Synthes GmbH
Luzernstrasse 21
4528 Zuchwil
Switzerland
Tel. +41 32 720 40 60
Fax +41 32 720 40 61
http://www.depuysynthes.com/

DePuy Synthes
COMPANIES OF Johnson & Johnson

To the ATTENTION of:
Operating Room Manager

18 November 2013

URGENT MEDICAL DEVICE PRODUCT RECALL

Part Description / Part Number

Part Number	Part Description	Lot Numbers
03.111.900	Drill Template for LCP Ulna Osteotomy Plate 2.7, for 2.0 mm shortening	all lots
03.111.901	Drill Template for LCP Ulna Osteotomy Plate 2.7, for 2.5 mm shortening	all lots
03.111.902	Drill Template for LCP Ulna Osteotomy Plate 2.7, for 3.0 mm shortening	all lots
03.111.903	Drill Template for LCP Ulna Osteotomy Plate 2.7, for 4.0 mm shortening	all lots
03.111.904	Drill Template for LCP Ulna Osteotomy Plate 2.7, for 5.0 mm shortening	all lots
03.111.905	Saw Guide for LCP Ulna Osteotomy Plate 2.7	all lots

Dear Madam / Dear Sir,

DePuy Synthes is initiating a voluntary recall of the above mentioned articles and lots of the Drill Template for LCP Ulna Osteotomy Plate 2.7 and the Saw Guide for LCP Ulna Osteotomy Plate 2.7. Our records indicate that you may have inventory that is impacted by this recall.

Reason for the Recall:

The Drill Template and the Saw Guide for the Ulna Osteotomy System may exhibit the following failure modes:

1. Jamming / bending / breaking of the screw connecting the Saw Guide to the Drill Template.
2. Jamming / bending / breaking of the K-wire during the fixation of the Drill Template.

Potential hazard:

The saw guide provides guidance to oblique osteotomies. The connecting screw is used to secure the saw guide onto the drill template. The presence of a jammed, bent, or broken connecting screw can result in a marginal surgical delay. Additional time may be required to adjust the jammed or bent connecting screw to secure the saw guide onto the drill template. When the connecting screw is broken, additional time may be required to locate the broken screw and any fragments. Due to the size of the screw and because it is not inserted into the bone, it is likely that the screw head will be located and retrieved if broken. If the saw guide remains seated in position, the surgeon may be able to complete the osteotomy with the aid of the guide. However, if the saw guide does not remain seated, the surgeon may choose to complete the osteotomy freehand without the aid of the saw guide.

Drill templates are used for predrilling of plate fixation holes before osteotomy cut to ensure correct rotational alignment. The presence of a K-wire that jams or breaks during use can result in a marginal surgical delay while the broken or jammed wire is retrieved and replaced. It is important to note that according to the reported complaints received at DePuy Synthes, when the K-wire breaks it occurs in or at the level of the drill template. Debris might be generated upon insertion of the k-wire into the drill template. The presence of unretrieved device fragments at the surgical site has the potential to elicit an adverse tissue reaction.

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. 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 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 DePuy Synthes.

7. Maintain a copy of this notice.

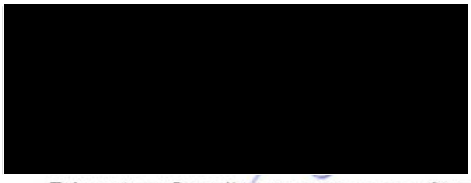
The applicable regulatory agencies are being notified. DePuy Synthes is voluntarily taking this action.

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

Thank you for your attention and cooperation.

DePuy Synthes

Field Action Manager



Director Quality Assurance Operations

CC:

NOTICE: MEDICAL DEVICE RECALL R2013565

Drill Template and Saw Guide of the Ulnar Osteotomy System

Verification Section

Part Number	Part Description	Lot Numbers
03.111.900	Drill Template for LCP Ulna Osteotomy Plate 2.7, for 2.0 mm shortening	all lots
03.111.901	Drill Template for LCP Ulna Osteotomy Plate 2.7, for 2.5 mm shortening	all lots
03.111.902	Drill Template for LCP Ulna Osteotomy Plate 2.7, for 3.0 mm shortening	all lots
03.111.903	Drill Template for LCP Ulna Osteotomy Plate 2.7, for 4.0 mm shortening	all lots
03.111.904	Drill Template for LCP Ulna Osteotomy Plate 2.7, for 5.0 mm shortening	all lots
03.111.905	Saw Guide for LCP Ulna Osteotomy Plate 2.7	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: _____