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DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Operating Room Manager

29 February 2016

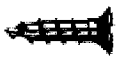
URGENT NOTICE:
MEDICAL DEVICE RECALL – R2016011
Cranial Screw PlusDrive™ ø 1.6 mm, Self-Drilling, L 3mm

Part Description, Part- and Lot Numbers

Product Descriptions	Part Numbers	Lot Numbers
Cranial Screw PlusDrive™ ø 1.6 mm, Self-Drilling, L 3 mm	400.833	9951621; 9955377
Cranial Screw PlusDrive™ ø 1.6 mm, Self-Drilling, L 3 mm	400.833.04C	9833543; 9814795; 9814793; 9814794

Dear Sir/Madam,

Synthes GmbH is initiating a voluntary medical device recall of the above mentioned Part and Lot Numbers of the Titanium Low Profile Neuro Screws, Self-Drilling, 3mm which are part of the Low Profile Neuro System. The Low Profile Neuro System is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

Part #	Description	Picture	Diameter	Color	Screw Type	Screw Tip
400.833(04C)	Cranial Screw PlusDrive™ ø 1.6 mm, Self-Drilling, L 3 mm		Ø 1.6 mm	Silver	Self-Drilling	Sharp

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

The affected 3 mm Titanium Low Profile Neuro Screws do not have lot numbers etched on them because they are too small to be etched with a part or lot number. Therefore, we are asking that you do the following:

- Remove and return all opened Titanium Low Profile Neuro Screw, Self- Drilling 3mm screws in your kits.
- Remove and return only affected lots of unopened screws in their original packaging.

Please note that the affected 3mm self-drilling screws can be distinguished by their sharp tip.

Reason for the Recall:

It was discovered that the affected part number and lots listed above are out of specification at the thread. This is related to a non-conformance where the thread height of these screws is under-sized. It was also identified that the cross section of the affected area is less than that of conforming screws such that the thread height of the screws is under-sized.

Potential hazard:

The decreased thread height may alter the self-drilling feature and result in difficulty inserting the screw. If the surgeon finds that the screw is not inserting as anticipated, the surgeon may choose to use a different screw or drill a pilot hole to insert the screw. However, because there is not a 1.1 mm drill that has a 3mm drill stop, the surgeon may opt for a replacement screw as the best alternative. Also in this scenario, drilling a pilot hole would remove some bone in which the shortened screw threads would otherwise gain purchase, potentially compromising the stability of screw fixation.

Attempting to insert additional screws or possibly drill with another instrument could result in a surgical delay. Should the surgeon decide not to use a screw that won't insert into the bone as anticipated, there are emergency screws available for use; these screws are also recommended if the retention is not adequate.

Should the user be able to insert the screw the decreased thread height may significantly reduce the retention ability of the screw in the bone. A screw that does not have sufficient purchase could result in device loosening or in a worst case scenario, lead to malunion-nonunion. These issues may require medical or surgical intervention to secure components or stabilize the structure or bone.

Customer immediate actions:

1. Immediately identify and quarantine all affected 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.

Alternative Products:

Part #	Description	Picture	Diameter	Color	Screw Type	Screw Tip
400.843	Cranial Screw PlusDrive™ ø 1.6mm, Self-Tapping, L 3 mm		Ø 1.6 mm	Silver	Self-Tapping	Blunt
400.853	Emergency Screw PlusDrive™ ø 1.9 mm, Self-Tapping, L 3 mm		Ø 1.9mm	blue	Self-Tapping	Blunt

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.

Synthes GmbH

David Carvin
Quality Manager

CC:

DePuy Synthes
COMPANIES OF Johnson & Johnson

Account Name: _____

URGENT NOTICE:
MEDICAL DEVICE RECALL – R2016011
Cranial Screw PlusDrive™ ø 1.6mm Self-Drilling, L 3mm

Verification Section

Part Description, Part- and Lot Numbers

Product Descriptions	Part Numbers	Lot Numbers
Cranial Screw PlusDrive™ ø 1.6 mm, Self-Drilling, L 3 mm	400.833	9951621; 9955377
Cranial Screw PlusDrive™ ø 1.6 mm, Self-Drilling, L 3 mm	400.833.04C	9833543; 9814795; 9814793; 9814794

____ We have located the identified product in stock; returned quantity is documented below.

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

RETURNED DEVICES (including quantity):

_____

_____

Name/Title (please print): _____

Address: _____

Phone Number: _____

Signature and Date: _____

Please complete and return this page to your local DePuy Synthes sales organization.

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.