[Recipients Address]

August 19, 2013

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

Reference: R-2013-15
Concerned Devices: Suture anchors of the BIORAPTOR◇, OSTEORAPTOR◇ and TWINFIX◇ ULTRA product lines

Dear Dr.

On August 6, 2013, Smith & Nephew initiated a voluntary field action for certain bio-absorbable suture anchors. The affected suture anchors include devices in the BIORAPTOR, OSTEORAPTOR and TWINFIX ULTRA product lines. We have amended that voluntary field action to include four additional part numbers. Please refer to the table on page 3 and 4 for all affected product numbers including the four additional part numbers (highlighted).

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

Product	**Suture anchors of the BIORAPTOR, OSTEORAPTOR and TWINFIX ULTRA product lines (see article and lot information attached)**
Reason for this Field Action	The field action is performed due to a packaging issue. Specifically, we have identified pin holes and/or tiny slits (0.5mm – 5.0 mm) in a small number of the primary pouches that may constitute a breach of the sterile barrier.
Risks to Health	A Health Hazard Evaluation was completed and determined that the reported failure mode may cause temporary or medically treatable adverse health consequences. The probability of serious adverse health consequences is remote. During an arthroscopic soft tissue repair, a fixation device is prepared for a procedure. The physician or prep nurse may not notice a small hole in the pouch at the time the product is placed into the sterile field. In most cases where that may occur, surgery would be completed successfully, and no follow-up would be required. In a small number of instances, there could be an adverse reaction, such as surgical site infection, which is treatable with aftercare by the physician. In rare instances, there exists the remote possibility that the patient could experience a systemic infection (sepsis) resulting in organ failure and death.

Actions to be taken by the user	1. Please inspect your inventory, locate any unused devices identified in the attached list of affected product and quarantine them 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.
Other Information	Within the European Economic Area and Switzerland the field action is coordinated by Smith & Nephew Orthopaedics AG (Switzerland). **Product Unaffected by the Recall:** **Product with a blue dot on the carton, has been inspected and is unaffected by the recall. If you receive product with a blue dot, you do not need to return it.** The photo to the right shows what the blue dot looks like and where it is located on each carton. 

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 confirm the receipt of this Field Safety Notice.

Part #	Description	# of Units to be Returned	No Product to Return (please place an X where appropriate)
72200689	BIORAPTOR 2.9 mm Suture Anchor, pack of 1 ULTRABRAID Suture		
72200690	BIORAPTOR 2.9 mm Suture Anchor Straight, pack of 2 ULTRABRAID Suture		
72200774	BIORAPTOR 2.9 mm Suture Anchor with 1 ULTRABRAID Suture		
72200775	BIORAPTOR® 2.9 mm Suture Anchor with 2 ULTRABRAID® Suture		
72200783	BIORAPTOR 2.9 mm Suture Anchor with DURABRAID® Suture		
72201991	OSTEORAPTOR 2.3 mm with 1 ULTRABRAID Suture, White		
72201992	OSTEORAPTOR 2.3 mm Suture Anchor with 1 ULTRABRAID COBRAID Suture, Black		
72201993	OSTEORAPTOR® 2.3 mm Suture Anchor with ULTRABRAID COBRAID® Suture, Blue		
72201994	OSTEORAPTOR 2.9 mm Suture Anchor with 1 ULTRABRAID COBRAID Suture, Blue		
72201995	OSTEORAPTOR 2.9 mm Suture Anchor with 2 ULTRABRAID Suture, White / Blue		
72201996	OSTEORAPTOR 2.9 mm Suture Anchor with 2 ULTRABRAID Suture, White / Black		
72202165	OSTEORAPTOR 2.9 mm Suture Anchor with 1 ULTRABRAID Suture, White		
72202597	TWINFIX® Ultra HA 4.5 mm Suture Anchor with 2 ULTRABRAID Suture, White / Blue		
72202602	TWINFIX Ultra PLLA/HA 5.5 mm Suture Anchor with 2 ULTRABRAID Suture, White / Black		
72202603	TWINFIX ULTRA PLLA/HA 5.5 mm Suture Anchor with 3 ULTRABRAID Suture		
72202608	TWINFIX® Ultra PLLA/HA 6.5 mm with 2 ULTRABRAID® Suture, White / Black		
72202610	TWINFIX Ultra PLLA/HA 6.5 mm with 3 ULTRABRAID Suture		

Part #	Description	# of Units to be Returned	No Product to Return (please place an X where appropriate)
72202624	TWINFIX Ultra HA 4.5 mm Suture Anchor with 2 ULTRABRAID Suture, Blue / Black		
72202626	TWINFIX Ultra HA 5.5 mm Suture Anchor with 2 ULTRABRAID Suture, Blue / Black		
72202631	TWINFIX Ultra HA 6.5 mm with 2 ULTRABRAID Suture, Blue / Black		
72203290	OSTEORAPTOR CURVED 2.3 mm Suture Anchor SA ULTRABRAID COBRAID Suture, Blue		
72203291	OSTEORAPTOR CURVED 2.3 mm Suture Anchor ULTRABRAID COBRAID Suture, Black		
72201805	RAPTORMITE° 3.7 mm PLLA with 2 ULTRABRAID Sutures Size 0 and Needles		
72202612	TWINFIX Ultra PLLA/HA 4.5 mm Suture Anchor with two ULTRABRAID Suture, Blue / Blue-Cobraid) with Needles		
72202616	TWINFIX Ultra PLLA/HA 5.5 mm Suture Anchor with two ULTRABRAID Suture, Blue / Blue-Cobraid) with Needles		
72202620	TWINFIX Ultra PLLA/HA 6.5 mm Suture Anchor with two ULTRABRAID Suture, Blue / Blue-Cobraid) with Needles		

☐ _____ concerned devices have been used/discarded in our facility.

Institution: _____ Reference: R-2013-15

Name: _____ Date / Signature: _____