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DePuy Synthes

Attention: Hospital Personnel

December 8, 2015

MEDICAL DEVICE VOLUNTARY RECALL – R930234
BATTERY POWER LINE II (BPL II) BATTERY OSCILLATOR

Product Description, Affected Part- and Serial Numbers

Product Description	Part Number	Serial Number
Battery Power Line II Battery Oscillator	530.710	101071; 101072; 101073; 101074; 101075; 101077; 101078; 101079; 101080; 101068; 101069; 101076; 101070; 101082; 101085;

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of certain serial numbers (listed above) of the affected Battery Power Line II Battery Oscillator (Part Number 530.710). The Battery Power Line (BPL II) Battery Oscillator is a heavy-duty, battery driven system intended for orthopedic and trauma applications designed for cutting bone.
Our records show that your facility possibly has the affected product(s) subject to this voluntary recall.

Reason for Recall
The BPL II Battery Oscillator handpiece (Part Number 530.710, Serial Numbers above) has the incorrect operating directions on the mode switch ring, i.e. it is labeled 'FWD, LOCK, REV' instead of ON, LOCK, ON' (Figure 1).

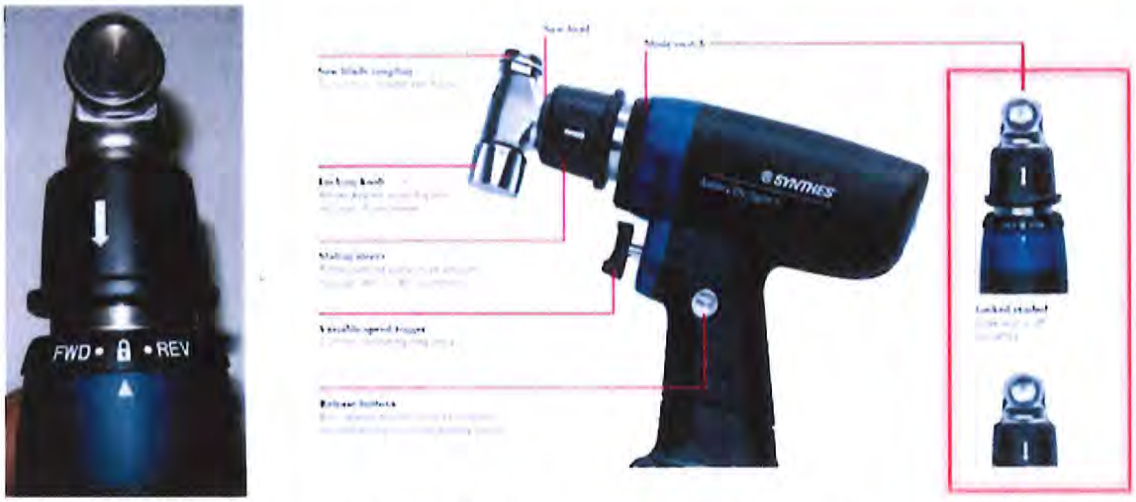

Figure 1: Image of BPL II Oscillating Handpiece with the incorrect jumper ring (left) and correct jumper ring (right)

Potential hazards

There is no malfunction of the device and there is no patient or user harm resulting from unintentionally placing the mode switch ring at the FWD or REV position; the device will continue to function normally and as intended.

The incorrect mode switch ring does not change the operation of the BPL II Battery Oscillator Handpiece; the handpiece is an oscillating saw that is not intended to have and does not have forward ("FWD") and reverse ("REV") functions.

Customer immediate actions

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

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.
- 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 for replacement and to arrange the return of affected devices.
- After rework the handpiece will be returned within 1-2 weeks.

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.

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

[redacted]

Pierre van Iwaarden
Field Action Manager

[redacted]

David Carvin
Sr. QA Manager, Product Safety and Performance

Cc:

DePuy Synthes

Account Name: _____

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☐ 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:

_____

Country:

_____

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.