

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

<u>Product Name</u>	<u>Product Code</u>
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
CORAIL AMT STANDARD NECK SEGMENT	L20431
CORAIL AMT COXA VARA NECK SEGMENT	L20432
CORAIL AMT HIGH OFFSET NECK SEGMENT	L20433

FSCA-identifier: PIE-1125109 Version 2

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

Date: July 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 are issuing an update to the Field Safety Notice/ Field Safety Corrective Action issued in May 2018 to include additional product codes.

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.



Figure 1: Image of Corail Neck Trials

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

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
L20431	See Attachment B	10603295258216	CORAIL AMT STANDARD NECK SEGMENT
L20432	See Attachment B	10603295258223	CORAIL AMT COXA VARA NECK SEGMENT
L20433	See Attachment B	10603295258230	CORAIL AMT HIGH OFFSET NECK SEGMENT

Clinical Implications and Patient impact

Fifteen 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. Any unit of the affected product codes containing an O-Ring will have the O-Ring removed by DePuy personnel. 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 C) 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 attachment lists the lots numbers of product codes L20431, L20432 and L20433 manufactured with an O-Ring present.

Product Code	Lot	Product Code	Lot	Product Code	Lot
L20431	1212901	L20431	5016193	L20433	1230768
L20431	1218481	L20431	5016194	L20433	1230769
L20431	1226220	L20431	5016195	L20433	1812717
L20431	1230761	L20431	5016196	L20433	1817782
L20431	1230762	L20431	5019838	L20433	1865894
L20431	1700575	L20431	5019841	L20433	1860266
L20431	1781381	L20431	1812714A	L20433	1874691
L20431	1812714	L20431	1812714A	L20433	1874694
L20431	1817780	L20432	1700576	L20433	1874697
L20431	1860264	L20432	1212912	L20433	2002012
L20431	1865892	L20432	1216680	L20433	1885308
L20431	1874689	L20432	1230766	L20433	1899216
L20431	1874692	L20432	1812715	L20433	1899217
L20431	1874695	L20432	1812716	L20433	1910189
L20431	1885306	L20432	1817781	L20433	2024021
L20431	1899212	L20432	1860265	L20433	2065508
L20431	1899213	L20432	1865893	L20433	2078241
L20431	1910187	L20432	1874690	L20433	1812717A
L20431	1979239	L20432	1874693	L20433	2142423
L20431	2002010	L20432	2002011	L20433	2043430
L20431	2024019	L20432	1885307	L20433	2102703
L20431	2043428	L20432	1874696	L20433	2102704
L20431	2043428	L20432	1899214	L20433	2129113
L20431	2078239	L20432	1899215	L20433	2153325
L20431	2078239	L20432	1910188	L20433	2153326
L20431	2102693	L20432	1979242	L20433	2173203
L20431	2102693	L20432	2024020	L20433	2065508
L20431	2129111	L20432	2043429	L20433	2078241
L20431	2129111	L20432	1812716A	L20433	1812717A
L20431	2153317	L20432	2153322	L20433	2142423
L20431	2153317	L20432	2078240	L20433	2043430
L20431	2153318	L20432	2102701	L20433	2102703
L20431	2153318	L20432	2129112	L20433	2102704
L20431	2153319	L20432	2153323	L20433	2129113
L20431	2153319	L20432	2153324	L20433	2153325
L20431	2153320	L20432	2153321	L20433	2153326
L20431	2153320	L20432	2173202	L20433	2173203

Product Code	Lot	Product Code	Lot	Product Code	Lot
L20431	2163174	L20432	2043429	L20433	2249175
L20431	2163174	L20432	1812716A	L20433	2252365
L20431	2249115	L20432	2153322	L20433	2249177
L20431	2249116	L20432	2078240	L20433	2249176
L20431	2252364	L20432	2102701	L20433	2274507
L20431	2274452	L20432	2129112	L20433	2284310
L20431	2275487	L20432	2153323	L20433	2284309
L20431	2284306	L20432	2153324	L20433	2309654
L20431	2284307	L20432	2153321	L20433	2336394
L20431	2309644	L20432	2173202	L20433	2336395
L20431	2309645	L20432	2284268	L20433	2309653
L20431	2309646	L20432	2284305	L20433	2309652
L20431	2336389	L20432	2284304	L20433	2362089
L20431	2336390	L20432	2336392	L20433	2362088
L20431	2362086	L20432	2336393	L20433	2380244
L20431	2362087	L20432	2309648	L20433	2384477
L20431	2380243	L20432	2309649	L20433	2384478
L20431	2384473	L20432	2309647	L20433	2416621
L20431	2384474	L20432	2384476	L20433	2401667
L20431	2386339	L20432	2384475	L20433	2416622
L20431	2401664	L20432	2386340	L20433	2424599
L20431	2401665	L20432	2416616	L20433	2465284
L20431	2416615	L20432	2401666	L20433	2487632
L20431	2416617	L20432	2416620	L20433	2465283
L20431	2416618	L20432	2416619	L20433	2465285
L20431	2465273	L20432	2465280	L20433	2465289
L20431	2465274	L20432	2481312	L20433	2515079
L20431	2465275	L20432	2465288	L20433	2490517
L20431	2465287	L20432	2490516	L20433	2513467
L20431	2490513	L20432	2526365	L20433	2490518
L20431	2490514	L20432	2511420	L20433	2526368
L20431	2513465	L20432	2565706	L20433	2526367
L20431	2513466	L20432	2565705	L20433	2565714
L20431	2526363	L20432	2565598	L20433	2572844
L20431	2526364	L20432	2572839	L20433	2565627
L20431	2539884	L20432	2609135	L20433	2565715
L20431	2539885	L20432	2572840	L20433	2617683
L20431	2565583	L20432	2609141	L20433	2609035
L20431	2572825	L20432	2605839	L20433	2609037
L20431	2572826	L20432	2605840	L20433	2617684

Product Code	Lot	Product Code	Lot	Product Code	Lot
L20431	2602513	L20432	2643412	L20433	2572845
L20431	2602514	L20432	2643411	L20433	2572846
L20431	2605764	L20432	2673436	L20433	2643414
L20431	2605765	L20432	2673435	L20433	2643413
L20431	2643408	L20432	2673437	L20433	2673439
L20431	2643409	L20432	2691533	L20433	2691548
L20431	2648066	L20432	2691532	L20433	2691549
L20431	2648067	L20432	2739092	L20433	2673440
L20431	2673433	L20432	2739091	L20433	2673438
L20431	2673434	L20432	2749286	L20433	2749290
L20431	2691497	L20432	2774417	L20433	2761213
L20431	2691501	L20432	2774418	L20433	2795714
L20431	2739089	L20432	2774419	L20433	2795715
L20431	2739090	L20432	2795762	L20433	2795716
L20431	2749282	L20432	2795763	L20433	2811226
L20431	2749283	L20432	2795761	L20433	2811225
L20431	2774407	L20432	2811229	L20433	2811232
L20431	2774408	L20432	2811230	L20433	2811231
L20431	2774409	L20432	2811235	L20433	2823044
L20431	2774410	L20432	2811236	L20433	2836720
L20431	2795717	L20432	2836712	L20433	2836721
L20431	2795718	L20432	2836713	L20433	5002113
L20431	2795719	L20432	2836714	L20433	2836722
L20431	2811227	L20432	5002116	L20433	5002111
L20431	2811228	L20432	5002114	L20433	5002110
L20431	2811233	L20432	5002115	L20433	5002112
L20431	2811234	L20432	5005845	L20433	5005841
L20431	2836707	L20432	5005844	L20433	5008237
L20431	2836708	L20432	5005843	L20433	5005842
L20431	2836709	L20432	5012219	L20433	5009207
L20431	5001519	L20432	5012220	L20433	5008236
L20431	5001520	L20432	5017033	L20433	5012217
L20431	5001521	L20432	5017035	L20433	5012218
L20431	5001522	L20432	5016191	L20433	5017028
L20431	5005846	L20433	1700574	L20433	5017030
L20431	5005847	L20433	1700577	L20433	5016197
L20431	5008238	L20433	1781383	L20433	5016198
L20431	5008239	L20433	1216682	L20433	5019843
L20431	5009208	L20433	1216681		
L20431	5016192	L20433	1230767		

Attachment C

This Letter acknowledges receipt of the Field Safety Notice related to FSCA Identifier: PIE-1125109 Version 2

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
L20431	Lots as per Attachment B	CORAIL AMT STANDARD NECK SEGMENT
L20432		CORAIL AMT COXA VARA NECK SEGMENT
L20433		CORAIL AMT HIGH OFFSET NECK SEGMENT

(Please check as appropriate)

- Yes, I have received the FSN.
- No affected products in stock.
- Yes, I have devices of the affected product code(s).

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

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: _____