

To the ATTENTION of:

EMEA – Materials Management/Operating Room Supervisor

Date: 20 November 2015

URGENT FIELD SAFETY NOTICE

neXtra® Cutter Shaver Blades – 3.5mm Aggressive Blade (Lot M1505053) and 3.5mm Ultra-Aggressive Blade (Lot M1505056)

Part Number	GTIN Number	Part Description	Lot Numbers
283315	10886705000067 (each) 20886705000064 (5 pack)	3.5mm Aggressive Blade	M1505053
287325	10886705000371 (each) 20886705000378 (5 pack)	Ultra-Aggressive Blade	M1505056

Dear Valued Customer:

*Mitek Sports Medicine** is initiating a Voluntary Field Safety Notice for the above products and lot numbers of shaver blades.

Mitek Sports Medicine shaver blades are intended to provide controlled cutting, shaving and abrading of tissue during orthopaedic procedures of the knee, shoulder, elbow, wrist, ankle, hip, small joints and temporal mandibular joint (TMJ). Our records indicate that you may have inventory that is impacted by this field action.

Description of the problem:

This field safety notice of 160 units is being conducted because the two products, reference numbers 283315 and 287325, were incorrectly labelled. The blade configuration in the affected lots does not match the description on the label.

We request that you immediately check all inventories to locate and return all affected product in your inventory per the attached instructions. This field safety notice applies only to the **specific lots** of shaver blades listed above.

Please do not return other products in response to this field safety notice. We cannot ship back or provide credit for any returned product that is not part of the affected product codes.

Potential hazard:

There were no patient safety risks identified as a result of the incorrectly labelled shaver blades, and there have been no complaints reported of any patient harm. The aggressiveness of the different blade designs is for surgeon preference.

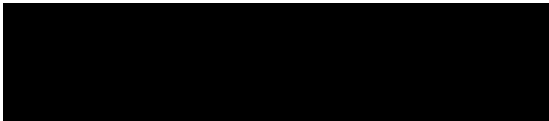
Customer immediate actions:

1. Review inventory located within your facility and quarantine any products listed in this field safety notice. Please return all affected inventory to GMED Healthcare at the address on the Business Reply Form.
2. Review, complete, sign and return the attached Business Reply Form to Elizabeth Messana (emessan1@its.jnj.com) in accordance with the directions on the Business Reply Form within 5 business days of receipt of this notification.
3. Forward this notice to anyone in your facility that needs to be informed.
4. If any product listed below has been forwarded to another facility, contact Elizabeth Messana (emessan1@its.jnj.com)
5. Keep a copy of this notice.

The applicable regulatory agencies are being notified. *Mitek Sports Medicine* is voluntarily taking this action.

We apologize for any inconvenience that this field action may cause and appreciate your cooperation with our request. Should you have any questions, please do not hesitate to contact your *Mitek Sports Medicine* Sales Consultant.

Sincerely,



Elizabeth P. Messana
Recall Coordinator
Quality Department

*Legal manufacturer name is DePuy Mitek, Inc.

URGENT FIELD SAFETY NOTICE

BUSINESS REPLY FORM

REF. NUMBER 1221934-11-20-15-001-R

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- ☐ We do not have any identified product in stock. We have retained a copy of this letter for our records.
- ☐ THE PRODUCTS LISTED BELOW ARE IN STOCK AND WILL BE RETURNED TO *MITEK SPORTS MEDICINE* FOR CREDIT at the address below per the standard returns process. A dollar credit will be posted to your account at the original invoice price.

Part Number	Part Description	Lot Number	Quantity Returning	
			Each	Pack

All affected products are to be returned to the address below for credit.

GMED Healthcare
EDC 8.12 Returns Department
Rue de Luxembourg 5
ZI Trazegnies
BE – 6180 Courcelles, Belgium
TEL: 32-7-146-9404

**Please complete this form and
 fax a completed copy to:
 +1-508-828-3750
 or email:
 (emessan1@its.jnj.com)
 ATTN: Recall Coordinator**

Facility Name: _____

Name/Title (please print): _____

Phone Number: _____

Signature/Date: _____