

June 8, 2026

URGENT SAFETY NOTICE**Action:** Product recall**Affected devices:** ACS® Uni IM adapter**Our reference no.:** FSCA_26002

Dear Sir or Madam,

We are sending you this safety notice to inform you about a product recall which implantcast GmbH has decided to issue for the for the ACS® Uni IM adapter:

Affected device	Article number
ACS® Uni IM adapter	42161709

These ACS® Uni IM adapters are used in combination with the following ACS® Uni femoral resection guides anatomic:

- REF 42161701: ACS® Uni femoral resection guide anatomic sz. 1
- REF 42161702: ACS® Uni femoral resection guide anatomic sz. 2
- REF 42161703: ACS® Uni femoral resection guide anatomic sz. 3
- REF 42161704: ACS® Uni femoral resection guide anatomic sz. 4

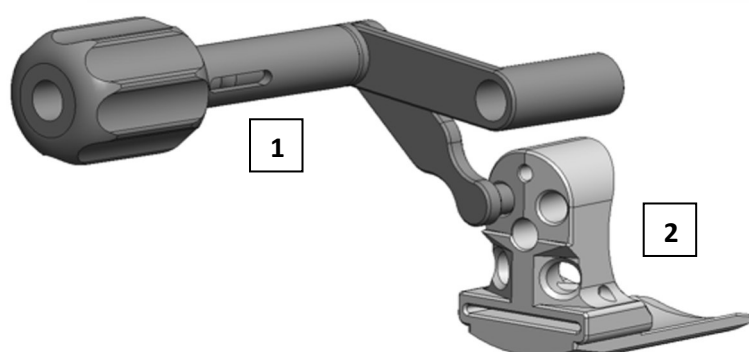


Background:

According to the surgical technique, the ACS® Uni IM adapter is intended to be combined with the ACS® Uni femoral resection guide. Due to incorrect tolerance specifications, it may occur intraoperatively that the adapter and resection guide cannot be connected to each other, or only to a limited extent, thereby potentially compromising patient safety.

The following illustration shows the connection between the two products:

1. ACS® Uni IM adapter
2. ACS® Uni femoral resection guide anatomic



You are receiving this letter because you have at least one instrument container in stock that may contain potentially affected ACS® Uni IM adapters.

The affected instrument containers are as follows:

Affected instrument container	Article number
ACS® Uni SG Femur Basic Container	42160652
ACS® Uni Femur Basic Container	42160682
ACS® Uni FB femoral basic container	42160692
ACS® Uni FB femoral basic US container	US160692

Each instrument container includes **one** ACS® Uni IM adapter.

Risk assessment / Patient follow-up:

All potential risks are detected intraoperatively. Accordingly, separate postoperative care is not required.

implantcast GmbH is not aware of any cases in which a defective ACS® Uni IM adapter has had an adverse effect on a patient.

Risk situations		
Description of the immediate health consequences which could result from using the affected device or being exposed to it.	Most likely consequence	Most serious consequence
	The ACS® Uni IM adapter and the ACS® Uni femoral resection guide anatomic can be assembled but cannot be separated from one another after successful preparation of the femur. The surgery can continue as planned without a relevant alternative surgical procedure. Impact on the patient: No immediate effects on the patient are to be expected. Postoperative care: No special follow-up care is required.	The ACS® Uni IM adapter and the ACS® Uni femoral resection guide anatomic cannot be assembled. The surgery is terminated, and no implant is placed during this procedure. It is still possible to implant the ACS® Uni System during a second procedure. Impact on the patient: A repeat surgery to complete the procedure is required after replacing the defective instruments. Postoperative care: Patient education, temporary immobilization (e.g., splint), wound care, and planning and performing a revision surgery as medically indicated.
Description of the long-term health consequences which could result from using the affected device or being exposed to it.	Most likely consequence	Most serious consequence
	None	None

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. Please return the affected instrument containers to implantcast GmbH.

We are aiming to complete this action by **June 22, 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 Knee Product Management team or our Product Management team.

Head of Knee Product Management

Jonas Tykfer

Phone: +49 4161 744 6155

Email: j.tykfer@implantcast.de

Head of Product Management

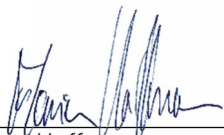
Dr. Steffen Aßmann

Phone: +49 4161 744 6396

Email: s.assmann@implantcast.de

Sincerely yours,

implantcast

A handwritten signature in blue ink, appearing to read 'Florian Hoffmann'.

Florian Hoffmann
Managing Director

A handwritten signature in blue ink, appearing to read 'Frank Ansorge'.

Frank Ansorge
PRRC Safety

Please return by email to: FSCA@implantcast.de

Response form for urgent safety notice

implantcast reference no.: FSCA_26002

Affected instrument container	Article number	LOT number
ACS® Uni SG Femur Basic Container	42160652	
ACS® Uni Femur Basic Container	42160682	
ACS® Uni FB femoral basic container	42160692	
ACS® Uni IM adapter	42161709	

By signing, you confirm:

1. Receipt of the safety information dated June 8, 2026, and that you have read and understood the information contained therein.
2. That all instrument containers containing the potentially defective ACS® Uni IM adapters, or all individual ACS® Uni IM adapters, will be returned to the following address:

implantcast GmbH
 AWS-Eingang
 FSCA_26002
 Alter Postweg 10b
 21614 Buxtehude, Germany

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