DePuy Synthes
MITEK SPORTS MEDICINE
COMPANIES OF Johnson&Johnson

DePuy Mitek, Inc.
325 Paramount Drive
Raynham, MA 02767

September 5, 2012

Urgent Voluntary Product Recall
FMS® Intermediary Tubing with One-Way valve and FMS® Outflow Tubing with One-Way valve

Consignee Name
Attn: Sports Medicine Physicians and Director Materials Management/Operating Room Supervisor
Address
City, State, Zip Code

Dear Director Materials Management/Operating Room Supervisor,

Please be aware that effective immediately, a **voluntary recall is being initiated for FMS® Tubing product reference number 281142 (lots with a 'D' designation) and 284649 (all lots) due to the product not performing as intended**. These products were released to market by *Mitek Sports Medicine**on or after August 15, 2013. The Intermediary Tubing for FMS Fluid Management Systems connects the Inflow Tubing to the arthroscopic sheath during arthroscopic procedures. The Intermediary Tubing (281142) is sold by itself or as part of the Outflow Tubing with One-Way valve (284649).

Internal testing has identified that the one-way check valve (pillow valve) included in the FMS Outflow Tubing set and the FMS Intermediary Tubing set may occasionally not be performing as intended. If the instructions described in the FMS Duo System and Solo System Operator's Manuals are not followed, this may result in backflow of irrigation fluid into the "One Day" Set, and when used with affected tubing, could potentially lead to patient cross-contamination. Please be aware that backflow of irrigation fluid can only occur if the check valve is not working properly and the pressure line is disconnected or the tension rocker is open.

When connected properly and used in accordance with the system's Operating Manual, tubing with an affected check valve will not allow backflow of irrigation fluid into the One Day Set, and would not lead to potential patient cross-contamination. To date**,** no injuries or adverse events related to this issue have been reported.

This recall includes FMS® Tubing as follows:

Product Codes Affected	**Lot Numbers**
281142 – FMS Intermediary Tubing with One-Way valve	All lots DXXXXXX
284649 – FMS Outflow Tubing with One-Way valve (FMS VUE™ or FMS DUO®+)	All lots

Our records indicate that you are the recipient of one or more of the product codes affected by this recall. We request that you take the following steps:

1. Immediately check all inventories to locate and return affected product following the enclosed instructions. It is important to report your inventory status even if you no longer have affected product.

2. If you are aware that affected product was used on or after August 15, 2013 and the system's operating manual was not followed (EITHER the pressure line was disconnected OR tension rocker opened inadvertently), it is important to follow up with potentially affected patients per each institution's Infectious Disease/Needle stick protocol. A sample patient letter is available upon request to assist you in this process. For further information and to request this letter, please email mitekscientific@its.jnj.com.

Please refer to the attached instructions to report your inventory status and for returning recalled product. This recall applies only to FMS® Tubing product codes.

If you have any questions, or concerns regarding this recall, please contact your local *Mitek Sports Medicine* consultant. We regret the need to undertake this voluntary recall, andyour *Mitek Sports Medicine* consultant will support you throughout this process. At *Mitek Sports Medicine*, we are dedicated to delivering products that meet the highest quality standards. We apologize for any inconvenience this recall may cause. Thank you for your cooperation and your patience.

Sincerely,

Suresh Aravind, MD
Worldwide Vice President , Strategic Medical Affairs

*DePuy Mitek, Inc., is the legal manufacturer issuing this recall. DePuy Synthes Mitek Sports Medicine distributes FMS tubing and is a division of DePuy Orthopaedics, Inc.

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Instructions for Reporting your Inventory Status and Returning Product

You are being sent this voluntary recall notification because our product ordering systems show that you have received FMS Tubing product(s). Please do not use or sell any of the identified recalled products included in this recall.

Products affected include the following FMS Tubing codes:

281142 – FMS Intermediary Tubing with One-Way valve	All lots DXXXXXX
284649 – FMS Outflow Tubing with One-Way valve (FMS VUE™ or FMS DUO®+)	All lots

Please complete the **International Business Reply** Form included in this package as soon as possible. This form is to be used to indicate your inventory status of the affected products.

The completed Business Reply Form can be faxed to +1-508-828-3750 or email a copy to mitekcomplaints@its.jnj.com.

Credit will be applied for all product returned. Please call your customer services representative.

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

GMED Healthcare
JDE 8.12 Returns Dept.
Rue de Luxembourg 5
ZI Trazegnies
BE - 6180 Courcelles
Belgium

TEL: 32-7-146-9404

It is very important that you complete the Business Reply Form as soon as possible even if you do not have any affected product inventory in your possession.

Please fax the completed Business Reply Form to +1-508-828-3750 or email to mitekcomplaints@its.jnj.com.

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INTERNATIONAL BUSINESS REPLY FORM

This letter acknowledges receipt of the recall letter dated (5 September 2013) issued by *Mitek Sports Medicine*.*

We have checked our current inventory for FMS® Tubing product.

☐ NO FMS® Tubing PRODUCTS IN STOCK.

☐ THE PRODUCTS LISTED BELOW ARE IN STOCK AND WILL BE RETURNED TO *MITEK SPORTS MEDICINE* FOR CREDIT. A dollar credit will be posted to your account at the original invoice price.

Product Code	*Lot Number*	*Quantity*

Print Name: _____

_____
Authorized Signature/Date

_____
Name of Facility/Dealer

_____
Address

_____
City, State, Zip

_____
Telephone Number

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

All affected products are to be returned to the address below for credit.
GMED Healthcare
JDE 8.12Returns Department
Rue de Luxembourg 5
ZI Trazegnies
BE - 6180 Courcelles
Belgium

TEL: 32-7-146-9404

Please make a copy of this form to include with your product return.

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