

Orthobion GmbH, Gottlieb-Daimler-Str. 5, 78467 Konstanz

[REDACTED]
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Datum : 19.02.2020

Ansprechpartner : [REDACTED]

Tel : [REDACTED]

E-Mail : [REDACTED]

URGEND: REPORTABLE EVENT OF MEDICAL DEVICES

To whom it may belong,

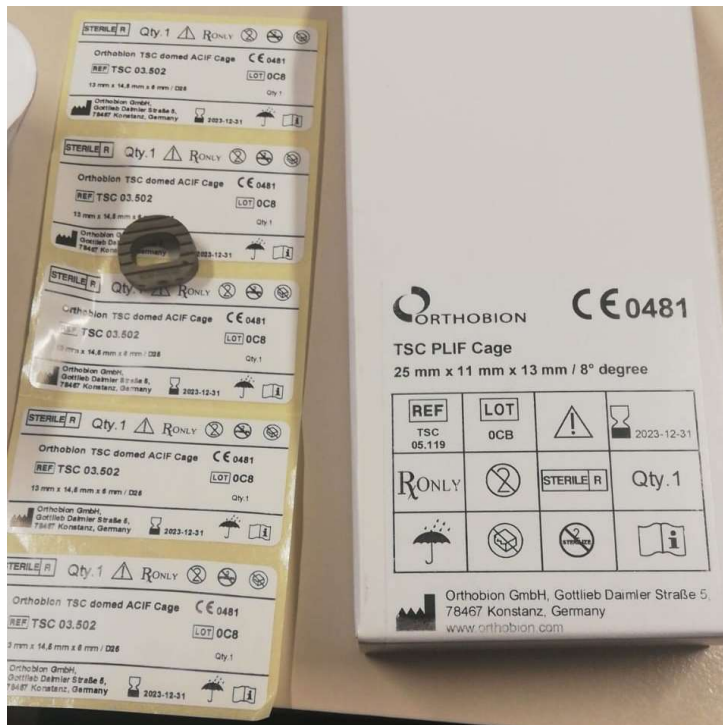
we want to inform you about a recall of Orthobion medical devices. Reason is a packaging issue.

Productdata:

LOT	REF	Description	MHD
OCB	05.119	TSC PLIF Cage	2023-12-31
OC8	03.502	TSC domed ACIF Cage	2023-12-31

Specification of the incident:

We are informed that in the inside of a TSC PLIF Labeled Cage a TSC ACIF domed Cage was packed. The following picture was sent to this incident:



Cause of this incident of LOT in the grey area was a mix up in the production. It was a human failure and both LOT could be complete affected.

Risk assesment:

There are two options:

Option 1: In the box is the cage as described on the outside label. This is not a problem.

Option 2: In the box is a TSC ACIF domed Cage. The Surgeon will recognize this immediately, because he is not able to connect a cervical cage with a lumbar instrument. Also the size and shape of the trial cage is complete different to the medical device.

Conclusion of the risk assesment:

There is no risk to the patient, because it is not possible to connect a cervical cage with a lumbar instrument. Also the size and shape of the trial cage is complete different to the wrong packed medical device.

Process of the recall:

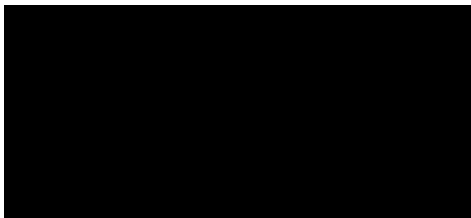
Please proceed in the following way:

1. Check your Stock and block the named LOT.
2. If you had saled this product, please inform your customers imediately with this letter about the recall.
3. Collect all products
4. Send the back to this address

Orthobion GmbH
c/o Mail Boxes ETC
Gottlieb-Daimler-Str. 7
78467 Konstanz
Deutschland

5. Inform us about the delivery with the tracking no to this E-Mail : spine@orthobion.com .
6. All recalled devices will be replaced.

With kind regards



Please confirm this letter and described recall process.

Name: _____

Position: _____

Date: _____

Signature: _____