جنب نقيب المستشفيات الخاصة في لبنان

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

الجهاز المعني بالمتابعة:
- Protheses, Gastroesophageal, Antireflux, EsophyX2
- Trade Mark: Endogastric Solutions Inc
- Local Representative:

بناءً على التقرير الصادر عن وكالة FDA، الذي يشير إلى وجود خلل في عمل الجهاز المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنيه.

مرفق ربط:
FDA التقرير الصادر عن وكالة FDA
- دائرة البرامج والمشاريع المستشفيات الحكومية
- المحفوظات

مuseum Street - Hussein Mansour Bldg. - Beirut, Lebanon - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: director@gmail.com
FDA Home > Medical Devices > Database

Medical & Radiation Emitting Device Recalls

510(k) Registration & Listing > Adverse Events > Recalls > FDA News > Product Safety recalls

New Search

Class 2 Recall
EndoGastric Solutions EsophyX2 Device

Date Posted
August 17, 2013

Recall Number
Z-1982-2013

Product

Code Information
UN-EXPRIED devices with Expiration dates (8/31/2013, 11/30/2013, 12/31/2013, and 1/31/2014) and following LOT numbers: 401132, 401147, 401152, 401159, 401167, 401207, 401214, 401219, 401220, 401225, 401227, 401230, 401233, 401236, 401246, 401248, 401251, 401257, 401258, 401259, 401267, 401268, 401271, 401274, and 401276. EXPPIRED 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, 400945, 400961, 400963, 400973, 400978, 400979, 400980, 400981, 400984, 400988, 400992, 400994, 400997, 400998, 410004, 410005, 410009, 410102, 410108, 410117, 410204, 410206, 410209, 41055, 410558, 410559, 41060, 41061, 41062, 41063, 41065, 41073, 41074, 41076, 41079, 41084, 41085, 41089, 41090, 41107, 41114, 41115, 41121, 41129, and 41130.

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: 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-EXPRIED 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 EXPPIRED devices are advised to contact their central supply departments to inquire if 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 5:00PM, 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.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesafda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmm.cfm
8. /scripts/cdrh/cfdocs/cfRL/rl.cfm
9. /scripts/cdrh/cfdocs/ctMADE/TextSearch.cfm
10. /scripts/cdrh/cfdocs/cfRES/res.cfm
11. /scripts/cdrh/cfdocs/cfPMR/pma.cfm
12. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
13. /scripts/cdrh/cfdocs/cfStandards/search.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=120509
8/27/2013