



رقم المحفوظات: ٤٨ / ٤٥

رقم الصادر: ١٤١١ / ٤٥٤٤٨

بيروت، في: ٣١ تموز ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار - بمتابعة جهاز طبي

ADM/MDM Ball Impactor Tips and ADM Rim Impactor Tips

الجهاز المعنى بالمتابعة:

- ADM/MDM Ball Impactor Tips and ADM Rim Impactor Tips
- Trade Mark: Stryker
- Local Representative: Ets.F.A Kettaneh

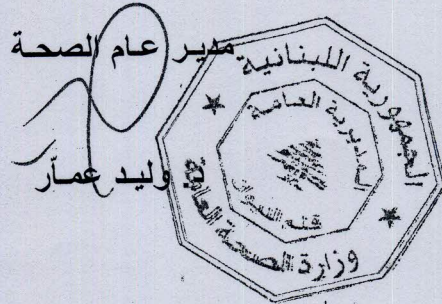
بناء على التقرير الصادر عن الوكالة الأسترالية TGA والذي يشير الى وجود خلل في عمل الصنف الوارد أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن الوكالة الأسترالية TGA

يبلغ:

- ✓ دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



Recall detail

Type of Productⁱ	Medical Device
TGA Recall Referenceⁱⁱ	RC-2013-RN-01033-1
Product Name/Descriptionⁱⁱⁱ	<p>ADM/MDM Ball Impactor Tip and ADM Rim Impactor Tip (reusable surgical instrument used to implant Stryker's Automatic Dual Mobility (ADM) and/or the Modular Dual Mobility (MDM) Acetabular Systems)</p> <p>ADM/MDM Ball Impactor Tip Catalogue Numbers: 12350013 (12350303A-T, 12350306-T, 12350306V-T, 12350306C-T)</p> <p>ADM Rim Impactor Tip Catalogue Numbers: 12350014 (12350303A-T)</p> <p>All Lot Numbers Affected</p> <p>ARTG Number: 181721</p>
Recall Action Level^{iv}	Hospital
Recall Action Classification^v	Class II
Recall Action Commencement Date^{vi}	4/10/2013
Responsible Entity^{vii}	Stryker Australia Pty Ltd
Reason / Issue^{viii}	<p>Stryker has received complaints associated with cracks and/or fractures of the Ball Impactor Tip and Rim Impactor Tip instruments. The potential hazards include;</p> <ul style="list-style-type: none"> - Cracked or fractured Ball impactor Tip/Rim Impactor Tip - Loose fragments form the Ball impactor Tip/Rim Impactor Tip - Insufficient locking strength of the MDM liner (Ball Impactor Tip only).
Recall Action^{ix}	Recall for Product Correction
Recall Action Instructions^x	Stryker is releasing updated surgical procedures and also updating the loan docketts, recommending the use of a slotted mallet to be used to impact the impactor handle, and emphasising that all tips should be inspected for deformation and cracks before use.
Contact Information^{xi}	02 9467 1111 - Stryker Orthopaedics

Footnotes

ⁱ Type of Product: Medicine, Medical Device, or Biological

ⁱⁱ TGA Recall Reference: Unique number given by the TGA

ⁱⁱⁱ Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.