Bricon GmbH
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Bricon GmbH | Eisenbahnstrasse 100 | 78573 Wurmlingen | Germany

Wurmlingen, 01.08.2023

Urgent Field Safety Notice – RECALL OF MEDICAL DEVICES: OCT Monoaxial 6,0x45mm and OCT Polyaxial 6,0x45mm screws

Dear Sir or Madam,
Dear Customer,

Our records indicate that you may be affected by this urgent safety information. Therefore, we contact you directly.

In the course of an internal audit, we discovered that we had placed screws on the market in accordance with incorrect specifications.
We will therefore recall all screws

Art. No.	Batch	Designation
BN.700.703.660.045	2023004460, 2023004699, 2023004545, 2023004459	OCT Monoaxial 6,0x45mm
BN.700.423.660.045	2023002709	OCT Polyaxial 6,0x45mm

from the market.

With this letter we want to inform you about the following points:
- Identification of affected products and batches
- Description of the problem
- Risks for users and patients
- Corrective Actions of Bricon GmbH

If you discover that you have a subsequent product, we kindly ask you to follow the following instructions of this safety information notice.
If you discover that you have forwarded the product(s) to third parties, we kindly ask you to forward this safety information accordingly.
Alternatively, you can inform the below listed contact person in this regard

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Identification of affected medical devices:

Art. No.	Batch	Designation
BN.700.703.660.045	2023004460, 2023004699, 2023004545, 2023004459	OCT Monoaxial 6,0x45mm
BN.700.423.660.045	2023002709	OCT Polyaxial 6,0x45mm

Description of the problem
The implants listed were placed on the market incorrectly.
The labelled screw diameter Ø6.5 does not correspond to the actual screw diameter of the screw Ø6.0.

Risks for users and patients
The implants listed do not have any other known technical errors that could pose a risk to users, patients or third parties. However, the use of one of the implants could have a negative impact on the stability of the pedicle screw system or the healing process.

Corrective Actions of Bricon GmbH
Since the products listed above are not 100% compliant with the technical specifications, we are hereby recalling all of the products mentioned that are still in circulation.

For this process, we ask for your support and compliance with the following steps:

1. Please confirm receipt of the letter by **August 31, 2023.**
We have prepared a confirmation of receipt for you below.

2. Please check whether you have one of the above listed products.

3. If you are in possession of one of the implants concerned, we ask you to note this on the receipt with the relevant contact details and to prepare the implants for collection.
We will arrange for the collection to be carried out and then take care of the commercial process.

4. Please keep a copy of the completed form for your records.

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If you have any questions about the process, please contact the following contact person:

Contact person:

Bricon GmbH
Eisenbahnstrasse 100
78573 Wurmlingen
Germany

Mr. Christian Denzel
Christian.Denzel@Bricon.com
TEL.: +49 (0) 7461-9336 666

We hereby apologize for any inconvenience caused by us and thank you for your cooperation.

Best regards,

Christian Denzel
Digital unterschrieben von
Christian Denzel
Datum: 2023.08.01 13:01:45 +02'00'

Christian Denzel
Head of Quality & Regulatory Affairs
PRRC

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CUSTOMER ACKNOWLEDGMENT

Contact details

Name Customer / Company / Clinic / User	
Contact person E-Mail / Phone	
Address Street, place, country	

I hereby confirm that I have received the urgent fiel safety notice of Bricon GmbH and that I have read, checked and understood all the provided information.

Signature Name (block letters) Date

a. This is to certify, that NONE of the mentioned implants are available ☐

b. This is to certify, that a listed implant exists (in my possession) ☐

Pickup address (only if **b.** is applicable)

Name Customer / Company / Clinic / User	
Address Street, place, country	
Contact person	
Phone No.	
E-Mail Address	

Please send the completed form to:

Christian.Denzel@bricon.com

The Bricon GmbH thanks you for your support.