Proven French innovation in orthopaedics

FIELD SAFETY NOTICE: Product Recall

June 12sd, 2018

Name of the trademark: SCULTRA II – STANDARD – Humeral Stem CIMENTED - Ø9mm L180mm

FSCA Ref.: RECALL-2018-02

Type of measure: Product recall

Batch number affected: 19412801

Please note that: This warning notice only affects the batch indicated on the attached list. No other batch of products is affected.

Dear Sir/Madam,

By this letter, we inform you about the recall of one of our products listed below.

According to our records, at least one of the products concerned, which are listed below, has been delivered to you and is concerned by this action.

Reference	Name	BATCH
A22811151	SCULTRA II – STANDARD – Tige Humérale CIMENTEE - Ø9mm L180mm	19412801

Incident description

Further to a customer complaint, it has been identified that there has been a labeling error during the manufacture of humeral stems cemented SCULTRA II STANDARD Reference A22811151 batch number 19412801.
It is probable that some units in this batch contain the wrong size of Humeral stems (6.5mm diameter instead of 9mm diameter).

Z.E. Athélia III - 13600 La Ciotat - France
Tel. : +33 4 42 71 42 71 | Fax : +33 4 42 71 42 80
E-mail : euros@euros.fr
www.euros-orthopaedics.com

Risk analysis

The potential risks associated with this incident are:

The most probable scenario	The worst-case scenario (unlikely)
Increase of the operating time: need to find an alternative solution (same reference in stock, other size, competitor product, …)	Possible implantation of a Ø6.5mm humeral stem instead of a Ø9mm humeral stem if the error is not detected during surgery. However clinical impact is negligible as the use of cement filling would ensure sufficient stability and performance of a Ø6.5mm humeral stem.

Measures to be taken by the user

Please carefully read this notice and take the measures listed below:

- Identify and immediately quarantine all the devices concerned not yet used.
- Return the products quarantined to EUROS at the following address:

Service Logistique
Z.E Athélia III
824 Voie Antiope
13600 La Ciotat
FRANCE

- Fill-in the attached reply coupon and send it to EUROS by email qualite@euros.fr or by fax to +33442714280
- Make sure that the safety information is transmitted to all those who need to be aware of it within the organization.
- Keep a copy of the acknowledgement of receipt in your vigilance files: you may be asked to provide it in case of documentation audit of your organization

Please reply to this notice within 7 days following its receipt.

Transmission of this safety notice

This notice has been sent to you because the records indicate that your organization has received this device with the affected batch number referenced above. This notice must be given to all those who need to be aware of it inside your organization or any organization where these products may have been transferred.

According to the European Medical Device Directive 93/42/EEC and applicable vigilance guidelines (MEDDEV reference 2.12/1), we confirm that the French competent authority (ANSM) and any other concerned competent authorities have been informed of this field safety corrective action.

We sincerely thank you for your help and cooperation in the application of this action and we are sorry for any inconvenience caused. We would like to confirm that EUROS is committed to ensuring patients safety and to commercializing reliable and efficient products.

Should you have any question, please do not hesitate to contact Mrs ANGELI Carine, EUROS Quality and Regulatory Affairs Manager.

Carine ANGELI
Quality & Regulatory affairs Manager

Z.E. Athélia III - 13600 La Ciotat - France
Tel. : +33 4 42 71 42 71 | Fax : +33 4 42 71 42 80
E-mail : euros@euros.fr

Confirmation of reception form

This form acknowledges receipt of the recall notice (RECALL-2018-02) transmitted by EUROS regarding the devices « SCULTRA II – STANDARD – Humeral Stem – CEMENTED – Ø9mm L180mm ».

Please tick and fill in the boxe(s) that concern(s) you:

❒ We didn't find any affected device in our stock. A copy of this letter is kept in our records.

❒ We identified the concerned device(s) in our stock. A copy of this letter is kept in our records:

Reference	Batch	Quarantined stock quantity	Quantity already used prior to receipt this recall notice
A22811151	19412801		

❒ We also distributed the affected device(s) to the following organizations:

Reference	Batch	Name and address of the establishment	Quantities distributed to this establishment
A22811151	19412801		
A22811151	19412801		

Form filled in by:
Name and profession:
Establishment:
Phone number:
Email address:
Signature and date:

Please fill in this document and send it by:
Mail : qualite@euros.fr
Fax : +33 4.42.71.42.80