DePuy Synthes
JOINT RECONSTRUCTION
COMPANIES OF Johnson & Johnson

Urgent Field Safety Notice (Recall) of CORAIL® Cementless Femoral Stem HA coated, 12/14 AMT, 135°, Standard, No Collar, Size 12 (Product Code: 3L92512 Lot: 5300693)

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

FSCA-identifier: **PIE-1104627**

Type of Action: **Field Safety Notice (Recall)**

Date: February 2018

Attention: 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

Type of device: CORAIL® Cementless Stem to be used for Total and Partial Hip Arthroplasty.

Model Name: CORAIL® Cementless Femoral Stem HA coated, 12/14 AMT, 135°, Standard, No Collar, Size 12. See Figure 1:

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.

DePuy France SAS is issuing a Field Safety Notice for Product Code: 3L92512, Lot: 5300693. 30 pieces of the impacted lot were manufactured.

Affected Implants:
Product Code: 3L92512, Lot: 5300693, GTIN 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.

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.

Please undertake the following urgent actions:

- Please cease using the affected devices immediately.
- Medical facilities are to determine if any of the recalled implants are on hand, and return affected implants immediately to their Sales Consultant.
- Review this notice and complete the Acknowledgement section (Attachment A) to signify that your facility has been informed of this recall. Return the completed Acknowledgement to your Sales Consultant within five (5) working days of this notice.
- Retain a copy of the completed Acknowledgement Form in your files along with this notice.
- Notify surgeons at your facility by providing them with a copy of this notice to ensure surgeons are aware of this recall.
- Share this notice with others in your facility who need to be informed.
- If any affected product has been forwarded to another facility, contact that facility immediately to communicate this field action with the facility/facilities. Inform DePuy Synthes if further facilities are affected.

Transmission of this Field Safety Notice:
This notice has been sent to you because our records indicate that you have received the affected product. This notice needs to be passed on to all those who need to be aware within your organization.

For any enquiries regarding this Field Safety Notice contact:

Bríd Horgan (DePuy), Recall Associate
e-mail *RA-DPYIE-VigilRecall@ITS.JNJ.com*
Tel no. +353 21 4914128

This FSN has been shared with the appropriate Regulatory Agency.

Yours sincerely,

John Wright, MD
Franchise Medical Leader - JMP
WW Vice-President, Medical Affairs

ATTACHMENT A

This Letter acknowledges receipt of the Field Safety Notice related to CORAIL® Cementless Femoral Stem HA coated, 12/14 AMT, 135°, Standard, No Collar, Size 12 (Product Code: 3L92512, Lot: 5300693).
FSCA Identifier: PIE-1104627

(Please check as appropriate)

Please fax or e-mail this completed document to [INSERT DePuy Marketing Company/Affiliate contact details]

☐ Yes, I have received the FSN

☐ Yes, I have/will return the affected devices

☐ Affected product has already been implanted

Please list the quantity of affected devices to be returned:

_____

Please list the quantity of affected devices that have already been implanted in a patient:

_____

Print Name: _____

_____
Signature

_____
Hospital Name

_____
City

_____
Country

_____
Telephone Number or e-mail address