

Date: 15 Aug 2017

URGENT FIELD SAFETY NOTICE:
Locking Compression Plate (LCP) Drill Sleeve – 884115 – Field Safety Notification

PLEASE DISTRIBUTE THIS INFORMATION TO THE APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT WHICH IS THE SUBJECT OF THIS NOTICE

Dear Sir/Madam:

Synthes GmbH is initiating a voluntary field safety notification for the below lots of the Locking Compression Plate (LCP) Drill Sleeve which is part of the 1.5 mm LCP Modular Mini Fragment System. The LCP Compact Hand 1.5 implants are intended for temporary fixation, correction or stabilization of bones in anatomical region of the hand. Drill/Protection Guide/Sleeves are intended for holding and guiding implants and instruments during orthopaedic surgery. These indications for use are specific to humans; there are no specific indications for veterinary use.

Potentially Affected Product:

Part Number	Part Description	Lot Numbers
03.114.001	LCP Drill Sleeve 1.5 f/Drill Bit ϕ 1.1mm	9972971, H028400, H161606, H288454

Reason for Field Safety Notification:

There may be difficulty attaching the affected lots of the drill sleeve to the plate.

Potential Patient Impact:

If the drill sleeve will not connect to the plate intraoperatively, surgical delay could occur. Additionally, if the pilot hole is drilled without the drill sleeve, the pilot hole could be off-center which could result in screw and/or plate loosening.

Mitigation:

- Pre-assemble the drill sleeve with the plate preoperatively. If you experience difficulty connecting the drill sleeve to the plate, use the additional 1.1 mm locking drill sleeve provided in the graphic case, or:
 - Align the 1.1 mm drill bit to the plate as perpendicular as possible and then drill freehand and the locking screw can be engaged in this manner.
 - If the drill hole must be used and no option to lock remains, a non-locking screw can be used.

Actions to be taken:

Our records show that your facility has received the product subject to this field safety notification. We ask that you review the information contained in this notification and complete the Verification Section located on page 3 of this letter.

Please take the following actions:

- Review the information listed in this notification.
- Forward this notice to anyone in your facility that needs to be informed.
- If any of the affected product has been forwarded to another facility, contact that facility.
- Keep a copy of this notice.
- Review, complete, sign, and return the attached reply form on page 3 of this letter to your local sales organization in accordance with the directions on the form within 5 business days of receipt of this notification.

Should you have any inquiries please do not hesitate to contact your sales consultant.

Thank you for your attention and cooperation.

Yours sincerely,



Lee Ching Hwee
Regulatory Affairs Manager

cc: Chairman Medical Board
Relevant Head of Departments

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Verification Section

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03.114.001	LCP Drill Sleeve 1.5 f/Drill Bit ø1.1mm	9972971, H028400, H161606, H288454

Please note that this is a Field Safety Notification only and it is not required to return the Synthes LCP Drill Sleeves.

- We have located the identified product in stock and acknowledge receipt of this information.
- We acknowledge receipt of this information, but do not have any identified product in stock.

CUSTOMER DETAILS	
Facility Name:	
Facility Address:	
Account Number:	
Reply Confirmation Completed by: (Please Print Name)	
Signature and Date: (REQUIRED FIELD)	
Title: (Please Print)	
Telephone Number: (Include Area Code and Extension)	
Email address:	
RA#: (If applicable)	

The above acknowledges receipt of the subject Field Safety Notification in reference to Field Action 884115 – Locking Compression Plate (LCP) Drill Sleeve.

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

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.