Date: 21 April 2023

URGENT FIELD SAFETY NOTICE
BIOKNOTLESS® Anchor

Subject Product:

Model Number	Lots	Description	UDI/GTIN
212724	All	BIOKNOTLESS Plus w/ Ethibond	10886705002108
212725	All	BIOKNOTLESS Plus w/ Panacryl	10886705002115
212726	All	BIOKNOTLESS Plus w/ OC	10886705002122
212722	All	BIOKNOTLESS Rapid W/ OC	10886705002085
212723	All	BIOKNOTLESS Rapid w/ Pan	10886705002092

Dear Valued Customer,

Please be advised that DePuy Mitek is initiating a Field Safety Notice (FSN) for all lots of the BIOKNOTLESS® Anchor products listed in the table above. The DePuy Mitek BIOKNOTLESS® Anchor is indicated for use in soft tissue to bone fixation.

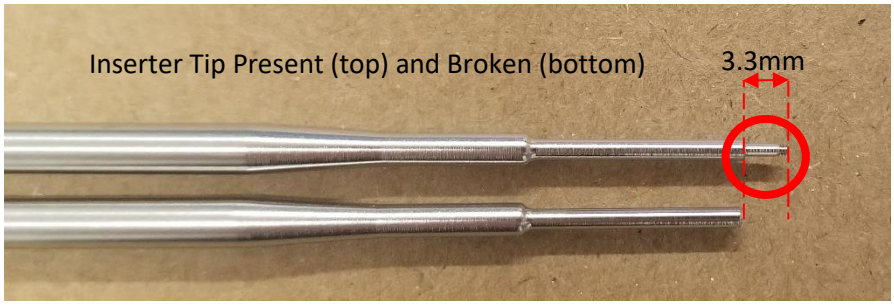
Our records show that you, or your facility, received one or more units of the product listed above. Please carefully review this notice for the steps that you should take to respond to this Field Safety Notice.

Reason for the Field Safety Notice:
This FSN is to alert users that applying bending force and/or bending force with impaction to the BIOKNOTLESS® Anchor Inserter may cause a fragment of the inserter tip to break off during use and be retained in the patient.

It is important for a surgeon to inspect the integrity of the inserter after it is removed from the anchor. Please refer to the IFU (IFU-108878 or IFU-109003) for the above listed subject products, which includes the following: "WARNING: DO NOT TWIST OR APPLY A BENDING FORCE TO THE INSERTER. THIS CAN DAMAGE THE ANCHOR, SUTURE, OR INSERTER TIP." When a bending force is applied to the inserter during anchor placement, inserter tip breakage can occur (see Figure 1 – Note: the inserter tip is ferromagnetic and can be affected by MRI). Maintaining linear alignment at all times is essential to avoid bending or torque. A surgeon-focused communication will be released following this notification to provide further clarity on the surgical technique for the subject product.

There is no manufacturing nonconformance or design defect associated with the subject products.

Figure 1. Surgical-Grade Stainless Steel Inserter and Inserter Tip (3.3mm L x 0.97mm Ø)



Potential Patient Impact:
A broken BIOKNOTLESS® Anchor inserter tip detected during surgery may require removal, potentially causing bone damage and longer surgery time.

If a BIOKNOTLESS® Anchor inserter tip breaks during surgery and is not removed, it may dislodge and migrate, which may lead to pain, joint problems, and/or tissue reactions. Health care providers must evaluate each patient and the individual situations and create a treatment plan, which may include surgery.

To date, the 18 complaints received for this issue have been associated with shoulder surgeries. Health care providers who have treated patients using the subject product should continue to follow those patients pursuant to the health care provider's standard of care.

Please Take the Following Steps:

1. **Product is NOT being removed from the field and does not need to be returned.**
2. Familiarize yourself with the content of this letter.
3. Review, complete **all** fields, sign, and return the attached business response form (BRF) on the last page of this letter to [Enter Affiliate Contact Information] within three (3) business days of receipt of this field safety notice. Please include "FA 2244073 BIOKNOTLESS" in the email subject line. **IMPORTANT:** Complete the BRF even if you do not have any of the subject product in your current inventory.
4. Forward this notice to any personnel in your facility who need to be informed.
5. If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice.
6. Post a copy of this notice in a visible area for awareness and keep a copy for your records.

This field safety notice has been reported to the relevant health authorities. If you have any questions, please contact your local DePuy Synthes Sales Consultant.

Thank you for your prompt attention and cooperation in this matter.

Sincerely,

Shannon Rook
Staff Quality Systems Recall Coordinator
Email: OneMD-Field-Actions@its.jnj.com

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Business Reply Form (BRF)

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Product Subject to this FSN: Our records show that your facility may have received the subject BIOKNOTLESS® Anchor.

Please complete this BRF **within three (3) business days upon receipt of this Notice** and email this form to [Enter Affiliate Contact Information]. **IMPORTANT:** Complete the BRF even if you currently do not have any product in your inventory.

Note: Product is NOT being removed from the field and does not need to be returned

☐ By signing this form, I am confirming that I have read and understand the notification.

Your Name:	Facility/Business Name:
Signed*:	Date:
Facility/Business Address, City:	
Account Number:	
J&J Sales Rep (as applicable):	
Date the notification was received:	
Email Address:	Telephone Number:
**Your signature provides confirmation that you have received and understood this notification.*	
Your comments are always welcome:	