

## **URGENT: MEDICAL DEVICE RECALL (REMOVAL)**

### **Mitek HEALIX ADVANCE™, HEALIX ADVANCE™ Knotless, MILAGRO® ADVANCE, and INTRAFIX™ Advance**

13 November, 2019

Dear Operating Room Supervisors, Materials Management Personnel, Risk Managers and Chief of Surgery:

DePuy Mitek, Inc. initiated a Voluntary Product Recall for specific product codes and lots of the Mitek HEALIX ADVANCE™, HEALIX ADVANCE™ Knotless, MILAGRO® ADVANCE, and INTRAFIX™ Advance (Attachment A). The anchor / interference screw components were manufactured with BIOCRYL™ Biocomposite Material instead of BIOCRYL RAPIDE® Biocomposite Material. BIOCRYL and BIOCRYL RAPIDE are biocompatible and effective material choices for absorbable, injection-molded sports medicine implant fixation. No complaints or adverse events related to this issue have been received for the affected product codes/lots.

#### **Potential Harms:**

Based on the analysis, it is expected that sport medicine implants made from BIOCRYL (PLLA+TCP) would perform equal to those made from BIOCRYL RAPIDE (PLGA + TCP) during the surgery and therapeutic healing period. As such, this product issue presents no foreseeable increased risk to patient safety nor does it alter the product benefit-risk profile.

#### **BIOCRYL and BIOCRYL RAPIDE Comparison:**

- Each material is used clinically today, but in different DePuy Mitek implant brands; both materials have more than 15 years of use in clinical applications. BIOCRYL was first launched in 2002 and BIOCRYL RAPIDE in 2004.
- The mechanical properties (strength, stiffness) of BIOCRYL and BIOCRYL RAPIDE are similar at the time of anchor deployment; BIOCRYL offers equivalent in vitro strength retention during the therapeutic healing period and out to 12 weeks.
- As for long-term absorption rates, BIOCRYL RAPIDE is expected to absorb in approximately two years versus approximately four years for BIOCRYL.

#### **Patient Communications**

DePuy Mitek, Inc. is not recommending prophylactic revision in the absence of symptoms. The company recommends health care practitioners, who have treated patients using affected product codes/lots, follow those patients post-operatively in the usual manner with no additional action recommended.

**EFFECTIVE IMMEDIATELY—DO NOT USE OR DISTRIBUTE THE FOLLOWING PRODUCT CODE / LOT:**

Product Code	Material Description	GTIN	Batch
222295	4.5 HELIX ADVANCE BR Anchor with ORTHOCO	10886705021314	5L45121 5L45253
222296	4.5 HELIX ADVANCE BR 3-Suture Anchor wit	10886705021321	5L23304 5L23305 5L23306 6L10443 6L10444 6L10445 6L10446
222330	HEALIX KNOTLESS ADV BR 4.75	10886705023462	5L45257 5L80897 5L80907 5L80914
222331	HEALIX KNOTLESS ADV BR 5.5	10886705023479	5L13543 5L45259 5L95439 5L95441
222886	5.5 HEALIX ADVANCE KNTLS BR	10886705030699	5L45132 5L95447
223129	4.5 HEALIXADV BR3SUTANC PCORD	10886705024735	5L23233 6L10242 6L10243 6L10244
231821	MILAGRO ADVANCE SCREW 8X30MM	10886705022267	5L29710 5L54397 6L10266
254807	INTRAFX ADVBR SCW8X30 W/SMSHTH	10886705026739	5L13602 5L80133

**Note: Unique Device Identifier (UDI):** UDI = DI + PI  
DI = Device Identifier = GTIN | PI = Production Identifier = Lot Number

**ACTION REQUIRED:**

1. Cease further distribution or use of the affected products and quarantine them.
2. Complete the Business Reply Form (BRF) (Attachment 2) confirming receipt of this notice and return it to your Depuy Mitek Sales Representative within three (3) business days. **Please return the BRF even if you do not have product subject to this recall.**
3. Keep this notice visibly posted for awareness until all product subject to this recall has been returned to your Depuy Mitek Sales Representative. While processing your returns, please maintain a copy of this notice with the product subject to this recall and keep a copy for your records.
4. Forward this notice to anyone in your facility that needs to be informed, including surgeons who have already implanted these products in patients.
5. If any impacted products have been forwarded to another facility, contact that facility and provide them with this letter.
6. Keep a copy of this notice.

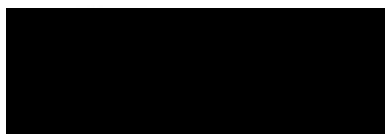
We apologize for any inconvenience that this removal may cause and appreciate your cooperation with our request. If you have questions about this field action, please contact your Depuy Mitek Sales Representative.

**Attachments:**

Attachment 1: Business Reply Form

Attachment 2: Affected Product Codes / Lot Numbers

Yours sincerely,



Lee Ching Hwee  
Manager, Regulatory Affairs

cc: Chairman Medical Board  
Relevant Head of Departments

## ATTACHMENT 1: Business Reply Form (BRF)

Your timely response to this customer notification is requested. Please complete this form and hand it to your Deputy Mitek Sales Representative **within 3 business days, even if you do not have product subject to this correction.**

If you have product subject to this recall to return, please make a photocopy of your completed Business Reply Form and enclose with your return. Thank you for your cooperation.

### Product Inventory – please check one

- The facility located the identified product in stock; return product(s) are listed in Attachment 2. A copy of this letter is being retained in the facility's records. I have read and understand the notification.
  
- The facility has no affected product for return. A copy of this letter is being retained in the facility's records. I have read and understand the notification.

Print Name of Person Completing Business Reply Form:	Sign & Date:
Customer Account Details (Name and Address)	

## ATTACHMENT 2: Affected Product Codes / Lot numbers

Product Code	Material Description	GTIN	Batch	Quantity Returning
222295	4.5 HELIX ADVANCE BR Anchor with ORTHOCO	10886705021314	5L45121	
			5L45253	
222296	4.5 HELIX ADVANCE BR 3-Suture Anchor wit	10886705021321	5L23304	
			5L23305	
			5L23306	
			6L10443	
			6L10444	
			6L10445	
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			5L95439	
			5L95441	
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			6L10242	
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			5L54397	
			6L10266	
254807	INTRAFX ADVBR SCW8X30 W/SMSHTH	10886705026739	5L13602	
			5L80133	
Total returning				

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