REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧١٥
رقم الصادر: ١٢/١/٢٨٧٠٦
بيروت، في: ٢ - ايار ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Prostheses, Gastroesophageal, Antireflux, EsophyX2

الجهاز المعني بالمتابعة:

- Prostheses, Gastroesophageal, Antireflux, EsophyX2
- Trade Mark: Endogastric Solutions Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA ،

الذي يشير الى وجود خلل في عمل الجهاز المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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Medical & Radiation Emitting Device Recalls

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Class 2 Recall
EndoGastric Solutions EsophyX2 Device

See Related Information[21]

Date Posted	August 17, 2013
Recall Number	Z-1982-2013
Product	EndoGastric Solutions EsophyX2 Device with Serosa Fastener and Accessories. Models R2001 and R2002. Indicated for the treatment of symptomatic chronic gastroesophageal reflux disease.
Code Information	UN-EXPIRED devices with Expiration dates (8/31/2013, 11/30/2013, 12/31/2013, and 1/31/2014) and following LOT numbers: 401132, 401147, 401152, 401156, 401159, 401167, 401207, 401214, 401219, 401220, 401225, 401227, 401230, 401233, 401236, 401246, 401248, 401251, 401257, 401258, 401259, 401267, 401269, 401271, 401274, and 401276. EXPIRED devices with Expired dates (1/31/2013, 2/28/2013, 3/31/2013 4/30/2013, 5/31/2013, 6/30/2013, and 7/31/2013) and following LOT numbers: 400923, 400927, 400934, 400937, 400940, 400943, 400949, 400961, 400963, 400973, 400976, 400979, 400980, 400981, 400984, 400986, 400992, 400994, 400997, 400998, 401004, 401005, 401009, 401012, 401016, 401017, 401024, 401026, 401029, 401056, 401058, 401059, 401060, 401061, 401062, 401063, 401065, 401072, 401074, 401076, 401079, 401084, 401085, 401092, 401094, 401107, 401114, 401115, 401121, 401129, and 401130.
Recalling Firm/ Manufacturer	Endogastric Solutions Inc 8210 154th Ave NE Redmond, Washington 98052-3877
For Additional Information Contact	Customer Service and Support 425-307-9269
Reason for Recall	Endogastric Solutions, Inc. has received a limited number of reports relating to the loss of tissue mold control when operating the R2001 or R2002 EsophyX2 device. In one case, surgical intervention was necessary to remove the device.
Action	Endogastric sent the Safety Alert: EndoGastric Solutions (EGS), EsophyX2 Device letter, dated June 5, 2013, to their consignees. Endogastric sent the second letter URGENT: MEDICAL DEVICE RECALL EsophyX2, dated July 26, 2013. This letter advised customers that the firm is voluntarily recalling EsophyX2 Devices with SerosaFuse Implantable Fastener and Accessories (Models R2001 and R2002) manufactured before February 2012. Customers who have UN-EXPIRED devices in their inventory are advised to discontinue use and fill out the Medical Device Recall Return Response form and return it to Endogastric. The Customer Service will contact customers with instructions on how to return the product to the company. Customers who may have EXPIRED devices are advised to with their central supply departments to ensure all identified products have been removed from inventory and destroyed. They should fill out the Medical Device Recall Return Response form with the lot numbers and quantity destroyed and return the completed form to the firm. Customers can call the Customer Service and Support at 425-307-9269, Monday through Friday, 8:00AM to 5:00 PM, Pacific Time for questions. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
Quantity in Commerce	5192 units in the US and 41 units outside the US
Distribution	Distributed nationwide and Italy.

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