Synthes GmbH
Luzernstrasse 21
4528 Zuchwil
Switzerland
Tel. +41 32 720 40 60
Fax +41 32 720 40 61
http://www.depuysynthes.com

DePuy Synthes

To the attention of:
Hospital Personnel

8 April 2015

URGENT NOTICE:
MEDICAL DEVICE RECALL (CORRECTION) – R2014068
OSCILLATING SAW ATTACHMENT

Part Description, Part and Serial Numbers

Part Descriptions	Part Numbers	Serial Numbers
Oscillating Saw Attachment, for Part Numbers 532.001, 532.010, 532.101, 532.110 and 05.001.175	532.021	All Serial Numbers

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall for all Serial Numbers of the Oscillating Saw Attachment for Colibri/Colibri II/Small Electric Drive (Part Number 532.021). This Oscillating Saw Attachment is designed for use in general traumatology, especially hand and foot applications involving surgical procedures such as cutting of bone and hard tissue.

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

Reason for the Recall:
It has been reported that the Oscillating Saw Attachment may disengage intra-operatively.

Potential hazard:
If the device is tested in the operative theatre and the unit does not function, the user most likely would discontinue use of the affected part, and a replacement Oscillating Saw Attachment would be procured, which may lead to surgical delay.

Injury to the patient can occur if the Attachment disengages intra-operatively. There is also a potential of injury to the user from the sharp edge of the subject Oscillating Saw during retrieval. One report of a serious injury was received where the part fell apart during surgery and resulted in cuts in the hand of a user.

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:

- Conduct inspection as documented in Document 1 (page 5). This inspection step has to be part of every reprocessing cycle.
- If you notice any disassembly of the attachment or if you are able to unscrew the attachment, do not use it and immediately send it back for repair.
- Devices which perform satisfactorily during the inspection described in Document 1 do not need to be returned for repair and may be used as intended. A review and repair will be implemented if necessary during your next scheduled maintenance inspection at your designated Synthes Service Centre..
- Please ensure the devices are sent in for maintenance according to the recommended annual schedule.
- Ensure anyone in your facility impacted by this notification reads this letter carefully.
- Maintain a copy of this communication with any affected product(s) identified above.
- Complete the Verification Section (page 4 of this letter) by checking the appropriate box indicating affected product has been located and inspected. Also, please indicate the serial numbers inspected, which are acceptable and which need to be returned for service. 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.
- To arrange for servicing of the devices, please contact your local DePuy Synthes sales organisation.

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.
- 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 page 4 of the notification.
-

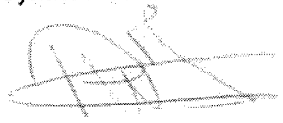
If any of the affected products has been forwarded to another facility, contact that facility to arrange return and provide them with this letter.

The applicable regulatory agencies are being notified.

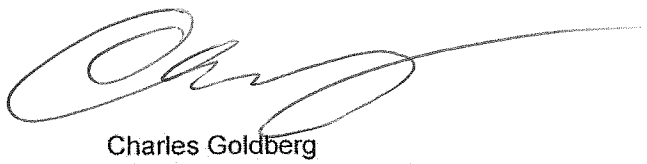
We apologize for any inconvenience that this product recall may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes sales consultant or contact person.

Thank you for your attention and cooperation.

Synthes GmbH



Pierre van Iwaarden
Field Action Manager



Charles Goldberg
Worldwide Director Complaint Management

Cc:

DePuy Synthes

Account Name: _____

URGENT NOTICE:
MEDICAL DEVICE RECALL (CORRECTION) – R2014068
OSCILLATING SAW ATTACHMENT

Part Description, Part and Serial Numbers

Part Descriptions	Part Numbers	SerialNumbers
Oscillating Saw Attachment, for Part Numbers 532.001, 532.010, 532.101, 532.110 and 05.001.175	532.021	All Serial Numbers

____ We located the identified product in stock and conducted the in-process inspection.
___Quantity inspected and acceptable
___Quantity inspected and returning for repair

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

INSPECTED DEVICES (listing of serial numbers):

_____

_____

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 or sales consultant

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.

DePuy Synthes

Document 1

Additional inspection step as part of the Function Control check to ensure correct operation of the Oscillating Saw Attachment (532.021)

The inspection steps described below must be performed during every reprocessing cycle for devices subject to this recall. They should be performed after cleaning and lubrication, and before sterilization.

Instructions:

1. Connect the Oscillating Saw Attachment to the Colibri (532. 001) or Colibri II (532.101) handpiece.

2. Firmly hold the handpiece as well as the attachment. The saw blade coupling offers a good grip to correctly hold the attachment.

3. Apply significant counterclockwise rotational force by hand to the attachment while holding the handpiece in a fixed position. Do not use any tool or lever to apply force.

4. Should you notice any disassembly of the attachment or if you are able to unscrew the attachment, do not use it and immediately send it back for repair.

5. Devices which perform satisfactorily during this inspection do not need to be returned for repair and may be used as intended. A review and repair will be implemented if necessary during your next scheduled maintenance inspection at your designated Synthes Service Centre.