implantcast GmbH · Lüneburger Schanze 26 · 21614 Buxtehude

implantcast GmbH
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August 3, 2026

URGENT SAFETY NOTICE

Action: Product recall

Affected devices: EcoFit® hip stem 133° cementless standard sz. 7.5 mm HA

Our reference no.: FSCA_26003

Dear Sir or Madam,

we are sending you this safety notice to inform you about a voluntary product recall which implantcast GmbH has decided to issue for the EcoFit® hip stem 133° cementless standard sz. 7.5 mm HA:

Affected device	Article number	Serial number
EcoFit® hip stem 133° cementless standard sz. 7.5 mm HA	30363075	25450BM126 to 25450BM150

Background:

It was determined that the combined coating of porous titanium (cpTi) and hydroxylapatite (HA) had not been applied to a specific portion of a batch of EcoFit® hip stems of the type mentioned above.

Our records show that you have been supplied with one or more of the affected devices, and therefore this product recall concerns you.

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

Risk assessment / Patient follow-up:

Depending on whether the absence of the coating is detected intraoperatively or whether the product is used, the following immediate or long-term risks may arise:

Risk situations		
	Most likely consequence	**Most serious consequence**
Description of the **immediate health consequences** which could result from using the affected device or being exposed to it.	The absence of the coating is detected intraoperatively **prior** to implantation. The affected implant is discarded. An alternative implant is used. **Effects on the patient:** No immediate health effects on the patient are expected. **Postoperative care:** No special follow-up care is required.	The absence of the coating is not detected. The uncoated implant is used. Any potential deeper seating of the hip stem can be corrected using other implant components, and the uncoated implant remains in the patient. **Effects on the patient:** The primary stability of the implant may be compromised. **Postoperative care:** X-rays taken during the affected patients' regular follow-up examinations should be evaluated specifically for signs of implant loosening. If radiological signs of loosening of the hip stem are evident, revision surgery is indicated.

Risk Situations – Continued		
	Most likely consequence	**Most serious consequence**
Description of the **long-term health consequences** which could result from using the affected device or being exposed to it.	The uncoated implant achieves sufficient primary stability. The lack of a coating leads to slowed osseointegration of the implant. **Effects on the patient:** The secondary stability of the implant may be compromised. **Postoperative care:** X-rays taken during the affected patients' regular follow-up examinations should be evaluated specifically for signs of implant loosening. If radiological signs of loosening of the hip stem are evident, revision surgery is indicated.	A lack of primary/secondary stability results in premature loosening of the implant. **Effects on the patient:** Repeat surgical intervention on the hip joint is required. **Postoperative care:** Patient education, temporary immobilization, and planning and performing a revision surgery as medically indicated.

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. All **products currently in your facility** must be **discontinued** immediately.
3. Please retain this safety notice for future reference.
4. Please fill out the accompanying response form and return it to implantcast GmbH within **five working days** by email to FSCA@implantcast.de.
5. The responsible field representative from implantcast GmbH will arrange for the replacement of the EcoFit® hip stem 133° cementless standard sz. 7.5 mm HA on-site and collect defective products.

We are aiming to complete this action by **August 14, 2026**. 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 responsible for hip systems or our head of product management.

Product Manager Hip Systems

[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_26003

Affected implant	Article number	LOT number
EcoFit® hip stem 133° cementless standard sz. 7.5 mm HA	30363075	25450BM126 to 25450BM150

By signing, you confirm:

1. Receipt of the safety information dated August 3, 2026, and that you have read and understood the information contained therein.
2. That the affected hip stems have been set aside so that they can no longer be used and are being held ready for pickup by a field representative of implantcast GmbH.

Please sign the form and return it by email to: FSCA@implantcast.de.

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