

**Urgent Field Safety Notice (Recall) for
Specific lots of the DELTA XTEND™ Reverse Shoulder System Modular Centered
and Eccentric Epiphysis Implants**

Product Name: DELTA XTEND™ Reverse Shoulder System Modular Centered and Eccentric Epiphysis Implants

FSCA-identifier: PIE-877191

Type of Action: Field Safety Notice (Recall)

Date: 18-September-2017

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: DELTA XTEND™ Reverse Shoulder System used for shoulder reconstruction.

Model Name: DELTA XTEND™ Reverse Shoulder System.

DePuy France SAS is issuing a Field Safety Notice (FSN) for specific lots of the DELTA XTEND™ Reverse Shoulder System Modular Centered and Eccentric Epiphysis Implants (see Figure 1).

Reason for the Field Safety Notice (Recall):

For the recalled lots, an investigation determined that lots produced in a specific machine were manufactured in a manner in which the post's diameter is out-of-specification. Further investigation determined that the issue is related to the circularity of the cylinder. The circularity issue may cause the epiphysis to interfere with the stem and the two implants (epiphysis and stem) may not be able to be assembled.

Clinical Implications and Patient impact:

The possible clinical implications related to affected lots of the DELTA XTEND Reverse Shoulder System Modular Centered and Eccentric Epiphysis Implants are as follows:

There are two potential instances in which the patient could be affected.

- If the epiphysis does not assemble to the stem and an alternative device is available, there may be a surgical delay of 15 to 59 minutes.



Figure 1: DELTA XTEND Epiphysis

- If the epiphysis does not assemble to the stem and there is not an alternative implant available, the patient's wound may need to be closed and the patient scheduled for a reoperation when a suitable device is available.

Note: Once the epiphysis is properly assembled to the stem, there is no additional risk to the patient.

Affected Implants: See Attachment A for full lot listing.

Catalog No.	Description
130720101	Modular Centered Epiphysis Size 1 HA
130720102	Modular Eccentric Epiphysis Size 1 Left HA
130720103	Modular Eccentric Epiphysis Size 1 Right HA
130720201	Modular Centered Epiphysis Size 2 HA
130720202	Modular Eccentric Epiphysis Size 2 Left HA
130720203	Modular Eccentric Epiphysis Size 2 Right HA

Intended Use:

The DELTA XTEND Reverse Shoulder System Modular Centered and Eccentric Epiphysis Implants are intended for use in total shoulder or hemi-shoulder replacement procedures in patients with non-functional rotator cuffs. HA components are for cementless use only.

Units Affected

DePuy France SAS is issuing a Field Safety Notice (Recall) for specific lots of the DELTA XTEND™ Reverse Shoulder System Modular Centered and Eccentric Epiphysis Implants. See Attachment A for full lot listing.

Depth of Field Safety Notice (Recall):

This Field Safety Notice (Recall) notice provides instructions for notifying Medical Professionals who may have purchased, received, or used the affected lots of the DELTA XTEND Reverse Shoulder System Modular Centered and Eccentric Epiphysis Implants.

The purpose of this device recall is to remove affected implants and to notify medical professionals of the possible effects of using the affected product.

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 DePuy Synthes Sales Consultant.
- Review this notice and complete the Acknowledgement Section Attachment B to signify that your facility has been informed of this Field Safety Notice (Recall). Return the completed Acknowledgement to your DePuy Synthes Orthopaedics 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 (Recall).

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- Forward this notice to others in your facility that 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.

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 the DELTA XTEND Reverse Shoulder System Modular Centered and Eccentric Epiphysis Implants Field Safety Notice (Recall) contact your DePuy Synthes Orthopaedics Sales Consultant.

This FSN has been notified to the appropriate Regulatory Agency.

Yours sincerely,



Lee Ching Hwee
Manager, Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments

ATTACHMENT A

Affected Product Codes / Lots for the DELTA XTEND Reverse Shoulder System Modular Centered and Eccentric Epiphysis Implants

Catalog No.	Lot No.	Catalog No.	Lot No.	Catalog No.	Lot No.	Catalog No.	Lot No.
130720101	5248487	130720101	5263798	130720101	5273263	130720101	5283246
130720101	5248488	130720101	5263799	130720101	5273264	130720101	5284416
130720101	5248489	130720101	5264519	130720101	5273265	130720101	5284417
130720101	5248490	130720101	5264520	130720101	5274694	130720101	5284418
130720101	5248491	130720101	5265494	130720101	5274695	130720101	5284419
130720101	5248497	130720101	5265495	130720101	5274696	130720101	5284420
130720101	5248498	130720101	5265496	130720101	5275978	130720101	5284421
130720101	5248499	130720101	5265497	130720101	5275979	130720101	5284422
130720101	5248500	130720101	5265498	130720101	5276798	130720101	5284991
130720101	5248501	130720101	5265499	130720101	5276799	130720101	5284992
130720101	5250420	130720101	5266088	130720101	5276800	130720101	5286447
130720101	5250421	130720101	5266089	130720101	5276801	130720101	5286448
130720101	5250422	130720101	5266090	130720101	5276802	130720101	5286449
130720101	5250423	130720101	5266592	130720101	5276803	130720101	5286684
130720101	5250424	130720101	5266593	130720101	5277832	130720101	5288257
130720101	5251136	130720101	5268090	130720101	5277833	130720101	5288258
130720101	5251137	130720101	5268091	130720101	5277834	130720101	5288259
130720101	5251138	130720101	5268092	130720101	5277835	130720101	5288478
130720101	5251139	130720101	5268093	130720101	5277836	130720101	5288479
130720101	5251140	130720101	5268474	130720101	5277843	130720101	5288480
130720101	5261339	130720101	5269235	130720101	5277844	130720101	5288481
130720101	5261340	130720101	5269741	130720101	5277845	130720101	5289306
130720101	5261341	130720101	5269742	130720101	5279892	130720101	5289307
130720101	5261342	130720101	5269743	130720101	5279893	130720101	5289308
130720101	5261343	130720101	5269744	130720101	5280180	130720101	5289309
130720101	5262077	130720101	5269745	130720101	5280181	130720101	5289311
130720101	5262078	130720101	5270942	130720101	5280182	130720101	5289599
130720101	5262079	130720101	5270943	130720101	5281491	130720101	5289600
130720101	5262080	130720101	5270944	130720101	5281492	130720101	5289601
130720101	5262081	130720101	5270945	130720101	5281493	130720201	5293593
130720101	5263090	130720101	5271415	130720101	5281494	130720101	5294996
130720101	5263091	130720101	5271416	130720101	5282646	130720101	5294997
130720101	5263203	130720101	5271417	130720101	5282647	130720101	5296832
130720101	5263204	130720101	5273260	130720101	5282648	130720102	5253183
130720101	5263205	130720101	5273261	130720101	5283244	130720102	5253184
130720101	5263206	130720101	5273262	130720101	5283245	130720102	5253185

Catalog No.	Lot No.
130720102	5262086
130720102	5262087
130720102	5262088
130720102	5263207
130720102	5263208
130720102	5263800
130720102	5263801
130720102	5263802
130720102	5263803
130720102	5264934
130720102	5264935
130720102	5264936
130720102	5264937
130720102	5264938
130720102	5265500
130720102	5265501
130720102	5266594
130720102	5266595
130720102	5266596
130720102	5266597
130720102	5270354
130720102	5270355
130720102	5270356
130720102	5270946
130720102	5270947
130720102	5271418
130720102	5271419
130720102	5271420
130720102	5271421
130720102	5271422
130720102	5271423
130720102	5273266
130720102	5273267
130720102	5274697
130720102	5274698
130720102	5276804
130720102	5276805
130720102	5276806
130720102	5277846
130720102	5279354
130720102	5279355
130720102	5279356

Catalog No.	Lot No.
130720102	5279894
130720102	5279895
130720102	5280183
130720102	5280184
130720102	5281495
130720102	5282649
130720102	5282650
130720102	5282651
130720102	5282652
130720102	5283247
130720102	5283248
130720102	5283249
130720102	5283250
130720102	5284423
130720102	5284424
130720102	5284425
130720102	5284426
130720102	5284993
130720102	5284994
130720102	5286685
130720102	5286686
130720102	5286687
130720102	5289312
130720102	5289313
130720102	5289314
130720102	5289315
130720102	5289607
130720102	5289608
130720103	5248482
130720103	5248483
130720103	5248484
130720103	5248485
130720103	5248486
130720103	5248492
130720103	5248493
130720103	5248494
130720103	5248495
130720103	5248496
130720103	5250425
130720103	5250426
130720103	5250427
130720103	5250428

Catalog No.	Lot No.
130720103	5250429
130720103	5251141
130720103	5251142
130720103	5251143
130720103	5251144
130720103	5251145
130720103	5262082
130720103	5262083
130720103	5262084
130720103	5262085
130720103	5263209
130720103	5263210
130720103	5263211
130720103	5263212
130720103	5264521
130720103	5264939
130720103	5264940
130720103	5264941
130720103	5264942
130720103	5264943
130720103	5264944
130720103	5264945
130720103	5264946
130720103	5266598
130720103	5266599
130720103	5266600
130720103	5266601
130720103	5266602
130720103	5267247
130720103	5268475
130720103	5268476
130720103	5268477
130720103	5268478
130720103	5268479
130720103	5270357
130720103	5270358
130720103	5270359
130720103	5270948
130720103	5270949
130720103	5270950
130720103	5273268
130720103	5273269

Catalog No.	Lot No.
130720103	5273270
130720103	5273271
130720103	5273272
130720103	5273273
130720103	5274699
130720103	5274700
130720103	5274701
130720103	5275980
130720103	5275981
130720103	5276807
130720103	5276808
130720103	5277837
130720103	5277838
130720103	5277839
130720103	5277847
130720103	5277848
130720103	5279357
130720103	5279358
130720103	5279359
130720103	5279360
130720103	5279361
130720103	5279362
130720103	5279363
130720103	5279364
130720103	5279365
130720103	5279366
130720103	5281496
130720103	5281497
130720103	5281498
130720103	5281499
130720103	5281500
130720103	5281501
130720103	5281502
130720103	5282653
130720103	5282654
130720103	5282655
130720103	5282656
130720103	5282657
130720103	5283251
130720103	5283252
130720103	5283253
130720103	5284427

Catalog No.	Lot No.	Catalog No.	Lot No.	Catalog No.	Lot No.	Catalog No.	Lot No.
130720103	5284428	130720201	5269075	130720202	5275985	130720203	5274703
130720103	5284429	130720201	5269076	130720202	5275986	130720203	5274704
130720103	5284995	130720201	5269077	130720202	5282658	130720203	5275987
130720103	5284996	130720201	5270360	130720202	5282659	130720203	5275988
130720103	5286450	130720201	5270361	130720202	5286457	130720203	5275989
130720103	5286451	130720201	5270362	130720202	5286458	130720203	5275990
130720103	5286452	130720201	5275982	130720202	5286459	130720203	5275991
130720103	5286453	130720201	5277840	130720202	5286460	130720203	5276809
130720103	5288260	130720201	5277841	130720202	5288482	130720203	5277842
130720103	5288261	130720201	5279891	130720202	5288483	130720203	5277849
130720103	5289316	130720201	5281503	130720202	5289321	130720203	5284430
130720103	5289317	130720201	5281504	130720202	5290274	130720203	5284431
130720103	5289318	130720201	5282527	130720203	5251944	130720203	5284997
130720103	5289319	130720201	5284412	130720203	5251945	130720203	5284998
130720103	5289320	130720201	5284413	130720203	5251946	130720203	5286461
130720103	5289614	130720201	5284414	130720203	5251947	130720203	5286462
130720103	5289615	130720201	5284415	130720203	5251948	130720203	5287323
130720103	5289616	130720201	5285764	130720203	5253698	130720203	5287324
130720103	5289618	130720201	5285765	130720203	5253699	130720203	5287325
130720103	5289619	130720201	5285766	130720203	5263912	130720203	5288262
130720103	5289620	130720201	5286454	130720203	5263913	130720203	5288484
130720103	5289621	130720201	5286455	130720203	5264947	130720203	5288783
130720103	5289622	130720201	5286456	130720203	5264948	130720203	5288784
130720201	5251938	130720201	5286688	130720203	5264949	130720203	5289322
130720201	5251939	130720201	5290272	130720203	5266092	130720203	5289323
130720201	5251940	130720201	5290273	130720203	5266093	130720203	5289324
130720201	5251941	130720202	5251942	130720203	5266603	130720203	5289625
130720201	5264014	130720202	5251943	130720203	5272193	130720203	5293598
130720201	5264044	130720202	5264015	130720203	5272194	130720203	5293599
130720201	5266091	130720202	5269078	130720203	5272195	130720203	5293600
130720201	5267248	130720202	5272192	130720203	5272196	130720203	5293601
130720201	5269071	130720202	5273274	130720203	5272197		
130720201	5269072	130720202	5273275	130720203	5273276		
130720201	5269073	130720202	5275983	130720203	5273277		
130720201	5269074	130720202	5275984	130720203	5274702		

ATTACHMENT B

This Letter acknowledges receipt of the Field Safety Notice related to specific lots of DELTA XTEND Reverse Shoulder System Modular Centered and Eccentric Epiphysis Implants.

(Please check as appropriate)

☐

Yes, I have received the FSN

☐

Yes, I have/will return the affected devices

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

Print Name: _____

Signature

Hospital Name

City

Country

Telephone Number or e-mail address