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--- URGENT ---
FIELD ACTION NOTIFICATION

TWINFIX◇ TI 2.8mm HS SUTURE ANCHOR WITH TWO 28" DURABRAID◇ SUTURE (USP #2)
Please see product detail below / in the attached list

Product No.	Description	Batch No.	Shipment Dates
72200796	TWINFIX TI 2.8mm HS Suture Anchor with two 28" DURABRAID Suture (USP #2)	2010547, 2025137, 2036695, 50763859, 50773071	May 09, 2018 - October 10, 2019

FSCA no.: R-2019-22
December 30, 2019

DESCRIPTION OF THE PROBLEM

Smith+Nephew, Inc. has voluntarily initiated a recall to remove multiple lots of TWINFIX TI 2.8mm HS SUTURE ANCHOR WITH TWO 28" DURABRAID SUTURE (USP #2) due to a potential for sterile barrier breach. A complaint was received that indicated the protective tube of the device came off inside the pouch enabling the pointed end of the device to puncture the package causing a breach of the sterile barrier, which could affect the sterility of the device.

In the most likely scenario, the failure mode would be identified prior to use. In a worst case scenario, the failure mode is not detected prior to use and the affected devices are used in a surgical procedure, potentially introducing a non-sterile device into the surgical sterile field. There have been no reported complaints for devices that have been used during a procedure.

REPORTING TO NATIONAL COMPETENT AUTHORITIES

Refer to the HHE Regulatory Assessment shown in Appendix 1 for reporting requirements.

If any subsidiary/distributor has further distributed the mentioned devices to other countries, please indicate asap to the Field Action Coordinator (FAC), including the information whether you will notify the consignee and the respective competent authority yourself or if you require support of the FAC.

ACTIONS TO BE TAKEN BY THE DISTRIBUTOR

- Identify and quarantine the devices in your warehouse.
- Identify and inform all users, which have received affected products with the attached Field Safety Notice for Recall.
- Collect return slips of the Field Action Notice for Recall (to confirm awareness of all affected users) and forward them to the specified contact below. If acknowledgement is not provided by any of the affected users provide evidence of three attempts to notify these users.
- Complete the acknowledgment section on page 3 and return it to the specified contact below.

■ Return collected devices as instructed below.

Please maintain awareness on this notice and resulting action until the Field Action is terminated to ensure effectiveness of the action. This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

DISTRIBUTION

Country	**Distribution Quantity**				
Material No.	**72200796**	**72200796**	**72200796**	**72200796**	**72200796**
Batch No.	**2010547**	**2025137**	**2036695**	**50763859**	**50773071**
Arabic Emirates	0	0	0	0	23
Canada	2	0	0	0	0
Switzerland	2	0	0	0	0
Spain	9	0	0	0	0
Finland	2	0	0	0	0
Puerto Rico	1	0	0	0	10
SG APAC HUB	0	0	0	53	64
Australia	0	0	0	4	0
Japan	0	0	0	63	10

RETURN INSTRUCTIONS

All Field Action Returns from PR1 Countries:

- If originally received from Baar are to be returned to GDC Baar via NB2C Return STO Process.
- If originally received from GDC OKC are to be returned to GDC OKC via NB2C Return STO Process.
- List Return STO Number on the Acknowledgement Section Form below.

All Field Action Returns from NON PR1 Countries:

- Will continue to be returned using the RA (ZRE) return process.
- Please contact Smith & Nephew's Global Field Actions Department via e-mail at FieldActions@smith-nephew.com or fax +41 62 832 06 07 to obtain a return authorization (RA) number.

Please write the **RA/STO number on the outside of your shipping container and on the documents attached** for efficient and accurate processing of the returned devices. Devices returned under these procedures should not be mixed with other stock and **must be returned within 30 days from the date of the initial notification**.

Shipping address:

Smith+Nephew Oklahoma | 76 South Meridian Avenue, Oklahoma City, OK 73107

CONTACT PERSON

For questions, please contact:
Garry Smith / Field Action Manager
P: 1 901 399 1970
F: 1 901 566 7975
fieldactions@smith-nephew.com

ACKNOWLEDGMENT SECTION

Please complete and return this feedback information by fax or e-mail to the contact specified above to prevent repetitive enquiries.

Product No.	Batch No.	Quantity to be Returned	No Product to Return
72200796	2010547		☐
72200796	2025137		☐
72200796	2036695		☐
72200796	50763859		☐
72200796	50773071		☐

- _____ *[Qty]* customers in my territory have provided written acknowledgement of receipt of the FSN.
- _____ *[Qty]* customers have not provided written feedback after three notification attempts.
- Return STO Number: _____ (for PR1 Countries only)
- Comments: _____

---------- *For those advised above to perform national competent authority (NCA) reporting:* ----------

- NCA reporting has been performed as instructed above and copies of the respective reporting documents (initial and final report) are provided to the Field Action Coordinator. YES ☐ NO ☐

  Rationale if NO: _____

Name/Title (please print): _____ Reference: R-2019-22

Date / City: _____ Signature: _____

Appendix 1: HHE Regulatory Assessment

REGULATORY ASSESSMENT	
Section 5: Regulatory Risk Assessment (Responsible Person: Regulatory Affairs)	
Only complete sections below if check box indicates region affected	
Affected Regions	Based on the information populated above, assess whether affected product may be in violation of the regional medical device regulatory laws and regulations. Provide a brief narrative regarding the basis of the violation (why/how is it violative). Include name of regional representative providing input as appropriate.
☒ US	Based on the assessment above, an undetected pouch breach would result in a severity level of 6. While the risk index falls in the "Low Risk" region, the worst-case severity is high enough such that field action is recommended.
☒ EUCAN	The devices are in violation of the EU regulations, as the sterile barrier may breach. (Armand Linge, EU RAQ Director)
☒ IRAMEA	The affected product is in violation of the applicable medical device regulations, as the overall risk profiled defined in the device Risk Management File is not maintained.(Manuel Urena – Sr. Director APAC-eMEA)
☒ LATAM	Based on the assessment above, an undetected pouch breach would result in a severity level of 6. While the risk index falls in the "Low Risk" region, the worst-case severity is high enough such that field action is recommended. (Pedro Rivera, RAQ Director, Latin America)
☒ ANZ	The product is in violation as there is potential deficiencies in safety, quality, efficacy, performance or presentation. (Minta Chen – Sr. RA/Q Manager)
☒ Japan	This issue may result in a potential infection for patients in the worst-case scenario. The field action for the affected lots is recommended. (Tadashi Ogashiwa, RAQ Director, Japan)

Section 6: Field Action Reportability Assessment
(Responsible Person: Regulatory Affairs)
Complete this section *only* if field Action is recommended, otherwise check N/A ☐

Only complete sections below if check box indicates region affected

Affected Regions	Reporting Requirements	YES	NO	Rationale
☒ US	Is the recommended Field Action being initiated (1) to reduce a risk to health posted by the product; **or** (2) to remedy a violation caused by the product which may present a risk to health? ***Refer to guidance in Health Risk Index Table. This must be Yes for Health Risk Index Rating "D" or if the patient severity (Table 1) is a 6 or above***	☒	☐	Based on the assessment above, an undetected pouch breach would result in a severity level of 6. While the risk index falls in the "Low Risk" region, the worst-case severity is high enough such that field action is recommended.
☒ EUCAN	Are both of the following conditions met: the action is initiated (1) for a technical or medical reason **and** (2) to reduce a risk of death or serious deterioration in the state of health associated with the use of the affected product(s)?	☒	☐	The worst-case scenario is rated as B, with a severity above 6; Most Likely Scenario is rated also as B. The condition to reduce a risk of death or serious deterioration in the state of health associated with the use of the affected product is met. A Field Action with removal is recommended for the EUCAN Region
☒ IRAMEA	Per local requirements	☒	☐	Reportable as per local regulations
☒ LATAM	Per local requirements	☒	☐	Based on the assessment above, an undetected pouch breach would result in a severity level of 6. While the risk index falls in the "Low Risk" region, the worst-case severity is high enough such that field action is recommended.
☒ ANZ	Per local requirements	☒	☐	Field action as per TGA guidelines
☒ Japan	Per local requirements	☒	☐	This issue may result in a potential infection for patients in the worst-case scenario. The field action for the affected lots is recommended.