



Carl Zeiss Meditec AG 73447 Oberkochen

To whom it may concern

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

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Field Safety Corrective Action (FSCA) Customer Letter – 1.5cm Spherical Applicators for INTRABEAM (Reference: FCA_OKO_2026_001 IORT Non-Conformance in Batch Release of 1.5cm Spherical Applicators)

Dear valued ZEISS customer,

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.

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

The measurements for the above-mentioned applicator from batch A0002 showed only slight deviations but present most likely no clinically relevant risk to patients. For safety reasons, the applicators from the batch must be tested, and replaced before further use. We would like to emphasize that for the seamless operation of the

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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

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Local Court Jena HRB 205623

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Chairman of the Supervisory Board:
Peter Kameritsch

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

INTRABEAM systems and its associated applicators a precautionary measure is undertaken to ensure full compliance with our high-quality standards and delivering quality products to our customers.

To support traceability and maintain these standards, we kindly request the block using the above-mentioned spherical applicators as soon as possible and return from your site. The collection and further handling will be coordinated by your local SSC team, who will contact you directly to arrange the next steps.

Please note that the affected applicators will be replaced with new ones to ensure continued availability for your clinical needs.

We apologize for any inconvenience this may cause and thank you for your cooperation and continued trust in ZEISS products and services.

Best regards
Carl Zeiss Meditec AG

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