

--- URGENT ---
FIELD ACTION NOTIFICATION

TIBIAXYS Hexalobular T10 Screwdrivers
Please see product detail below

Product No.	Description	Batch No. / UDI No.	Shipment Dates
219135ND	TIBIAXYS Hexalobular T10 Screwdrivers	FTL9, FTLA and FVRG	February 12, 2020- November 15, 2021

FSCA no.: V-2021-04
January 4, 2022

DESCRIPTION OF THE PROBLEM

This letter is to inform you that Smith + Nephew is conducting a voluntary field action for a group of Integra manufactured TIBIAXYS Hexalobular T10 screwdrivers due to a manufacturing error. The affected screwdrivers are out of specification and may not mate with the Surfix Alpha Lock screw.

In the event the instrument is presented for use the screwdriver will most likely mate with the lock screw and function as intended. Contrarily, in the worst case the screwdriver does not mate with the lock screw resulting in the migration of the screw as it is not locked on the plate. This rare occurrence could lead to a delay in bone union resulting in additional rehabilitation or the potential for pain due to soft tissue injury which could lead to subsequent removal of the screw.

REPORTING TO NATIONAL COMPETENT AUTHORITIES

In the US this field action is considered a US Class II Recall. As the EU market is affected, FSCA reporting within the EU region is required. Field Action Reporting to local governments in RoW is the responsibility of the local subsidiary/distributor(s).

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	Product No.	Batch No. / UDI No.	Distribution Qty.
NL	219135ND	FVRG, FTL9	3
FR	219135ND	FTL9	1
DK	219135ND	FTL9, FTLA, FVRG	6
BE	219135ND	FTL9, FTLA, FVRG	74
CH	219135ND	FTL9, FTLA	13
ZA	219135ND	FTL9	4
TH	219135ND	FTL9	2

RETURN INSTRUCTIONS

- Please contact Smith & Nephew's Global Field Actions Department via e-mail at FieldActions@smith-nephew.com.

CONTACT PERSON

For questions, please contact:
Garry Smith / Quality Manager
P: 1 901 399 1970
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. / UDI No.	Quantity to be Returned	No Product to Return
			<input type="checkbox"/>

■ [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: V-2021-04

City: _____ Country: _____

Date _____ Signature: _____