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08.05.2025

# URGENT SAFETY INFORMATION

**Action**: Product recall

**Products concerned:** CarpoFit® monoblock broaches

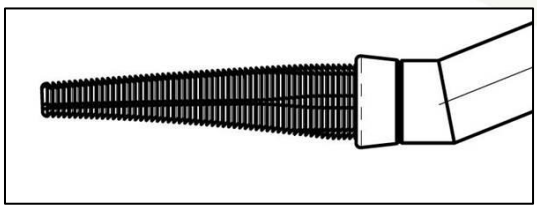
**implantcast reference no.:** FSCA_25001

Dear Sir or Madam,

By means of this urgent safety information we would like to advise you about a recall which has been voluntarily initiated by implantcast GmbH for the products listed below:

| Item Description | REF Number | LOT Number[1] |
|---|---|---|
| CarpoFit® monoblock broach sz. 5 mm | 00510945 | n.a. |
| CarpoFit® monoblock broach sz. 6 mm | 00510946 | n.a. |
| CarpoFit® monoblock broach sz. 7 mm | 00510947 | n.a. |
| CarpoFit® monoblock broach sz. 8 mm | 00510948 | n.a. |

It was noted that in the above-mentioned CarpoFit® monoblock rasps, a product fault may be possible with regard to the alignment of the rasp head. An excerpt from the technical drawing will illustrate this:



[1] The product recall concerns all products of the above-mentioned REF numbers. A limitation to individual lots is not possible.



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

As one can see in the picture, the rasp head shows a curve. In the defective products, the rasp head was rotated by 180° and welded onto the rasp handle. This defect pattern could be found in individual products of all sizes and could not be limited to specific lots. It should be mentioned that not all rasps show the product defect described.

You are being informed, as you have at least one instrument container on stock which might contain potentially defect CarpoFit® monoblock broaches.

The instrument containers in question are as follows:

| **Affected Instrument Container** | **REF Number** |
|---|---|
| CarpoFit® – container | 00519900 |
| CarpoFit® container 1 | 00519901 |

Each instrument container contains all broach sizes (sizes 5 to 8)

**Risk Assessment / Patient Aftercare:**

All possible risks are detected intraoperatively. Therefore, a specific patient aftercare is not necessary.

implantcast GmbH knows no case, in which a patient was affected due to a faulty CarpoFit® monoblock broach.

<table>
<tr><th colspan="3">Hazardous Situations</th></tr>
<tr><td rowspan="2">Description of direct health consequences that could result from the use of or exposure to the product in question.</td><td>Most Probable Consequence</td><td>Most Serious Consequence</td></tr>
<tr><td>The fault in the rasps is detected intraoperatively <u>before</u> the rasping process:<br><br>The faults rasp may be turned by 180° and then used.<br><u>No effect on the patient is to be expected.</u></td><td>The fault in the rasps is <u>not</u> detected before the rasping process:<br><br>Preparation is performed using a faulty rasp. This <u>may</u> result <u>in a bone fissure or a tilting / incomplete impacting of the stem.</u><br><br>Both will be notices latest when trial positioning and stability testing is performed and will be corrected intraoperatively.</td></tr>
<tr><td rowspan="2">Description of long-term health consequences that could result from the use of or exposure to the product in question.</td><td>Most Probable Consequence</td><td>Most Serious Consequence</td></tr>
<tr><td>None</td><td>None</td></tr>
</table>

**Course of action to be conducted:**

1. Please read this safety information carefully and make sure all relevant departments and officeholders are informed about its content.

2. Please keep this safety information.

3. Please fill in the attached reply form and return it to implantcast GmbH within **five working days** via E-mail to FSCA@implantcast.de.
4. Please return affected instrument container to implantcast GmbH.

The target date for completion of this action is **23.05.2025**. Your prompt response will enable us to meet this deadline and to ensure that all non-compliant products are removed from the market as soon as possible.

We confirm that the respective European National Competent Authorities have been notified about this urgent safety information according to MDR EU 2017/745.

On behalf of implantcast GmbH we would like to thank you for your help and support with the implementation of this measure and apologize for any inconvenience caused.

We would like to assure you that implantcast GmbH does all in its power to ensure that only such products are on the market that comply with your and our high standards of quality.

Should any questions arise, please contact our product manager for CarpoFit® system or our director sales and marketing.

**Product Manager**

[redacted]

**Director Sales and Marketing**

[redacted]

Sincerely yours

[redacted]

Leiter Marketing und Vertrieb

[redacted]

PRRC-Safety

Please return by e-mail to FSCA@implantcast.de

## Reply form urgent safety information

**implantcast Referenz-No.:** FSCA_25001

| Affected Instrument Container | REF Number | LOT Number |
|---|---|---|
| CarpoFit® – container | 00519900 | |
| CarpoFit® container 1 | 00519901 | |

**BY SIGNING YOU CONFIRM:**

1. Having received the urgent safety information dated 08.05.2025 as well as having taken note of the received information.

2. That all instrument containers that contain possibly defecitve CarpoFit® monoblock broaches will be returned to the following address:

   implantcast GmbH
   AWS-Eingang
   FSCA_25001
   Alter Postweg 10b
   21614 Buxtehude

**Please sign the reply form and return it by E-Mail to: FSCA@implantcast.de.**

| | |
|---|---|
| Hospital and Address | |
| implantcast Customer Number | |
| Name of Contact Person | |
| Function of Contact Person | |
| Phone No. of Contact Person | |
| Date | Signature |