

TELEFAX

Attention: To the Managing Director and to the
Quality Assurance Manager

Company: Zimmer

Fax:

From: Dr. Marek Spalinger

Date: 12. July 2005

Zimmer GmbH

Sulzer Allee 8 / P.O. Box
CH-8404 Winterthur, Switzerland

Phone +41-(0)52 262 7209
Fax +41-(0)52 244 3419

URGENT FIELD NOTICE: IMMEDIATE ACTION REQUIRED

**Product Recall: Revitan Straight/Curved Disassembly Sleeve;
REF # 01.00409.814; LOT #: 05.160746**

Ladies and Gentlemen

Effective immediately, the above referenced product may not be used.

Sleeve may fracture or deform during revision surgery of a Revitan Straight/Curved stem and prevent standard disassembly of the implanted components.

In order to avoid further usage of the product in question, we kindly ask you to freeze your own stock and to immediately send a representative to recollect all stock at the recipient(s) warehouse (including end-customers such as hospitals consignment stock, loan sets and so on) and return them immediately but not later than 29. July 2005 under separate cover and labelled with "QUARANTINE, DO NOT USE" to:

Zimmer GmbH
Att. Mr Marco Schmid
Altgasse 44
CH-6341 Baar, Switzerland

Please confirm immediate recollection by fax as soon as possible.


The number of products you received can be seen on the „Delivery List“ we will send you by separate mail. If you can return all recalled products, no further action must be taken.

If you can not return all recalled products, please inform in writing by the same date the Product Surveillance Manager, Dr. Marek Spalinger, about the reason therefore and the present location of the product.

For an immediate replacement with the new *Disassembly Sleeve* 01.00409.816 please contact your Export Assistant in Baar. Please note that together with the new *Disassembly Sleeve* 01.00409.816 also the special *Setting Device for Disassembly Sleeve* 01.00409.815 has to be ordered.

We would like to apologise for any inconvenience caused by this product recall. Please do not hesitate to call us if you have any questions or concerns.

Yours faithfully



Dominique Gallusser
Brand Manager



Dr. M. Spalinger
Manager Product Surveillance

Cc: P. Bachmann, M. Schmid
Disposition, Product Group Director, Product Manager

Urgent_Field_Notice Revitan Sleeve.doc - 12.07.05
Form AAU Q.462, Rev. 5

marek.spalinger@zimmer.com