DePuy Synthes
COMPANIES OF Johnson&Johnson

Urgent Field Safety Notice (Recall) of CORAIL® Cementless Femoral Stem HA Coated Standard Size 11 and Size 12

Product Name: **CORAIL® Cementless Femoral Stem HA Coated Standard Size 11 and Size 12**

FSCA-identifier: **PIE-1177218**

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

Date: June 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

DePuy France SAS is issuing a Field Safety Notice for the CORAIL® Cementless Femoral Stem HA Coated Standard Size 11 and Size 12. This recall is being issued as boxes labelled as CORAIL Cementless Femoral Stems HA Coated Size 11 contained CORAIL Cementless Femoral Stems HA Coated Size 12. This was reported through a customer complaint. The opposite scenario was also found during inspection at the supplier, where boxes labelled as Size 12 contained Size 11 stems.

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.

Model Name: CORAIL® Cementless Femoral Stem HA Coated Standard Size 11 and Size 12 See Figure 1:

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

Units Affected

DePuy France SAS is issuing a Field Safety Notice for the following lots;

Product Code	Lot No.	GTIN No.	Model Name
3L92512	5308136	10603295168782	CORAIL® Cementless Femoral Stem HA Coated Standard Size 12
3L92511	5307603	10603295168775	CORAIL® Cementless Femoral Stem HA Coated Standard Size 11
3L92512	5300694	10603295168782	CORAIL® Cementless Femoral Stem HA Coated Standard Size 12

Product Code	Lot No.	GTIN No.	Model Name
3L92511	5300997	10603295168775	CORAIL® Cementless Femoral Stem HA Coated Standard Size 11
3L92511	5300994	10603295168775	CORAIL® Cementless Femoral Stem HA Coated Standard Size 11
3L92512	5300692	10603295168782	CORAIL® Cementless Femoral Stem HA Coated Standard Size 12
3L92511	5300631	10603295168775	CORAIL® Cementless Femoral Stem HA Coated Standard Size 11
Unique Device Identifier (UDI): UDI = DI + PI | DI = Device Identifier = GTIN | PI = Production Identifier = Lot Number			

Clinical Implications and Patient impact:
To date, there have been 2 complaints for surgical delay. The possible clinical implications related to CORAIL® Cementless Femoral Stem HA Coated Standard Size 11 and Size 12 product mix may include the following:

- If observed during surgery, there are two potential instances in which the patient could be affected:
    - Size 12 stem package containing Size 11 inside box
        - Surgical Delay
    - Size 11 stem package containing Size 12 inside box
        - Surgical Delay
        - Bone Fracture intra-op

- If not observed during surgery, there are two potential instances in which the patient could be affected:
    - Size 12 stem package containing Size 11 inside box
        - Loosening
        - Poor Joint Mechanics
        - Dislocation
    - Size 11 stem package containing Size 12 inside box
        - Poor Joint Mechanics
        - Dislocation
        - Surgical Delay
        - Bone Fracture intra-op

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:

Clare Mathers (DePuy), Recall Associate
e-mail *RA-DPYIE-VigilRecall@ITS.JNJ.com*
Tel no. +353 21 4914581

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, Standard, Size 11 and Size 12
FSCA Identifier: PIE-1177218

(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 lot number(s) and quantity of affected devices to be returned:

Please list the lot number(s) and 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