



رقم المحفوظات: ٣٨١٤٥
رقم الصادر: ١٣/١٤٤٦
بيروت، في: ٢٦ نيسان ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Joint prosthesis, hip, acetabular cup, Zimmer Trilogy
acetabular system shells

الجهاز المعنى بالمتابعة:

- Joint prosthesis, hip, acetabular cup, Zimmer Trilogy acetabular system shells.
- Trade Mark: Zimmer Inc
- Local Representative: Intermedic S.A.L

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

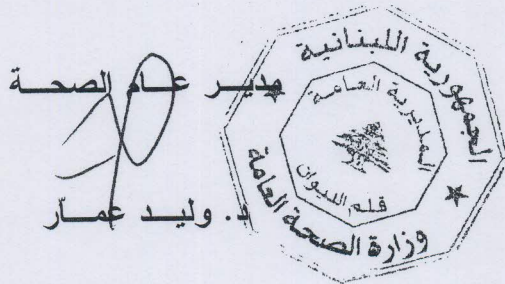
والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في استعمال الصنف الوارد
أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



Subject:

URGENT MEDICAL DEVICE NOTIFICATION

Affected Product: Zimmer Trilogy® Acetabular System Shells

Pore size and pore volume are two key characteristics of implant coatings. An internal inspection of Trilogy shells reveals 100% of the shells inspected meet the specification for pore size. The same inspection revealed that an estimated 97% met the specification for pore volume, while an estimated 3% were slightly below the lower range of the specification (as low as 28% vs. 30% porosity specification).

It is important to note that reported literature^{1,2} indicates a more direct correlation between pore size than pore volume in facilitating bone in-growth, and that 100% meet this specification. This correlation is further substantiated by the clinical success of the Trilogy shell that is documented in external registries such as the Australian Orthopaedic Association National Joint Replacement Registry, which indicates in the 2011 Annual Report³ that the Trilogy shell is among the least revised shells compared to all brands and manufacturers.

Validation of the diffusion bonding process for the Trilogy shell has been completed and provides assurance that the current process is resulting in product that conforms to the minimum acceptable porosity.

Risks:

A potential risk associated with low porosity is loosening due to lack of sufficient bone in-growth.

When adjunct fixation is not used, the risk for shell loosening may be increased. Zimmer's evaluation of peer reviewed literature, external joint registries and customer reported complaint data indicates that a shell with a porosity 2% below the specification is unlikely to pose an elevated risk.

Your Responsibilities:

Please keep this notification in mind if you have patient (s) that present with unexplained pain after ruling out other causes or if you observe shell radiolucency during routine patient follow-up.

If after reviewing this notification you have further questions , please contact your local Zimmer representative.

Other Information:

This voluntary notification will be reported to the U.S. Food and Drug Administration and local Competent Authority.

Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product.

Vigilance Reporting: Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 7 to the local health authority in your country.

Sincere regards

Jaime Weeks

Post Market Surveillance & Regulatory Compliance Associate Director



zimmer

References:

1. Itala, A I., H O. Ylanen, C Ekholm, K H. Karlsson, and H T. Aro. "Pore Diameter of More than 100 Micron is not Requisite for Bone Ingrowth in Rabbits." *Journal of Biomedical Materials Research* 58.6 (2001): 679-683.
2. Bobyn, J D., R M. Pilliar, H U. Cameron, and G C. Weatherly. "The Optimum Pore Size for the Fixation of Porous-Surfaced Metal Implants by the Ingrowth of Bone." *Clin Orthop Relat Res* 150 July (1980): 263-270.
3. "Hip and Knee Arthroplasty Annual Report 2011." *Australian Orthopaedic Association National Joint Replacement Registry*: 11.

