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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/٤٥
رقم الصادر: ١٣/١/١٤٠٩٢
بيروت، في: ٢٤ نيسان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Prostheses, Joint, Hip, Total Extension Sleeves

الجهاز المعني بالمتابعة:

- Prostheses, Joint, Hip, Total Extension Sleeves
- Trade Mark: Biomet Inc
- Local Representative:

بناء على التوصية الصادرة عن الشركة المصنعة الذي يحذر فيه من استعمال الصنف المذكور أعلاه نظراً لاحتمال تعرضه للكسر بعد الزرع ، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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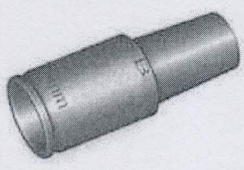
24. Oct. 2012

Urgent Field Safety Notice

To the Attention of: User, Hospital Director, Medical Device Vigilance Coordinator

Subject:

Product	Reference	Lot-N°	Photo (Example)
HYPERION EXTENSION SLEEVE 25MM	99A770.02	All	
HYPERION EXTENSION SLEEVE 30MM	99A770.03		

Dear Biomet Customer,

This Urgent Field Safety Notice is to inform you of a Field Safety Corrective Action initiated by Biomet Deutschland GmbH which involves the products listed above. Our records indicate that we have shipped affected products to your hospital. We kindly request you to locate and immediately discontinue the use of any of these products. Please provide the products directly to your Biomet sales representative or to your local Biomet Distributor.

The reason for this action:

Biomet Deutschland GmbH has initiated this action following a limited number of complaints that Hyperion Extension Sleeves (Reference 99A770.02 and 99A770.03) may fracture after implantation.

Hyperion Extension Sleeves are part of the Hyperion hip system which is a fully modular revision hip system. The Hyperion Extension Sleeves are available with a nominal length of 25mm and 30mm. The Hyperion Extension Sleeves can be used if proper fixation of the proximal component in the femur at the designated site is not possible.

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Handelsregister Berlin-Charlottenburg HRB 17818
UST-ID: DE 136 74 1947 • St-Nr. 29/007/01994 • Zoll-Nr. DE2843064

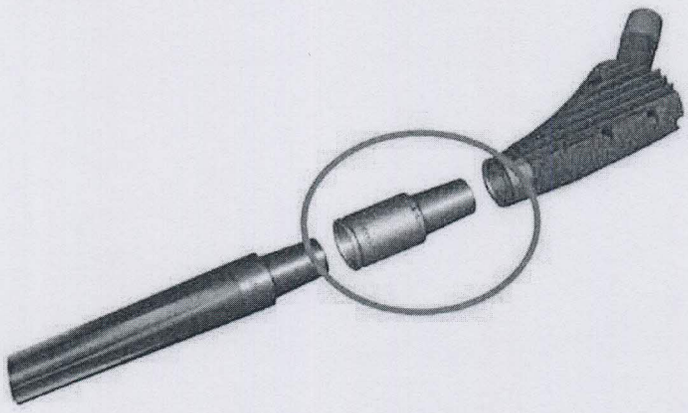

Photo 1: Extension Sleeve

An analysis of recent complaints has revealed that an increase of fractures is reported at the area of the connecting cone. The fracture rate is currently 1.24% which is below the expected re-revision rate for revision surgeries described in literature.

The clinical performance of revision systems can be affected by multiple factors. Presently, Biomet Deutschland GmbH is conducting a thorough investigation into the reported fractures. While we do not have complete patient information at this stage, there is evidence to suggest that risks such as patient obesity and off label use of extra long offset heads may have contributed to some of these fractures.

As a precautionary measure, Biomet Deutschland GmbH has decided now to initiate a voluntary recall of the Hyperion Extension Sleeves.

The related national Competent Authority has been informed about this voluntary recall.

What you should do now:

1. To assist us with this action please immediately discontinue the use of any of the products identified in this notice.
2. Locate any affected products and remove them from your inventory. Please place the affected products in a quarantine area pending return to Biomet or to your local Biomet distributor. A free of charge pick-up service will be available upon request.

3. Please pass this information on to each person in your organization that uses or orders these products. Additionally, please ensure that a copy of this letter is provided to any other organization to which the affected products may have been transferred.
4. Sign and return the enclosed "Fax-back form", and – if applicable – indicate the number of products that you expect to return. Please also sign and return the "Fax-Back form in case you don't have any of the concerned articles on stock anymore. This confirms the facts that you have received, duly read, understand and will fully comply with this notice.

We thank you for your support.

Please accept our sincere apologies for any inconvenience caused by this matter.

If you have any questions regarding this communication, please contact your Biomet local contact.

Yours sincerely
Biomet Deutschland GmbH

i.V.
[redacted]
Senior Manager QA / Regulatory Compliance Germany, Middle- and Eastern Europe