HOSPITAL ADDRESS

Eragny, May 25th, 2022

Registered letter with acknowledgment of receipt
To the attention of the Hospital Director and the Vigilance Officer

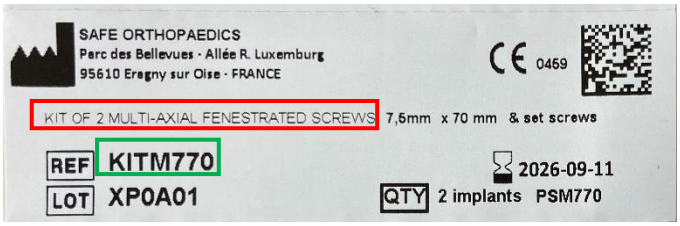
Object: URGENT - FIELD SAFETY NOTICE / AVIS DE SECURITE

Concerned devices: kits of the product range KITM « KIT OF 2 MULTI-AXIAL SCREWS » SteriSpine PS
References / Lots concerned: Ref # KITM535 : Lot # BB0A01 - Ref # KITM540 : Lot # 15BC011/R10 ; BC0A03 - Ref # KITM545 : Lot # BD0A03 - Ref # KITM635: Lot # BE0A03/1 - Ref # KITM640 : Lot # BF0A07 ; 15BF001/R10 - Ref # KITM645 : Lot # 15BG004/R10 ; 15BG006/R10 ; 15BG001/R10 ; BG0A02 - Ref # KITM735 : Lot # 15BK010/R10 ; BK0A01 ; BK0A02 - Ref # KITM740 : Lot # BL0A01 - Ref # KITM770 : Lot # XP0A01 - Ref # KITM780 : Lot # XR0A01
File reference: FSN2022-02/02 Patient Label

Dear Sir or Madam,

Safe Orthopaedics was informed by its subcontractor about a labeling error on the patient labels of the product range KITM « KIT OF 2 MULTI-AXIAL SCREWS » mentioned in the object of this current letter.

The non-conformity on the patient labels concerns the designation of the product. The designation of the product refers to the product range KITMF « KIT OF 2 MULTI-AXIAL FENESTRATED SCREWS » instead of the product range KITM «KIT OF 2 MULTI-AXIAL SCREWS »



The reference, the traceability as well as the dimensions of the screws of the product are conform. The implants in the kits are in compliance with the reference mentioned on the label.

The designation mentioned on the traceability label of the box, inside and outside, is conform, and corresponds to the product reference.

This incident occurred during the printing of labels by our subcontractor. Investigations revealed that several batches were affected, and corrective actions were defined with our subcontractor to avoid this error again.

Consequences and risks for the user and/or patient:

No consequence for the user or the patient if the implant is placed.

The only identified consequence is a potential risk of confusion during the traceability record in patient file, if the personal healthcare reads the product designation on patient label.

SafeOrthopaedics Parc des Bellevues Allée R. Luxemburg, Le Californie 95610 Eragny sur Oise - FRANCE
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That means that personal healthcare should check the conformity with the control of the main label on the box and the control of products.

What you have to do:

Safe Orthopaedics identified that you had at least one affected device in your establishment deposit. We invite you to read this notice carefully and to take the measures described below:

Kindly:

1) Carefully read this notice and disseminate this notice to all relevant departments in your organization.
2) Inform immediately Safe Orthopaedics if one of the concerned devices was distributed to other organizations and communicate the contact details to facilitate the communication with the users.
3) Inform Safe Orthopaedics of any adverse effect observed regarding this notice and your local competent authority according to vigilance requirements established in new Regulation MDR 2017/745 and the guidance MEDDEV 2.12-1 rev 8.
4) Stop all distribution and use of the products concerned, withdraw all products wherever they are and put them in quarantine.
5) Complete the Field Safety notice FSN2022-02 response form and attach it to the inventory list of the pieces put in quarantine per manufacturing lot, regardless the level of your stock (even zero). Indeed, your confirmation will allow Safe Orthopaedics to carry out a complete traceability of this recall and avoid any unnecessary reminder.
6) As far as the products being implanted are concerned, Safe Orthopaedics recommend to correct their traceability in the patients' files being concerned.
7) Return Field Safety notice FSN2022-02 response form it to Safe Orthopaedics by email qara@safeorthopaedics.com, or by fax +33 1 34 21 12 00.

We would be much obliged if you could reply to this notice within 10 days from the receipt date regarding to products in your inventory.

Upon receipt, our Sales Customer department will contact you to organize returns of the unused products placed in quarantine, and the product replacement.

We confirm that the relevant competent authorities, have been notified of the actions described herein.

Be assured that the safety and well-being of patients and healthcare professionals is the priority of Safe Orthopaedics, and we thank you in advance for your comprehension, your confidence, and your collaboration. For further questions, please contact your Safe Orthopaedics representative.

Please accept the expression of our distinguished greetings.

Sincerely,

Sophie MARQUILLIE
Quality and regulatory affairs Director

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