REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧/٢٥
رقم الصادر: ١٣/١/٢٨٧١٢
بيروت، في: ٢ آذار ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Cementless Columbus knee System

الجهاز المعني بالمتابعة:

- Cementless Columbus knee System
- Trade Mark: B Braun Medical Inc
- Local Representative:

بناء على التقرير الصادر عن الوكالة الأوسترالية 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 الأوسترالية TGA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية وزارة الصحة العامة المديرية العامة

Museum Street - Hussein Mansour Blg. - Beirut, Lebanon - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2013-RN-00637-1
Product Name/Description[iii]	Cementless Columbus Knee System Multiple components ARTG Number: 96481
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class II
Recall Commencement Date[vi]	27/06/2013
Responsible Entity[vii]	B Braun Australia Pty Ltd
Reason / Issue[viii]	B. Braun is withdrawing the cementless version of the Columbus Knee System from the Australian Register of Therapeutic Goods (ARTG) and is issuing a hazard alert to implanting surgeons. The decision to withdraw the cementless version of the Columbus Knee System was based on an analysis of data collected by the Australian National Joint Replacement Registry (NJRR), which revealed that the cementless Columbus Knee System had a higher than acceptable revision rate. The cumulative revision rate (including all 33 revisions) for the cementless Columbus Knee System is 2.7% (95% CI: 1.6, 4.6) at one year from the time of implantation, 6.9% (95% CI: 4.8, 9.7) at three years, and 7.5% (95% CI: 5.3, 10.5) at five years, respectively, which is higher compared to all other total knee replacements with a cumulative revision rate of 1.0% (95% CI: 1.0, 1.0) at one year from the time of implantation, 2.7% (95% CI: 2.7, 2.8) at three years, and 3.6% (95% CI: 3.6, 3.7) at five years.
Recall Action[ix]	Hazard Alert
Recall Action Instructions[x]	Given the nature of the problem, orthopaedic surgeons are advised that there is no need to contact patients who have received an cementless Columbus Knee System additionally in addition to regular examinations; however, it is recommended that implanting surgeons conduct regular clinical and radiological examinations on those patients, in accordance with routine patient post-arthroplasty care, and advise them of this issue at that stage. For more details, please see http://www.tga.gov.au/safety/alerts-device-columbus-knee-system-130709.htm
Contact Information[xi]	02 9629 0200 - B Braun Australia

Footnotes

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

[ii] TGA Recall Reference: Unique number given by the TGA

The TGA publishes Australian recall actions in a searchable database to ensure the public has access to information about therapeutic products that have been recalled from the Australian market. If you are concerned about your health or if you have experienced an adverse event please seek advice from a health professional as soon as possible. Please read all the important information at the beginning of this report.

[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 and hospital as appropriate.
- Consumer - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] Recall Action Classification: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- Class I recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk to health.
- Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not Class I.
- Class III recall action occurs when the product deficiency may not pose a significant hazard to health, but action may be initiated for other reasons eg. quality related issues.

[vi] Recall Commencement Date: The date the recall strategy and communication was agreed by the TGA.

[vii] Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

[viii] Reason / Issue: Reason for the recall action.

[ix] Recall Action: Recall action is an action taken to resolve a problem with a therapeutic good already supplied in the market for which there are issues or deficiencies in relation to safety, quality, efficacy (performance) or presentation. There are three distinct recall actions - recall, recall for product correction and hazard alert.

- Recall - The permanent removal of an affected therapeutic good from supply or use in the market.
- Recall for product correction - Repair, modification, adjustment or re-labelling of a therapeutic good. The corrective action may take place at the user's premises or any other agreed location.
- Hazard alert - Information issued to healthcare professionals about issues or deficiencies relating to an implanted medical device or biological product and advice about the ongoing management of patients.

[x] Recall Action Instructions: What the customer should do.

[xi] Contact Information: Who the customer should contact for additional information and clarification regarding the recall action.

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