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To the attention of:
Hospital Personnel

Return Receipt Requested

18 August 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2014517
APPLICATION INSTRUMENT FOR STERNAL ZIPFIX

Attention: Hospital Personnel

Part Description, Affected Part- and Lot Numbers

Part Descriptions	Part Numbers	Lot Numbers
Application Instrument for Sternal ZIPFIX	03.501.080	Please refer to Attachment 1 (page 5) for the complete list of affected lot numbers

Synthes GmbH is initiating a medical device recall of certain lots of the Application Instrument for Sternal ZIPFIX. The Sternal ZIPFIX is used for closure of the sternum following sternotomy to stabilize the sternum and promote fusion.
Our records indicate that you may have inventory that is impacted by this recall.

Reason for Recall
In the specified lots of the Application Instrument for Sternal ZIPFIX listed on page 5:

- The end cap may loosen, thus reducing the tension applied to the implant.
- The end cap may detach, allowing the tensioning spring to also become detached, and making the instrument non-functional.

Potential Patient Impact
If the Tension Coil spring detaches completely from the ZIPFIX Application instrument while closing the sternum, it is possible that the spring or nut could fall into the thoracic cavity and go undetected. If the nut/spring is retained in the thoracic cavity, adverse tissue reaction may occur. No such occurrence has been reported to date.
In addition, if the spring and/or nut remains in the patient, the patient is then at risk if exposed to an MRI. A patient undergoing MRI is at risk for the following additional harms if the retained spring/nut goes undetected: Soft Tissue Irritation, Discomfort or Pain related to thermal injuries, Bone Damage/Fracture Post-op.
Surgical delay may occur if the surgeon resorts to using an alternative sternal closure. In the event that the nut/spring loosens or detaches, surgical delay may occur while a replacement is requested.

Customer immediate actions
Please verify whether you have any of the affected products and take the following actions, as appropriate.
If any of the affected products has been forwarded to another facility, contact that facility to arrange return and provide them with this letter.

If you **DO HAVE** any of the identified affected product(s), please take the following steps:

- Immediately identify and quarantine all products listed above in a manner that ensures the affected products will not be used.
- Return any affected product as soon as possible, but within 30 business days. A free of charge repair will be performed for the returned items.
- Once the product is returned to Synthes GmbH, it will be dealt with the highest priority and shipped back to your facility.
- Keep a copy of this communication with any affected product(s) identified above.
- Ensure anyone in your facility impacted by this notification reads this letter carefully.
- Complete the Verification Section (page 4 of this letter) by checking the appropriate box indicating affected product has been located. Also, please indicate the number of devices found and their Lot Number. Please include your name, title, address, telephone number and signature in the spaces provided.
- Return the completed Verification Section to your local DePuy Synthes contact person.
- Contact your local DePuy Synthes contact person to arrange the return of the affected devices for a free of charge repair.

If you **DO NOT HAVE** any of the identified affected product(s), please take the following steps:

- Complete the attached Verification Section (page 4 of this letter) by checking the appropriate box indicating that no affected product has been located. Please include your name, title, address, telephone number and signature in the spaces provided. This return documentation acknowledges your receipt of medical device recall information.
- Return the completed Verification Section to your local DePuy Synthes contact person.

The applicable regulatory agencies are being notified.

If you have any questions, please contact your DePuy Synthes sales consultant.
Thank you for your attention to this issue.

Synthes GmbH

Paul Bielderman MD
Field Action Manager

Anne Brisson
Senior QA Manager Product Safety

Cc:

Account Name: _____

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☐ We located the identified product in stock and will return affected product to Synthes GmbH for repair. The returned quantity including is documented below, and a copy of this letter is kept for our records.

☐ We acknowledge receipt of this information, but do not have any identified product in stock. The returned quantity is zero, a copy of this letter is kept for our records.

RETURNED DEVICES (including quantity) and/or COMMENTS:

_____

_____

_____

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____

Please complete and return this page your local DePuy Synthes contact person

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.

Attachment 1: Products/ Lot Number subject to this recall

Part Description	Part Number	Lot Numbers
Application Instrument for Sternal ZIPFIX	03.501.080	3677481; 3653990; 3680914; 3696945; 3712934; 3752057; 3773561; 3783913; 3783492; 3788496; 3822332; 7505075; 7521227; 7526800; 7529403; 7587358; 7587361; 7584770; 7516728; 7606881; 7591576; 7635218; 7635229; 7641659; 7646490; 7653178; 7652152; 7659168; 7671934; 7678019; 7666085; 7694377; 7689244; 7700691; 7705157; 7738572; 7679825; 7720599; 7738573; 7740498; 7742713; 7767497; 7771488; 7787467; 7755478; 7797642; 7803768; 7806881; 7797648; 7818677; 7818682; 7827088; 7821672; 7831855; 7833606; 7868589; 7858407; 7872152; 7954899; 7958465; 7965113; 7976695; 8025792; 7970521; 8043201; 8047428; 8052698; 8056707; 8056711; 8068078; 8096643; 8130975; 8100630; 8130898; 8145793; 8159386; 8159385; 8166417; 8186954; 8207764; 8207769; 8209190; 8215969; 8215999; 8289116; 8271958; 8297063; 8290968; 8290959; 8398311; 8318394; 8402612;