



رقم المحفوظات: ١٤/١٤٢٦٩
رقم الصادر: ٢
بيروت، في: ٢٠١٣

جانب نقيب أطباء الأسنان في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Dental Implants, Bellatek Zirconia Abutments

الجهاز المعنى بالمتابعة:

- Dental Implants, Bellatek Zirconia Abutments
- Trade Mark: Biomet 3i Inc
- Local Representative: Biomedic s.a.r.l

بناء على التقرير الصادر عن الوكالة الأسترالية TGA والذي يشير الى وجود خلل في عمل

الصنف الوارد أعلاه، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين.

مرفق ربطاً:

- التقرير الصادر عن الوكالة الأسترالية TGA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2013-RN-00939-1
Product Name/Description ⁱⁱⁱ	Bellatek Zirconia Abutments Encode Zirconia Designer Abutment Product Part Numbers: EDAZ LDA Encode Designed Zirconia Abutment Product Part Numbers: EDAZX ARTG Number: 120288
Recall Action Level ^{iv}	Retail
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	9/09/2013
Responsible Entity ^{vii}	Biomet 3i Australia Pty Ltd
Reason / Issue ^{viii}	Biomet 3i has received a number of reports relating to BellaTek Zirconia Abutment fractures. The device is fracturing at a higher than acceptable rate.
Recall Action ^{ix}	Recall
Recall Action Instructions ^x	Affected customers are requested to return any BellaTek Zirconia Abutment cases to Biomet 3i for replacement with an alternative product or full credit.
Contact Information ^{xi}	1800 802 457 - Biomet 3i Customer Service

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.

^{iv} Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- Wholesale - includes wholesalers and state purchasing authorities.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale