

[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 |

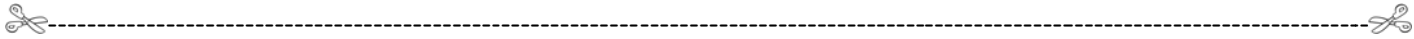
Dear Dr.

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 | <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:

Contact Details of Subsidiary / Distributor

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 |