2).

If the retaining ring is mounted the inside out, the snap-on lip cannot offer a positive lock but will be squashed and the retaining ring cannot fulfill its function (see Fig. 3).

Figure 1 shows a 2M Inlay 15 ° with PE retaining ring.

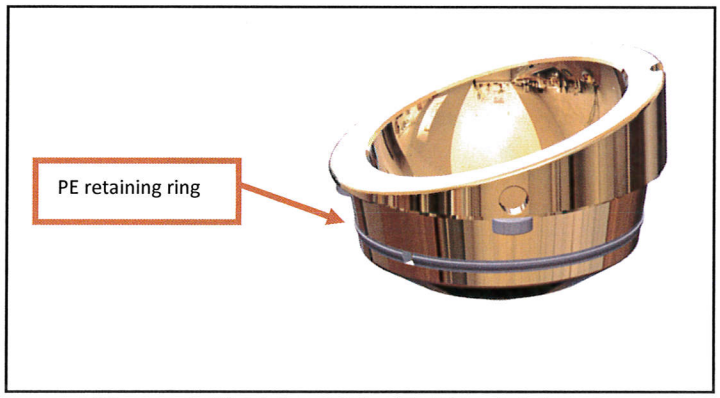

Figure 1: 2M Inlay 15 ° with PE retaining ring

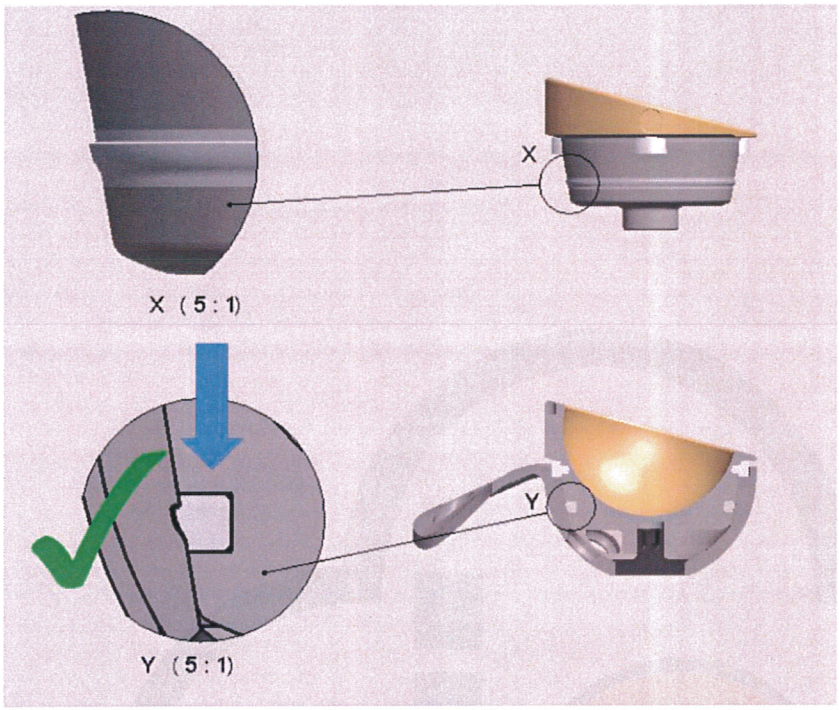

Figure 2:

Correct mounting:

The upper part of the figure shows the snap-on lip of the 2M Inlay 15 °, zoomed in on the left. The nib of the latch lip points upwards.

In the lower part of the figure, the proper fit of the inlay in a hip cup can be seen (right). The enlargement of the detail shows the latch lip pointing upwards (left).

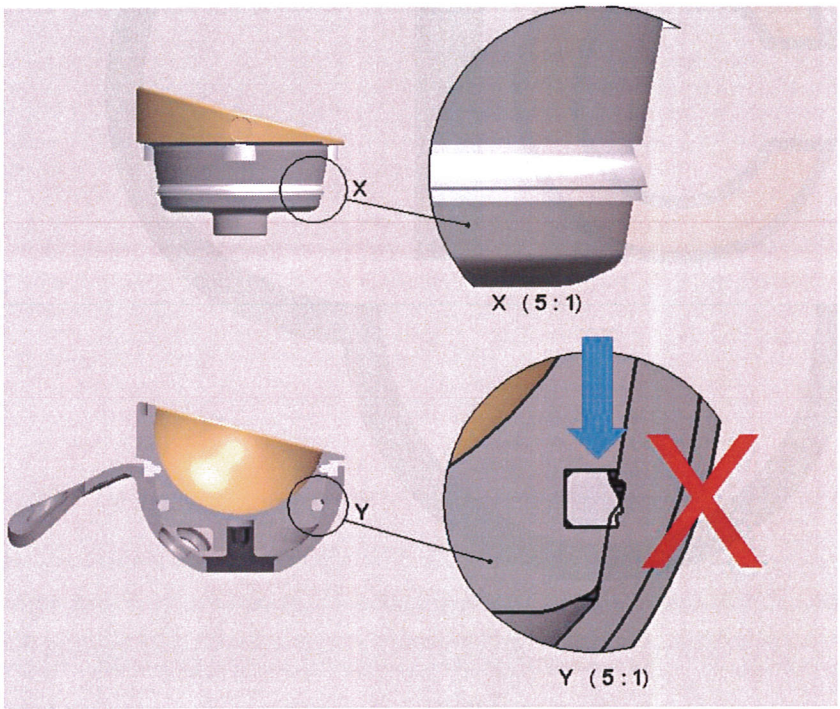

Figure 3:

Wrong mounting

The upper part of the figure shows the snap-on lip of the 2M Inlay 15 ° mounted the wrong way round, zoomed in on the right. The nib of the latch lip points downwards.

The lower part of the figure shows the incorrect fit of the inlay in a hip cup (left). The enlargement of the detail shows the latch lip pointing downwards (right). This alignment no longer offers the originally intended safety function.

Risk Assessment:

Improper mounting will not guarantee the correct and secure positioning of the 2M inlay in the hip cup.

Course of Action:

1. With immediate effect all 2M insert 15° 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 fax-form and return the fax 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 in operations. **Information regarding the aftercare of the patients which have already received a 2M insert 15° will still be defined.**

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.

The envisaged deadline for completion of this course of action is 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®- / LUMiC-System or our Head of Marketing:

Produkt Manager

[redacted]

Produkt Manager

[redacted]

Head of Marketing

[redacted]

Yours sincerely

implantcast

[redacted]

Head of Quality Management

[redacted]

Safety Officer

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

FAX-REPLY FORM

URGENT FIELD SAFETY CORRECTIVE ACTION

implantcast Reference No.:

Products concerned:

- **2M insert 15° for MUTARS® RS cup and LUMiC® TiN**

PLEASE TICK AS APPROPRIATE:

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

☐ WE CONFIRM 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.

REF	LOT	Quantity

Please sign the form and send it back to us (FAX: +49 4161 744 201) 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:**