

MEDICAL DEVICE CORRECTION NOTICE
C-2018-31

February 21, 2019

Smith & Nephew, Inc. has initiated a Field Correction for currently produced SPEEDLOCK[®] Knotless Fixation Implants, Catalog # OM-7500, due to an interference fit issue between the SPEEDLOCK Implant inserter and drill guides (Catalog # OM-9715 and OM-9716). The potential interference fit of the SPEEDLOCK Inserter (OM-7500) could prevent the insertion of the SPEEDLOCK implant through the drill guides. A drill guide is used at two stages of the procedure per the SPEEDLOCK IFU P/N 62513 revision B. The drill guide is first used in the procedure to align corresponding drill to prepare the implantation site, and then used later in the procedure to guide the user in delivering the SPEEDLOCK implant to the prepared site. No interference fit occurs when the drill guide is used with a drill; however, an interference fit occurs when the drill guide is used with the SPEEDLOCK Knotless Fixation devices.

Please see product details below:

Product	Description	Lot	Shipment Date
OM-7500	SPEEDLOCK	SEE ATTACHED	February 20, 2018 - November 13, 2018

Potential Risk with Use of the Product

Not all cases require the use of the drill guide. If the user elects to implant the SPEEDLOCK device by using the drill guide, the drill guide may interfere with the movement of the SPEEDLOCK inserter device. In the worst-case scenario, the user will notice the interference fit before the procedure is completed. The surgeon would use a new instrument or elect not to use the drill guide to complete the procedure.

Actions for Hospital Representatives

1. Please check your inventory and complete the attached Inventory Correction Certification Form.
2. Communicate this potential interference with operating personnel so that they can plan to use the cannula to guide and deliver the SPEEDLOCK implant to the prepared site or elect to make adjustments to their proposed surgical plan as appropriate.



Inventory Correction Certification Form

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PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT

Acknowledgement of Correction Notification

By signing below, I acknowledge that I have received the notification and I have taken the appropriate actions.

Printed Name: _____ Title _____

Telephone: (____) _____ - _____

Date: ____/____/____

Facility Name:

Account Number:

Signature _____

Check One:

☐

I have checked my inventory and my facility no longer possesses any device from the affected lots.

☐

I have checked my inventory and my facility still possesses a device(s) from the affected lots and I acknowledge the correction notification.

PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO:

Email: FieldActions@smith-nephew.com

Fax: +1-901-566-7975

Affected Lot Numbers

Material	Lot
OM-7500	1170568
OM-7500	1174407
OM-7500	1184079
OM-7500	1184824
OM-7500	1185957
OM-7500	1185958
OM-7500	2002717
OM-7500	2002718
OM-7500	2008573
OM-7500	2008574
OM-7500	2009209
OM-7500	2009707
OM-7500	2009708
OM-7500	2009709
OM-7500	2010033
OM-7500	2010034
OM-7500	2010957
OM-7500	2014729
OM-7500	2017030
OM-7500	2018133
OM-7500	2018966
OM-7500	2019931
OM-7500	2019932
OM-7500	2021430
OM-7500	2021431
OM-7500	2021432
OM-7500	2021865
OM-7500	2021866
OM-7500	2021884