

URGENT: MEDICAL DEVICE RECALL (REMOVAL)
**CORAIL® Cementless Femoral Stem HA coated, 12/14 AMT, 135°, Standard,
No Collar, Size 12 (Product Code: 3L92512 Lot: 5300693)**

April 29, 2019

Dear Trust Chief Executives, the Clinical Director of the Orthopaedic Department, the Orthopaedic Theatre Manager, the Safety Liaison Officer, General Managers of Private Sector Hospitals, Distributors:

PRODUCT NAME	PRODUCT CODE	DESCRIPTION / SIZE	PRODUCT LOTS	GTIN
CORAIL® Cementless Stem to be used for Total and Partial Hip Arthroplasty	3L92512	CORAIL® Cementless Femoral Stem HA coated, 12/14 AMT, 135°, Standard, No Collar, Size 12	5300693	10603295168782

Intended Use:

CORAIL® Cementless Stem is used for Total and Partial Hip Arthroplasty. Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Partial hip arthroplasty (hip hemiarthroplasty) is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem.

Reason for the Recall:

The company received a complaint that a carton of CORAIL® Cementless Femoral Stem HA coated, 12/14 AMT, 135°, Standard, No Collar, Size 12 (Product Code: 3L92512 Lot: 5300693) contained a CORAIL® Cementless Femoral Stem HA Coated Size 11. The labelling on the packaging and the laser marking on the part indicated a size 12 unit.

Initial investigation determined that this issue occurred due to an error during the polishing process. DePuy France SAS believes that other units packaged and etched as Product Code: 3L92512 Lot: 5300693 may also be size 11 units, not size 12 which is indicated on the package and etching. No other lots distributed to the field are affected by this recall.



Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
2 Science Park Drive, #07-13, Ascent, Singapore Science Park 1, Singapore 118222
Tel: +65 6918 8000
Business Reg No. 52836279L Company Reg No. 197402104W

Units Affected

DePuy France SAS is issuing a Field Safety Notice for Product Code: 3L92512, Lot: 5300693. Thirty (30) pieces of the affected lot were manufactured. No other lots distributed to the field are affected by this recall.

Depth of Recall:

This recall notice provides instructions for notifying Medical Professionals who may have purchased, received or used the affected lot of CORAIL® Cementless Femoral Stem HA coated, 12/14 AMT, 135°, Standard, No Collar, Size 12 (Product Code: 3L92512 Lot: 5300693).

The purpose of this device recall is to remove affected implants and to notify medical professionals of the possible effects if affected product has already been implanted.

Clinical Implications and Patient impact:

The possible clinical implications of a surgeon implanting a smaller device (a size 11 device rather than the intended size 12 device) are as follows:

- Loosening
- Poor Joint Mechanics
- Dislocation

The implications indicated above could potentially require revision surgery. Following are general examples of possible risks/hazards of revision surgery:

1. Infection
2. Additional scarring
3. Neural and vascular damage
4. Additional pain to the patient
5. Functional problems resulting from items 1 – 4 above
6. Anaesthesia-associated risks

DePuy France SAS is not recommending prophylactic revision in the absence of symptoms. The company recommends that surgeons discuss potential clinical implications and risks with symptomatic patients who received the affected implants.

ACTION REQUIRED:

1. Please cease using the affected devices immediately.
2. Medical facilities are to determine if any of the recalled implants are on hand and return affected implants immediately to your Depuy Sales Representative.
3. Review this notice and complete the Business Reply Form (Attachment 2) to signify that your facility has been informed of this recall. Return the completed Business Reply Form to your Depuy Sales Representative within three (3) working days of this notice.

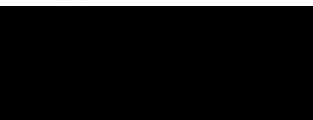
4. Retain a copy of the completed Business Reply Form in your files along with this notice.
5. Notify surgeons at your facility by providing them with a copy of this notice to ensure surgeons are aware of this recall.
6. Share this notice with others in your facility who need to be informed.
7. If any affected product has been forwarded to another facility, contact that facility immediately to communicate this field action with the facility/facilities. Inform your Depuy Sales Representative if further facilities are affected.

Attachments:

Attachment 1: Product Identification Tool

Attachment 2: Business Reply Form

Yours sincerely,



Lee Ching Hwee
Manager, Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments

**ATTACHMENT 1: CORAIL® Cementless Femoral Stem HA coated, 12/14
AMT, 135°, Standard, No Collar, Size 12**



Figure 1: CORAIL Standard Offset Stem (Collarless).
Image from the CORAIL® Hip System Product Rationale
and Surgical Technique CA#DSEM/JRC/0616/0665(2).
Issued: 06/17.

ATTACHMENT 2: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete this form and hand it to your Deputy Sales Representative **within 3 business days, even if you do not have product subject to this correction.**

If you have product lots subject to this recall (removal) to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

Product Inventory – please check one

- ☐ We have NO CORAIL® Cementless Femoral Stem HA coated lots subject to this recall (removal)
- ☐ NO CORAIL® Cementless Femoral Stem HA coated lots has already been implanted
- ☐ We have CORAIL® Cementless Femoral Stem HA coated lots subject to this recall (removal) and are returning the following products:

PRODUCT NAME	PRODUCT CODE	LOT #	Quantity Returning (Eaches)	Quantity Implanted (Eaches)
CORAIL® Cementless Stem to be used for Total and Partial Hip Arthroplasty	3L92512	5300693		

Print Name of Person Completing Business Reply Form:	Sign & Date:
Customer Account Details (Name and Address)	