

To the attention of recipient

Registered letter with acknowledgment of receipt

URGENT MEDICAL DEVICE

FIELD SAFETY NOTICE

Subject: **Field Safety Notice regarding Unity CS Inserts**

Devices concerned: **Refer to the list of part numbers and batches concerned**

Our/Ref.: **FA 2022 002 – FSN Rev: 1.0 – Date: 19 July 2022**

Person in charge of the follow-up: Clementine Caullet

Dear Sir or Madam,

The purpose of this letter is to advise you that Corin has initiated a voluntarily recall action of 30 batches of Unity CS Inserts, listed in appendix.

Reason for the Voluntary Recall:

Following a complaint from a subsidiary, Corin has identified a number of Unity CS Insert batches without the CE mark affixed on the product label and in distribution in the European and GB markets. Whilst this deviation does not impact from a safety perspective as Unity CS is CE marked, it does present a contravention of regulatory requirements.

Intended Use:

The Unity Knee CS Tibial insert is designed to securely fix with the locking mechanism on the Unity Knee™ tibial tray and is compatible with the Unity Knee™ CR Femoral Component only. The condylar stabilized (CS) fixed tibial insert is intended to be implanted in knee joints, where there is a deficiency on the posterior cruciate ligament (PCL) or where the PCL is absent.

Potential Patient Risk:

There is no impact to a patient implanted with one of these devices.

Identification of the customer concerned by the field action:

Our records indicate that you have received one or more of the products listed in the Appendix. Therefore, we ask for your help to implement this field action by taking the following actions.

Actions to be carried out by the customer

- Return the devices displaying the RGA note on the exterior of the parcel to:
RA/Vigilance Department, Corin UK Ltd, The Corinium Centre, Cirencester, Gloucestershire, GL7 1YJ, United-Kingdom
- Complete the acknowledgement of receipt and forward it to the Vigilance department of Corin UK at vigilance@coringroup.com to confirm receipt of this Field Safety Notice.

For any complementary information concerning this event, please contact: Clementine Caullet on +44(0)7788 391 659 or by e-mail to vigilance@coringroup.com.

We are taking every measure to satisfy you and we are grateful for your understanding and cooperation.

We thank you for working with us and for your continued trust in our company.

Yours faithfully,



Global Regulatory Affairs Director

Appendix: Affected batches

List of references or UDI number and numbers of batches concerned.

[Table to be adapted to the recipient]

Commercial references/Part number or UDI number	Name	Batch number	[Optional: Quantity received by recipient]

Acknowledgment of receipt

Please complete this acknowledgment of receipt and return it within 14 days

by e-mail to vigilance@coringroup.com

Login: FA 2022 002 – FSN Rev: 1.0 – Date: 19 July 2022:

Hospital / Company's name: _____

NAME: _____

Function: _____

Address: _____

Phone number: _____

Quantity	Part number	Lot code	Name	Quantity Used	Quantity Returned

I certify that:

- I have received from the company CORIN the notice concerning the field action FA 2022 002 and have released it to the involved persons.
- I have checked the presence in stock of the concerned devices and proceed to their quarantine. Thus, I fill up in the above table.

Date: _____

Signature: _____