

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

DePuy Synthes Craniomaxillofacial Distraction System - May Reverse Directions After Surgery

Recall Class: Class I

Date Recall Initiated: April 16, 2014

Product: The DePuy Synthes Craniomaxillofacial (CMF) Distraction System (AB Distractor Bodies and BC Distractor Bodies). Also called an External Mandibular Fixator And/Or Distractor and a Bone Plate.

Manufacturing Dates: April 20, 2009 through April 15, 2011

Distribution Dates: November 3, 2009 to April 14, 2014

See the Recall Notice

(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=126898>) or the Firm Customer Notice

([http://www.depuyshynthes.com/binary/org/DPY_SYN/Products/Images/CMF/Recall%20213%20CNL%20CMF%20Distraction%20System%20\(AB%20%20BC%20Distractor%20Bodies\)%20Customer%20Notification%20Final%204-15-2014.pdf](http://www.depuyshynthes.com/binary/org/DPY_SYN/Products/Images/CMF/Recall%20213%20CNL%20CMF%20Distraction%20System%20(AB%20%20BC%20Distractor%20Bodies)%20Customer%20Notification%20Final%204-15-2014.pdf)) for a complete listing of affected products with part and lot numbers.

Use: The DePuy Synthes Craniomaxillofacial (CMF) Distraction System is an implant used to lengthen and/or stabilize the lower jawbone (mandibular body) and the side of the lower jaw (ramus). This device is used in pediatric and adult patients to correct birth (congenital) or post-traumatic defects of the jaw by gradually lengthening the bone (distraction).

Recalling Firm:

Synthes (USA)
1302 Wrights Lane East
West Chester, PA 19380

Reason for Recall: DePuy Synthes is recalling certain lots of the Craniomaxillofacial Distraction System because the device may reverse direction and lose the desired distraction distance after surgery.

- Infants are at the highest risk for injury if the device fails because sudden obstruction of the trachea can occur. This could lead to respiratory arrest, and result in death.
- Children or adults with the ability to maintain an open airway are at less risk for serious injury because failure of the device would not result in tracheal obstruction and could be medically reversible.
- In all patient populations, failure of the device may result in the need for surgical intervention to replace the failed device.

There have been 15 reports of injury associated with the use of this device.

Public Contact: Customers who have questions about this recall may contact DePuy Synthes Customer Support at 1-800- 479-6328, Monday – Friday, 9:00 a.m. to 8:00 p.m. Eastern Time or the sales consultant.

FDA District: Philadelphia District Office

More Information about this Recall:

On April 16, 2014, DePuy Synthes sent an **Urgent Notice** ([http://www.depuysynthes.com/binary/org/DPY_SYN/Products/Images/CMF/Recall%20213%20CNL%20CMF%20Distraction%20System%20\(AB%20%20BC%20Distractor%20Bodies\)%20Customer%20Notification%20Final%204-15-2014.pdf](http://www.depuysynthes.com/binary/org/DPY_SYN/Products/Images/CMF/Recall%20213%20CNL%20CMF%20Distraction%20System%20(AB%20%20BC%20Distractor%20Bodies)%20Customer%20Notification%20Final%204-15-2014.pdf)) to their customers. The notice identified the problem, affected products and tells customer to:

- Review their inventory and remove affected lots from stock.
- Call DePuy Synthes at 1-800-479-6329 for a return authorization number
- Complete and return the verification in the letter included with the notice.

About Class I Recalls

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program** (<https://www.accessdata.fda.gov/scripts/medwatch/>) either online, by regular mail or by FAX.

Additional Resources

- **Firm Customer Notice**
([http://depuysynthes.com/binary/org/DPY_SYN/Products/Images/CMF/Recall%20213%20CNL%20CMF%20Distraction%20System%20\(AB%20%20BC%20Distractor%20Bodies\)%20Customer%20Notification%20Final%204-15-2014.pdf](http://depuysynthes.com/binary/org/DPY_SYN/Products/Images/CMF/Recall%20213%20CNL%20CMF%20Distraction%20System%20(AB%20%20BC%20Distractor%20Bodies)%20Customer%20Notification%20Final%204-15-2014.pdf)) ↗
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Class 1 Device Recall DePuy Synthes Craniomaxillofacial Distraction System



6 510(k)⁷ | DeNovo⁸ | Registration & Listing⁹ | Adverse Events¹⁰ | Recalls¹¹ | PMA¹² | Classification¹³ | Standards¹⁴
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**Class 1 Recall
 DePuy Synthes Craniomaxillofacial
 Distraction System**



Date Posted	August 20, 2014
Recall Status¹	Open
Recall Number	Z-2148-2014
Recall Event ID	<u>68071</u> ²³
Premarket Notification 510(K) Number	<u>K060138</u> ²⁴
Product Classification	<u>External Mandibular Fixator And/Or Distractor</u> ²⁵ - Product Code <u>MQN</u> ²⁶
Product	DePuy Synthes Craniomaxillofacial Distraction System (AB Distractor Bodies and BC Distractor Bodies)
Code Information	Part nos. 04.315.003, 04.315.004, 04.315.005, 04.315.006 04.315.023 04.315.024 04.315.025 04.315.026 04.315.027 04.315.028 04.315.053 04.315.054 04.315.055 04.315.056 04.315.063 04.315.064 04.315.065 04.315.066 04.315.067 04.315.068, with lot nos.: 6245205, 7129328, IS10400 6246203, 6582199, 6794535, 6814674, 6877737, 6921359, 6981567, 7008430, 7081952, 7129329, 7460419, 7556148 6246984, 6342006, 6964974, 7129330, 7460420, 6246983, 7389334, 7422735, 7515818 6245460, 6342005, 6454138, 6495399, 6651393, 6816023, 6898959, 6921360, 7306561, 7515824 6307904, 6365443, 6410544, 6438375, 6625839, 6651392, 6984928, 7241620, 7351855, 7390470, 7408179, 7458272, 7458273, 7458274, IS10394 6450702, 6454139, 6553925, 6625840, 6883404, 6921586, 7031344, 7185897, 7389329, 7408181, 7422706, 7422707, 7422708, 7458299, 7515832, IS10385 6393118, 6393119, 6410545, 6454140, 6512859, 6625841, 6651391, 6984925, 7185895, 7408182, 7422703, 7422704, 7422705, 7515829, 7515830 6393120, 7408180, 7515833 7122918, 7389333, 7422700, 7545381, IS10388 6252759, 7129331, 7155891, 7418771, 7448753 6245463, 6438376, 6981568, 6983876, 7063885, 7129332, 7309797, 7418772, 7418848, 7448754 6251769, 7081953, 7310030, 7365542, 7418849, 7448752, 7448758, 7556149 6245458, 6342007, 7129333, 7556150, IS10399 6245462, 6342003, 6824546, 6824551, 6883290, 6883301, 7082907, 7266972, 7476792, 7476810, 7657623 6280719, 6342004, 6394297, 6651390, 6737168, 6767617, 6824547, 6824550, 6883304, 6883305, 6961025, 6984927, 7041138, 7056051, 7111867, 7185893, 7266967, 7351857, 7351858, 7351859, 7351861, 7422701, 7545379, 7657820, IS10395, 6651389, 6702172, 6883306, 6883307, 6942444, 6984926, 7111868, 7185892, 7306562, 7306563, 7306564, 7499078, 7515834, 7657629, IS10389 6651388, 6741835, 6824553, 6883309, 6913921, 6942445, 6961024, 7082908, 7111869, 7122924, 7185888, 7515835, 7657633 6921585, 6942446, 7185887, 7306565, 7306566, 7408183, 7476791, 7567066, 7579433, 7657635, IS10390, IS10391, 6275129, 7082905, 7185890, 7266969, 7422697, 7609200, IS10386, IS10387
Recalling Firm/ Manufacturer	Synthes, Inc. 1302 Wrights Ln E West Chester, Pennsylvania 19380-3417
For Additional Information Contact	Customer Support 610-719-5000
Manufacturer Reason for Recall	DePuy Synthes is initiating a recall of certain lots of the Craniomaxillofacial Distraction System (AB Distractor Bodies and BC Distractor Bodies) because they may reverse post-operatively.

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Class 2 Device Recall Synthes Craniomaxillofacial (CMF) Distraction System



[510\(k\)⁶](#) | [DeNovo⁹](#) | [Registration & Listing⁹](#) | [Adverse Events¹⁰](#) | [Recalls¹¹](#) | [PMA¹²](#) | [Classification¹³](#) | [Standards¹⁴](#)
[CFR Title²¹](#) | [Radiation-Emitting¹⁶](#) | [X-Ray¹⁷](#) | [Medsun¹⁸](#) | [CLIA¹⁹](#) | [TPLC²⁰](#) | [Inspections²¹](#)

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Class 2 Recall Synthes Craniomaxillofacial (CMF) Distraction System



Date Posted	July 12, 2013
Recall Status¹	Open
Recall Number	Z-1726-2013
Recall Event ID	<u>65670²³</u>
Premarket Notification 510(K) Number	<u>K060138²⁴</u>
Product Classification	<u>External Mandibular Fixator And/Or Distractor²⁵</u> - Product Code <u>MQN²⁶</u>
Product	Synthes CMF Distraction System The product is intended for use as a bone stabilizer and lengthening (and/or transport) device for correction of congenital deficiencies or post-traumatic defects of the mandibular body and ramus, where gradual bone distraction is required. It is intended for single use only.
Code Information	Part # 04.315.067 with lot #s 6184270 and/or 22612-04.
Recalling Firm/ Manufacturer	Synthes USA HQ, Inc. 1302 Wrights Ln E West Chester, Pennsylvania 19380-3417
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Synthes Recall Information Center 610-719-5450
Manufacturer Reason for Recall	The firm initiated a voluntary recall of the BC Distractor Body which is part of the Craniomaxillofacial (CMF) Distractor System, due to a mis-alignment issue. There have been instances reported within the impacted lots in which the slot in the barrel of the BC distractor was rotated such that it was not possible to attach the B-type and C-type foot plates.
FDA Determined Cause²	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
Action	SYNTHES sent an Urgent Notice: Medical Device Recall letter dated June 12, 2013, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were requested to examine their inventory for affected product, remove it from use, and return it to Synthes. If they have affected product they were instructed to call Synthes at 1-800-479-6329 to obtain a Return Authorization Number. Complete the Verification Section at the end of the letter and indicate the number of devices found and note the Return Authorization Number and return to Credit>Returns, Synthes, 1101 Synthes Avenue, Monument, CO 80132. If customers did not have the affected product they were asked to complete the Verification Section and fax to 610-251-9005. Customers with questions were instructed to call 610-719-5450 or e-mail FieldAction@synthes.com . For questions regarding this recall call 610-719-5450.
Quantity in Commerce	10
Distribution	Nationwide Distribution including PA, CT, DE, and NY.
Total Product Life Cycle	TPLC Device Report ²⁷