



Carl Zeiss Meditec AG 73447 Oberkochen

To whom it may concern

Division/Dept.: Complaints Management & Vigilance / Product Management

Your contact: Ratul Hassan & Ketan Adhav

**Carl Zeiss Meditec AG**

Oberkochen location  
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Germany

Phone: 07364 200

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Date: 01.06.2026

**Urgent Field Safety Notice (FSN) – 1.5cm Spherical Applicators for INTRABEAM (Reference: FCA\_OKO\_2026\_001 IORT Non-Conformance in Batch Release of 1.5cm Spherical Applicators)**

Dear Colleagues and Sales Partners,

As part of Carl Zeiss Meditec's continuous focus on reliability and safety we continuously monitor the performance of our products. This letter is to inform you about Field Safety Corrective Action (FSCA) for 1.5 cm Spherical Applicators for INTRABEAM which is being conducted. Purpose of this letter is to provide guidance on how to perform the FSCA in detail.

**Problem Description:**

This is to inform you that, as part of our continuous quality monitoring, we have identified a deviation related to specific 1.5 cm spherical applicators used with the INTRABEAM system. In consequence, we, Carl Zeiss Meditec AG, have decided to recall the corresponding Spherical Applicators from batch A0002, to inform customers and prevent usage of the Spherical Applicators until the investigation is completed.

The measurements for a certain applicator from batch A0002 showed only slight deviations but present no clinically relevant risk to patients. For safety reasons, the applicators from the batch must be identified, tested, and replaced before further use.

Address of Record:  
Goeschwitzer Strasse 51 - 52  
07745 Jena, Germany

Address for Delivery:  
Carl Zeiss Meditec AG  
Carl-Zeiss-Promenade 10  
07745 Jena

Banks:  
Deutsche Bank Jena  
Account: 624536900 (BLZ 820 700 00)  
IBAN: DE90 8207 0000 0624 5369 00  
BIC/ SWIFT: DEUT DE 8EXXX

Commerzbank Jena  
Account: 258072800 (BLZ 820 400 00)  
IBAN: DE31 8204 0000 0258 0728 00  
BIC/ SWIFT: COBADEFFXXX

Commercial Register:  
Local Court Jena HRB 205623

VAT-ID No.: DE 811 922 737  
WEEE-Reg.-No.: DE55298748

Chairman of the Supervisory Board:  
Peter Kameritsch

Board of Management:  
Andreas Pecher (CEO)  
Justus Felix Wehmer

**Hazard involved:**

Carl Zeiss Meditec AG has not received any reports and complaints about any adverse effects associated with the inconsistency described. In order to ensure the highest quality of products being delivered to our customers, the spherical applicators are being recalled until the detailed investigations are concluded.

**Affected Products:**

Based on our internal assessment, this relates to applicators from the following batch:

Batch Number: **A0002**

Affected Product serial number: **A63085; A63086; A63096; A63101; A63102; A63105; A63107; A63108; A63109; A63110; A63112; A63139; A63141**

**Action steps to be taken by the end user:**

In an effort to conduct this FSCA, it is required that you perform the following steps:

- 1) Immediately identify affected applicators using the serial numbers listed above.
- 2) Stop clinical use of affected applicators.
- 3) Quarantine affected devices to prevent further use.
- 4) Complete and return the "Confirmation sheet of blocking" and "Confirmation sheet of Replacement".
- 5) Arrange return of affected devices according to the manufacturer's instructions.
- 6) Await replacement applicators from the manufacturer.

**Acknowledgment:**

Please confirm receipt of this notice by completing and returning the attached Confirmation sheet of blocking (as soon as possible) and the Confirmation sheet of Replacement by 31st of August 2026.

Best regards  
Carl Zeiss Meditec AG

Digital unterzeichnet  
von: Adhav Ketan Kiran  
OGN/SEB/19  
Datum: 2026.06.01  
11:14:17 +02'00'

Adhav, Ketan Kiran  
Product Manager  
MED-MNS  
(Product Management Spine NES (MED-MCS))

Digitally signed by  
Hassan Ratul  
OGPH/ASS/A  
Date: 2026.06.01  
11:24:46 +02'00'

Hassan, Ratul  
Vigilance & Complaint Manager  
MED-PQVD  
(Quality Vigilance & Complaint of Devices (MED))



**FSCA\_OKO\_2026\_001 IORT Non-Conformance in Batch Release of  
1.5cm Spherical Applicators  
Confirmation Sheet for blocking the usage of affected spherical  
Applicators**

IORT: Non-Conformance in Batch Release of 1.5cm Spherical Applicators

To be filled in completely by responsible person for blocking

Customer (name, address) \_\_\_\_\_

\_\_\_\_\_

Site of installation \_\_\_\_\_

\_\_\_\_\_

*Details of assignment:*

Serial number of the affected 1.5cm Spherical Applicators system: \_\_\_\_\_

Mat. No. 304534-6000-557

\_ unit 1.5cm Spherical Applicator(s) with the SN \_\_\_\_\_, SN \_\_\_\_\_ has been blocked  
from using by:

Date: \_\_\_\_\_ Responsible person for RMA's Signature: \_\_\_\_\_

I herewith acknowledge the receipt of the Field Safety Notice (FSN). Further I confirm that I have transferred the content of the attached FSN to all affected departments on which this action has an impact. I understand the necessity of above mentioned instructions carefully.

Please forward the completed blocking confirmation sheet to your Zeiss contact person.