Hospital/clinical Director,
Head of operating room,
Pharmacist/ Vigilance correspondent,

Registered letter with acknowledgment of receipt

FIELD SAFETY NOTICE/RECALL LETTER

Subject: **FSCA notice: Unity CR Femur Right size 6 and size 7**

Devices concerned:

Part Number	Lot Code	Device name
112.001.32	529803	Unity CR Femur Right size 6 
112.001.34	532405	Unity CR Femur Right size 7 

Our/Ref.: **FA-COR-2023-004 – FSN Rev: 1.0 – Date: 20 Sept 2023**

Person in charge of the recall: **Marie-Anne Euzen**

Dear Sir or Madam,

The purpose of this letter is to advise you that Corin is voluntarily recalling two specific lot numbers of the Unity CR Femurs identified above.

Intended Use:
The Unity Knee is a fixed bearing total knee replacement system.

Reason for the Voluntary Recall:
Following a report from the field, Corin has identified a Unity CR Insert Right size 6 from batch 529803 incorrectly labelled as a Unity CR Insert Right size 7 from batch 532405. The failure was identified and the part was not implanted. No other complaint was received on parts from these batches. It is unknown how many parts from these batches are affected. All non-implanted parts of these batches are being recalled.

Potential Risk:
Due to the size being very similar, the failure may not be detected during surgery and an incorrect implant size may be implanted.

Implanting the incorrect size could trigger two situations:

- The implant is too small for the bone preparation. Impaction would be difficult with the risk of causing bone damage and/or improper seating of the implant.

- The implant is too big for the bone preparation. The cement may not have bridged all gaps between the implant and the bone, or the implant may not be seated properly. If the implant overhangs the bone, the edges could cause soft tissue irritation. It is also possible that forcing the pegs in could cause the femoral bone to crack.

These events would have been identified during the surgery or on post-op X-ray. Only events that would have a minor impact on the device performance would have remained undetected.

There is no issue of compatibility with the other components of the Unity system, as this system is compatible with implants which are 2 sizes smaller or 2 sizes larger. Therefore, Corin does not recommend to explant the affected devices, nor recommends any increased monitoring of patients that have been implanted with any of the devices within the scope of this voluntary recall.

Identification of the customer concerned by the field action:

Our data indicates that you have received product from these batches. We request you to perform the actions listed below.

If you are a distributor, we ask for you to communicate this Field Safety Notice to the applicable hospitals and return any unused product to Corin.

Actions to be taken by the Customer:
- Communicate this FSN to the affected customers if applicable

- Quarantine the devices

- Return the devices to Corin Limited, displaying the RGA note on the exterior of the parcel, to:
RA/Vigilance Department; Corin Ltd; Corinium Centre; Cirencester; Gloucestershire; GL7 1YJ, United-Kingdom

-Complete the acknowledgement of receipt and forward it to the Vigilance department of Corin UK to confirm receipt of this Field Safety Notice.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

For all questions on this Field Safety Notice/Recall Letter, please contact me at +1 772-321-2478 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,

Lucinda Gerber
Global Quality, Regulatory and Clinical Director

Acknowledgment of receipt

Please complete this acknowledgment of receipt and return it within **7 days**
by e-mail to **vigilance@coringroup.com**

Login: FA-COR-2023-004 – FSN Rev:1.0 – Date: 20 Sept 2023

Hospital / Company's name: _____

NAME: _____

Function: _____

Address: _____

_____

_____

Phone number: _____

Part number	Lot code	Name	Quantity Returned	Quantity Implanted
112.001.32	529803	Unity CR Femur Right size 6		
112.001.34	532405	Unity CR Femur Right size 7		

I certify that:

- I have received from the company CORIN the notice concerning the field action # FA-COR-2023-004 and have released it to the involved persons and affected customers (if applicable)
- I have the affected products and I proceed to their quarantine; thus, I fill up in the above table.
- The affected products were implanted; thus, I fill up in the above table.

Date: _____ Signature: _____