

Urgent Notice

15 April 2014

Voluntary Product Recall Notification: Craniomaxillofacial (CMF) Distraction System

Dear Health Care Professional,

DePuy Synthes CMF has initiated a voluntary recall of the CMF Craniomaxillofacial Distraction System (AB Distractor Bodies and BC Distractor Bodies), used to lengthen the mandibular body and ramus in patients with congenital deficiencies or post-traumatic defects. Please refer to the attached affected product listing, and be aware that products in your possession may be affected.

This recall is being initiated because the distractor may reverse direction post-operatively. Loss or inadequate distraction may result in moderate poor joint mechanics. In patients with unconsolidated bone or compromised mandible anatomy, there is a risk of airway obstruction.

Mitigation Steps for Patients with Distractors Currently Implanted

In the presence of inadequate distraction or reversal of a previously achieved distraction distance, the patient may need to undergo prolonged distraction therapy. In some instances, revision surgery may be needed to replace the device.

Since frequent screening is part of the standard of care in the distraction process, failure to advance should be detected and permanent impairment is not anticipated. **However, remaining vigilant and closely monitoring patients for any distractor reversal is recommended.**

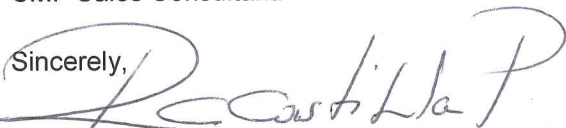
For any clinical questions regarding ongoing management of patients undergoing distraction, please contact DePuy Synthes CMF Scientific and Medical Affairs at SciMedAffairs@its.jnj.com.

Your institution has received this recall notice with instructions to immediately check all inventory to identify and return product. Please work with your local DePuy Synthes CMF Sales Consultant to identify alternative systems.

We apologize for the inconvenience this voluntary recall may cause. At DePuy Synthes CMF, we are dedicated to delivering products that meet the highest quality standards. We regret the need to undertake this recall and we are committed to resolving this issue.

Thank you for your cooperation. For additional questions about this recall, please contact your DePuy Synthes CMF Sales Consultant.

Sincerely,



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Medical Director-Strategic Medical Affairs & Medical Sciences
The DePuy Synthes Companies

Figure 1: Product/Lot Subject to this Recall

| Product Description | Part Number | Lot Numbers |
|---|--------------------|---|
| AB Distractor Body, end activated, distraction length 15 mm, for CMF Distractor | 04.315.003 | IS10400 |
| AB Distractor Body, end activated, distraction length 20 mm, for CMF Distractor | 04.315.004 | 6794535; 6814674; 6981567; 7008430; 7081952; 7129329; 7556148; IS10401 |
| AB Distractor Body, end activated, distraction length 30 mm, for CMF Distractor | 04.315.006 | 7389334 |
| BC Distractor Body, end activated, distraction length 15 mm, for CMF Distractor | 04.315.023 | 6245460; 6342005; 6454138; 6495399; 6651393; 6816023; 7306561; 7515824 |
| BC Distractor Body, end activated, distraction length 20 mm, for CMF Distractor | 04.315.024 | 6307904; 6365443; 6410544; 6438375; 6625839; 6651392; 6984928; 7241620; 7351855; 7390470; 7408179; IS10394 |

Figure 1: Product/Lot Subject to this Recall

| Product Description | Part Number | Lot Numbers |
|---|--------------------|---|
| BC Distractor Body, end activated, distraction length 25 mm, for CMF Distractor | 04.315.025 | 6454139; 6553925; 6625840; 6883404; 7031344; 7185897; 7389329; 7408181; 7422706; 7422707; 7458299; IS10385 |
| BC Distractor Body, end activated, distraction length 30 mm, for CMF Distractor | 04.315.026 | 6393118; 6393119; 6410545; 6454140; 6512859; 6625841; 6651391; 6984925; 7185895; 7408182; 7422703; 7422704; 7422705 |
| BC Distractor Body, end activated, distraction length 35 mm, for CMF Distractor | 04.315.027 | 7408180 |
| BC Distractor Body, end activated, distraction length 40 mm, for CMF Distractor | 04.315.028 | 7122918, 7422700 |
| AB Distractor Body, end activated, distraction length 15 mm, with Universal | 04.315.053 | 7129331; 7155891; 7448753; IS10396 |

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| Product Description | Part Number | Lot Numbers |
|---|--------------------|---|
| Joint, for CMF Distractor | | |
| AB Distractor Body, end activated, distraction length 20 mm, with Universal Joint, for CMF Distractor | 04.315.054 | 6438376; 6981568; 7063885; 7129332; 7309797; 7418848; 7448754 |
| AB Distractor Body, end activated, distraction length 25 mm, with Universal Joint, for CMF Distractor | 04.315.055 | 7310030; 7418849; 7448752; 7556149 |
| AB Distractor Body, end activated, distraction length 30 mm, with Universal Joint, for CMF Distractor | 04.315.056 | 6342007; 7129333; 7556150 |
| BC Distractor Body, end activated, distraction length 15 mm, with Universal Joint, for CMF Distractor | 04.315.063 | 6824546; 6883290; 6883301; 7082907; 7476792; IS10392 |
| BC Distractor Body, end activated, distraction length 20 mm, with Universal Joint, for CMF Distractor | 04.315.064 | 6280719; 6342004; 6651390; 6737168; 6824547; 6824550; 6961025; 7041138; 7111867; 7266967; 7351857; 7351861; 7422701; 7657636; IS10395 |

Figure 1: Product/Lot Subject to this Recall

| Product Description | Part Number | Lot Numbers |
|---|--------------------|---|
| BC Distractor Body, end activated, distraction length 25 mm, with Universal Joint, for CMF Distractor | 04.315.065 | 6942444; 7111868; 7185892; 7306562; 7306563; 7306564; 7499078 |
| BC Distractor Body, end activated, distraction length 30 mm, with Universal Joint, for CMF Distractor | 04.315.066 | 6651388; 6741835; 6883309; 6913921; 6942445; 6961024; 7082908; 7111869; 7122924; 7185888 |
| BC Distractor Body, end activated, distraction length 35 mm, with Universal Joint, for CMF Distractor | 04.315.067 | 6942446; 7185887; 7306566; 7408183; 7476791; 7579433 |
| BC Distractor Body, end activated, distraction length 40 mm, with Universal Joint, for CMF Distractor | 04.315.068 | 6275129; 7082905; 7185890; 7266969; 7422697; 7579432; IS10386; IS10387 |