

Wurmlingen, 06.05.2021

Urgent Field Safety Notice – RECALL OF MEDICAL DEVICES: Shark CP Screw FIX, 4,0 x 16 mm, SD

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 from batch **01099089**
of the type **Shark CP screw FIX, 4.0 x 16 mm, SD**
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.

Identification of affected medical devices:

Art. No.	Designation
700.515.119.116	Shark CP Schraube FIX, 4,0 x 16 mm, SD

Affected batches: 01099089

Description of the problem

The implants listed were incorrectly placed on the market.
The length of the screws falls short of the specification and therefore does not correspond to the marking of "16mm".

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 cervical plate 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 **May 21st, 2021**.
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.

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

Contact person:

Bricon GmbH
Eisenbahnstrasse 100
78573 Wurmlingen
Germany

Mr. Oskar Döring
oskar.doering@briconmedical.com
TEL.: +49 (0) 7461-9336 666

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

Best regards,

Oskar Döring
Manager Quality & Regulatory Affairs
Safety Officer for medical devices

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 field safety notice of Bricon GmbH and that I have read, checked and understood all the provided information.

Signature	Name (block letters)	Date
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- 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:

incidents@briconmedical.com

The Bricon GmbH thanks you for your support.