DePuy Mitek
325 Paramount Drive
Raynham, MA 02767

September 6, 2012

Urgent Voluntary Product Recall
SPIRALOK® Suture Anchors

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

Dear Director Materials Management/Operating Room Supervisor,

We want to inform you that effective immediately, DePuy Mitek is initiating a global voluntary recall of all product codes and lots of SPIRALOK® Anchors and discontinuing the product line. SPIRALOK Anchors are primarily used to re-attach soft tissue to bone in rotator-cuff repair surgery, but are also indicated for use in the foot/ankle, knee and elbow.

Based on internal testing and post market clinical information, the SPIRALOK anchor is not robust for foreseeable use conditions. We are removing the product from the market and encouraging surgeons to use alternative, readily available anchors in the DePuy Mitek portfolio. Please refer to the included "Dear Doctor" letter which should be provided to Orthopaedic physicians within your facility.

This recall includes all SPIRALOK Anchor product codes as follows: **222960, 222961, 222962, 222963, 222964, 222965, 222966, 222967, 222968, 222969, 222970, 222971, 222985, 222986, 222987 and 222988**.

Our records indicate that you are the recipient of one or more of the product codes affected by this recall. We request that you immediately check all inventories to determine if you have any affected product.

Please refer to the attached instructions to report your inventory status and for returning recalled product. This recall applies only to SPIRALOK Anchor product codes. **Please do not return other products in response to this recall. We cannot ship back or provide credit for any returned product that is not part of the recalled product codes.**

At DePuy Mitek, we are dedicated to delivering products that meet the highest quality standards. We regret the need to undertake this voluntary recall. Your DePuy Mitek Representative will support you during the recall process and will work to provide alternative product codes to the best of our ability within current inventory levels.

If you have any questions, or concerns with regard to this recall, please contact your local DePuy Mitek Representative. We apologize for any inconvenience this recall may cause. Thank you for your cooperation and your patience.

Sincerely,

George Cakounes
WW Quality Manager

Instructions for Reporting your Inventory Status, Returning Product, and Obtaining Replacement Product.

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

Products affected include all SPIRALOK Anchor codes: 222960, 222961, 222962, 222963, 222964, 222965, 222966, 222967, 222968, 222969, 222970, 222971, 222985, 222986, 222987 and 222988.

Please complete the following 2 steps:

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

2. New orders are needed to obtain replacement product. 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
EDC Quality 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.