

March 04, 2016

URGENT FIELD SAFETY NOTICE: Medical Device Field Safety Corrective Action / Recall

Reference: R-2015-26

Concerned Devices: TOPAZ[®] MicroDebrider's

Please Note: TOPAZ EZ (ACH4041-01) and TOPAZ XL (AC4045-01 and ACH4045-01) wands are not included in this recall and are available for order.

Product No.	Description	Batch No.					
ACH4040-01	TOPAZ MicroDebrider IFS	1031506	1031507	1032123	1032325	1032741	1032742
		1033443	1033965	1033966	1034397	1039120	1041765
		1044089	1044090	1045862	1048237	1048933	1049185
		1052071	1056212	1060586	1060979	1063394	1064599
		1067696	1067748	1069174	1071358	1074125	1075714
		1070521	1070812	1071974	1078025	1077499	1082811
		1084095	1084094	1085458	1086436	1086437	1087917
		1094313	1097573	1103824	1107183	1107297	1113562
		1113563	1114534	1114535	1114536	1115896	
AC4040-01	TOPAZ MicroDebrider	1031518	1032308	1032309	1032310	1032755	1032756
		1033972	1033973	1034225	1034226	1035283	1035284
		1038547	1043507	1046556	1047064	1048722	1049266
		1051812	1052070	1054443	1055730	1059865	1063661
		1067691	1067273	1067747	1068019	1069172	1071357
		1072853	1072854	1070497	1070808	1071971	1076849
		1077450	1079140	1079220	1078115	1081753	1082361
		1082810	1086380	1094312	1094721	1097571	1101041
		1107295	1109045	1111935	1111936	1113534	1113535
		1113536	1114532	1115888	1115891	1116959	1116130
		1116720	1117209	1117214			

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of a group of TOPAZ[®] MicroDebrider Wands. During internal functional testing, it was determined that product failed to meet shelf-life at the expiration date indicated on the product labels.

PLEASE NOTE: This notice is coming from Smith & Nephew because Smith & Nephew Inc. purchased ArthroCare Corporation on May 29, 2014. For the purpose of this communication, the products being recalled were manufactured, packaged, labeled, and branded by ArthroCare Corporation at the time of shipment. The manufacturer of the products being recalled is ArthroCare Corporation.

This field action has been reported to the relevant competent authorities.

Risks to Health	There are no immediate or long-range health consequences anticipated from use or exposure to the affected devices. The products may not meet their intended use specifications.
Actions to be taken by the user	<ol style="list-style-type: none">1. Locate and quarantine affected unused devices immediately.2. Return quarantined product to your national Smith & Nephew agency/distributor.3. Complete the return slip and fax it to your national Smith & Nephew agency/distributor.4. Please make sure this safety information is passed on to all those who need to be aware of it within your organization.5. Please maintain awareness on this notice and resulting action until the Field Safety Corrective Action is terminated to ensure effectiveness of the action.

Smith & Nephew is committed to distribute only products of the highest quality standards and to provide any required support. We regret that this has occurred and any inconvenience it may cause or has caused you, your patients, or your staff.

If you have any questions please feel free to contact us under the following contact details:

Smith & Nephew Advanced Surgical Devices UK & I
Fax: + 44 (0)1480 423 201, or
Email: greg.williams@smith-nephew.com or anica.alcala@smith-nephew.com

Bill Aubrey, RA Group Manager



Return Slip

Please complete and return this feedback information to the contact specified above to prevent repetitive enquires.

We hereby confirm that we are aware of this Field Safety Notice concerning the TOPAZ MicroDebrider's. The Field Safety Notice was communicated within our organisation.

Please mark accordingly:

In our facility we do not have any of the affected product in stock
 or

We will return the following products:

Product No.	Description	Batch No. / Quantity to be Returned							
ACH4040-01	TOPAZ MicroDebrider IFS	1031506	1031507	1032123	1032325	1032741	1032742		
		1033443	1033965	1033966	1034397	1039120	1041765		
		1044089	1044090	1045862	1048237	1048933	1049185		
		1052071	1056212	1060586	1060979	1063394	1064599		
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AC4040-01	TOPAZ MicroDebrider	1113563	1114534	1114535	1114536	1115896			
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		1033972	1033973	1034225	1034226	1035283	1035284		
		1038547	1043507	1046556	1047064	1048722	1049266		
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		1113536	1114532	1115888	1115891	1116959	1116130		
1116720	1117209	1117214							

Institution:

Reference: R-2015-26

Date / Signature:

Name:

Telephone: