

URGENT FIELD SAFETY NOTICE

Bone screws for cancellous bone

Product name: Bone screws for cancellous bone
FSCA number: 02/2021
Action type: Voluntary Field Safety Notice on medical device
Date: 10/09/2021

Single Registration Number (SRN) IT-MF-000010690

To the kind attention of: Health Directors; Orthopaedic Head Physicians;
 Orthopaedic Surgeons; Vigilance Directors; Chief
 Executive Officers (only for Private Facilities)

Code: See Table 1

Unique Device Identification (UDI-DI): See Table 1

Device type: Bone screws for cancellous bone

Lot number: See Table 1

Sterilization number: See Table 1

Notes: /

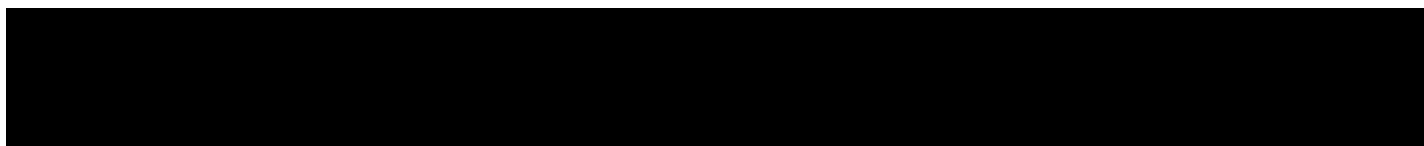
<i>Product code</i>	<i>Product description</i>	<i>Product lot number</i>	<i>Sterilization lot number</i>	<i>Unique Device Identification (UDI-DI):</i>
8420.15.020	BONE SCREW Ø6,5 H.25MM	2103525	2100099	08033390018852
8420.15.010	BONE SCREW Ø6,5 H.20MM	2103825	2100099	08033390018845

Table 1: Product information

Product description

Bone screws for cancellous bone are intended to be fixed to cancellous bone and are mainly used in combination with hip acetabular cups, knee and shoulder prosthesis.

All sizes have diameter of 6.5 mm, but they differ on the length: the length of bone screws for cancellous bone ranges from 15 mm to 90 mm, with 5 mm of increment. See product image below:



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Figure 1: LimaCorporate bone screw for cancellous bone

Problem description

Internal analyses following a complaint received from the market highlighted a potential anomaly on the external labeling of the devices listed in Table 1.

In details, the length of the bone screw reported on the label might not correspond to the actual length of the screw:

- With reference to product code 8420.15.020, lot 2103525, ster. 2100099: the product code and the length reported in the label identify the bone screws with diameter 6,5 mm and length 25 mm, while the actual length of the screw might be 20 mm;
- With reference to product code 8420.15.010, lot 2103825 ster. 2100099: the product code and the length reported on the label, identify the bone screws with diameter 6,5 mm and length 20 mm, while the actual length of the screw might be 25 mm;



Figure 2: Products labels

Depending on the anatomical section where the screws are implanted, the erroneous implantation of a screw 5 mm longer or shorter than planned, in the worst-case circumstances may lead to the following consequences:

- Knee: the length mismatch is detected intra-operatively after the implantation of the screw in the proximal tibia and the screw has to be replaced with the correct one,
- Hip: an overlong screw might penetrate into the pelvis, causing possible damages, while a screw too short might contribute to the premature loosening of the acetabular cup,
- Shoulder: if an overlong screw is implanted in the glenoid at the superior position, it would be possible to irritate or injure the suprascapular nerve.

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However, in the most likely case scenarios, the erroneous implantation of a screw 5 mm longer or shorter than planned, is not expected to cause negative consequences for the patient.

LimaCorporate is not aware of any consequences occurred due to this potential information discrepancy.

To avoid any further implantation of the potentially affected screws, LimaCorporate decided to voluntarily recall from the Hospitals all the items with the product information listed in Table 1.

As a further precautionary measure, this Field Safety Notice is going to be issued to all the Hospitals where at least one product with codes/lot numbers listed in Table 1 has already been implanted, with the aim to inform the surgeons of the potential mismatch.

The surgeons are advised to continue monitoring the patients according to the standard clinical follow-up protocol and act accordingly.

Action to be taken

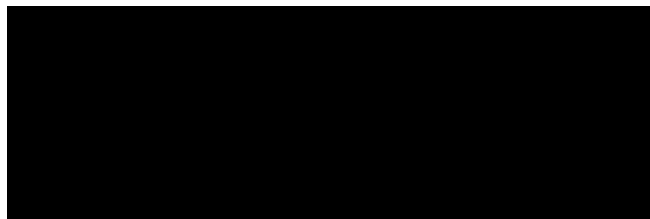
We kindly ask You to:

1. Check your stock to locate and quarantine the affected devices received. Affected devices are required to be sent back to LimaCorporate together with a hard copy of the attached Response Form;
2. Fill out, sign and send the attached Response Form to the email address pms@limacorporate.com, as a confirmation that You have read and acknowledged the content of this FSN;

If needed, please address any inquiry on this FSN to the email address medicalcomplaints@limacorporate.com.

Dissemination of this FSN

This notice needs to be passed on all those who need to be aware within your organization. This Field Safety Notice will be sent to the Competent Authorities of the Countries involved in this Field Safety Corrective Action.



RESPONSE FORM

FSCA 02/2021

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To be completed, signed and sent to LimaCorporate urgently.

Please check the following box:

☐ I have read and understood the instructions provided in this Field Safety Notice.

Person name: _____

Title: _____

Structure name: _____

Date and Signature: _____

☐ I have checked my stock and have the following devices:

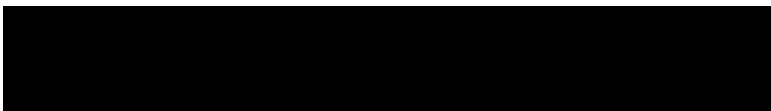
Product code	Lot number	Sterilization number	Quantity

Please fax or e-mail completed response form to:

Dr. Federica Malvaso - Dr. Lea Caramma

E-mail: pms@limacorporate.com

Fax: +39 0432 945512

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