Zimmer GmbH
P.O. Box
CH-8404 Winterthur
Phone +41 (0)52 262 60 70
Fax +41 (0)52 262 03 64
www.zimmer.com

Urgent Field Safety Notice

Product Name: Patient Labels for Zimmer Products manufactured prior to March 2010

FSCA-identifier: FA-2012-01

Type of action: Notification

Date: 6 August 2012

Attention: Trust Chief Executives; Clinical Director Orthopaedic Department; Orthopaedic Theatre; Manager; Safety Liaison Officer; General Manager (Private Sector)

Type of Device: Orthopaedic Implants manufactured by Zimmer GmbH, Winterthur (Switzerland) prior to March 2010

Notification:

Zimmer GmbH is initiating this Field Safety Corrective Action to inform customers with consignment to **check patient labels** against product labels during the surgery, for products manufactured by the Zimmer GmbH production site in Winterthur (Switzerland), before March 2010.

Figure 1, presented below, provides an example of a representative product label which indicates the Zimmer GmbH production site, following the "dark" production plant symbol, and also indicates the production date, following the "white" production plant symbol.

In rare cases, product information on the patient label, with respect to REF number/ LOT number might not coincide with the corresponding information on the product label.

While the information printed on the product label is always correct, the information on the patient label (in rare cases) may be wrong. Please note that, although it is unlikely that lots in your consignment delivered to you with manufacturing date prior to March 2010 are affected, we are issuing this letter as preventative information.

Zimmer GmbH
P.O. Box
CH-8404 Winterthur
Phone +41 (0)52 262 60 70
Fax +41 (0)52 262 03 64
www.zimmer.com

Figure 1: Example of a representative product label providing (1) is the manufacturing date ("white" production plant symbol), and (2) the manufacturing site ("dark" production plant symbol)

Although the identified issue has been corrected at Zimmer GmbH, Winterthur, for products manufactured after March 2010, Zimmer recommends, as a general practice, **to always check the patient label by comparing its information** to the product label at the time of the surgery (please see figure 2).

Figure 2: Example of the product label (left) and patient label (right)

Zimmer GmbH Winterthur has checked remaining inventories of the concerned products on stock at Zimmer. Therefore, future product deliveries from Zimmer from these products should no longer contain any discrepancies

Action to be taken:

Our records indicate that your hospital currently has products from affected lots in its consignment inventories. Therefore we kindly request that you read this letter and make sure personnel involved in surgery and patient file administration are informed accordingly.

Zimmer GmbH
P.O. Box
CH-8404 Winterthur
Phone +41 (0)52 262 60 70
Fax +41 (0)52 262 03 64
www.zimmer.com

As stated above, we ask you to **check the patient label by comparing its information** to the product label during the surgery.

However if the patient label should not match with the product label, we kindly ask you to follow these instructions:

(1) Use whatever your institutional protocol is to **manually** record patient information using the correct information contained on the outer box label;
(2) **Report** the error to Zimmer.

Distribution of this Field Safety Notice:

This notice needs to be distributed to all personnel within your organisation who need to be aware, or to any organisation where the potentially affected devices have been transferred to.

Contact reference person (or local contact person):

Anne-Catherine Morancy Meister
Sr. Postmarket Surveillance Engineer
Zimmer GmbH
Sulzer Allée
8404 Winterthur
Switzerland
Tel : +41 52 262 72 45

anne.morancy@zimmer.com

This notice has been notified to the appropriate Regulatory Agencies.

John Bremmers
Director Regulatory Affairs& PMS

Winterthur, 6 August 2012