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May 26, 2025

URGENT SAFETY NOTICE

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

Affected devices: MUTARS® proximal femur and MUTARS® proximal femur revision

Our reference no.: FSCA_25002

Dear Sir or Madam,

Please find enclosed safety-related information which implantcast GmbH has decided to issue for the following documents:

Instructions for use (IFU)	**Reference no.**
MUTARS® tumor and revision system	09300013
Surgical technique	**Reference no.**
MUTARS® proximal femur	MPFESTxx*
MUTARS® proximal femur revision	MPFRSTxx*

*xx = placeholder for the respective language and country codes

These documents are valid for all instruments and sizes of the MUTARS® proximal femur and MUTARS® proximal femur revision. The stated additional limits of use were specified in particular for the MUTARS® proximal femur (revision) devices as part of a hip arthroplasty involving transition to the MDR certification:

Bankverbindung:
Sparkasse Harburg-Buxtehude
IBAN: DE51 2075 0000 0050 0448 66
SWIFT-BIC: NOLADE21HAM

Handelsregister: HRB 120629, Tostedt
Geschäftsführer: Jens Saß
Erfüllungsort und Gerichtsstand: Buxtehude
USt. ID Nr.: DE 1164 639 57

Stem size [mm]	Reconstruction length[1] (RL) [mm]	Weight restriction [kg]	
		MUTARS® proximal femur	MUTARS® proximal femur revision
MUTARS® femoral stems cemented, MUTARS® stems cemented modular			
Ø 11 / 120	RL ≤ 220	75	75
	220 < RL ≤ 320	~~75~~ **70**	75
	RL > 320	~~75~~ **60**	75
Ø 11 / 160	RL ≤ 240	~~75~~ **70**	75
	240 < RL ≤ 330	~~75~~ **60**	75
	RL > 330	~~75~~ **60**	~~75~~ **60**
Ø 11 / 200	RL ≤ 120	~~75~~ **70**	75
	120 < RL ≤ 230	~~75~~ **60**	75
	RL > 230	~~75~~ **60**	~~75~~ **60**
Ø 13 / 200	RL > 300	~~none~~ **70**	None
MUTARS® femoral stems cementless			
Ø 12 / 120	RL > 310	None	~~none~~ **60**

75	unchanged
~~75~~ **70**	new

You are receiving this safety notice as you were supplied a MUTARS® proximal femur from implantcast in the past. It is therefore possible that you will have treated patients with a hip arthroplasty to which the new limits of use now apply.

Background:
As part of the MUTARS® proximal femur (revision) system's certification in accordance with the new European Regulation MDR (EU) 2017/745, additional finite element analyses were conducted which simulate the endurance tests in accordance with ISO 7206-4. This results in additional weight and combination restrictions on use.

The results of the simulation have prompted implantcast GmbH to stipulate limits of use for some products and sizes as a precautionary measure. This decision is not due to a safety problem with the implants. Since the aforementioned items were placed on the market, no abnormalities in relation to fractures have been found.

[1] The reconstruction length refers to the distance between the resection edge and the center of the center of rotation.

implantcast GmbH has decided to mark separately the weight-restricted stems in the surgical techniques MUTARS® proximal femur and MUTARS® proximal femur revision in the chapter "Implants" as shown in the following example.

MUTARS® femoral stem cemented

Material: implavit®; CoCrMo in accordance with ISO 5832-4

Article number	*Diameter*	*Length*
57600011	11 mm	120 mm
57600013	13 mm	120 mm
57600015	15 mm	120 mm
57600017	17 mm	120 mm
57601116*	11 mm	160 mm
57601316*	13 mm	160 mm
57601516*	15 mm	160 mm
57601716*	17 mm	160 mm
57601120*	11 mm	200 mm
57601320*	13 mm	200 mm
57601520*	15 mm	200 mm
57601720*	17 mm	200 mm
57601524*	15 mm	240 mm
57601724*	17 mm	240 mm

** Not contained in the loan set and must be requested separately.*

Key:

(S) *Available with silver coating*
(N) *Available with TiN coating*
Observe weight limit
Observe the reconstruction length limits
Locking screw holes

The system overview also details the individual weight restrictions for the reconstruction lengths, as shown in the graphic below.

Weight limits of the MUTARS® femoral stems

⚠ Attention: The following table shows the weight limits of the MUTARS® femoral stems and the MUTARS® femoral stems modular in relation to the reconstruction length of the MUTARS® proximal femur.

Weight limits for MUTARS® femoral stems cemented and MUTARS® femoral stems cemented modular based on the reconstruction length of the MUTARS® proximal femur.

Stem size	Reconstruction length	Weight limit
Ø 11 mm / 120 mm	≤ 220 mm	75 kg
	230 mm - 320 mm	70 kg
	> 320 mm	60 kg
Ø 11 mm / 160 mm	≤ 240 mm	70 kg
	250 mm - 330 mm	60 kg
	> 330 mm	60 kg
Ø 11 mm / 200 mm	≤ 120 mm	70 kg
	130 mm - 230 mm	60 kg
	> 230 mm	60 kg
Ø 13 mm / 200 mm	> 300 mm	70 kg

The following additional warnings were added to the instructions for use (IFU):

Instructions for use (IFU) MUTARS® tumor and revision system:
"Further weight restrictions must be noted with the proximal femur replacement. These depend on the used femoral stem and the reconstruction length."

Risk assessment / Patient follow-up:

This is a precautionary restriction of the area of use 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® proximal femur (revision) system, implantcast GmbH has only been made aware of two incidents where one of the aforementioned MUTARS® femoral stems has fractured as part of a hip replacement and the currently introduced weight restriction was exceeded.

Information on follow-up measures for patients who have already been treated with a combination excluded here or who exceed the weight restriction:

In the case of an existing implantation, there is no increased risk for the patient, taking into account the actual failure rate of the scenarios analyzed here.

There is no need for special follow-up measures.

Action required:

1. Please read this safety notice carefully and make sure that all the relevant departments and operatives are informed about its contents.
2. Please retain this safety notice for future reference.
3. Please fill out the accompanying response form and return it to implantcast GmbH within **five working days** by email to FSCA@implantcast.de.

We are aiming to complete this action by **June 13, 2025**. Your prompt response will enable us to meet this deadline.

We confirm that we have notified the responsible national European authorities of this urgent safety notice.

On behalf of implantcast GmbH, we thank you for your assistance and support in implementing this measure, and we would like to apologize for any inconvenience caused.

We give you our assurance that implantcast GmbH does everything possible to make sure that all devices we supply meet your and our own high-quality standards.

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

Product Manager

[redacted]

Head of Product Management

[redacted]

Sincerely yours,

implantcast

[redacted]

Managing Director

[redacted]

PRRC Safety

Please return by email to: FSCA@implantcast.de

Response form for urgent safety notice

implantcast reference no.: FSCA_25002

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- By signing, you confirm you have received and read the safety notice dated May 26, 2025.
- Please **sign** the form and email it back to us: FSCA@implantcast.de.

Please note that no changes have been made to the design or manufacture of the MUTARS® proximal femur (revision) system. This does not entail a product recall either. There is no need to return the product. This safety notice solely affects the instructions for use (IFU) and surgical techniques.

Hospital and address	
implantcast customer number	
Name of contact	
Position of contact	
Tel. no. of contact	
Date	Signature