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implantcast GmbH
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22. August 2024

URGENT SAFETY INFORMATION

Measure: Product Recall

Affected device: BIOLOX® delta cup insert Ø 32/44mm

Our Reference No.: FSCA_24002

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 BIOLOX® delta cup inserts:

Affected Products	Reference Number	Serial numbers
BIOLOX® delta cup insert Ø 32/44mm	02203244	23-3238804 to 23-3238825 (n=20)

It has been discovered that one batch of BIOLOX® delta cup inserts **Ø 36**/44mm was incorrectly labelled as BIOLOX® delta cup inserts **Ø 32**/44mm. As a result, the implant inside the packaging is not the **Ø 32**/44mm size as indicated on the labels, but the **Ø 36**/44mm size.

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

Risk Assessment / Patient Aftercare:

If the incorrect cup insert size is not identified intraoperatively, it may be combined with an ic-head BIOLOX® delta taper 12/14mm Ø 32mm. This combination leads to an increased risk of dislocation, increased wear of the ceramic components and an increased risk of fracture. In addition, the prosthesis could produce annoying noises during movements.

With this incompatible combination, a revision is recommended as soon as possible. The replacement of both ceramic components is indicated. Intraoperatively, the stem taper and cup taper should also be checked for damage and the recommended procedure outlined below should be followed:

Component	Type of damage	Recommended action
Stem taper	No major damage	Use of an ic-head revision BIOLOX® delta taper 12/14mm
	Major damage	Revision of the stem
Cup taper	No major damage	Use of a BIOLOX® delta cup insert
	Major damage	Use of an implacross® PE cup insert or revision of the cup

If the incorrect cup insert size is identified intraoperatively and a compatible ic-head BIOLOX® delta taper 12/14mm **Ø 36mm** is used, the patient documentation must be manually adjusted as the patient stickers are also labelled with the incorrect size BIOLOX® delta cup insert **Ø 32**/44mm. The size information on the insert label should be corrected to 36/44mm.

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 **BIOLOX® delta cup inserts** of the LOT 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 **04.09.2024**. 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 MDR EU 2017/745.

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 BIOLOX® system or our director sales and marketing.

Product Manager

[redacted]

Director Sales and Marketing

[redacted]

Sincerely yours

implantcast

[redacted]

Director Sales and Marketing

[redacted]

PRRC-Safety

Please return by e-mail to FSCA@implantcast.de

Reply form urgent safety information

implantcast Reference-No.: FSCA_24002

Affected products: BIOLOX® delta cup insert Ø 32/44mm

REF	LOT	Product Description
02203244	23-3238804 to 23-3238825 (n=20)	BIOLOX® delta cup insert Ø 32/44mm

BY SIGNING YOU CONFIRM:

1) having received the urgent safety information dated 22.08.2024 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_24002
Alter Postweg 10b
21614 Buxtehude
Germany

Please sign the reply form and return it by E-Mail to: FSCA@implantcast.de

Hospital and Address	
implantcast Customer Number	
Name of Contact Person	
Function of Contact Person	
Phone No. of Contact Person	
Date	Signature