

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

1-901-396-2121
1-800-821-5700
www.smith-nephew.com



MEDICAL DEVICE CORRECTION NOTICE
C-2016-34

July 12, 2016

Smith & Nephew, Inc. has initiated a Field Correction of several lots of TRIGEN® INTERNAL HEX CAPTURED RECON SCREW BLUE 6.4MM x 65MM due to a packaging error. Based on internal evaluation, Smith & Nephew has identified several lots of the screws that were distributed with an incorrect IFU. The Fracture Fixation 81078017 IFU was packaged with the device instead of the correct IFU, Intramedullary Nail System 81090283.

Please see product details below:

Product No	Description	Lot	Shipment Dates
71642365	TRIGEN® INTERNAL HEX CAPTURED RECON SCREW BLUE 6.4MM x 65MM	See attached	March 2011 – June 2016

Potential Risk with Use of the Product

The use of or exposure to the referenced device is not likely to cause adverse health consequences. In the event the user does not notice the IFU error, the provided device meet specification; therefore the procedure can be completed as intended.

Actions for Hospital Representatives

1. Please inspect your inventory and complete the attached Inventory Correction Certification Form.
2. If you have the affected products, please maintain awareness of this notice.

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

1-901-396-2121
1-800-821-5700
www.smith-nephew.com



Inventory Correction Certification Form

C-2016-34

July 12, 2016

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 and confirm receipt of the correct IFU.

PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO:

Email: FieldActions@smith-nephew.com

Fax: +1-901-566-7975

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

1-901-396-2121
1-800-821-5700
www.smith-nephew.com



Lot Numbers

Item	Batch	Item	Batch
71642365	16AM08458	71642365	13EM19522
71642365	15MM14706	71642365	13EM07822
71642365	15MM14708	71642365	13EM08756
71642365	15LM07487	71642365	13BM05789
71642365	15MM01161	71642365	13AM18101
71642365	15MM01162	71642365	12JM11351
71642365	15MM14705	71642365	12JM10258
71642365	15FM19594	71642365	12JM12865
71642365	15GM00978	71642365	12JM12207
71642365	15FM20876	71642365	12JM09146
71642365	15GM12739	71642365	12FM16742
71642365	15HM10653	71642365	12FM15060
71642365	15HM08399	71642365	12AM15314
71642365	15FM02129	71642365	12BM01456
71642365	15CM17948	71642365	12AM15315
71642365	15CM19083	71642365	11JM08875
71642365	15BM14766	71642365	11FM16343
71642365	13HM20835	71642365	10JM08292
71642365	13HM20836	71642365	10HM14558
71642365	13HM20837	71642365	10FM02676
71642365	13GM20485		
71642365	13GM11807		
71642365	13GM20483		
71642365	13GM11808		
71642365	13GM18304		
71642365	13GM20486		