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To the attention of:
Hospital Personnel

October 16, 2015

URGENT NOTICE:
MEDICAL DEVICE VOLUNTARY RECALL- R930222
ATTACHMENT FOR ACETABULAR AND MEDULLARY REAMING (511.785)

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of certain Serial Numbers of the Attachment for Acetabular and Medullary Reaming (Part Number 511.785) used with the Compact Air Drive II. The Compact Air Drive II (CAD II) is an air-driven power tool for use in traumatology, endoprosthetics and spinal column surgery. Several attachments and cutting tools are used with the CAD II handpiece for drilling, sawing and reaming bones in the human skeleton. The item that is the subject of this recall is exclusively used for reaming of bones.

Part Description, Affected Part- and Serial Numbers

Part Description	Part Number	Serial Numbers
Attachment for Acetabular and Medullary Reaming	511.785	16384,16385,16386,16387, 16389,16390,16391,16392, 16393,16394,16395,16396, 16397,16403,16405,16411.

Our records show that your facility possibly has the specified product(s) subject to this recall.

Reason for the Recall:
The geometrical shape of a subcomponent of this attachment was inadvertently changed. This change allows potential unintended reverse (counter-clockwise) motion if the subcomponent is aligned in a specific orientation when the attachment is connected to the handpiece and both triggers are pressed.

Potential hazards:
This attachment (511.785) is intended to be used without reverse motion. Unintentional activation in reverse could potentially damage flexible drilling or reaming shafts and could potentially cause serious injury to the patient.

Customer immediate actions:

Please verify whether you have any of the affected products and take the following actions, as appropriate.

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

- Ensure anyone in your facility impacted by this notification reads this letter carefully.
- Immediately identify and quarantine all products listed above in a manner that ensures the affected products will not be used.
- Maintain a copy of this communication with any affected product(s) identified above.
- Complete the Verification Section (page 3 of this letter) by checking the appropriate box indicating affected product has been located. Also, please indicate the number of devices found and their Serial Numbers. 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 sales organisation to arrange the return of the affected devices for a free of charge replacement.

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

- Complete the attached Verification Section (page 3 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.
- If any of the affected products has been forwarded to another facility, contact that facility to arrange return and provide them with this letter.

The applicable regulatory agencies are being notified.

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 or contact person.

Thank you for your attention and cooperation.

Sincerely,

Paul Ames
Field Action Manager, Synthes GmbH

Jennifer Breston
Complaint Handling Unit Senior Manager, Power Tools

Account Name: _____

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☐ We have located the identified product in stock; returned quantity including Serial Number(s) 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 Serial Number and quantity):

_____

Name/Title (please print):

_____

Address:

_____

Phone Number: _____

Signature and Date: _____

RGA # (If applicable):_____

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.