FIELD SAFETY NOTICE: Product Recall

January 29th, 2021

Name of the trademark: EUROP UNI FIXE – Tibial insert – Size 1

FSCA Ref.: FSCA-2021-01

Type of measure: Product recall

Batch number affected: 24304602 and 24304802

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
A271411071	EUROP – UNI FIXE – Tibial Insert – Right Medial / Left Lateral – Size 1 – Thickness 7 mm	24304802
A271410131	EUROP – UNI FIXE – Tibial Insert – Left Medial / Right Lateral – Size 1 – Thickness 13 mm	24304602

Incident description

Further to a customer complaint, it has been identified that there has been a labeling error during the manufacture of tibial inserts EUROP UNI FIXE Reference A271411071 batch number 24304802 and Reference A271410131 batch number 24304602.
It is probable that some units in these batches contain the wrong size of tibial insert (respectively thickness 13mm instead of 7mm and thickness 7mm instead of 13mm).

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)
This error can be detected during implants preparation (thickness engraved on the insert) or during the insert impaction. If an insert with the same size and the same thickness is available in the facility : increase of the operating time to find the implant in the warehouse. If no insert with the same size and the same thickness is available in the facility: - An insert with upper size and same thickness can be implanted. This could led to an increase of the surgery duration with the tibial baseplate removal (if already implanted) and the cement removal if applicable. - An insert with upper thickness. This could led to an increase of the surgery duration if an additional tibial cut is performed or a more tightened joint if no additional cut is performed.	New surgery in the event that the substitution device in not perfectly suited to the patient

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, Regulatory Affairs and Clinical Director.

Carine ANGELI
Quality, Regulatory affairs & Clinical Director

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 (FSCA-2021-01) transmitted by EUROS regarding the devices « EUROP – UNI FIXE – Tibial Insert – Right Medial / Left Lateral – Size 1 – Thickness 7 mm » and « EUROP – UNI FIXE – Tibial Insert – Left Medial / Right Lateral – Size 1 – Thickness 13 mm ».

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
A271411071	24304802		
A271410131	24304602		

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