

REPUBLIC OF LEBANON

MINISTRY OF PUBLIC HEALTH

The Director General



الجمهورية اللبنانية

وزارة الصحة العامة

المدير العام

رقم المحفوظات: ٧١٢٥  
رقم الصادر: ١٧/١/٢٨٧.٦  
بيروت، في: ٢ - ايار ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

**الموضوع:** إشعار بمتابعة جهاز طبي مغروس

Prostheses, Gastroesophageal, Antireflux, EsophyX2

الجهاز المعنى 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

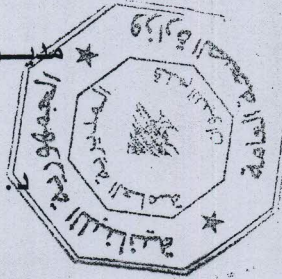
يبلغ:

- دائرة البرامج والمشاريع

- المستشفيات الحكومية

- المحفوظات

مدير عام الصحة  
وليد عمار





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**Medical & Radiation Emitting Device Recalls**

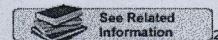


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**Class 2 Recall  
 Endogastric Solutions EsophyX2  
 Device**



<b>Date Posted</b>	August 17, 2013
<b>Recall Number</b>	Z-1982-2013
<b>Product</b>	Endogastric Solutions EsophyX2 Device with Serosa Fastener and Accessories. Models R2001 and R2002. Indicated for the treatment of symptomatic chronic gastroesophageal reflux disease.
<b>Code Information</b>	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.
<b>Recalling Firm/ Manufacturer</b>	Endogastric Solutions Inc 8210 154th Ave NE Redmond, Washington 98052-3877
<b>For Additional Information Contact</b>	Customer Service and Support 425-307-9269
<b>Reason for Recall</b>	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.
<b>Action</b>	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.
<b>Quantity in Commerce</b>	5192 units in the US and 41 units outside the US
<b>Distribution</b>	Distributed nationwide and Italy.

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