RÉPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
Le Directeur Général

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨١/٢٥
رقم الصادر: ١٣/٧٥٥٨
بيروت، في: ٥ - كانون الثاني ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي Infusion Pump,

الجهاز المعني بالمتابعة:

- Infusion Pump, WOLFPAK, Medrop, Vipat
- Trade Mark: First Medical Source LLC
- Local Representative:

بناء على التقرير الصادر عن وكالة الـ fda،

الذي يفيد بوجود خلل في عمل الصنف المذكور أعلاه، قد يؤدي الى مضاعفات على المريض،

نرجو منكم تعميم هذه النشرة على جميع المستشفيات.

مرفق ربطاً:

- التوصية الصادرة عن وكالة الـ fda.

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

المدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
وزارة الصحة العامة
المديرية العامة للشؤون

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U.S. Food & Drug Administration

Enforcement Report - Week of December 5, 2012

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Product Detail

Product Description	Medpro Elastomeric Infusion Pump. AccuFlux, Model # CT-0020-100H. Product Usage: The devices are intended for patients requiring intravenous, percutaneous, subcutaneous, intra-operative sites or epidural administration of medications. It is the responsibility of the user to ensure that the medication is prepared and administered accordance with the drug manufacturers package insert. The devices deliver controlled amounts of medication directly to the intraoperative site for pain management and or antibiotic administration. The devices infuse the medication at an hourly flow rate. Medications are infused intraoperatively and postoperatively through intramuscular or subcutaneous routes. The devices are also intended for controlled delivery of local anesthetics in close proximity to nerves for post operative regional anesthesia and pain management. Routes of administration may be intraoperative or percutaneous. It is for continuous infusion of medications for general infusion use, including antibiotic delivery and chemotherapy.
Recall Number	Z-0161-2013
Classification	Class I
Code Info	AccuFlux, Lot#: 91209.
Product Distributed Qty	500 units
Reason For Recall	Please be aware that this is not a new recall. The firm has taken action; but, due to administrative issues this recall is now being reclassified by the Agency as a Class I. The recall was initiated because First Medical Source has confirmed that these lots may have a higher flow rate than specified. The use of this product may lead to over-administration of drug solutions to the patients. The product may fail to meet nominal flow rate of ±15%.

Event Detail

Event Id	60030
Product Type	Devices
Status	Terminated
Recalling Firm	First Medical Source LLC
City	Laguna Beach
State	CA
Country	US
Voluntary / Mandated	Voluntary: Firm Initiated
Recall Initiation Date	2011-07-09
Initial Firm Notification of Consignee or Public	E-Mail
Distribution Pattern	US Nationwide distribution in the state of IL

U.S. Food and Drug Administration
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