

MEDICAL DEVICE CORRECTION NOTICE
C-2016-59

February 23, 2017

Smith & Nephew, Inc. has initiated a Field Correction for several lots of Disposable Kits for Patient Positioning due to a labeling error. The provided label does not reflect the current legal manufacturer and when applicable, the current CE Mark. The product label incorrectly lists TENET Medical Engineering as the legal manufacturer, with TENET CE Mark when applicable, as opposed to Smith & Nephew.

Please see product details below:

Product No	Description	Lot	Shipment Dates
72202931	SPIDER ANKLE STABILIZATON KITS	See Attached	February 2016 through September 2016
72203833	SPIDER2 SHOULDER STABLIZATION KITS		
7210559	DISPOSABLE FACE MASK		
7210573	KIT STABILIZATION SHOULDER		
7210574	KIT STABILIZATION ELBOW		
72201550	SMALL WRIST STABILIZATION KITS		
72203238	LEG STABILIZATON KITS		
72203300	SWITCH DRAPE		

Potential Risk with Use of the Product

There is no risk to patient or user due to this product mislabeling. The only affected labeling information is the CE mark and 'manufactured for' section. All expiration dates and manufacture dates are still correct. All information critical to use of the product is unaffected.

Actions for Hospital Representatives (cc: Chairman Medical Board and relevant Head of Departments)

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.

Inventory Correction Certification Form

C-2016-59

February 23, 2017

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. Although I acknowledge the correction notification, the device(s) will not be returned.

PLEASE RETURN THIS COMPLETED FORM VIA EMAIL OR FAX TO:

Email: FieldActions@smith-nephew.com

Fax: +1-901-566-7975

Affected Batches

Item	Item Description	Batch
72202931	SPIDER ANKLE STABILIZATION KITS	20151010
72203833	SPIDER2 SHOULDER STABILIZATION KIT	20150805
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W96007
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W96110
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W96239
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W96303
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W96446
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W96525
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W96646
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W96723
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W96939
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W97046
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W97137
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W97252
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W97389
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W97515
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W97632
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W97760
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W97854
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W97905
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W98030
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W98250
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W98371
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W98518
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W98651
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W98769
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W98962
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W99089
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W99216
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W99274
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W99477
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W99602
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W99717
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100060
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100139
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100287
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100415
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100333
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100416
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100391
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100407
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100417
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100408
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100409
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100418
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100410
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100419
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100411
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100420
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100412
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100421
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100413
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100422

Item	Item Description	Batch
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100423
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100414
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100973
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100972
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100974
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100975
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100976
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W101307
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100977
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100978
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W102001
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100979
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W102002
7210559	DISPOSABLE FACE MASK (CASE OF 8)	W100980
7210573	KIT STABILIZATION SHOULDER (12)	20150601
7210573	KIT STABILIZATION SHOULDER (12)	D151591
7210573	KIT STABILIZATION SHOULDER (12)	D151671
7210573	KIT STABILIZATION SHOULDER (12)	D151971
7210573	KIT STABILIZATION SHOULDER (12)	D151681
7210573	KIT STABILIZATION SHOULDER (12)	D152011
7210573	KIT STABILIZATION SHOULDER (12)	D151731
7210573	KIT STABILIZATION SHOULDER (12)	D151741
7210573	KIT STABILIZATION SHOULDER (12)	D151751
7210573	KIT STABILIZATION SHOULDER (12)	D151871
7210573	KIT STABILIZATION SHOULDER (12)	20150707
7210573	KIT STABILIZATION SHOULDER (12)	D152021
7210573	KIT STABILIZATION SHOULDER (12)	D152111
7210573	KIT STABILIZATION SHOULDER (12)	20150804
7210573	KIT STABILIZATION SHOULDER (12)	D152161
7210573	KIT STABILIZATION SHOULDER (12)	D152181
7210573	KIT STABILIZATION SHOULDER (12)	20150812
7210573	KIT STABILIZATION SHOULDER (12)	D152251
7210573	KIT STABILIZATION SHOULDER (12)	D152251A
7210573	KIT STABILIZATION SHOULDER (12)	D152271
7210573	KIT STABILIZATION SHOULDER (12)	D152361
7210573	KIT STABILIZATION SHOULDER (12)	20150903
7210573	KIT STABILIZATION SHOULDER (12)	D152461
7210573	KIT STABILIZATION SHOULDER (12)	D152471
7210573	KIT STABILIZATION SHOULDER (12)	D152521
7210573	KIT STABILIZATION SHOULDER (12)	D152551
7210573	KIT STABILIZATION SHOULDER (12)	20150915
7210573	KIT STABILIZATION SHOULDER (12)	D152651
7210573	KIT STABILIZATION SHOULDER (12)	20151005
7210573	KIT STABILIZATION SHOULDER (12)	20151120
7210573	KIT STABILIZATION SHOULDER (12)	D160111
7210573	KIT STABILIZATION SHOULDER (12)	D160121
7210573	KIT STABILIZATION SHOULDER (12)	D160131
7210573	KIT STABILIZATION SHOULDER (12)	D160141
7210573	KIT STABILIZATION SHOULDER (12)	D160181
7210573	KIT STABILIZATION SHOULDER (12)	01272016
7210573	KIT STABILIZATION SHOULDER (12)	D160281
7210573	KIT STABILIZATION SHOULDER (12)	D160321
7210573	KIT STABILIZATION SHOULDER (12)	D160341
7210573	KIT STABILIZATION SHOULDER (12)	D160391

Item	Item Description	Batch
7210573	KIT STABILIZATION SHOULDER (12)	D160401
7210573	KIT STABILIZATION SHOULDER (12)	D160461
7210573	KIT STABILIZATION SHOULDER (12)	D160471
7210573	KIT STABILIZATION SHOULDER (12)	D160601
7210573	KIT STABILIZATION SHOULDER (12)	D160611
7210573	KIT STABILIZATION SHOULDER (12)	D160671
7210573	KIT STABILIZATION SHOULDER (12)	D160681
7210573	KIT STABILIZATION SHOULDER (12)	D160741
7210573	KIT STABILIZATION SHOULDER (12)	D160841
7210573	KIT STABILIZATION SHOULDER (12)	D161101
7210573	KIT STABILIZATION SHOULDER (12)	D161121
7210573	KIT STABILIZATION SHOULDER (12)	D161131
7210573	KIT STABILIZATION SHOULDER (12)	D161141
7210573	KIT STABILIZATION SHOULDER (12)	D161161
7210573	KIT STABILIZATION SHOULDER (12)	D161171
7210573	KIT STABILIZATION SHOULDER (12)	D151181
7210573	KIT STABILIZATION SHOULDER (12)	D161301
7210573	KIT STABILIZATION SHOULDER (12)	D161381
7210573	KIT STABILIZATION SHOULDER (12)	D161401
7210573	KIT STABILIZATION SHOULDER (12)	D161441
7210573	KIT STABILIZATION SHOULDER (12)	D161451
7210573	KIT STABILIZATION SHOULDER (12)	D152371
7210574	KIT STABILIZATION ELBOW (12)	20151015
72201550	SMALL WRIST STABILIZATION KITS (5 PER)	D160701
72203238	LEG STABILIZATION KITS TENET 7646	20150923
72203238	LEG STABILIZATION KITS TENET 7646	20151025
72203238	LEG STABILIZATION KITS TENET 7646	20160119
72203300	SWITCH DRAPE TENET 7633	D152291
72203300	SWITCH DRAPE TENET 7633	D152581
72203300	SWITCH DRAPE TENET 7633	D152591
72203300	SWITCH DRAPE TENET 7633	D152641
72203300	SWITCH DRAPE TENET 7633	D152641A
72203300	SWITCH DRAPE TENET 7633	D152731
72203300	SWITCH DRAPE TENET 7633	D152761
72203300	SWITCH DRAPE TENET 7633	D160061
72203300	SWITCH DRAPE TENET 7633	D160071
72203300	SWITCH DRAPE TENET 7633	D160201
72203300	SWITCH DRAPE TENET 7633	D160271
72203300	SWITCH DRAPE TENET 7633	D160881
72203300	SWITCH DRAPE TENET 7633	D160891
72203300	SWITCH DRAPE TENET 7633	D160901
72203300	SWITCH DRAPE TENET 7633	D160911
72203300	SWITCH DRAPE TENET 7633	D160961
72203300	SWITCH DRAPE TENET 7633	D161231
72203300	SWITCH DRAPE TENET 7633	D161251
72203300	SWITCH DRAPE TENET 7633	D161461
72203300	SWITCH DRAPE TENET 7633	D161541
72203300	SWITCH DRAPE TENET 7633	D161601
72203300	SWITCH DRAPE TENET 7633	D161651
72203300	SWITCH DRAPE TENET 7633	D161831
72203300	SWITCH DRAPE TENET 7633	D161861
72203300	SWITCH DRAPE TENET 7633	D161881
72203300	SWITCH DRAPE TENET 7633	D161891