



zimmer

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Customer information on:

Innex® CR Femoral cemented, size S+, R
Reference number 01.02001.002, Lot 2409757

Innex® CR Femoral cemented, size S+, L
Reference number 01.02001.008, Lot 2412426

To whom it may concern:

We inform you that Zimmer initiated a recall on the above referenced implant on 2008-02-27 for the two above referred item numbers and lots, due to a potential laser marking error and mix-up of 2 site of products. Based on the product experience report a surgeon found the Innex® CR Femoral cemented (REF; 01.02001.002) implant which had the wrong site marked. The left Innex® CR femoral, cemented implant had a marker "Right".

Outcome 1 – Correct Product: There is no added risk to the patient if the correct device is contained in the package.

Outcome 2 – Discrepant Product Discovered with Identical Replacement: When an improperly laser-marked device is discovered in surgery and another correctly packaged implant of the same item number is available, there is no added risk to the patient. A slight delay in surgery time may occur.

Outcome 3 – Discrepant Product Discovered, No Identical Replacement: If the discrepancy is discovered in surgery and no identical replacement device is available, the surgeon would be forced to change the type of the implant. Instead of the cemented version, the surgeon has also decided to use the cementless version.

Outcome 4 – Discrepant Product Discovered, No Identical Replacement: If the discrepancy is discovered in surgery and no identical replacement device is available, no implants can be used and femoral spacer has to be implanted instead of original femoral implant. Revision to be made after original implant is available.


Outcome 5 – Discrepant Product and Undiscovered: Revision to be made on each individual case upon surgeon medical judgment.

We want to reassure you that the manufacturer, Zimmer GmbH, is in the process of identifying and implementing changes to their packaging process in order to prevent similar types of mix-ups in the future. Any remaining stock units of the affected lots were quarantined following discovery.

I would like to thank you for your co-operation in advance and regret any inconveniences caused by this recall. Should you require any further information, please do not hesitate to contact me on patrick.tarnutzer@zimmer.com or by phone +41 79 743 10 86

Yours faithfully

Zimmer GmbH


Patrick Tarnutzer
Manager Product Surveillance