implantcast GmbH · Lüneburger Schanze 26 · 21614 Buxtehude

implantcast GmbH
Lüneburger Schanze 26
21614 Buxtehude
Tel: +49 4161 744-0
Fax: +49 4161 744-200
E-Mail: info@implantcast.de
Internet: www.implantcast.de

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 |

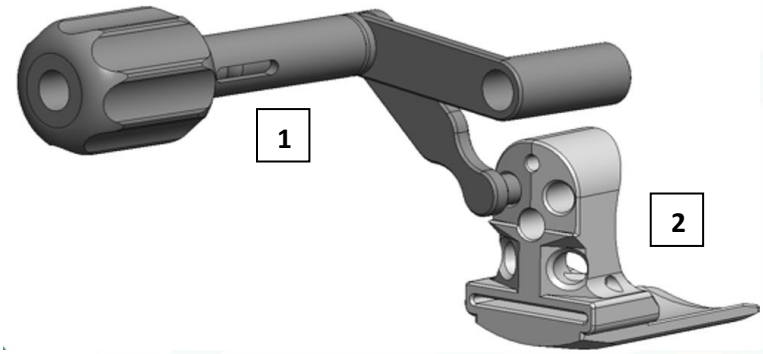
These ACS® Uni IM adapters are used in combination with the following ACS® Uni femoral resection guides anatomic:

- 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.<br><br>**Impact on the patient:**<br>No immediate effects on the patient are to be expected.<br><br>**Postoperative care:**<br>No special follow-up care is required. | The ACS® Uni IM adapter and the ACS® Uni femoral resection guide anatomic cannot be assembled.<br>The surgery is terminated, and no implant is placed during this procedure.<br>It is still possible to implant the ACS® Uni System during a second procedure.<br><br>**Impact on the patient:**<br>A repeat surgery to complete the procedure is required after replacing the defective instruments.<br><br>**Postoperative care:**<br>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**

[redacted]

**Head of Product Management**

[redacted]

Sincerely yours,

[redacted]

Managing Director

[redacted]

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 |