جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
The ENSEAL G2 Tissue Sealers, Electrosurgical Units

الجهاز المعني بالftimea:
- The ENSEAL G2 Tissue Sealers, Electrosurgical Units
- Trade Mark: Ethicon Endo Surgery Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة ال
وتوصية الصادرة عن الشركة المصنعة والتي تشير إلى وجود خطأ في عمل الجهاز مما يؤثر
على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنيه.

مرفق ربطًا:
- التوصية الصادرة عن الشركة المصنعة
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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Medical & Radiation Emitting Device Recalls

- s3
- Medical Devices
- Databases

New Search

Class 2 Recall
ENSEAL® 5 mm Diameter Tissue Sealer G2 14 cm Length Curved Jaw,

Date Posted
March 21, 2012

Recall Number
Z-1244-2012

Product
ENSEAL® 5 mm Diameter Tissue Sealer G2 14 cm Length Curved Jaw, Model # NSL2G2C14 and ENSEAL® 5 mm Diameter Tissue Sealer G2 25 cm Length Curved Jaw, Model # NSL2G2C25. Ethicon Endo-Surgery, LLC Guaynabo, Puerto Rico 00969 The ENSEAL® G2 Tissue Sealers are indicated for bipolar coagulation and mechanical transection of tissue during laparoscopic and open procedures. The devices are bipolar electrosurgical instruments for use with an electrosurgical generator. They are intended for use during open or laparoscopic, general and gynecological surgery to cut and seal vessels, and to cut, grasp and dissect tissue during surgery. Indications for use include open and laparoscopic, general and gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc.), or any procedure where vessel ligation (cutting and sealing), tissue grasping and dissection is performed. The devices can be used on vessels up to (and including) 7 mm and bundles as large as will fit in the jaws of the instruments.

Code Information
Product Code 00NSL2G2C14, Lot # H44Y2P, Exp Date Nov-2013; Product Code 00NSL2G2C25, Lot # H44ZBV, Exp Date Nov-2013 & Lot # JAA16C, Exp Date Dec-2013

Recalling Firm/Manufacturer
Ethicon Endo-Surgery Inc
4545 Creek Rd
Cincinnati, Ohio 45242-2803

For Additional Information Contact
Thomas A. Morris
513-337-3419

Reason for Recall
Ethicon Endo-Surgery initiated a voluntary global recall for specific production lots of ENSEAL® G2 Curved and Straight Tissue Sealers due to two potential issues that may occur related to the activation button: (i) Continuous Activation: The ENSEAL® device/system may continue to activate when the activation button is released prior to reaching the end of cycle (tone 3) (ii) No Activation

Action
Ethicon Endo-Surgery sent an Urgent Medical Device Recall letter dated February 10, 2012, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to immediately stop use of the affected product, fill out the attached Business Reply Form (BRF) and return to and return the affected product to: Ethicon Endo-Surgery ATT: ENSEAL G2 Recall 4545 Creek Road Cincinnati, Ohio 45242 Customers were instructed to choose one of the following response options. Return the Business Reply Form to their sales representative. Call 1-800-873-3636, Option 6 Fax the BRF to 1-513-337-4138 For any questions regarding this recall call 513-337-3419.

Quantity in Commerce
72 pieces

Distribution
Worldwide Distribution - USA including AZ, CA, CT, FL, IL, IN, KS, KY, MA, MI, MO, NC, NY, OH, PA, TN & TX and the countries of Arab Emirates, Austria, Belgium, France, Germany, Great Britain, Italy, Jordan, Kingdom of Saudi Arabia, Lebanon, Portugal, Slovenia, Sweden and Turkey

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /cfrPMN/pmnm.cfm
8. /cfr/rl.cfm

Medical & Radiation Emitting Device Recalls

J.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

• [Link]

FDA Home Medical Devices Databases

New Search

Class 2 Recall
ENSEAL® 5 mm Diameter Tissue Sealer G2 14 cm Length Straight Jaw

Date Posted
March 21, 2012

Recall Number
Z-1246-2012

Product
ENSEAL® 5 mm Diameter Tissue Sealer G2 14 cm Length Straight Jaw, Model # NSLGS14 and ENSEAL® 5 mm Diameter Tissue Sealer G2 25 cm Length Straight Jaw, Model # NSLGS252. Ethicon Endo-Surgery, LLC, Guaynabo, Puerto Rico 00969. The ENSEAL® G2 Tissue Sealers are indicated for bipolar coagulation and mechanical transection of tissue during laparoscopic and open procedures. The devices are bipolar electrosurgical instruments for use with an electrosurgical generator. They are intended for use during open or laparoscopic, general and gynecological surgery to cut and seal vessels, and to cut, grasp and dissect tissue during surgery. Indications for use include open and laparoscopic, general and gynecological surgical procedures (including urologic, thoracic, plastic and reconstructive, bowel resections, hysterectomies, cholecystectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomies, etc.), or any procedure where vessel ligation (cutting and sealing), tissue grasping and dissection is performed. The devices can be used on vessels up to (and including) 7 mm and bundles as large as the jaws of the instruments.

Code Information
Product Code 00NSLGS14, Lot #, H4425R, Exp Date, Nov-2013; Product Code 00NSLGS2825, Lot #, H44257, Exp Date, Nov-2013 & Lot # J4A28X, Exp Date, Dec-2013

Recalling Firm/Manufacturer
Ethicon Endo-Surgery Inc
4545 Creek Rd
Cincinnati, Ohio 45242-2803

For Additional Information Contact
Thomas A. Morris
513-337-3419

Reason for Recall
Ethicon Endo-Surgery initiated a voluntary global recall for specific production lots of ENSEAL® G2 Curved and Straight Tissue Sealers due to two potential issues that may occur related to the activation button: (i) Continuous Activation: The ENSEAL® device/system may continue to activate when the activation button is released prior to reaching the end of cycle (tone 3). (ii) No Activation

Action
Ethicon Endo-Surgery sent an Urgent Medical Device Recall letter dated February 10, 2012, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to immediately stop use of the affected product, fill out the attached Business Reply Form (BWF) and return to and return the affected product to Ethicon Endo-Surgery ATT: ENSEAL G2 Recall 4545 Creek Road Cincinnati, Ohio 45242 Customers were instructed to choose one of the following response options: Return the Business Reply Form to their sales representative Call 1-800-873-3638, Option 6 Fax the BWF to 1-513-337-4138 For any questions regarding this recall call 513-337-3419.

Quantity in Commerce
84 pieces

Distribution
Worldwide Distribution - USA including AZ, CA, CT, FL, IL, IN, KS, KY, MA, MI, MO, NC, NY, OH, PA, TN & TX and the countries of Arab Emirates, Austria, Belgium, France, Germany, Great Britain, Italy, Jordan, Kingdom of Saudi Arabia, Lebanon, Portugal, Slovenia, Sweden and Turkey

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. .../fda/cfr/107793
8. .../cfrl/ri.cfm