



Dr. A. Winter, 24.03.2009
Tel.: 040/52 97-5076
Fax.: 040/52 97-5808

To:
see E-Mail Distribution List

Urgent Field Safety Notice
Product: Ultrapro™ Mesh
Action: Product Return

Dear Sirs,

please be informed that we are conducting a voluntary Field Safety Corrective Action for one lot of Ultrapro™ Mesh, a device used in the repair of hernias or other abdominal fascial defects.

Product Code	Lot Nummer
UMM3	AL9DQSB0

NOTE: ULTRAPRO™ MESH PRODUCT CODES AND LOT NUMBERS NOT LISTED ARE NOT AFFECTED AND SHOULD NOT BE RETURNED.

We are taking this action because the above mentioned lot was intended for the United States market, but has been distributed to EU countries and other countries outside of the U.S. There is no difference in the actual product properties or performance of the mesh, however, the product labeling is only in the English language and it also does not contain the required CE mark. As a result, we are asking that you return the product, so we may replace it with product that is appropriately labeled for your market.

We therefore ask you

- to place the above product still in your stock under quarantine (**Physical quarantine – cage or other suitable restriction to access**)
- to check with your customers if they still have any of the the above product in their stock.
If yes: have the products sent back to you as soon as possible.

Please send the devices that you receive back to us within 30 days. Additionally please fill out the attached form (Recall Confirmation) and send a copy of the form to us via fax to the number + 49 40 5297 25461.

Please return devices to the following address:
Johnson & Johnson MEDICAL GmbH
Oststrasse 1
D-22844 Norderstedt
Germany

Please enclose a copy of the Recall Confirmation form "Affiliate Survey" with the devices.
Please send the courier tracking no. of your shipment to bbarbkne@its.jnj.com.

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Telefon: 040 / 52 97-01 . Telefax: 040 / 52 97-53 79 . E-Mail: JnJMEDICALGmbH@its.jnj.com . www.jnjgateway.com
Bank: Deutsche Bank AG (BLZ 200 700 00) Konto 096 338 0100 . IBAN DE51 2007 0000 0963 3801 00 . BIC/SWIFT: DEUTDEHH
Lieferanschrift: Johnson & Johnson MEDICAL GmbH, Robert-Koch-Straße 1, 22851 Norderstedt . Postanschrift: D-22841 Norderstedt
Sitz der Gesellschaft: Norderstedt. Amtsgericht: Kiel, Handelsregister: HRB 1045NO, WEEE-Reg.-Nr. DE 28443550
Geschäftsführer: Cornelia Groehl, Vorsitzende – Dr. Markus Fieber, Ralf Felix Gotter, Maria-Johanna Schaecher, Sonja Willems

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the affected devices have been transferred.

Contact person at Johnson & Johnson MEDICAL GmbH:
Mr Bernd Barbknecht
Quality Systems
bbarbkne@its.jnj.com
Telephone: +49 40 5297 5461

The undersigned confirms that this notice has been notified to the appropriate European Regulatory Agency.

Kind regards
Johnson & Johnson MEDICAL GmbH



Dr. 
Quality Systems