Distributor/Hospital Adress
NEDHERLANDS

Eragny, the 16th december 2022

Mail delivered by hand by a representative of Safe Orthopedics

For the attention of the Materiovigilance Correspondent

Objet: URGENT- FIELD SAFETY NOTICE / AVIS DE SECURITE

Devices concerned: Cement Pushers kit et Needle Kit
Reference concerned: PICD-CPI/PICD-CFI ET SPICD-CA2/SPICD-NDB2
Batches concerned: WA21050402; WA21050403 ; WA211002503 ; WA22012101 ; WA22101801; WA19080212; WA19080213
File Reference: FSN2022-03

Dear Sir or Madam,

Safe Orthopedics has detected an anomaly concerning the instructions for use of the Cement Pushers and Kit Needle **kits.**
The problem concerns an inversion of the instructions for use during the packaging of the kits following an initial inversion of the references of the instructions in the internal assembly instruction.

This incident occurs during the packaging of the kits. The investigation revealed seven affected batches. The corrective actions have been defined internally in order to avoid the reproduction of this error.

Consequences and risks for the user and/or the patient:

No consequences for the user or the patient because the designation of the product on the outer label of the kit is compliant. The kit that the surgeon will need during surgery is easily identifiable. The surgeon has all the elements for the safe use of the products (good labelling, compliant products, compliant surgical technique). In addition, the operating room staff can check which product it is before opening the kit thanks to the window of the packaging box allowing the composition of the kit to be viewed. **The identified consequence is a risk of doubt if the operating room staff read the instructions for use before using the product.**

To date, we have not received any complaints in connection with this confusion.

The product will not be recalled; however a field correction will be made.

What you need to do:

Safe Orthopedics has identified that you still have at least one of the affected devices on deposit at your facility. We urge you to read this notice carefully and take the actions described below:

Orthopaedics Pare des Bellevues Allée R. Luxemburg, Le Californie 95610 Eragny sur Oise - FRANCE
SA au capital de 4 864 022,40€ - RCS Pontoise 520 722 646 -APE 3250A

Thank you kindly to:

1. Read this notice, and share this notice within your institution, and the institutions to which devices have been transferred or may be affected by this action.
2. Inform Safe Orthopedics if any of the affected devices have been distributed to other organizations and provide contact details so that Safe Orthopedics can contact users directly.
3. Inform Safe Orthopedics in the event of an adverse effect observed in connection with this notice, in your country, as well as your national competent authority, in accordance with the principles of materiovigilance defined in the new MDR 2017/745 regulation and the MEDDEV 2.12-1 rev 8 guide.
4. Cease all distribution or use of the affected devices, remove these devices wherever they are and place them in quarantine until they have been reworked/retouched.
5. Complete the attachment "Certificate of Safety Notice" with the inventory of the quantities placed in quarantine by batch number regardless of the level of your stock, even if your stock is zero. Your confirmation will allow us to carry out full traceability of this recall and avoid any unnecessary reminders.
6. Return the duly completed, dated and signed certificate by e-mail to qara@safeorthopedics.com, or by fax to 01 34 21 12 00.
7. Retouching of non-compliant products will be done by your sales representatives. Compliant instructions will be included in the kits affected by this rework.

Your competent authority has been informed of this safety notice.

The company Safe Orthopedics, concerned about the irreproachable quality of the products it distributes, thanks you for your understanding, your confidence and your collaboration.

If you have any questions, please contact your Safe Orthopedics representative.

Yours sincerely.

Direction QARA

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