

URGENT: MEDICAL DEVICE RECALL (REMOVAL)

1.0mm Cloverleaf Footplates and AB & BC Distractor Bodies

20 December, 2019

Dear Operating Room Supervisors, Materials Management Personnel, and Chief of Surgery:

Synthes GmbH is initiating a voluntary medical device product removal of 1.0mm Cloverleaf Footplates and AB & BC Distractor Bodies. The product information is listed in the table below. This medical device product removal is not being initiated to reduce a risk to health posed by the devices.

The 1.0mm Cloverleaf Footplates and AB & BC Distractor Bodies are part of the Synthes Craniomaxillofacial (CMF) Distraction System. The CMF Distraction System is a modular family of internal distraction devices to lengthen the mandibular body and ramus.

Reason for the Medical Device Product Removal:

The products subject to this action are being removed from the market to prevent any future potential incompatibility with devices being re-designed and re-introduced into the CMF Distraction System.

Potential Patient Impact:

There is no product safety impact or risk of patient harm. Health care practitioners that have treated patients using the subject CMF Distraction System devices should continue to follow those patients as per the standard of care.

EFFECTIVE IMMEDIATELY – DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT CODE/ LOT:

Part Number	Part Description	Lot
04.315.211	1.0MM Mandible Cloverleaf Foot A-Type For CMF Distractor	U102814, U104526, U106821, U106822, U107108, U107120, UQ68462, UR73628, UR80627, 5781568, 5781569, 5781570, 6028611
04.315.212	1.0MM Mandible Cloverleaf Foot B-Type For CMF Distractor	5865840, 6028000, 6028002, 6028005, 6003052, 6228017, 6873094, 6911238, 6911239, 6918059, 6940283, 7081439, 7120855, 7538848, 7538928, U102250, U102876, U105966, U110891, U117615, U123136, U131792, U132852, U136357, U137440, U137727, U142139, UQ57670, UQ68479, UR75885, UR82658, US93600
04.315.213	1.0MM Mandible Cloverleaf Foot C-Type For CMF Distractor	5423039, 5423046, 5423414, 5865845, 6027951, 6027953, 6027954, 6027955, 6064161, 6873087, 6873091, 6911243, 6911257, 6956157, 7004798, 7355195, 7607069, U102370, U102446, U109867, U117616, U129261, U130938, U131793, U137441,



Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
2 Science Park Drive, #07-13, Ascent, Singapore Science Park 1, Singapore 118222
Tel: +65 6918 8000
Business Reg No. 52836279L Company Reg No. 197402104W

Part Number	Part Description	Lot
		U149331, UQ57555, UQ68480, UR70668, UR73257, UR73629, UR75934, UR76720, US94266
04.315.003	AB Distractor Body End ACT 15mm for CMF Distractor	5545513, 5558000, 5558002, 5584067, 5877995, 6029089, 6029090, 21612-01, 21656-03
04.315.004	AB Distractor Body End ACT 20mm for CMF Distractor	5550910, 5558001, 6000863, 6029088, 21612-02
04.315.005	AB Distractor Body End ACT 25mm for CMF Distractor	22611-05, 5545518, 5558003, 6000864, 6029076, 6168024, 21612-03, 21612-03A
04.315.006	AB Distractor Body End ACT 30mm for CMF Distractor	5548209, 5557999, 5862668, 5878128, 6029082, 6168918, 6168919, 6168921, 22663-01, 21612-04, 22637-02
04.315.023	BC Distractor Body End ACT 15mm for CMF Distractor	5372309, 5558850, 5558851, 5558852, 5558853, 6000872, 6000873, 6226241, 6233859, 6160687, 21247-02, 21618-03, 22375-01
04.315.024	BC Distractor Body End ACT 20mm for CMF Distractor	5372310, 5559873, 5559874, 5559875, 5559876, 5559877, 5828443, 5828444, 5878117, 6024565, 6064453, 6075057, 6075061, 6136907, 6136929, 22375-02, 21618-05, 22658-04, 22658-03, 21247-03
04.315.025	BC Distractor Body End ACT 25mm for CMF Distractor	5372311, 5561698, 5561705, 5561707, 5584066, 5862683, 5877997, 6029081, 6081245, 6081246, 6109380, 6112116, 21618-07, 22375-03, 21247-04, 21618-07A
04.315.026	BC Distractor Body End ACT 30mm for CMF Distractor	5372312, 5562773, 5562854, 5563945, 5828445, 5828446, 5829286, 6081243, 6081244, 6099323, 6118902, 6136977, 21247-05, 21618-09, 22375-04, 21618-09A, 22658-01
04.315.027	BC Distractor Body End ACT 35mm for CMF Distractor	5877050, 5877051, 5877052, 5888432, 6000875, 6071203, 6119767, 6168010, 6168976, 6183319, 22408-02, 22612-03, 22408-01, 22359-06, 22658-05, 22612-06
04.315.028	BC Distractor Body End ACT 40mm for CMF Distractor	5878143, 5878144, 5883054, 5888817, 6029096, 6119766, 6136976, 6168007, 22408-03, 22532-01, 22611-10
04.315.053	AB Distractor Body End ACT W/U-Joint 15mm for CMF Distractor	5587772, 5587773, 5587774, 5625097, 6000874, 21612-05
04.315.054	AB Distractor Body End ACT W/U-Joint 20mm for CMF Distractor	5587775, 5587776, 5587777, 6000870, 6029085, 6168920, 6196473, 6282013, 21612-06, 22611-08

Part Number	Part Description	Lot
04.315.055	AB Distractor Body End ACT W/U-Joint 25mm for CMF Distractor	5590700, 5590723, 5878125, 6028974, 21612-07
04.315.056	AB Distractor Body End ACT W/U-Joint 30mm for CMF Distractor	5579198, 5597077, 5597092, 5878002, 6029091, 6029092, 21656-16, 21612-08
04.315.063	BC Distractor Body End ACT W/U-Joint 15mm for CMF Distractor	5390575, 5612498, 5612500, 6222255, 6228011, 6228012, 21618-11, 21247-08
04.315.064	BC Distractor Body End ACT W/U-Joint 20mm for CMF Distractor	5390576, 5612499, 5612502, 5853755, 5853756, 5853795, 6071201, 6071202, 6071206, 6230808, 6232544, 6282164, 21247-09, 21618-13, 21656-19, 22179-17, 22229-11
04.315.065	BC Distractor Body End ACT W/U-Joint 25mm for CMF Distractor	5390577, 5612495, 5612496, 5613291, 5862699, 6028982, 6136930, 6136931, 6136932, 6165615, 6183321, 21247-10, 21618-15, 22648-06, 22624-01, 22552-11
04.315.066	BC Distractor Body End ACT W/U-Joint 30mm for CMF Distractor	5390578, 5610566, 5610567, 5703744, 5710985, 5744145, 5832448, 6011937, 6012515, 6012516, 6012518, 6022960, 6022961, 6029078, 6029080, 6102795, 6104332, 6115444, 6166162, 6183320, US85534, 21247-11, 21618-17, IS10013, 21618-17A, 22179-18, 22617-01, 22611-14
04.315.067	BC Distractor Body End ACT W/U-Joint 35mm for CMF Distractor	6000965, 6001011, 6001012, 6001014, 6009271, 6118875, 6118876, 6118877, 6184269, 6184270, 22612-04, 22408-05, 22408-04, 22637-01, 22610-02, 22612-04
04.315.068	BC Distractor Body End ACT W/U-Joint 40mm for CMF Distractor	6000966, 6001016, 6001018, 6001019, 6009272, 6022080, 6097965, 6119768, 6119769, 6275129, 22408-06, 22603-01, 22648-01, 22611-01

Health care practitioners who have treated patients using this product should follow those patients post-operatively in the usual manner with no additional action required.

Product subject to the recall in your inventory can be identified by product code described in above table. All unused Cloverleaf Footplates and AB & BC Distractor Bodies subject to this recall are required to be returned. Please utilize attachment 1 for assistance in identifying the product lots subject to this recall.

ACTION REQUIRED:

1. Examine your inventory immediately to determine if you have product subject to this action on hand and quarantine such product(s).
2. Remove the products subject to this voluntary recall and communicate the issue to relevant operating room or materials management personnel, or anyone else in your facility who needs to be informed.
3. If any product subject to this recall has been forwarded to another facility, contact that facility to arrange return. Please consider including a copy of this recall letter when communicating.
4. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and hand it to your Depuy Synthes sales representative within three (3) business days. **Please return the BRF even if you do not have product subject to this recall (removal).**
5. Keep this notice visibly posted for awareness until all products subject to this recall has been returned to your Depuy Synthes sales representative. While processing your returns, please maintain a copy of this notice with the products subject to this recall (removal) and keep a copy for your records.
6. Customers are required to return unused **impacted Cloverleaf Footplates and AB & BC Distractor Bodies** subject to this recall that are in their inventory immediately.
7. To return products subject to this action, please contact your Depuy Synthes sales representative.

If you require any assistance with returning the impacted products, please contact your Depuy Synthes sales representative.

At Depuy Synthes, our first priority is to our customers and their patients, and that includes the safe and effective use of our products. We recognize the recall of this product may be disruptive to your facility and we apologize for any inconvenience this may cause.

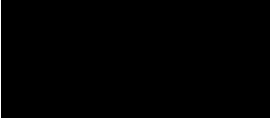
If you have additional questions regarding this action or to report any customer complaints, please contact your Depuy Synthes sales representative.

Attachments:

Attachment 1: Business Reply Form

Attachment 2: Affected Product Information List

Yours sincerely,



Lee Ching Hwee
Manager, Regulatory Affairs

cc: Chairman Medical Board
Relevant Head of Departments

ATTACHMENT 1: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete this form and hand it to your Depuy Synthes sales representative **within 3 business days, even if you do not have product subject to this recall (removal) to return.**

If you have product lots subject to this recall (removal) to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

Product Inventory – please check one

- ☐ The facility has located the identified product in stock; returned product(s) are listed in Attachment 2. A copy of this letter is being retained in the facility's records. I have read and understand the notification.
- ☐ The facility has no affected product for return. A copy of this letter is being retained in the facility's records. I have read and understand the notification.

Print Name of Person Completing Business Reply Form:	Sign & Date:
Customer Account Details (Name and Address)	

Attachment 2: Affected Product Information List

Part Number	Part Description	GTIN	Lot	Quantity Returning
04.315.211	1.0MM Mandible Cloverleaf Foot A-Type For CMF Distractor	07611819948235	U102814, U104526, U106821, U106822, U107108, U107120, UQ68462, UR73628, UR80627, 5781568, 5781569, 5781570, 6028611	
04.315.212	1.0MM Mandible Cloverleaf Foot B-Type For CMF Distractor	07611819948242	5865840, 6028000, 6028002, 6028005, 6003052, 6228017, 6873094, 6911238, 6911239, 6918059, 6940283, 7081439, 7120855, 7538848, 7538928, U102250, U102876, U105966, U110891, U117615, U123136, U131792, U132852, U136357, U137440, U137727, U142139, UQ57670, UQ68479, UR75885, UR82658, US93600	
04.315.213	1.0MM Mandible Cloverleaf Foot C-Type For CMF Distractor	07611819948259	5423039, 5423046, 5423414, 5865845, 6027951, 6027953, 6027954, 6027955, 6064161, 6873087, 6873091, 6911243, 6911257, 6956157, 7004798, 7355195, 7607069, U102370, U102446, U109867, U117616, U129261, U130938, U131793, U137441, U149331, UQ57555, UQ68480, UR70668, UR73257, UR73629, UR75934, UR76720, US94266	
04.315.003	AB Distractor Body End ACT 15mm for CMF Distractor	07611819947856	5545513, 5558000, 5558002, 5584067, 5877995, 6029089, 6029090, 21612-01, 21656-03	
04.315.004	AB Distractor Body End ACT 20mm for CMF Distractor	07611819947863	5550910, 5558001, 6000863, 6029088, 21612-02	
04.315.005	AB Distractor Body End ACT 25mm for CMF Distractor	07611819947870	22611-05, 5545518, 5558003, 6000864, 6029076, 6168024, 21612-03, 21612-03A	
04.315.006	AB Distractor Body End ACT 30mm for CMF Distractor	07611819947887	5548209, 5557999, 5862668, 5878128, 6029082, 6168918, 6168919, 6168921, 22663-01, 21612-04, 22637-02	
04.315.023	BC Distractor Body End ACT 15mm for CMF	07611819947955	5372309, 5558850, 5558851, 5558852, 5558853, 6000872, 6000873, 6226241,	

Part Number	Part Description	GTIN	Lot	Quantity Returning
	Distractor		6233859, 6160687, 21247-02, 21618-03, 22375-01	
04.315.024	BC Distractor Body End ACT 20mm for CMF Distractor	07611819947962	5372310, 5559873, 5559874, 5559875, 5559876, 5559877, 5828443, 5828444, 5878117, 6024565, 6064453, 6075057, 6075061, 6136907, 6136929, 22375-02, 21618-05, 22658-04, 22658-03, 21247-03	
04.315.025	BC Distractor Body End ACT 25mm for CMF Distractor	07611819947979	5372311, 5561698, 5561705, 5561707, 5584066, 5862683, 5877997, 6029081, 6081245, 6081246, 6109380, 6112116, 21618-07, 22375-03, 21247-04, 21618-07A	
04.315.026	BC Distractor Body End ACT 30mm for CMF Distractor	07611819947986	5372312, 5562773, 5562854, 5563945, 5828445, 5828446, 5829286, 6081243, 6081244, 6099323, 6118902, 6136977, 21247-05, 21618-09, 22375-04, 21618-09A, 22658-01	
04.315.027	BC Distractor Body End ACT 35mm for CMF Distractor	07611819947993	5877050, 5877051, 5877052, 5888432, 6000875, 6071203, 6119767, 6168010, 6168976, 6183319, 22408-02, 22612-03, 22408-01, 22359-06, 22658-05, 22612-06	
04.315.028	BC Distractor Body End ACT 40mm for CMF Distractor	07611819948006	5878143, 5878144, 5883054, 5888817, 6029096, 6119766, 6136976, 6168007, 22408-03, 22532-01, 22611-10	
04.315.053	AB Distractor Body End ACT W/U-Joint 15mm for CMF Distractor	07611819948020	5587772, 5587773, 5587774, 5625097, 6000874, 21612-05	
04.315.054	AB Distractor Body End ACT W/U-Joint 20mm for CMF Distractor	07611819948037	5587775, 5587776, 5587777, 6000870, 6029085, 6168920, 6196473, 6282013, 21612-06, 22611-08	
04.315.055	AB Distractor Body End ACT W/U-Joint 25mm for CMF Distractor	07611819948044	5590700, 5590723, 5878125, 6028974, 21612-07	
04.315.056	AB Distractor Body End ACT W/U-Joint 30mm for CMF Distractor	07611819948051	5579198, 5597077, 5597092, 5878002, 6029091, 6029092, 21656-16, 21612-08	
04.315.063	BC Distractor Body End ACT W/U-Joint 15mm for CMF Distractor	07611819948099	5390575, 5612498, 5612500, 6222255, 6228011, 6228012, 21618-11, 21247-08	

Part Number	Part Description	GTIN	Lot	Quantity Returning
04.315.064	BC Distractor Body End ACT W/U-Joint 20mm for CMF Distractor	07611819948105	5390576, 5612499, 5612502, 5853755, 5853756, 5853795, 6071201, 6071202, 6071206, 6230808, 6232544, 6282164, 21247-09, 21618-13, 21656-19, 22179-17, 22229-11	
04.315.065	BC Distractor Body End ACT W/U-Joint 25mm for CMF Distractor	07611819948112	5390577, 5612495, 5612496, 5613291, 5862699, 6028982, 6136930, 6136931, 6136932, 6165615, 6183321, 21247-10, 21618-15, 22648-06, 22624-01, 22552-11	
04.315.066	BC Distractor Body End ACT W/U-Joint 30mm for CMF Distractor	07611819948129	5390578, 5610566, 5610567, 5703744, 5710985, 5744145, 5832448, 6011937, 6012515, 6012516, 6012518, 6022960, 6022961, 6029078, 6029080, 6102795, 6104332, 6115444, 6166162, 6183320, US85534, 21247-11, 21618-17, IS10013, 21618-17A, 22179-18, 22617-01, 22611-14	
04.315.067	BC Distractor Body End ACT W/U-Joint 35mm for CMF Distractor	07611819948136	6000965, 6001011, 6001012, 6001014, 6009271, 6118875, 6118876, 6118877, 6184269, 6184270, 22612-04, 22408-05, 22408-04, 22637-01, 22610-02, 22612-04	
04.315.068	BC Distractor Body End ACT W/U-Joint 40mm for CMF Distractor	07611819948143	6000966, 6001016, 6001018, 6001019, 6009272, 6022080, 6097965, 6119768, 6119769, 6275129, 22408-06, 22603-01, 22648-01, 22611-01	
Total Returning				

Note: Unique Device Identifier (UDI): UDI = DI + PI
DI = Device Identifier = GTIN | PI = Production Identifier = Lot Number



Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
2 Science Park Drive, #07-13, Ascent, Singapore Science Park 1, Singapore 118222
Tel: +65 6918 8000
Business Reg No. 52836279L Company Reg No. 197402104W