DePuy Mitek
325 Paramount Drive
Raynham, MA 02767

January 27, 2012

Urgent Voluntary Product Recall
Lupine – 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 voluntary recall of **specific lots** of LUPINE Suture Anchors. This voluntary recall is being initiated because of a manufacturing assembly issue. There is a potential that the identified lots may be assembled with an incorrect suture configuration. If the incorrect suture configuration goes undetected it could result in a loose repair.

The products affected are all lot numbers lower than 3571653 of lupine product codes: 210704, 210705, 210707, 210708, 210709, 210710, 210711, 210712, 222980, and 222981.

Our records indicate that you are the recipient of one or more of the lots affected by this recall. We request that you immediately check all inventories to determine if you have any affected product. If you have any questions about the lot numbers in your possession please refer to Attachment A List of International Affected Products for a detailed list of affected product codes and lot numbers. Attachment B is being provided as an example of product labeling to help identify where to find the product code and lot number information of the product labeling. Attachment C is being provided to show pictorial examples of the correct suture configuration for your reference.

Please refer to the instructions below to report your inventory status, return and obtain replacement product. This recall applies only to those products identified in Attachment A. Please do not return other products in response to this recall.

At DePuy Mitek, we are dedicated to delivering products that meet the highest quality standards. We regret the need to undertake this voluntary recall and we are committed to resolving this issue and restoring available inventory to meet your needs. In the interim, 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 or Johnson & Johnson Healthcare Systems directly at 1-877-379-4871. We apologize for any inconvenience this recall may cause. Thank you for your cooperation and your patience.

Sincerely,
James Kenney
Quality Assurance 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 product(s) meeting some of the lot numbers below.
Please do not use or sell any of the identified recalled products included in this recall.

Refer to the attached list of affected lots to identify affected product.

Please complete the following 2 steps:

1. Please complete the **International Affiliate 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 and include a copy of this form with any product being returned.

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 also fax the completed business reply form to 1-508-828-3750.