13 May 2024

URGENT SAFETY INFORMATION

Action: Safety-related changes to the instructions for use and surgical technique

Affected Products: MUTARS® RS Stem and MUTARS® RS Extension Sleeve

Our Reference Number: FSCA_24001

Dear Sir or Madam,

Herewith we would like to inform you about a safety-relevant information which is voluntarily carried out by implantcast GmbH for the following documents:

Instructions For Use (IFU)	Reference Number
MUTARS® RS Revision System	09300015
Surgical Technique	**Reference Number**
MUTARS® RS Revision System	MURSSTxx

These documents are valid for all instruments and sizes of the MUTARS® RS Revision System. In particular, the following MUTARS® RS products for hip arthroplasty with transition to MDR certification are subject to the specified restrictions on use:

Affected Product	Article Number	New Application Restrictions
MUTARS® RS extension piece 25mm	67300025	Maximum 3 extension pieces per supply
MUTARS® RS extension piece 25mm HA	67300125	
MUTARS® RS stem cemented sz. 12/200mm	67611220	Weight restriction up to 70 kg
MUTARS® RS stem cemented sz. 12/200mm TiN	67611220N	
MUTARS® RS stem cementless sz. 14/250mm HA	67622514	Weight restriction up to 65 kg
MUTARS® RS stem cementless sz. 12/150mm HA	67621512	No application with ic femoral heads of neck lengths XXL and XXXL
MUTARS® RS stem cementless sz. 12/200mm HA	67622012	
MUTARS® RS stem cementless sz. 15/250mm HA	67622515	Application with ic femoral heads of neck lengths XXL and XXXL only up to a maximum reconstruction length of 82 mm[1]

You are receiving this safety information because you have been supplied with one of the above stems and/or one of the above extension pieces by implantcast in the past. It is therefore possible that you have supplied patients with a hip arthroplasty for which the new restrictions on use are now valid.

Background:
As part of the certification of the MUTARS® RS revision system in accordance with the new European regulation MDR (EU) 2017/745, additional finite element analyses simulating the fatigue tests according to ISO 7206-4 & -6 were carried out. This results in additional weight and combination restrictions for the application.

The results of the simulation have prompted implantcast GmbH to impose precautionary restrictions on the use of some products and sizes. This decision is not due to a safety problem with the implants. No anomalies with regard to fractures have been detected since the above-mentioned articles were placed on the market.

implantcast GmbH has decided to label the weight-restricted stems in the MUTARS® RS Revision System surgical technique separately in the "Implants" chapter as shown in the following example.

[1] permitted assemblies:
MUTARS® RS proximal component size 42 mm / 127° (or 42 mm / 135°) + MUTARS® RS metaphyseal component size 40 mm;
MUTARS® RS proximal component size 32 mm / 127° (or 32 mm / 135°) + MUTARS® RS metaphyseal component size 40 mm;
MUTARS® RS proximal component size 32 mm / 127° (or 32 mm / 135°) + MUTARS® RS metaphyseal component size 50 mm

MUTARS® RS stem cemented
Material: implavit®; CoCrMo acc. to ISO 5832-4

article number	*size*	*length*	*maximum weight*	
67601212	12	120 mm	70 kg	

The instructions for use (IFU) have been marked with the following warnings:

Instructions for Use (IFU) MUTARS® RS Revision System:
"ATTENTION: The use of more than 3 extension pieces is not permitted."
"Please note that for hip arthroplasty, the cemented MUTARS® RS stems of size Ø12/200mm are subject to a weight restriction of up to 70 kg and the cementless MUTARS® RS stem of size Ø14/250mm is subject to a weight restriction of up to 65 kg."
Please also note that the use of the MUTARS® RS Revision System in combination with the ic femoral heads of neck lengths XXL and XXXL is subject to restrictions. [...]" Not permitted: when using the cementless MUTARS® RS stems of sizes Ø12/150mm, Ø12/200mm, and Ø14/250mm or MUTARS® RS stems cemented. Permitted: only when using cementless MUTARS® RS stems (excluding stem sizes Ø12/150mm, Ø12/200mm, and Ø14/250mm) and a maximum one MUTARS® RS extension piece. When using the cementless MUTARS® RS stem size Ø15/250 mm, only up to a maximum assembly length of 82 mm permitted (permitted assemblies: MUTARS® RS proximal component size 42 mm / 127° (or 42 mm / 135°) + MUTARS® RS metaphyseal component size 40 mm; MUTARS® RS proximal component size 32 mm / 127° (or 32 mm / 135°) + MUTARS® RS metaphyseal component size 40 mm; MUTARS® RS proximal component size 32 mm / 127° (or 32 mm / 135°) + MUTARS® RS metaphyseal component size 50 mm).

Risk Assessment / Patient Aftercare:

This is a precautionary restriction of the scope of application based on the results of a worst-case simulation. This decision is not due to a safety problem with the implants. Since the market launch of the MUTARS® RS system, implantcast GmbH has only been notified of one incident in which one of the aforementioned MUTARS® RS stems broke during a hip replacement and the currently introduced weight restriction was exceeded. There are no known incidents of failure caused by the use of more than three extension pieces or a combination with ic femoral heads of neck lengths XXL and XXXL, which is excluded here.

Information on aftercare measures for patients who have already been treated with one of the combinations excluded here or who exceed the weight restriction:

In case of an implantation that has already taken place, there is no increased risk for the patient, taking into account the actual failure rate of the scenarios considered here.

There is no need for separate aftercare.

Actions to be taken:

1. Please read this safety information carefully and ensure that all relevant departments and function holders are informed of its contents.
2. Please keep this safety information in a safe place.
3. Please complete the enclosed response form and return it to implantcast GmbH within **five working days** via e-mail to FSCA@implantcast.de or FAX +49 4161 744 201.

The target date for completion of this action is **24 May 2024**. Your prompt response will enable us to meet and ensure this deadline.

We confirm that we have informed the competent national European authorities about this urgent safety information.

On behalf of implantcast GmbH, we would like to thank you for your help and support in carrying out this measure and apologise for any inconvenience caused.

We would like to assure you that implantcast GmbH does everything in its power to ensure that only products that meet your and our high quality standards are on the market.

If you have any questions, please contact our Product Manager for the MUTARS® RS hip system or our Head of Marketing and Sales.

Product Manager

[redacted]

Head of Marketing and Sales

[redacted]

With kind regards

[redacted]

Head of Marketing and Sales

[redacted]

Responsible Person according to Article 15 MDR EU 2017/745

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

or by fax to: +49 4161 744 201

Response Form Urgent Safety Information

implantcast Reference Number: FSCA_24001

Instructions For Use (IFU)	Reference Number
MUTARS® RS Revision System	09300015
Surgical technique	**Reference Number**
MUTARS® RS Revision System	MURSSTxx

- By signing this document, you confirm that you have received the safety information dated 13 May 2024 and that you have taken note of the information contained therein.
- Please **sign** the form and send it back to FAX: +49 4161 744 201 or e-mail: FSCA@implantcast.de.

Please note that there has been no change regarding the design or manufacture of the MUTARS® RS Revision System. This is also not a product recall. A product return is not necessary. This safety information merely has an impact on the instructions for use (IFU) and surgical techniques.

Hospital and Address	
Name of Contact Person	
Function of Contact Person	
Phone Number of Contact Person	
Date	Signature