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DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Operating Room Manager

15. December 2014

URGENT MEDICAL DEVICE PRODUCT RECALL

Part Number	Lot Number	Description
397.232	1698700;4688882;4868698;5129449;5345722;6009689;6235842;6407718;1702300;4688883;4916060;5129450;5356127;6021041;6241331;6407719;1715800;4772507;4916061;5129453;5382066;6023019;6258401;6446480;175220;4772508;4916062;5247085;5422622;6023020;6258402;6446481;1685602;4814278;4991953;5247087;5664372;6040195;6300954;6452871;1695100;4814280;4991962;5263641;5664373;6040196;6321761;6452872;1695101;4814281;4992455;5267067;5685461;6056610;6345256;6623687;1706600;4868678;5032047;5267068;5820702;6097962;6345257;6633304;1776300;4868685;5080386;5287150;5839165;6181398;6355110;1798900;4868691;5080387;5287152;5855648;6212655;6407717	Cheek Retractor, f/MatrixMANDIBLE U-shaped, flexible

Dear Valued Customer,

Synthes GmbH is issuing a medical device recall related to the above mentioned lots of Cheek Retractor for MatrixMANDIBLE U-shaped, flexible (labelled as "Retractor, f/MatrixMANDIBLE"). It is used in the following systems:

MatrixMANDIBLE™ Plating System, MatrixORTHOGNATHIC™ Plating System, Craniomaxillofacial (CMF) Distraction System, Curvilinear Distraction System, 2.4 Mandible, 2.4 UniLOCK, Compact 2.0 Compact 2.0 Lock, and Compact Orthognathic 1.5/2.0

Our records indicate that you may have inventory or loan sets that are subject to this product recall. Synthes kindly requests you to review the information and complete the Verification Section at the end of this letter.

Description of the problem:
The Cheek Retractor for MatrixMANDIBLE U-shaped may not function as intended due to the potential for failure and/or corrosion of the internal spring which has been manufactured from an incorrect material.

Potential hazard:
There is potential for subcomponent spring breakage originating from the incorrect raw material used in the fabrication of the spring in the Cheek Retractor for MatrixMANDIBLE U-shaped, flexible. There is a potential for harm to patients including surgical delay if the retractor does not work during a procedure and a replacement needs to be found; adverse tissue reaction and/or infection could occur if the retractor is used and corroded material from the spring falls into the wound and is not removed during irrigation.

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Requested Immediate Customer actions:

1. Immediately identify and quarantine all unused product listed above in a manner that ensures the affected product will not be used.

2. Review, complete, sign and return the attached reply form to your local Synthes sales organization within 5 business days of receipt of this notification.

3. Return any affected product within 30 business days. Credit or replacement will be provided based on product availability.

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

5. If any product listed below 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 Synthes GmbH.

7. Keep a copy of this notice with the affected product.

The applicable regulatory agencies are being notified. Synthes GmbH is taking this action voluntarily.

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

Synthes GmbH

Dr. med. Maria I. Behrens MDRA
Field Action Manager

Markus Wien
Director Quality Assurance Operations

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15. December 2014

NOTICE: MEDICAL DEVICE REMOVAL R2014186-2

Verification Section

Part Number	Lot Number	Description
397.232	1776300; 1798900; 4688882; 4688883; 4772507; 4772508; 4814278; 4814278; 4814280; 4814281; 4868678; 4868685; 4868691; 4868698; 4916060; 4916061; 4916062; 4916062; 4991953; 4991962; 4992455; 5032047; 5080386; 5080387; 5129449; 5129450; 5129453; 5247085; 5247087; 5263641; 5267067; 5267068; 5287150; 5287152; 5345722; 5356127; 5382066; 5422622; 5664372; 5664373; 5685461; 5820702; 5839165; 5855648; 5855648; 6009689; 6009689; 6021041; 6023019; 6023020; 6040195; 6040196; 6056610; 6097962; 6181398; 6212655; 6235842; 6241331; 6258401; 6258402; 6300954; 6321761; 6321761; 6345256; 6345257; 6355110; 6407717; 6407718; 6407719; 6446480; 6446481; 6452871; 6452872; 6623687; 6633304	Cheek Retractor, f/MatrixMANDIBLE U-shaped, flexible

☐ We have located the identified product in stock; returned quantity is documented below, and a copy of this letter is being retained for our records.

☐ We do not have any identified product in stock; returned quantity is zero. We have retained a copy of this letter for our records.

RETURNED DEVICES (including quantity) and/or COMMENTS:

_____

_____

_____

_____

_____

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____