REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧/٢٥
رقم الصادر: ١٢/١/٢٢٢٥٩
بيروت، في: ٣ تشرين الأول ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Flush syringe, Monoject

الجهاز المعني بالمتابعة:

- Flush syringe, Monoject
- Trade Mark: Covidien LLC
- Local Representative: Dima Health Care/ Mediline

بناء على التقرير الصادر عن وكالة ال FDA
والذي يشير الى وجود خطأ في محتوى الملصق للصنف المذكور أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
وزارة الصحة العامة

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

Safety

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Covidien Initiates a Voluntary Recall of Certain Lots of Monoject™ Prefill Flush Syringes Sold in the United States and Bermuda

Contact
Consumer:
1-800-962-9888 option 1, then option 2

Media:
Lisa Clemence
508-452-4375

FOR IMMEDIATE RELEASE - August 19, 2013 - Mansfield, MA – Covidien today announced that it has initiated a voluntary recall of certain lots of Monoject™ prefill flush syringes.

Reasons for Recall: This recall is being conducted due to the risk that a number of the syringes were filled with water but not subjected to the autoclave sterilization process. These products are labeled as either sodium chloride flush or heparin lock flush. Some of these syringes have the mismatched syringe tip cap, syringe label, filled volume and wrapper. However, for the sodium chloride flush syringes with matched tip cap, syringe label, filled volume and wrapper, there are no visual cues for the clinician to identify the problematic products.

Risk to Health: If non-sterile fluid is administered there is a health risk of life-threatening infection to the blood stream or other areas. Also if the clinician uses the heparin lock flush syringe containing only water on peripheral or venous catheters, the patency of the intravascular device may not be maintained and clotting may occur. This could result in non-functional intravenous access requiring the device to be replaced.

Affected lots:

Product ID	Description	Lot #
8881570121	Monoject™ 0.9% Sodium Chloride Flush Syringe, 12 mL Syringe with 10 mL Fill	13A0084N 13A0094 13B0364 13C0504 13C0514
8881570123	Monoject™ 0.9% Sodium Chloride Flush Syringe, 12 mL Syringe with 3 mL Fill	13A0084N
8881570125	Monoject™ 0.9% Sodium Chloride Flush Syringe, 12 mL Syringe with 5 mL Fill	13A0084N
8881580121	Monoject™ 10 Units/mL Heparin Lock Flush, 12 mL Syringe with 10 mL Fill	13A0084N
8881580123	Monoject™ 10 Units/mL Heparin Lock Flush, 12 mL Syringe with 3 mL Fill	13A0084N
8881580125	Monoject™ 10 Units/mL Heparin Lock Flush, 12 mL Syringe with 5 mL Fill	13A0084N
8881590121	Monoject™ 100 Units/mL Heparin Lock Flush, 12 mL Syringe with 10 mL Fill	13A0084N
8881590123	Monoject™ 100 Units/mL Heparin Lock Flush, 12 mL Syringe with 3 mL Fill	13A0084N

8881590125	Monoject™ 100 Units/mL Heparin Lock Flush, 12 mL Syringe with 5 mL Fill	13A0084N 13D0824N

Only Monoject™ prefill flush syringes from the lot numbers listed above are affected by this action. The lot numbers can be found on the shipper case, carton and individual syringes. Customers are required to identify, segregate and return any affected products in their inventory.

Customers have been notified of this issue by letter dated August 16, 2013. To return the affected product for credit, please contact our Customer Service group at 1-800-962-9888, option 1, then option 2, and request a Return Goods Authorization Number (RGA).

Healthcare professionals and customers may report adverse events or quality problems experienced with the use of this product to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, by fax or by phone.

- **Online:** http://www.fda.gov/MedWatch/report.htm[1]
- **Regular Mail:** use postage-paid FDA form 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[2]. Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- **Fax:** 1-800-332-0178
- **Phone:** 1-800-332-1088

Contacts:

Jacqueline Strayer
Senior Vice President
Corporate Communications
508-261-8305
jacqueline.strayer@covidien.com

Coleman Lannum, CFA
Vice President
Investor Relations
508-452-4343
cole.lannum@covidien.com

Lisa Clemence Director
Corporate Communications
508-452-4375
lisa.clemence@covidien.com

Todd Carpenter
Senior Director
Investor Relations
508-452-4363
todd.carpenter@covidien.com

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Photo: Product Labels[5]

Recalled Product Photos Are Also Available on FDA's Flickr Photostream.[6]

Page Last Updated: 08/26/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

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