

**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: 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).
- 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:

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

This FSN has been notified to the appropriate Regulatory Agency.

Yours sincerely,



John Wright, MD
Franchise Medical Leader - JMP
WW Vice-President, Medical Affairs

ATTACHMENT A

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

Catalog No.	Lot No.
130720101	5248487
130720101	5248488
130720101	5248489
130720101	5248490
130720101	5248491
130720101	5248497
130720101	5248498
130720101	5248499
130720101	5248500
130720101	5248501
130720101	5250420
130720101	5250421
130720101	5250422
130720101	5250423
130720101	5250424
130720101	5251136
130720101	5251137
130720101	5251138
130720101	5251139
130720101	5251140
130720101	5261339
130720101	5261340
130720101	5261341
130720101	5261342
130720101	5261343
130720101	5262077
130720101	5262078
130720101	5262079
130720101	5262080
130720101	5262081
130720101	5263090
130720101	5263091
130720101	5263203
130720101	5263204
130720101	5263205
130720101	5263206

Catalog No.	Lot No.
130720101	5263798
130720101	5263799
130720101	5264519
130720101	5264520
130720101	5265494
130720101	5265495
130720101	5265496
130720101	5265497
130720101	5265498
130720101	5265499
130720101	5266088
130720101	5266089
130720101	5266090
130720101	5266592
130720101	5266593
130720101	5268090
130720101	5268091
130720101	5268092
130720101	5268093
130720101	5268474
130720101	5269235
130720101	5269741
130720101	5269742
130720101	5269743
130720101	5269744
130720101	5269745
130720101	5270942
130720101	5270943
130720101	5270944
130720101	5270945
130720101	5271415
130720101	5271416
130720101	5271417
130720101	5273260
130720101	5273261
130720101	5273262

Catalog No.	Lot No.
130720101	5273263
130720101	5273264
130720101	5273265
130720101	5274694
130720101	5274695
130720101	5274696
130720101	5275978
130720101	5275979
130720101	5276798
130720101	5276799
130720101	5276800
130720101	5276801
130720101	5276802
130720101	5276803
130720101	5277832
130720101	5277833
130720101	5277834
130720101	5277835
130720101	5277836
130720101	5277843
130720101	5277844
130720101	5277845
130720101	5279892
130720101	5279893
130720101	5280180
130720101	5280181
130720101	5280182
130720101	5281491
130720101	5281492
130720101	5281493
130720101	5281494
130720101	5282646
130720101	5282647
130720101	5282648
130720101	5283244
130720101	5283245

Catalog No.	Lot No.
130720101	5283246
130720101	5284416
130720101	5284417
130720101	5284418
130720101	5284419
130720101	5284420
130720101	5284421
130720101	5284422
130720101	5284991
130720101	5284992
130720101	5286447
130720101	5286448
130720101	5286449
130720101	5286684
130720101	5288257
130720101	5288258
130720101	5288259
130720101	5288478
130720101	5288479
130720101	5288480
130720101	5288481
130720101	5289306
130720101	5289307
130720101	5289308
130720101	5289309
130720101	5289311
130720101	5289599
130720101	5289600
130720101	5289601
130720201	5293593
130720101	5294996
130720101	5294997
130720101	5296832
130720102	5253183
130720102	5253184
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

Catalog No.	Lot No.
130720102	5277846
130720102	5279354
130720102	5279355
130720102	5279356
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

Catalog No.	Lot No.
130720103	5248493
130720103	5248494
130720103	5248495
130720103	5248496
130720103	5250425
130720103	5250426
130720103	5250427
130720103	5250428
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
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130720103	5264946
130720103	5266598
130720103	5266599
130720103	5266600
130720103	5266601
130720103	5266602
130720103	5267247
130720103	5268475

Catalog No.	Lot No.
130720103	5268476
130720103	5268477
130720103	5268478
130720103	5268479
130720103	5270357
130720103	5270358
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130720103	5274701
130720103	5275980
130720103	5275981
130720103	5276807
130720103	5276808
130720103	5277837
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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

Catalog No.	Lot No.
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
130720103	5284428
130720103	5284429
130720103	5284995
130720103	5284996
130720103	5286450
130720103	5286451
130720103	5286452
130720103	5286453
130720103	5288260
130720103	5288261
130720103	5289316
130720103	5289317
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130720103	5289319
130720103	5289320
130720103	5289614
130720103	5289615
130720103	5289616
130720103	5289618
130720103	5289619
130720103	5289620
130720103	5289621

Catalog No.	Lot No.
130720103	5289622
130720201	5251938
130720201	5251939
130720201	5251940
130720201	5251941
130720201	5264014
130720201	5264044
130720201	5266091
130720201	5267248
130720201	5269071
130720201	5269072
130720201	5269073
130720201	5269074
130720201	5269075
130720201	5269076
130720201	5269077
130720201	5270360
130720201	5270361
130720201	5270362
130720201	5275982
130720201	5277840
130720201	5277841
130720201	5279891
130720201	5281503
130720201	5281504
130720201	5282527
130720201	5284412
130720201	5284413
130720201	5284414
130720201	5284415
130720201	5285764
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130720201	5285766
130720201	5286454
130720201	5286455
130720201	5286456
130720201	5286688
130720201	5290272

Catalog No.	Lot No.
130720201	5290273
130720202	5251942
130720202	5251943
130720202	5264015
130720202	5269078
130720202	5272192
130720202	5273274
130720202	5273275
130720202	5275983
130720202	5275984
130720202	5275985
130720202	5275986
130720202	5282658
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130720202	5286460
130720202	5288482
130720202	5288483
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130720203	5251947
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130720203	5263912
130720203	5263913
130720203	5264947
130720203	5264948
130720203	5264949
130720203	5266092
130720203	5266093
130720203	5266603
130720203	5272193

Catalog No.	Lot No.
130720203	5272194
130720203	5272195
130720203	5272196
130720203	5272197
130720203	5273276
130720203	5273277
130720203	5274702
130720203	5274703
130720203	5274704
130720203	5275987
130720203	5275988
130720203	5275989
130720203	5275990
130720203	5275991
130720203	5276809
130720203	5277842
130720203	5277849
130720203	5284430
130720203	5284431
130720203	5284997
130720203	5284998
130720203	5286461
130720203	5286462
130720203	5287323
130720203	5287324
130720203	5287325
130720203	5288262
130720203	5288484
130720203	5288783
130720203	5288784
130720203	5289322
130720203	5289323
130720203	5289324
130720203	5289625
130720203	5293598
130720203	5293599
130720203	5293600
130720203	5293601

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

Print Name: _____

Signature

Hospital Name

City

Country

Telephone Number or e-mail address