

14 January 2016

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

Reference: R-2015-25
 Concerned Devices: BEAVER® 4.0mm Banana Blade

Product No.	Description	Batch No.			
		72203307	BEAVER 4.0mm Banana Blade	3009063	3009559
		3011688	3012095	3012366	3014560
		3016455	3018390	3020194	3022929
		3025736	3027818	3030178	3032892
		3036529	3071312	3071546	3074279
		3074280	3076377	3076427	3085969
		3089220	3093258	3098516	3101929
		3104300	3107341	3111387	3114657
		3115976	3119607	3123832	3124356
		3124896	3125448	3128384	

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of several lots of the BEAVER Blade 4.0mm as it does not meet Smith & Nephew’s specifications. A number of customer complaints were received indicating that during arthroscopic hip surgery the blades are experiencing brittle fracture.

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

Risks to Health	In the event the blade breaks and falls into the patient; it could potentially be difficult to retrieve and may lead to a surgical delay.
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 or email to the contacts provided on the return slip. 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**

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 BEAVER Banana Blade. 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							
72203307	BEAVER 4.0mm Banana Blade	3009063		3009559		3010117		3010720	
		3011688		3012095		3012366		3014560	
		3016455		3018390		3020194		3022929	
		3025736		3027818		3030178		3032892	
		3036529		3071312		3071546		3074279	
		3074280		3076377		3076427		3085969	
		3089220		3093258		3098516		3101929	
		3104300		3107341		3111387		3114657	
		3115976		3119607		3123832		3124356	
		3124896		3125448		3128384			

Institution : _____ Reference: R-2015-25
 Phone: _____
 Name: _____ Date / Signature: _____