

# FIELD ACTION NOTIFICATION



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## --- URGENT --- FIELD SAFETY CORRECTIVE ACTION (Recall)

**Tecomet Blades**  
Please see product detail below

Product No.	Description	Batch No.
71369208	THIN OSTEOTOME BLADE 8MM X 3 IN	See Attached
71369210	THIN OSTEOTOME BLADE 10MM X 3 IN	
71369212	THIN OSTEOTOME BLADE 12MM X 3 IN	
71369220	THIN OSTEOTOME BLADE 20MM X 3 IN	
71369310	RADIAL OSTEOTOME BLADE SIZE 10	
71369312	RADIAL OSTEOTOME BLADE SIZE 12	
71369314	RADIAL OSTEOTOME BLADE SIZE 14	
71369316	RADIAL OSTEOTOME BLADE SIZE 16	
71369408	THIN OSTEOTOME BLADE 8MM X 5 IN	
71369410	THIN OSTEOTOME BLADE 10MM X 5 IN	
71369412	THIN OSTEOTOME BLADE ROUNDED END 20MM	
71369420	THIN OSTEO BLD ROUND END 20MM	

**FSCA no.: R-2017-03**  
**March 30, 2017**

### DESCRIPTION OF THE PROBLEM

This letter is to inform you that Smith & Nephew, Inc. has initiated a field action to voluntarily remove from the market a group of OSTEOTOME BLADES due to a labeling error. The expiration dates printed on the labels are incorrect; the dates are after the actual expiration date of the sterilized package.

### REPORTING TO NATIONAL COMPETENT AUTHORITIES

The respective RA/QA personnel in **Austria, Belgium, Switzerland, Spain, France, Great Britain, Italy, Netherlands, Poland, Russia and Canada** to report this FSCA to its national competent authority.

In **Australia, Japan, Columbia, Costa Rica, Venezuela, Trinidad and Tobago, Puerto Rico, Mexico, Arab Emirates, Dubai, Thailand, South Africa, Singapore, India and China** reportability of this Field Action is to be determined by the respective RA/QA personnel. Please provide the Field Action Coordinator with copies of the respective reporting documents (initial and final report).

Regulatory Affairs Europe will report this FSCA to the national competent authorities in, **Denmark, Estonia, Finland, Norway, Sweden** on behalf of the subsidiary or distributor.

If any subsidiary/distributor has further distributed the mentioned devices to other countries, please indicate asap to the Field Action Coordinator (FAC), including the information whether you will notify the consignee and the respective competent authority yourself or if you require support of the FAC.

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## ACTIONS TO BE TAKEN BY THE DISTRIBUTOR

- Identify and quarantine the devices in your warehouse.
- Identify and inform all users, which have received affected products with the attached Field Safety Notice (FSN)
- Collect return slips of the FSN (to confirm awareness of all affected users) and forward them to the specified contact below. If acknowledgement is not provided by any of the affected users provide evidence of three attempts to notify these users.
- Complete the acknowledgment section on page 3 and return it to the specified contact below.
- Return collected devices as instructed below.

Please maintain awareness on this notice and resulting action until the Field Action is terminated to ensure effectiveness of the action. This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

### Distribution Breakdown by Country

Country/Region	Qty
<b>ANJ</b>	<b>3896</b>
Australia	3629
Japan	267

<b>EUCAN</b>	<b>9769</b>
Austria	101
Belgium	295
Switzerland	20
Denmark	1129
Spain	1539
Finland	351
France	783
Great Britain	4302
Italy	401
Netherlands	435
Norway	29
Poland	24
Sweden	13
Russia	14
Canada	326
Estonia	7
<b>LATAM</b>	<b>734</b>
Columbia	158
Costa Rica	130
Venezuela	352
Trinidad & Tobago	4
Puerto Rico	84
Mexico	6

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IRAMEA	1677
Arab Emirates	64
Dubai	4
Thailand	20
South Africa	579
Singapore	7
India	61
China	942

### RETURN INSTRUCTIONS

Please contact Smith & Nephew's Global Field Actions Department via e-mail at [fieldactions@smith-nephew.com](mailto:fieldactions@smith-nephew.com) or fax +41 62 832 06 07 to obtain a return authorization (RA) number.

Please write the RA number on the outside of your shipping container and on the documents attached for efficient and accurate processing of the returned devices. Devices returned under these procedures should not be mixed with other stock and **must be returned within 30 days from the date of the initial notification.**

Shipping address:

Smith & Nephew Inc. | Attn: Global Field Actions | Global Distribution Center | 76 South Meridian Avenue | Oklahoma City, OK

### CONTACT PERSON

For questions, please contact:

Garry Smith / Field Action Coordinator

P: 1 901 399 1970

F: 1 901 566 7975

[fieldactions@smith-nephew.com](mailto:fieldactions@smith-nephew.com)

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## ACKNOWLEDGMENT SECTION

Please complete and return this feedback information by fax or e-mail to the contact specified above to prevent repetitive enquiries.

Product No.	Description	Batch No.	Quantity to be Returned	No Product to Return
				<input type="checkbox"/>

■  [Qty] customers in my territory have provided written acknowledgement of receipt of the FSN.

■  [Qty] customers have not provided written feedback after three notification attempts.

■ Comments: \_\_\_\_\_

----- For those advised above to perform national competent authority (NCA) reporting: -----

■ NCA reporting has been performed as instructed above and copies of the respective reporting documents (initial and final report) are provided to the Field Action Coordinator. YES NO

Rationale if NO: \_\_\_\_\_

Name/Title (please print): \_\_\_\_\_ Reference: R-2017-03

Date / City: \_\_\_\_\_ Signature: \_\_\_\_\_

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## Product and Lot Numbers

Material	Batch				
<b>71369208</b>	431612	448956	455856	461831	477931
	482918	488987	490565	492345	4500030972
	4500031584	07LSY0036	07LSY0039	08CSY0039	08CSY0041
	08CSY0052	08CSY0056	08JSY0011	08JSY0014	08KSY0012
	08LSY0006	08LSY0048	08LSY0049	08MSY0019	09BSY0008
	09BSY0009	09BSY0010	09DSY0011	09DSY0013	09FSY0004
	09HSY0001	09HSY0005	09JSY0001	10CSY0002	10CSY0012
	10ESY0007	10ESY0008	10ESY0020	10HSY0008	11ASY0005
	11ASY0009	11BSY0005	11CSY0013	11DSY0001	11ESY0005
	11FSY0002	11GSY0001	11GSY0018	11GSY0021	11HSY0063
	11JSY0002	12ASY0016	12BSY0011	12CSY0003	12DSY0023
	12DSY0026	12FSY0026	12HSY0005	12HSY0022	12KSY0020
	12LSY0016	12MSY0002	13ASY0008	13ASY0009	13BSY0005
	13BSY0011	13BSY0037	13ESY0010	13ESY0011	13HSY0002
	13HSY0005	13KSY0010	13KSY0046	13MSY0001	14BSY0014
	14CSY0003	14CSY0032	14DSY0014	14GSY0019	14HSY0004
	14KSY0001	14LSY0008	15ASY0012	15ASY0021	15CSY0005
	15DSY0001	15ESY0012	15FSY0017	15FSY0060	15HSY0005
	15JSY0046	15KSY0035	15MSY0008	16ASY0001	16DSY0021
	16ESY0057	16FSY0001	16GSY0021		

Material	Batch				
<b>71369210</b>	472439	472579	472580	477931	482918
	493639	11150707	4357136921	4500027315	4500030673
	4500032565	07AM06944	07LSY0047	07LSY0048	08BSY0012
	08BSY0014B	08BSY0016	08FSY0051	08JSY0012	08JSY0033
	08KSY0015	08KSY0018	08LSY0011	08LSY0044	08LSY0044A
	08MSY0018	09BSY0011	09BSY0025	09DSY0012	09DSY0014
	09FSY0005	09HSY0002	09HSY0006	09HSY0006A	09JSY0002
	09JSY0005	09JSY0006	09JSY0007	09JSY0008	09JSY0009
	09KSY0002	10CSY0003	10CSY0013	10CSY0014	10ESY0012
	10ESY0017	10GSY0006	10HSY0007	10MSY0007	11ASY0004
	11ASY0008	11CSY0014	11DSY0002	11DSY0012	11ESY0006
	11FSY0003	11FSY0004	11GSY0002	11GSY0019	11GSY0020
	11HSY0016	11HSY0023	12CSY0004	12DSY0024	12DSY0027
	12FSY0025	12HSY0006	12HSY0021	12HSY0035	12KSY0021
	12LSY0017	12MSY0003	12MSY0011	13BSY0006	13BSY0012
	13BSY0038	13BSY0039	13ESY0006	13FSY0016	13HSY0003
	13HSY0006	13HSY0007	13KSY0047	13MSY0002	14ASY0033
	14BSY0011	14CSY0004	14CSY0033	14DSY0013	14DSY0015
	14GSY0018	14HSY0005	14HSY0011	14KSY0002	14LSY0009
	15ASY0013	15BSY0008	15CSY0006	15ESY0024	15FSY0018
	15FSY0061	15JSY0003	15KSY0036	15MSY0004	16ASY0006
	16BSY0012	16DSY0023	16ESY0078	16FSY0007	16JSY0005
	16KSY0007	472580B			

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Material	Batch				
<b>71369212</b>	431604	452406	456888	472579	483297
	485498	3000084920	4500025459	4500030972	4500032273
	4500032565	4500034104	07MSY0001	08CSY0035	08FSY0034
	08FSY0035	08FSY0035A	08LSY0013	08MSY0017	09BSY0023
	09BSY0026	09BSY0026A	09DSY0008	09FSY0006	09HSY0003
	09HSY0007	09JSY0003	10CSY0004	10CSY0015	10CSY0016
	10DSY0002	10ESY0009	10ESY0015	10ESY0019	11CSY0009
	11CSY0015	11FSY0007	11GSY0003	11GSY0022	11GSY0023
	11HSY0062	11JSY0003	11MSY0018	12ASY0010	12BSY0012
	12CSY0005	12DSY0022	12DSY0028	12FSY0027	12HSY0007
	12HSY0036	12KSY0016	12KSY0022	12LSY0018	12LSY0023
	12MSY0012	13ASY0007	13BSY0040	13DSY0009	13DSY0017
	13ESY0008	13ESY0009	13HSY0004	14ASY0034	14CSY0005
	14CSY0034	14DSY0016	14DSY0018	14GSY0016	14KSY0030
	14LSY0010	14MSY0012	15ASY0023	15DSY0005	15ESY0020
	15FSY0019	15HSY0011	15JSY0045	15KSY0022	15LSY0070
	16ASY0002	16BSY0009	16DSY0022	16ESY0058	16ESY0077
	16JSY0006				

Material	Batch				
<b>71369220</b>	431612	431614	433667	455856	469005
	472439	477931	483297	483890	491378
	493639	494049	494154	4500029102	4500034104
	07MSY0006	07MSY0011	07MSY0011A	08CSY0037	08CSY0042
	08ESY0082	08FSY0037	08FSY0037B	08FSY0037C	08JSY0008
	08LSY0014	09BSY0012	09JSY0010	09JSY0011	09JSY0012
	10CSY0005	10CSY0017	10CSY0018	10KSY0033	11GSY0004
	11GSY0024	11JSY0009	11KSY0068	11MSY0019	12ASY0011
	12BSY0013	12DSY0015	12DSY0029	12FSY0006	12FSY0030
	12HSY0023	12HSY0037	12KSY0023	12LSY0019	12MSY0004
	12MSY0018	13BSY0007	13BSY0014	13BSY0041	13FSY0017
	13FSY0019	13LSY0009	13LSY0011	13MSY0003	14ASY0001
	14BSY0026	14CSY0035	14GSY0017	14KSY0017	14LSY0012
	15BSY0009	15ESY0009	15ESY0038	15FSY0053	15GSY0017
	15JSY0004	16ASY0003	16BSY0013	16ESY0076	472439A
	491378A				

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Material	Batch				
<b>71369310</b>	431604	442526	448956	463451	469005
	473044	477931	481940	488987	493639
	494049	494154	4357136931	4500034104	07MSY0014
	08CSY0043	08CSY0050	08CSY0053	08CSY0053B	08JSY0007
	08LSY0012	08MSY0016	10CSY0006	10HSY0006	11DSY0003
	11ESY0007	11FSY0008	11GSY0009	11GSY0025	11JSY0010
	11MSY0020	12ASY0012	12BSY0017	12CSY0006	12HSY0008
	12HSY0038	12KSY0029	12LSY0024	12MSY0024	13BSY0030
	13BSY0031	13FSY0018	13FSY0020	13LSY0010	13MSY0004
	14ASY0002	14CSY0007	14CSY0036	14GSY0026	14LSY0011
	15ASY0015	15DSY0013	15FSY0015	15KSY0037	16ASY0007
	16BSY0014	16GSY0022	463451A	469005B	

Material	Batch				
<b>71369312</b>	431612	433667	448956	466339	469005
	473044	473406	477931	484324	485498
	4500029102	4500032273	07LSY0028	07MSY0023	07MSY0027
	08CSY0051	08CSY0055	08CSY0055A	08JSY0032	08LSY0052
	09BSY0018	09BSY0027	10GSY0007	11ASY0006	11DSY0048
	11FSY0009	11GSY0005	11HSY0008	11JSY0011	11MSY0017
	12ASY0013	12BSY0018	12DSY0019	12FSY0005	12HSY0024
	12HSY0039	12LSY0020	13BSY0015	13FSY0015	13FSY0021
	13KSY0011	13MSY0005	14BSY0010	14CSY0008	14FSY0010
	15ASY0014	15CSY0007	15FSY0062	15JSY0005	15LSY0069
	16ASY0004	16ESY0060	448956B	488987A	495483A

Material	Batch				
<b>71369314</b>	431604	431612	431614	448956	469005
	472361	472767	483297	483890	488786
	496187	4500029102	07LSY0037	07LSY0042	08ESY0005
	08ESY0005A	08ESY0007	08ESY0008	08JSY0009	08JSY0009A
	08LSY0050	09BSY0019	09FSY0003	10CSY0007	10ESY0013
	11GSY0006	11HSY0009	11KSY0003	11KSY0069	11MSY0021
	12FSY0002	12FSY0029	12GSY0007	12HSY0025	12HSY0040
	12KSY0024	12LSY0021	12MSY0005	12MSY0013	12MSY0025
	13BSY0009	13BSY0016	13FSY0022	13JSY0022	13KSY0048
	13MSY0006	14CSY0006	14CSY0038	14HSY0006	15ASY0009
	15ASY0018	15ASY0022	15FSY0016	15JSY0006	15KSY0023
	15KSY0039	15MSY0005	16ESY0059	16ESY0075	488369A

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Material	Batch				
<b>71369316</b>	431604	431612	431614	448956	477931
	484324	485498	488987	495483	450002910
	4500029102	4500031658	08CSY0044	08ESY0009	08ESY0010
	08ESY0011	08JSY0034	08LSY0010	10CSY0008	10ESY0014
	11KSY0004	11KSY0024	12BSY0006	12BSY0014	12DSY0020
	12HSY0009	12HSY0041	12MSY0026	13BSY0032	13FSY0012
	13FSY0023	13HSY0008	14BSY0015	14CSY0039	14GSY0025
	14KSY0003	15DSY0002	15FSY0020	15MSY0006	16BSY0010
	477931B				

Material	Batch				
<b>71369408</b>	431612	452406	455856	463451	472439
	472579	483890	485498	494049	495483
	4357136940	4500029102	4500029865	4500032273	4500032667
	4500064768	07LSY0010	08BSY0013	08BSY0015	08FSY0032
	08FSY0033	08FSY0033A	08JSY0013	08LSY0009	09BSY0015
	09FSY0007	09HSY0004	09HSY0008	09JSY0004	09JSY0004A
	10CSY0009	10CSY0009A	10CSY0019	10CSY0020	10ESY0016
	10HSY0005	10KSY0008	11ASY0011	11BSY0006	11DSY0004
	11DSY0014	11DSY0049	11ESY0008	11FSY0010	11GSY0007
	11HSY0010	11JSY0004	11JSY0012	11MSY0022	12ASY0014
	12BSY0019	12CSY0001	12CSY0007	12DSY0016	12ESY0001
	12FSY0028	12GSY0008	12HSY0026	12HSY0042	12KSY0025
	12MSY0027	13BSY0008	13BSY0033	13BSY0042	13DSY0008
	13FSY0013	13FSY0024	13JSY0024	13KSY0013	13KSY0014
	13KSY0049	13MSY0007	13MSY0028	14BSY0009	14CSY0031
	14CSY0040	14GSY0021	14HSY0012	14KSY0031	14LSY0013
	14LSY0015	15ASY0010	15ASY0016	15BSY0012	15CSY0020
	15DSY0014	15ESY0021	15FSY0025	15GSY0018	15JSY0007
	15KSY0024	15MSY0010	16ASY0005	16BSY0011	16ESY0081
	472579A				

Material	Batch				
<b>71369420</b>	431604	431612	431614	467087	469005
	472361	477931	481940	485498	488987
	490565	491378	492345	4500032273	07LSY0034
	07LSY0041	07MSY0013	08FSY0052	08LSY0020	08LSY0020A
	08LSY0042	08MSY0020	09BSY0030	11DSY0007	11ESY0011
	11FSY0006	11HSY0013	11HSY0060	11JSY0008	11JSY0019
	12KSY0027	12MSY0008	12MSY0016	13BSY0036	13FSY0026
	13KSY0016	14GSY0013	14KSY0005	15ASY0020	15ESY0015
	15JSY0009	15MSY0009	16ESY0079	477931A	477931B
	477931C	490565A	492345A		



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Material	Batch				
<b>71369410</b>	452406	455856	456888	467087	469005
	477931	483890	485094	485498	492100
	492345	4500028121	4500029102	4500032565	07MSY0025
	08CSY0040	08FSY0036	08JSY0001	08JSY0010	08JSY0010A
	08JSY0031	08JSY0031A	08KSY0009	08LSY0005	08LSY0021
	08LSY0022	08MSY0004	09BSY0028	09HSY0009	10CSY0010
	10CSY0021	10CSY0022	10ESY0010	10ESY0018	10KSY0034
	11CSY0010	11DSY0005	11DSY0013	11DSY0050	11ESY0009
	11FSY0005	11GSY0008	11GSY0027	11HSY0011	11HSY0059
	11JSY0005	12ASY0015	12BSY0016	12DSY0017	12ESY0002
	12FSY0004	12GSY0031	12HSY0027	12HSY0043	12KSY0026
	12MSY0006	12MSY0028	13BSY0017	13BSY0034	13ESY0007
	13FSY0025	13JSY0023	13KSY0012	13LSY0012	14BSY0001
	14BSY0025	14CSY0041	14GSY0020	14HSY0013	14KSY0004
	14KSY0032	14LSY0016	15ASY0017	15ASY0019	15ASY0024
	15CSY0008	15DSY0003	15ESY0013	15FSY0021	15HSY0006
	15JSY0010	15KSY0038	15MSY0007	16ASY0008	16BSY0015
	16ESY0080	496187A			

Material	Batch				
<b>71369412</b>	431604	431612	456888	467087	469005
	477931	483297	483890	485498	490565
	492345	493639	4500027315	4500029102	4500030972
	4500034104	07LSY0011	07LSY0035	07LSY0038	07LSY0040
	08GSY0007	08GSY0007A	08GSY0008	08MSY0015	09BSY0029
	10CSY0011	10CSY0023	10ESY0011	11DSY0006	11DSY0011
	11ESY0010	11HSY0012	11HSY0061	11JSY0007	12BSY0015
	12DSY0018	12DSY0030	12FSY0003	12GSY0030	12HSY0028
	12HSY0044	12LSY0022	12MSY0007	12MSY0015	13BSY0010
	13BSY0013	13BSY0018	13BSY0035	13KSY0015	13MSY0008
	14ASY0035	14CSY0009	14CSY0042	14KSY0033	14LSY0014
	15BSY0011	15DSY0004	15ESY0014	15JSY0008	16ASY0009
	16BSY0016	16KSY0002	469005A		