

**To the attention of:
Hospital Personnel**

29 July 2015

**URGENT NOTICE:
MEDICAL DEVICE VOLUNTARY RECALL – R2014182
BATTERY POWER LINE II OSCILLATOR (BPL II OSCILLATOR)**

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of certain Serial Numbers of the affected Battery Oscillator II (Part Number 530.710). The Battery Power Line (BPL II) is a heavy-duty battery driven system intended for orthopedic and trauma applications including drilling, reaming, inserting/removing Kirschner wires and pins and cutting bone. The Battery Oscillator II is designed for cutting bone.

Part Description, Affected Part- and Serial Numbers

Part Description	Part Number	Serial Number
Battery Oscillator II, Handpiece	530.710	100265; 100293; 100296; 100315

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

Reason for the Recall:

It has been reported that the saw head of the affected Battery Oscillator II may separate from the drive unit or begin to come loose during usage or testing.

Potential hazards:

Although the loosening or detachment of the saw head would be easily recognizable, leading most likely to the discontinued use of the affected part, the procurement of a replacement power tool may lead to surgical delay affecting the safety of the patient.

Continued use of the drive unit with a loosening saw head could lead to injury to the patient, injury to the user, or pieces falling into the surgical field. These injuries may need surgical or medical intervention. Surgical delay and postoperative local infection are also potential risks.

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 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 Serial 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 sales organisation to arrange the return of the affected devices for a free of charge service.

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.
- 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


Anne Brisson
Senior QA Manager Product Safety

Cc:

Account Name: _____

**URGENT NOTICE:
MEDICAL DEVICE VOLUNTARY RECALL- R2014182
BATTERY POWER LINE II OSCILLATOR (BPL II BATTERY
OSCILLATOR)**

Part Description, Part- and Serial Numbers

Part Description	Part Number	Serial Number
Battery Oscillator II, Handpiece	530.710	100265; 100293; 100296; 100315

- We have located the identified product in stock; returned quantity including Serial Number 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.