



رقم المحفوظات: ٧/٢٠٠
رقم الصادر: ١٢/١/٢٠٢٢
بيروت، في:

٣ تموز ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

The ENSEAL G2 Tissue Sealers, Electrosurgical Units

الجهاز المعنى بالمتابعة:

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

بناء على التقرير الصادر عن وكالة ال FDA

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

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدیر عام الصحة
د. وليد عمار

FDA Home³ Medical Devices⁴ Databases⁵

Medical & Radiation Emitting Device Recalls

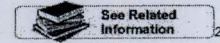


510(k)⁷ | Registration & Listing⁸ | Adverse Events⁹ | Recalls¹⁰ | PMA¹¹ | Classification¹² | Standards¹³ | Inspections¹⁴ | CFR Title 21¹⁵ | Radiation-Emitting Products¹⁶ | X-Ray Assembler¹⁷ | Medsun Reports¹⁸ | CLIA¹⁹ | TPLC²⁰

New Search

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Class 2 Recall
The ENSEAL® G2 Tissue Sealers



Date Posted January 31, 2013
Recall Number Z-0758-2013
Product Ethicon Endo-Surgery Inc. The ENSEAL® G2 Tissue Sealers are indicated for bipolar coagulation and mechanical transection of tissue during laparoscopic and open procedures. Model Numbers: NSLG2C14 NSLG2C25 NSLG2C35 NSLG2C45 NSLG2S14 NSLG2S25 NSLG2S35 NSLGS545

Code Information Product Code NSLG2C14, Lot # H44Y2P, Exp. Date 11-2013, Lot # J4AR58, Exp. Date 4-2017, Lot # J4AT3V, Exp. Date 4-2017, Lot # J4AW5A, Exp. Date 5-2017, Lot # J4AX7D, Exp. Date 5-2017, Lot # J4C34A, Exp. Date 6-2017, Lot # J4C448, Exp. Date 7-2017, Lot # J4C449, Exp. Date 7-2017, Lot # J4C85G, Exp. Date 7-2017, Lot # J4CF5Z, Exp. Date 9-2017 and Lot # J4CG31, Exp. Date 9-2017. Product Code NSLG2C25, Lot # H44Z6V, Exp. Date 11-2013, Lot # J4A16C, Exp. Date 12-2013, Lot # J4AT1P, Exp. Date 4-2017, Lot # J4AR5L, Exp. Date 4-2017, Lot # J4AU2K, Exp. Date 5-2017, Lot # J4AV17, Exp. Date 5-2017, Lot # J4AW75, Exp. Date 5-2017, Lot # J4AW76, Exp. Date 5-2017, Lot # J4AY0T, Exp. Date 5-2017, Lot # J4C09P, Exp. Date 6-2017, Lot # J4C30A, Exp. Date 6-2017, Lot # J4C34L, Exp. Date 6-2017, Lot # J4C44N, Exp. Date 7-2017, Lot # J4C928, Exp. Date 7-2017, Lot # J4C92C, Exp. Date 7-2017, Lot # J4C968, Exp. Date 8-2017, Lot # J4CA4P, Exp. Date 8-2017, Lot # J4CF0D, Exp. Date 8-2017, Lot # J4CH3W, Exp. Date 9-2017, Lot # J4CJ5Y, Exp. Date 9-2017, Lot # J4CJ99, Exp. Date 9-2017 and Lot # J4CK1H, Exp. Date 9-2017. Product Code NSLG2C35, Lot # H44V7N, Exp. Date 10-2013, Lot # H44V7M, Exp. Date 10-2013, Lot # H44V7P, Exp. Date 10-2013, Lot # H44X9M, Exp. Date 11-2013, Lot # H44X9L, Exp. Date 11-2013, Lot # H44X9R, Exp. Date 11-2013, Lot # H44Z3R, Exp. Date 11-2013, Lot # H44Z4C, Exp. Date 11-2013, Lot # H44Z54, Exp. Date 11-2013, Lot # J4A085, Exp. Date 12-2013, Lot # J4A134, Exp. Date 12-2013, Lot # J4AN7K, Exp. Date 4-2017, Lot # J4AN8E, Exp. Date 4-2017, Lot # J4AN8D, Exp. Date 4-2017, Lot # J4AP7W, Exp. Date 4-2017, Lot # J4AR5P, Exp. Date 4-2017, Lot # J4AT05, Exp. Date 4-2017, Lot # J4AT9G, Exp. Date 4-2017, Lot # J4AT9V, Exp. Date 4-2017, Lot # J4AU2Z, Exp. Date 5-2017, Lot # J4AV2R, Exp. Date 5-2017, Lot # J4AV2V, Exp. Date 5-2017, Lot # J4AV4P, Exp. Date 5-2017, Lot # J4AV4Z, Exp. Date 5-2017, Lot # J4AW3F, Exp. Date 5-2017, Lot # J4AW3N, Exp. 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| 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 | Potential for self activation while the device is in use, which may result in unintended thermal damage. |
| Action | Ethicon Endo-Surgery Inc. sent a "URGENT MEDICAL DEVICE RECALL" letter dated November 28, 2012, to all affected customers. The letter identified the the product the problem and the action needed to be taken by the customer. The customers were instructed to: 1. Examine your inventory immediately to determine if you have affected product on hand and remove the affected product(s). 2. Complete the Business Reply Form and fax it to Stericycle at 1-877-787-0367 within 3 business days, even if you do not have affected product. Please reference Event 3436. If you have product to be returned, keep a copy of this form for your records. 3.To return affected product, photocopy your completed Business Reply Form, place it in the box with your product, and affix the pre-printed UPS shipping label to return to Stericycle. Note: Returned product will be credited. Should you have any questions, please contact your local representative or call our Customer Support Center, 1-800-873-3636, Option 6. |
| Quantity in Commerce | 58,338 Instruments |
| Distribution | Worldwide Distribution - USA including the states of AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, VA, WA, WI, & WV. and the countries Arab Emirates, Australia, Belgium, Canada, Chile, China, Colombia, Cyprus, Hong Kong, Indonesia, Israel, India, South Korea, Kuwait, Malaysia, Panama, Philippines, Puerto Rico, Russia, Saudi Arabia, Singapore, Slovenia, Thailand, Turkey & Vietnam. |

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