

16 February 2016

**URGENT NOTICE:
MEDICAL DEVICE RECALL – R930229
Universal Battery Charger II (UBC II)**

Please distribute this information to appropriate personnel at your facility.

Dear Sir/Madam,

Part Description, Part and Lot Numbers

Part Description	Part Number	Lot Numbers
Universal Battery Charger II (UBC II)	05.001.204	10615 to 12616

Synthes GmbH is initiating a medical device recall (removal) of certain serial numbers (listed above) of the Universal Battery Charger II (UBC II), part number 05.001.204. The UBC II is used for charging and/or conditioning of authorized Synthes batteries and power modules.



Our records indicate that you may have inventory that is impacted by this recall or may have been using affected product(s) from a loan set.

Reason for the Recall

The UBC II (part number 05.001.204, serial numbers above) has a component which may fail prematurely due to a manufacturing defect. If the component fails, the charger's firmware recognizes the malfunction and prevents batteries from being charged. The blue LED on the front of the charger will flash to indicate that the device must be sent in for repair, in accordance with the User's Manual.



Potential Patient Impact:

When component failure occurs, the device firmware causes the UBC II to enter “safe mode” which prevents the batteries from charging; this could potentially lead to a surgical delay.

To date, there have been no reports of adverse events associated with this non-conformance.

Customer immediate actions:

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

You do not need to return the UBC II unless it is displaying the blue flashing light that indicates it requires service. Please inspect your chargers to ensure they are operating in accordance with the User’s Manual (DSEM/PWT/1114/0050).

Should your battery charger malfunction and display a flashing blue light, please contact your local DePuy Synthes sales organisation for return of the device and to arrange for a repair or replacement.

In addition, we ask that you please take the following 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 on page 4 of this letter to your local DePuy Synthes sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product as soon as possible, but within 30 business days. A credit note will be issued for the returned items.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any of the affected products 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 DePuy Synthes.
7. Keep a copy of this notice.

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.

Thank you for your attention and cooperation.

Yours Sincerely,



Lee, Ching Hwee
Senior Regulatory Affairs Executive

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Please check (✓) accordingly:

- ☐ We acknowledge receipt of this information, but do not have any identified product in stock; returned quantity is zero.
- ☐ We located the identified product in stock and they are operating correctly; the quantity & serial number(s) are documented below.

Product Operating Correctly:

Product Code	(Lot Number)	Quantity (Number in “Eaches”)

- ☐ We located the identified product in stock and have found some units with the described malfunction; the quantity & serial number(s) are documented below.

Product Malfunction- flashing blue light:

Product Code	(Lot Number)	Quantity (Number in “Eaches”)

Please sign, date and stamp below. Your signature provides confirmation that you have received and understood this notification.

Customer Name

Title

Signature & Date

Stamp (*Stamp shall bear facility name*)

Please complete this Verification Section and return to your Depuy Synthes representative or fax it to +65 6720 0750 within **(5) five business days** of receipt of the Field Safety Notice.