Urgent Field Safety Notice
(Field Safety Corrective Action) for CORAIL® AMT Neck Trials Surgical Instruments

Product Name	Product Code
CORAIL AMT NECK SEG 125D STD	L94003
CORAIL AMT NECK SEG 125D KLA	L94004
CORAIL AMT NECK SEG 135D STD	L94005
CORAIL AMT NECK SEG 135D KHO	L94006
CORAIL AMT NECK SEG 135D SHORT	L94007

FSCA-identifier: PIE-1125109

Type of Action: Field Safety Notice (Field Safety Corrective Action)

Date: May 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/Field Safety Corrective Action for all lots of the above-mentioned product codes. This correction is being issued to address the potential for debris/material to be found behind the O-Rings for some CORAIL Neck Trials.

A company representative will contact you shortly to rework affected devices at your facility or provide directions on replacing affected devices with reworked devices. Until the company reworks the affected units and to reduce the possibility of debris/material being left behind the O-Rings, the company recommends adhering to the instructions for use in IFU-W90946 Rev B.

Cleaning instructions from IFU-W90946 Rev B are included for your reference as Attachment A in this Field Safety Notice.

Figure 1: Image of Corail Neck Trial

Type of Device

The below mentioned CORAIL Neck Trials are surgical instruments used in CORAIL total and partial hip arthroplasty. No other CORAIL devices are affected by this Field Safety Notice.

Affected Product

Product Code	Lot Number	GTIN No.	Model Name
L94003	All Lots	10603295325147	CORAIL AMT NECK SEG 125D STD
L94004	All Lots	10603295325154	CORAIL AMT NECK SEG 125D KLA
L94005	All Lots	10603295325161	CORAIL AMT NECK SEG 135D STD
L94006	All Lots	10603295325178	CORAIL AMT NECK SEG 135D KHO
L94007	All Lots	10603295325185	CORAIL AMT NECK SEG 135D SHORT

Clinical Implications and Patient impact

Twelve complaints have been received related to debris behind the O-Ring. The company evaluated this issue and to date determined that none of these complaints have resulted in patient harm and found no increased risk to the patient.

Field Safety Corrective Action

As a precautionary measure, the company determined that reworking the affected devices and removing the O-Rings is the appropriate corrective action. The function of the device is unaffected by this change as DePuy currently markets products of the same design (i.e. without an O-Ring). This Field Safety Notice provides instructions for notifying medical facilities that may have used, purchased, or received the affected units. The purpose of this Field Safety Corrective Action is to alert medical facilities of the rework plan to remove the O-Ring from the affected devices.

Please undertake the following urgent actions:

- Please continue to follow the instructions for use in IFU-W90946 Rev B regarding cleaning of these devices.
- Medical facilities are to determine if any of the affected instruments are on hand, and contact their Sales Consultant to arrange for rework or replacement of these instruments.
- Review this notice and complete the Acknowledgement section (Attachment B) to signify that your facility has been informed of this Field Safety Notice. 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 Field Safety Notice.

- 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

Extract from IFU-W90946 Rev B:

From Page 6 Section G of IFU-W90946 Rev B - Manual Cleaning: All Devices:

- Prepare an enzymatic cleaning solution in accordance to the manufacturer's instructions.
- Soak soiled devices for a minimum recommended time specified by the enzymatic cleaning solution manufacturer or 5 minutes, whichever is longer.
- Prepare a pH neutral (pH 7-9) detergent cleaning solution in accordance to the manufacturer's instructions.
- Use a soft non-metallic bristle brush (plastic bristles, like nylon) to thoroughly scrub all traces of blood and debris from the device surfaces for one minute.
- Rinse the device with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone.
- Pay particular attention to thoroughly flush lumens, articulating areas, and flexible segments with warm, 30°C - 40°C (85°F –104°F), tap water.
- Ultrasonically clean the device components for 10 minutes in neutral pH detergent (pH 7-9), prepared in accordance with the manufacturer's instructions.
    - NOTE: Ultrasonic cleaning is only effective if the surface to be cleaned is immersed in the cleaning solution. Air pockets will decrease the efficacy of ultrasonic cleaning. Be sure to minimize air pocket or bubble formation by flushing lumens, cavities, crevices or springs with cleaning solution while the instrument is immersed in the ultrasonic cleaner tank.
- Rinse the device components with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone.
- Perform a final rinse with Reverse Osmosis Deionized (RODI) or Purified (PUR) Water.
- Dry the device components immediately after final rinse with a clean towel or clean compressed air until visibly dry.

From Page 8 Section L of IFU-W90946 Rev B - Automated Cleaning:

- Prepare an enzymatic cleaning solution in accordance to the manufacturer's instructions.
- Soak devices for a minimum recommended time specified by the enzymatic cleaning solution manufacturer or 5 minutes, whichever is longer.
- All devices should be pre-cleaned in accordance with the appropriate Manual Cleaning Instructions section.
- Rinse the device with warm, 30°C - 40°C (85°F – 104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone.

- Pay particular attention to thoroughly flush lumens, articulating areas, and flexible segments with warm, 30°C - 40°C (85°F –104°F), tap water for a minimum of one minute and until visual evidence of debris, soil, and cleaning solution are gone.
- Load the device components so that the lumens can drain.
- Clean, using the “INSTRUMENTS” cycle in a validated washer disinfector and a pH neutral cleaning agent intended for use in automated cleaning using the minimum cycle parameter set below:

Phase	Time (Minutes)	Temperature	Detergent Type
Pre Wash	2:00	Cold Tap Water	N/A
Enzyme wash	1:00	< 40°C	Enzymatic Cleaner
Wash	2:00	66°C	Neutral pH Detergent
Rinse	0:15	> 40°C	N/A
Thermal Decontamination*	5:00	> 93°C	N/A
Dry	7:00	115.5°C	N/A

* Reverse Osmosis Deionized (RODI) or Purified (PUR) Water

Attachment B

This Letter acknowledges receipt of the Field Safety Notice related to FSCA Identifier: PIE-1125109

Product Code	Lot Number	Model Name
L94003	All Lots	CORAIL AMT NECK SEG 125D STD
L94004	All Lots	CORAIL AMT NECK SEG 125D KLA
L94005	All Lots	CORAIL AMT NECK SEG 135D STD
L94006	All Lots	CORAIL AMT NECK SEG 135D KHO
L94007	All Lots	CORAIL AMT NECK SEG 135D SHORT

(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.

☐ No affected products in stock.

☐ Yes, I have devices of the affected product code(s).

Product Code	Lot Number	Quantity in stock

Please add more rows to the table if needed.

Print Name: _____

Signature: _____

Hospital Name: _____

City: _____

Country: _____

Telephone Number or e-mail address: _____