# REPUBLIC OF LEBANON

MINISTRY OF PUBLIC HEALTH

The Director General



الحمهورية اللبن وزارة الصحة العام

المدير العام

# 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

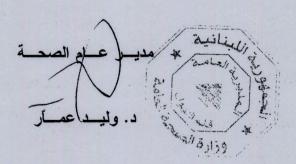
- Local Representative: Biomedic s.a.r.l

بناء على التقرير الصادر عن الوكالة الأوسترالية TGA والذي يشير الى وجود خلل في عمل الصنف الوارد أعلاه، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين.

# مرفق ريطاً:

التقرير الصادر عن الوكالة الأوسترالية TGA

- دائرة البرامج والمشاريع
  - المستشفيات الحكومية المحفوظات



### Recall detail

Type of Producti	Medical Device
TGA Recall Reference	RC-2013-RN-00939-1
Product Name/Description <sup>iii</sup>	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 <sup>iv</sup>	Retail
Recall Action Classification <sup>v</sup>	Class II
Recall Action Commencement Date <sup>vi</sup>	9/09/2013
Responsible Entity <sup>vii</sup>	Biomet 3i Australia Pty Ltd
Reason / Issueviii	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 Actionix	Recall
Recall Action Instructions <sup>x</sup>	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 <sup>xi</sup>	1800 802 457 - Biomet 3i Customer Service

## **Footnotes**

- <sup>1</sup> 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