

[Recipients Address]

July 19, 2016

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

Reference: R-2016-33

Concerned Devices: WHIPKNOT SOFT TISSUE CINCH #5 SUTURES

Product No.	Description	Batch No.
7211015	WHIPKNOT SOFT TISSUE CINCH #5 SUTURES	See attached

Dear Dr.

This letter is to inform you that Smith & Nephew, Inc. has initiated a voluntary field safety corrective action of several batches of WHIPKNOT SOFT TISSUE CINCH #5 SUTURES due to a potential packaging issue. A Smith & Nephew internal evaluation revealed the packaging design to be insufficient to prevent a potential sterile barrier breach (pin hole) in the Tyvek film of the pouch.

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

Risks to Health	If the sterile barrier breach is not detected prior to use, the compromised packaging potentially could lead to a non-sterile device entering the surgical field. This could result in a post-operative adverse reaction which typically is reversible with aftercare by the physician. To-date, there have been no complaints or adverse events associated with this issue.
Actions to be taken by the user	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:

Contact Details of Subsidiary / Distributor – please indicate the full address of
No. 5 Tai Seng Drive, #02-01 Singapore 535217

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. 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
7211015	WHIPKNOT SOFT TISSUE CINCH #5 SUTURES		
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Institution: _____

Reference: R-2016-33

Name: _____ Date / Signature: _____

Affected Batches

Item	Batch	Batch	Batch	Batch	Batch	Batch
7211015	50387867	50388745	50389780	50390947	50392219	50392401
7211015	50393765	50394079	50395093	50396528	50396841	50397925
7211015	50399974	50400293	50401451	50402461	50402959	50403376
7211015	50403941	50405570	50406358	50407001	50407434	50407950
7211015	50407951	50408878	50409545	50410397	50411389	50412044
7211015	50413155	50414113	50415145	50415520	50415873	50416326
7211015	50416832	50417399	50417668	50418103	50418994	50420164
7211015	50421033	50421623	50422190	50422891	50422892	50423320
7211015	50424442	50424933	50426325	50427350	50428379	50429275
7211015	50429625	50433984	50434656	50436573	50437136	50437526
7211015	50437759	50438338	50439087	50439765	50439766	50440062
7211015	50440837	50441687	50442651	50442880	50444065	50446669
7211015	50446768	50446770	50448070	50448602	50449028	50450098
7211015	50450473	50451227	50452947	50453834	50454699	50456357
7211015	50457059	50457933	50458614	50460363	50461194	50462494
7211015	50463802	50464798	50466235	50466505	50467033	50467808
7211015	50468830	50469933	50471415	50472190	50473438	50474159
7211015	50475156	50475855	50477527	50478007	50478622	50479617
7211015	50481285	50481730	50483050	50483361	50485995	50487659
7211015	50488891	50492846	50492847	50492848	50492849	50492851
7211015	50492852	50493064	50493806	50494458	50495857	50496836
7211015	50498479	50499120	50499121	50500273	50502177	50503259
7211015	50503943	50505008	50506627	50507250	50507728	50508689
7211015	50510084	50513573	50514115	50515369	50516858	50517711
7211015	50518586	50519608	50519938	50521068	50521840	50522157
7211015	50522313	50522481	50522791	50523907	50524119	50524707
7211015	50525171	50526231	50526605	50527117	50527848	50528880
7211015	50529519	50529834	50530093	50530468	50530782	50530799
7211015	50531351	50531553	50532380	50532717	50533143	50533646
7211015	50534235	50534638	50537501	50549463	50549468	50553176
7211015	50553177	50553178	50553585	50554431	50555221	50555642
7211015	50556017	50556125	50558051	50559082	50560192	50560193
7211015	50562713	50563407	50565147	50565408	50567384	50569692
7211015	50570896	50572075	50574212	50575366	50577597	50578036
7211015	50578037	50579348	50580730	50581344	50583475	50584361
7211015	50584362	50584363	50586084	50586561	50588245	50589286
7211015	50590542	50591919	50592295	50594969	50598322	50599811
7211015	50603228	50603355	50603357	50603972	50604722	50605882

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QA/ RA Manager to sign here

