Smith & Nephew, Inc.
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Urgent Medical Device First Recall Notice
R-2017-05

March 15, 2017

This letter is to inform you that Smith & Nephew, Inc. has initiated a field action to voluntarily recall the batches of ACUFEX® TRUNAV Retrograde Drills listed below. There is the potential for the cutting blade to detach from the device and/or the distal drill head to fracture during retrograde reaming.

Please see product details below:

Product Number	Description	Batch Number				
72204037	RETROGRADE DRL 5.5MM	G11243	G11244	G18810	G18813	G32171
		G32172				
72204038	RETROGRADE DRL 6MM	G10766	G10782	G18814	G18815	G32178
		G32179				
72204039	RETROGRADE DRL 6.5MM	G10785	G10787	G18816	G18817	
72204040	RETROGRADE DRL 7MM	F93290	F93297	G10709	G10712	G15944
		G15945	G27849			
72204041	RETROGRADE DRL 7.5MM	F93305	F93306	G11233	G11234	G27843
		G27847				
72204042	RETROGRADE DRL 8MM	F92143	F92147	G10380	G10382	G11216
		G11217	G11231	G11232	G15940	G15943
		G18835	G18836	G30219	G30220	G30254
		G30255	G32180	G32182	G32183	G32184
72204043	RETROGRADE DRL 8.5MM	F93301	F93303	G04665	G27840	G27841
72204044	RETROGRADE DRL 9MM	F86213	F86216	G04654	G04655	G04656
		G10376	G10377	G11224	G11226	G11237
		G11238	G15935	G15936	G15937	G18822
		G18823	G18824	G18826	G18837	G18838
		G18840	G18841	G30215	G30216	G30247
		G30248	G30256	G32169	G32173	G32174
		G32175	G32176	G32177		
72204045	RETROGRADE DRL 9.5MM	F93298	F93299	F93300	G11240	G11242
		G30252	G30253			
72204046	RETROGRADE DRL 10MM	F91770	F92141	G10378	G10379	G10788
		G10790	G11229	G11230	G11235	G11236
		G15938	G15939	G18830	G18832	G27835
		G27835	G27836	G30217	G30218	G30250
		G30251	G32170			
72204047	RETROGRADE DRL 10.5MM	G10802	G10804	G18818		

72204048	RETROGRADE DRL 11MM	G15888	G15934	G18833		
72204049	RETROGRADE DRL 11.5MM	G11227	G18820			
72204050	RETROGRADE DRL 12MM	G11228	G18821			

Shipment Date Range: November 2016 through March 2017

Information Relating to Patient Safety
In the event the affected devices are presented for use, the cutting blade could detach from the device and/or the distal drill head could fracture during use. This could result in an irretrievable foreign body within the joint space that potentially could lead to iatrogenic injuries.

Follow-up Recommendations
A postoperative x-ray in two planes should be completed as part of the routine follow-up protocol for patients. It is also recommended, where a breakage has occurred, the x-rays are specifically examined for the potential presence of loose metallic fragments, particularly in the posterior part of the knee joint, but also throughout the entire joint space.

Actions

1. Please ensure that each surgeon who has used the affected Retrograde Drills is provided a copy of this letter and made aware of the information relating to patient safety/follow-up recommendations.
2. Please follow the instructions on the attached Response Form.

Smith & Nephew is committed to distributing only products of the highest quality standards and to providing support to surgeons and patients who use those products.

If you have any questions, please contact us at the following email FieldActions@smith-nephew.com.

Yours sincerely,

Andy Weymann, MD
Chief Medical Officer
Smith & Nephew

Enclosure: Response Form

Urgent Medical Device Recall Notice
R-2017-05
Response Form

March 15, 2017

PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT

Required Actions:

1. Please inspect your inventory and locate any unused devices from the listed product and batch numbers on the first page of this Field Action Notification, and quarantine them immediately.
    a. <<(Only if distributors are on the consignee list) If you are a distributor, you must notify your customers of the field action and ensure that these actions are carried out.>>
2. If you have no product to return, please put an X in the appropriate location below.
3. If you have product to return, please list the batch numbers and quantities of each batch that you are returning in the appropriate boxes below.
4. Complete the remainders of the form sign and send to FieldActions@smith-nephew.com or fax to 901-566-7975.
   Please Note – even if you have no product to return, this form must be completed, signed and returned.
5. Once the form is received by Smith & Nephew, you will be sent a Return Authorization (RA) number.

If you have any questions or concerns regarding this recall please contact FieldActions@smith-nephew.com.

No Product to Be Returned ☐

Product Part Number	Batch Number (List Specific Batch #'s to be Returned)	Quantity of Units to be Returned

We hereby confirm that we are aware of this Medical Device Field Action and it has been communicated within our organization.

Printed Name (required): _____Title: _____

Signature (required):_____ Date (required):____/____/____

Email:_____ Telephone: (___) _____-_____

S&N Account Number: _____ RA Number (S&N use only):_____
Name of Organization(s) Covered by Response: _____

Return affected product to: Smith & Nephew | Attn: Global Field Actions | 76 South Meridian Avenue| Oklahoma City, OK 73107