REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٥ / م ع
رقم االصادر : ١٣/١/٢٥٩٤٢
بيـــروت، في : ٥ - آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

<u>الموضوع:</u> إشعار بمتابعة جهاز طبي مغروس

Implants, Active, Infusion Pumps Programmable Pump. Medstream 20ml and 40ml reservoir Infusion Pumps

<u>الجهاز المعني بالمتابعة:</u>
- Implants, Active, Infusion Pumps Programmable Pump. Medstream 20ml and 40ml reservoir Infusion Pumps. - Trade Mark: Codman Johnson & Johnson - Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الـوارد أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة علـى جميـع المستشـفيات المعنية.

<u>مرفق ربطاً:</u>

- التوصية الصادرة عن الشركة المصنعة

<u>يبلغ:</u>

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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CODMAN NEURO

DePuy Synthes

Companies of Johnson & Johnson

Field Safety Notice:
MedStream™ Programmable Infusion System

June 10, 2013

Dear Healthcare Professional,

This letter provides important safety information and patient management recommendations related to a small number of MedStream pumps that may have a miscalibrated Fill Level Sensor (FLS). *Codman Neuro* is notifying all physicians managing patients who have a MedStream pump to assist in identification and management of affected devices. Further, Codman is recalling all non-implanted pumps.

Devices Potentially Affected

All serial numbers distributed to-date with product codes 91-4200 (20 ml pump) and 91-4201 (40 ml pump) are potentially affected. Product supply will be unavailable while we work to resolve this issue.

Description of the Device Issue

The FLS is a feature of the MedStream pump that measures the drug volume remaining in the pump reservoir and reports this value via the MedStream Control Unit (Programmer). The drug volume measurement is used to calculate a recommended refill date based on the average daily flow rate of the pump.

In some instances, the FLS calibration may have been altered during the sterilization process. A miscalibrated FLS may under or over report the drug volume remaining in the pump. This error may have the following impact on the pump's function:

- The pump's low reservoir alarm, normally set to sound at 3mL, may sound too late or too early.
- The recommended pump refill date computed by the Control Unit will be incorrect.

Potential Clinical Impact

The clinical manifestations of a pump with a miscalibrated FLS may include:

- A clinically significant drug underdose if the pump reservoir runs empty.
- A return of underlying symptoms and/or withdrawal symptoms may occur if the volume in the pump is incorrectly reported AND the physician responds by altering dosage levels.

For underdose signs and symptoms, please refer to the drug labeling.

Prevalence of the Issue

Based upon reported complaints, approximately 1% of implanted MedStream pumps may have been affected by this issue. There have not been any reports of corresponding deaths or permanent patient injuries.

Action Required

1. **Fill out the attached Acknowledgement Form and return to Codman.** This is needed even if you do not have any pumps to return. ***If you do have pumps to return***, contact your local Codman representative for assistance and detailed instructions.

2. **Identify Pumps with a Miscalibrated FLS.** Follow the recommendations in the enclosed document, "Worksheet to Identify Pumps with a Miscalibrated FLS," during each patient's next scheduled refill session, or sooner if the patient is symptomatic.

3. **If a pump is identified as having a miscalibrated FLS, notify *Codman Neuro* using the same worksheet.**

4. **Please follow the recommendations below for managing patients who are identified as having a pump with a miscalibrated FLS .** (No further action is needed for patients who have pumps that are not affected.)

    a. Pump refill dates will need to be calculated manually at *every* refill appointment. For assistance with this process, contact your *Codman Neuro* representative.

    b. Explain to your patient that their pump's drug volume sensor is miscalibrated, which will affect the low reservoir alarm and the computed refill date. However, the pump is still delivering medication accurately and other pump functions are normal. A sample letter to assist in notifying patients is enclosed for your use.

    c. Continue to educate patients and caregivers about the signs and symptoms of drug underdose and withdrawal. Instruct patients to seek immediate medical assistance if signs or symptoms of drug underdose or withdrawal appear.

Additional Resources

For additional information, please contact your *Codman Neuro* representative, or contact *Codman Neuro* Clinical Support at <*affiliate contact information*>. Please report any malfunction or adverse event related to this device to *Codman Neuro* to <*affiliate contact information*>.

Patient safety is the highest priority for *Codman Neuro*. We are committed to addressing your questions. We appreciate your assistance with this matter and regret any inconvenience this may cause for you or your patients.

Sincerely,

J. Thomas Megerian MD, PhD
Vice President - Strategic Medical Affairs and Medical Sciences

Enclosures:
- Worksheet to Identify Pumps with a Miscalibrated FLS
- Sample Patient Letter
-Acknowledgement Form