

To the ATTENTION of: Operating Room Manager

4 December 2014

URGENT MEDICAL DEVICE PRODUCT RECALL

Part Description / Part Number

Part Number	Part Description	Lot Number
05.001.175	Small Electric Drive	All Lots

Dear Valued Customer,

Synthes GmbH is initiating a voluntary recall of all lots of the above mentioned article of Small Electric Drive (SED). The Small Electric Drive is designed for use in general traumatology, especially hand and foot applications involving surgical procedures such as drilling, burring, reaming, pin and wire placement, cutting of bone and hard tissue. Our records indicate that you may have inventory that is impacted by this recall.

Description of problem:

It has been reported that the Small Electric Drive (SED) may experience failure modes such as the device not functioning, the device operating solely in reverse mode, the device not operating in reverse when intended or an unintended start of the device.

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 power tool would be procured, which may lead to surgical delay.

An unintended start of the hand piece or wrong mode/direction could cause bone/soft tissue damage, peripheral nerve damage and /or vascular damage because the hand piece has the potential to progress further into the surgical site when the operator is not intending this motion. These injuries may need surgical or medical intervention.

Alternative Product Options:

We are investigating the root cause of these malfunctions, however we do not currently have a definitive solution to address the issue. We understand that the recall of this device may have an impact on your surgical schedule; as such, DePuy Synthes Power Tools would like to propose options to assist you with a replacement for your Small Electric Drive Product (05.001.175).

Option 1: DePuy Synthes will provide you (at no charge) with a Colibri II (532.101), along with an electric adaptor (05.001.108) and a wire driver (532.022) to use instead of your Small Electric Drive.



Option 2: DePuy Synthes will provide to you (at no charge) a K-wire attachment for wires 0.6mm-1.6mm in diameter (05.001.037) to use with the Electric Pen Drive handpiece.



Option 3: DePuy Synthes will provide you (at no charge) with a Colibri II (532.101) along with the relevant housing, batteries, charger and appropriate wire driver (532.022) to use instead of your Small Electric Drive.



If you would like to take advantage of any of these options, a No Charge Purchase Order will be required.

Customer immediate actions:

1. Immediately identify and quarantine all unused products listed above in a manner that ensures the affected products will not be used.
2. Review, complete, sign and return the attached reply form to your local DePuy Synthes sales organisation in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product within 30 business days.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any product listed below has been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until all products listed below have been returned to Synthes GmbH.
7. Maintain a copy of this notice.

The applicable regulatory agencies are being notified. Synthes GmbH is voluntarily taking this action.

We apologise for any inconvenience that this product removal may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your DePuy Synthes sales representative.

Thank you for your attention and cooperation.

Synthes GmbH

Ann-Kathrin Schlupe
Field Action Coordinator

Markus Wien
Director Quality Assurance Operations

NOTICE: MEDICAL DEVICE RECALL R2014005**SMALL ELECTRIC DRIVE (SED)****Verification Section**

Part Number	Part Description	Lot Number
05.001.175	Small Electric Drive	All Lots

We have located the identified product in stock; returned quantity 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 quantity) and/or COMMENTS:

Hospital name: _____

Name/Title (please print) _____

Phone Number: _____

Signature and Date: _____