RÉPUBLIQUE LIBANAISE
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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٤/٢/٢٥
رقم الصادر: ١٢/١/٥٥٢٢٢
بيروت، في: ٣٠ تموز ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
GemStar Pump- Single channel infusion device

الجهاز المعني بالمتابعة:

- GemStar Pump- Single channel infusion device
- Trade Mark: Hospira Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA
والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الوارد 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
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Medical & Radiation Emitting Device Recalls

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Class 1 Recall
GemStar Infusion System

See Related Information[20]

Date Posted	April 30, 2013
Recall Number	Z-1169-2013
Product	The GemStar Pump is a small and lightweight, single channel infusion device designed for use in the home, in the hospital, or anywhere electronic infusion is required. The GemStar Pump can be powered by AC mains adaptor, rechargeable battery pack, docking station, or two disposable AA alkaline batteries. When powered by batteries, The GemStar Pump is ideal for ambulatory patients. The GemStar Pump is a small and lightweight, single channel infusion device designed for use in the home, in the hospital, or anywhere electronic infusion is required.
Code Information	List Numbers: 13000, 13100, 13150
Recalling Firm/ Manufacturer	Hospira Inc. 275 N Field Dr Lake Forest, Illinois 60045-2579
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Mr. Chris Eustace 224-212-4892
Reason for Recall	Pump shutting off during use without warning.
Action	Hospira sent an Important Device Information letter dated March 18, 2013, to all affected customer. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to inspect the affected product for signs of leakage, corrosion or other damage prior to each use. In addition, each time the batteries are replaced the battery compartment should be inspected for damage. If a device exhibits damage caused by leakage, it should immediately be removed from clinical service and Hospira should be contacted at 1-800-441-4100 to arrange for return of the device for repair. If the product has been further distributed they should notify their consignees and confirm they have done so by returning the reply form to Stericycle. For questions regarding this recall call 224-212-4892.
Quantity in Commerce	List Number 13000: 25,119 pumps; List Number 13100: 185 pumps; List Number 13150: 13,497 pumps
Distribution	Worldwide Distribution - USA (nationwide) and internationally to Australia, New Zealand, China, Hong Kong, Taiwan, Japan, Korea, Philippines, Thailand, Malaysia, Canada, Austria, Bahrain, Belgium, Croatia, Denmark, Egypt, Finland, France, Germany, Gibraltar, Greece, Hungary, Iceland, Ireland, Israel, Italy, Jordan, Kuwait, Lebanon, Libya, Luxembourg, Malta, Netherlands, Norway, Oman, Portugal, Qatar, Romania, Saudi Arabia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, UK, United Arab Emirates, Brazil, Chile and Colombia.

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Medical & Radiation Emitting Device Recalls

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See Related Information[20]

Class 1 Recall
GemStar Infusion System

Date Posted	April 30, 2013
Recall Number	Z-1170-2013
Product	The GemStar Pump is a small and lightweight, single channel infusion device designed for use in the home, in the hospital, or anywhere electronic infusion is required. The GemStar Pump can be powered by AC mains adaptor, rechargeable battery pack, docking station, or two disposable AA alkaline batteries. When powered by batteries, The GemStar Pump is ideal for ambulatory patients. The GemStar Pump is a small and lightweight, single channel infusion device designed for use in the home, in the hospital, or anywhere electronic infusion is required.
Code Information	List Numbers: 13086, 13087, 13088
Recalling Firm/ Manufacturer	Hospira Inc. 275 N Field Dr Lake Forest, Illinois 60045-2579
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Mr. Chris Eustace 224-212-4892
Reason for Recall	Pump shutting off during use without warning.
Action	Hospira sent an Important Device Information letter dated March 18, 2013, to all affected customer. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to inspect the affected product for signs of leakage, corrosion or other damage prior to each use. In addition, each time the batteries are replaced the battery compartment should be inspected for damage. If a device exhibits damage caused by leakage, it should immediately be removed from clinical service and Hospira should be contacted at 1-800-441-4100 to arrange for return of the device for repair. If the product has been further distributed they should notify their consignees and confirm they have done so by returning the reply form to Stericycle. For questions regarding this recall call 224-212-4892.
Quantity in Commerce	List Number 13086: 286 pumps; List Number 13087: 45,376 pumps; List Number 13088: 23,942 pumps
Distribution	Worldwide Distribution - USA (nationwide) and internationally to Australia, New Zealand, China, Hong Kong, Taiwan, Japan, Korea, Philippines, Thailand, Malaysia, Canada, Austria, Bahrain, Belgium, Croatia, Denmark, Egypt, Finland, France, Germany, Gibraltar, Greece, Hungary, Iceland, Ireland, Israel, Italy, Jordan, Kuwait, Lebanon, Libya, Luxembourg, Malta, Netherlands, Norway, Oman, Portugal, Qatar, Romania, Saudi Arabia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, UK, United Arab Emirates, Brazil, Chile and Colombia.

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