Urgent Field Safety Notice (Field Safety Corrective Action)
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
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: 31 Jul 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 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.

Figure 1: Image of Corail Neck Trial

This is 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

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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.

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 representative. 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 your Sales Consultant 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 your Sales Consultant.

Notification of this FSN has been provided to the appropriate Regulatory Agency.

Yours sincerely,

[redacted]

Lee Ching Hwee
Manager, Regulatory Affairs
cc: Chairman Medical Board
Relevant Head of Departments

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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
L20431	1212901
	1218481
	1226220
	1230761
	1230762
	1700575
	1781381
	1812714
	1817780
	1860264
	1865892
	1874689
	1874692
	1874695
	1885306
	1899212
	1899213
	1910187
	1979239
	2002010
	2024019
	2043428
	2078239
	2102693
	2129111
	2153317
	2153318
	2153319
	2153320

Product Code	Lot
L20431	2163174
	2249115
	2249116
	2252364
	2274452
	2275487
	2284306
	2284307
	2309644
	2309645
	2309646
	2336389
	2336390
	2362086
	2362087
	2380243
	2384473
	2384474
	2386339
	2401664
	2401665
	2416615
	2416617
	2416618
	2465273
	2465274
	2465275
	2465287
	2490513

Product Code	Lot
L20431	2490514
	2513465
	2513466
	2526363
	2526364
	2539884
	2539885
	2565583
	2572825
	2572826
	2602513
	2602514
	2605764
	2605765
	2643408
	2643409
	2648066
	2648067
	2673433
	2673434
	2691497
	2691501
	2739089
	2739090
	2749282
	2749283
	2774407
	2774408
	2774409

Product Code	Lot
L20431	2774410
	2795717
	2795718
	2795719
	2811227
	2811228
	2811233
	2811234
	2836707
	2836708
	2836709
	5001519
	5001520
	5001521
	5001522
	5005846
	5005847
	5008238
	5008239
	5009208
	5016192
	5016193
	5016194
	5016195
	5016196
	5019838
	5019841
	1812714A
L20432	1212912

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Product Code	Lot
L20432	1216680
	1230766
	1700576
	1812715
	1812716
	1817781
	1860265
	1865893
	1874690
	1874693
	1874696
	1885307
	1899214
	1899215
	1910188
	1979242
	2002011
	2024020
	2043429
	2078240
	2102701
	2129112
	2153321
	2153322
	2153323
	2153324
	2173202
	2284268
	2284304

Product Code	Lot
L20432	2284305
	2309647
	2309648
	2309649
	2336392
	2336393
	2384475
	2384476
	2386340
	2401666
	2416616
	2416619
	2416620
	2465280
	2465288
	2481312
	2490516
	2511420
	2526365
	2565598
	2565705
	2565706
	2572839
	2572840
	2605839
	2605840
	2609135
	2609141
	2643411

Product Code	Lot
L20432	2643412
	2673435
	2673436
	2673437
	2691532
	2691533
	2739091
	2739092
	2749286
	2774417
	2774418
	2774419
	2795761
	2795762
	2795763
	2811229
	2811230
	2811235
	2811236
	2836712
	2836713
	2836714
	5002114
	5002115
	5002116
	5005843
	5005844
	5005845
	5012219

Product Code	Lot
L20432	5012220
	5016191
	5017033
	5017035
	1812716A
L20433	1216681
	1216682
	1230767
	1230768
	1230769
	1700574
	1700577
	1781383
	1812717
	1817782
	1860266
	1865894
	1874691
	1874694
	1874697
	1885308
	1899216
	1899217
	1910189
	2002012
	2024021
	2043430
	2065508
	2078241

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Product Code	Lot
L20433	2102703
	2102704
	2129113
	2142423
	2153325
	2153326
	2173203
	2249175
	2249176
	2249177
	2252365
	2274507
	2284309
	2284310
	2309652
	2309653
	2309654
	2336394
	2336395
	2362088
	2362089
	2380244
	2384477
	2384478
	2401667
	2416621
	2416622
	2424599
	2465283

Product Code	Lot
L20433	2465284
	2465285
	2465289
	2487632
	2490517
	2490518
	2513467
	2515079
	2526367
	2526368
	2565627
	2565714
	2565715
	2572844
	2572845
	2572846
	2609035
	2609037
	2617683
	2617684
	2643413
	2643414
	2673438
	2673439
	2673440
	2691548
	2691549
	2749290
	2761213

Product Code	Lot
L20433	2795714
	2795715
	2795716
	2811225
	2811226
	2811231
	2811232
	2823044
	2836720
	2836721
	2836722
	5002110
	5002111
	5002112
	5002113
	5005841
	5005842
	5008236
	5008237
	5009207
	5012217
	5012218
	5016197
	5016198
	5017028
	5017030
	5019843
	1812717A

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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	See Attachment B	CORAIL AMT STANDARD NECK SEGMENT
L20432	See Attachment B	CORAIL AMT COXA VARA NECK SEGMENT
L20433	See Attachment B	CORAIL AMT HIGH OFFSET NECK SEGMENT

(Please check as appropriate)

Please submit a copy of this completed document to your Sales Consultant.

☐ 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

Name, Sign and Date	**Hospital Name, Address, Phone and Stamp**

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