20 June 2016

URGENT NOTICE:
MEDICAL DEVICE RECALL – 410682
Mandible Distractor, Monoaxial and Proximal Foot Plate

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

Part Description, Part and Lot Numbers

Part Description	Part Number	Lot Numbers
Mandible Distractor, monoaxial, right, distraction length 20mm	487.962	See Attachment 1
Mandible Distractor, monoaxial, left, distraction length 20mm	487.963	See Attachment 1
Mandible Distractor, monoaxial, right, distraction length 30mm	487.964	See Attachment 1
Mandible Distractor, monoaxial, left, distraction length 30mm	487.965	See Attachment 1
Proximal Foot Plate, right, f/Mandib. Distractor, monoaxial	487.974	See Attachment 1
Proximal Foot Plate, left, f/Mandib. Distractor, monoaxial	487.975	See Attachment 1

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part-Numbers of the Mandible Distractor and Proximal Foot Plate, inclusive of all lots. These products are intended for mandibular bone lengthening where gradual bone distraction is required, including conditions such as congenital mandibular deficiencies or post-traumatic defects.

Our records indicate that you may have inventory that is impacted by this recall or have been using affected product(s) from a loan set.

Reason for the Recall

The fastener on the Mandible Distractor may become prematurely separated from the Proximal Foot Plate.

Potential Patient Impact:

In the event that the Mandible Distractor becomes disengaged from the Proximal Foot Plate during device implantation, surgical delay may occur if another device is not available in the surgical suite. If the Mandible Distractor becomes disengaged from the Proximal Foot Plate after device implantation, repeat surgery may be required to replace

the Mandible Distractor/Foot Plates. There may be a risk of local infection as a result of repeat surgery caused by the disengagement since the product is in the oral cavity.

There is no DePuy Synthes replacement device available. Synthes GmbH offers several alternative devices which are also intended for distraction of the mandible, including the Stainless Steel Mandible Distractor System, the Titanium Multi-Vector Distractor Module System, and the Curvilinear Distraction System. Please refer to the Indications and Instructions for Use for these alternate systems to determine their suitability for your patients.

Customer immediate actions:

1. Immediately review your inventory to identify and quarantine all affected products listed above in a manner that ensures the affected products will not be used.

2. Review, complete, sign and return the attached reply form on page 3 of this letter to your local DePuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.

3. Return any affected product as soon as possible, but within 30 business days. A credit note will be issued for the returned items.

4. Forward this notice to anyone in your facility that needs to be informed.

5. If any of the affected products has been forwarded to another facility, contact that facility to arrange return.

6. Maintain awareness of this notice until all products listed below have been returned to DePuy Synthes.

7. Keep a copy of this notice.

We apologize for any inconvenience that this product recall may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes sales consultant.

Thank you for your attention and cooperation.

Yours Sincerely,

[redacted]

Lee, Ching Hwee
Associate Manager, Regulatory Affairs

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Please check (√) accordingly:

☐ We acknowledge receipt of this information, but do not have any identified product in stock; returned quantity is zero.

☐ We located the identified product in stock; returned quantity is documented below:

Product Code	(Lot Number)	Quantity (Number in "Eaches")

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

_____ _____
Customer Name Title

_____ _____
Signature & Date Stamp ***(Stamp shall bear facility name)***

Please complete this Verification Section and return to your Depuy Synthes representative or fax it to +65 6720 0750 within **(5) five business days** of receipt of the Field Safety Notice.

Johnson & Johnson Medical Singapore
a division of Johnson & Johnson Pte Ltd.
No. 2 International Business Park, #07-01, Tower One, The Strategy, Singapore 609930
Tel: +65 6827 6000 Fax: +65 6720 0750
Business Reg No. 52836279L Company Reg No. 197402104W

Attachment 1. Part Description, Part- and Lot Numbers subject to this recall

Part Description	Part Number	Lot Numbers
Mandible Distractor, monoaxial, right, distraction length 20mm	487.962	4042147; 4664395; 6164423; 6397761; 6171239; 4664392; 5229307; 5071337; 5422905; 5621088; 7537258; 7927945; 6171240; 4548558; 4042146
Mandible Distractor, monoaxial, left, distraction length 20mm	487.963	4281408; 4454536; 5414450; 6291848; 4475459; 7865438; 6879052; 5414451; 9890200; 7626782
Mandible Distractor, monoaxial, right, distraction length 30mm	487.964	4485940; 5021030; 5051836; 6538895; 5559855; 4538241; 5292906; 5140379; 5559854; 4454474; 4091232; 4038562; A4JY067; 6250793; 5321398; 5321399; 5332085; 6720328; 6932326; 5321397; 5559649; 5391292; 6397763; 7489024; 5175699; 7609552; 5868674; 6551653; 5559642
Mandible Distractor, monoaxial, left, distraction length 30mm	487.965	4664398; 5859708; 6720329; 4375629; 5859707; 5021031; 5175697; 4664397; 4435710; 4420112; 5143278; 4091229; 5859711; 4038563; 5321402; 5321404; 5857578; 4746860; 5859710; 5391281; 5282148; 6551654; 5391293; 4375627; 5321401; 6287524; 6287525; 7458399; 5332086; 7865439; 9916673; 6538904
Proximal Foot Plate, right, f/Mandib. Distractor, monoaxial	487.974	4044599; 4745317; 4600267; 4038565; 6199927; 6877042; 4873174; 4744818; 5298113; 5469087; 5820678; 5304974; 5202231; 5202232; 6044556; 6778533; 4873173; 5202233; 5202234; 5860826; 5354033; 6983832; 7880980; 7931712
Proximal Foot Plate, left, f/Mandib. Distractor, monoaxial	487.975	4767010; 4851968; 5277361; 4479352; 4597089; 4038566; 4418691; 6164421; 6819614; 5433149; 5847357; 5883452; 6107614; 5346057; 5445638; 5419963; 6164420; 7865426; 6107608; 5847302; 6107609; 7537257; 5828442; 4851967; 7489031

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