



رقم المحفوظات: ٤٥ / ٣٨١
رقم الصادر: ١٢١١ / ٦١٧٤
بيروت، في: ١٥ شباط ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

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

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خطأ في عمل الجهاز مما يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

دائرة البرامج والمشاريع

- المستشفيات الحكومية

- المحفوظات



U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

FDA Home³ Medical Devices⁴ Databases⁵



510(k)⁷ Registration & Listing⁸ Adverse Events⁹ Recalls¹⁰ PMA¹¹ Classification¹² Standards¹³ CFR Title 21¹⁴ Radiation-Emitting Products¹⁵ X-Ray Assembler¹⁶ Medsun Reports¹⁷ CLIA¹⁸ TPLC¹⁸

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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 # NSLG2C14 and ENSEAL® 5 mm Diameter Tissue Sealer G2 25 cm Length Curved Jaw, Model # NSLG2C25. 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 00NSLG2C14, Lot # H44Y2P, Exp Date Nov-2013; Product Code 00NSLG2C25, Lot # H44Z6V, Exp Date Nov-2013 & Lot # J4A16C, 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 _z G2 Curved and Straight Tissue Sealers due to two potential issues that may occur related to the activation button: (i) Continuous Activation: The ENSEAL _z 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 Greek 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

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J.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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New Search

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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 # NSLG2S14 and ENSEAL® 5 mm Diameter Tissue Sealer G2 25 cm Length Straight Jaw, Model # NSLG2S25. 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 00NSLG2S14, Lot #, H44Z5R, Exp Date, Nov-2013; Product Code 00NSLG2S25, Lot #, H44Z57, 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 _z G2 Curved and Straight Tissue Sealers due to two potential issues that may occur related to the activation button: (i) Continuous Activation: The ENSEAL _z 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 Greek 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	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.

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Ethicon Endo Surgery

Ref: Z-0758-2013

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. Date 5-2017, Lot # J4AW8P, Exp. Date 5-2017, Lot # J4AW8Y, Exp. Date 5-2017, Lot # J4AX37, Exp. Date 5-2017, Lot # J4AX5Z, Exp. Date 5-2017, Lot # J4AX6E, Exp. Date 5-2017, Lot # J4AX8T, Exp. Date 5-2017, Lot # J4AX8U, Exp. Date 5-2017, Lot # J4AZ3P, Exp. Date 6-2017, Lot # J4AZ3V, Exp. Date 6-2017, Lot # J4AZ4W, Exp. Date 6-2017, Lot # J4AZ51, Exp. Date 6-2017, Lot # J4C11M, Exp. Date 6-2017, Lot # J4C11H, Exp. Date 6-2017, Lot # J4C15E, Exp. Date 6-2017, Lot # J4C17G, Exp. Date 6-2017, Lot # J4C174, Exp. Date 6-2017, Lot # J4C187, Exp. Date 6-2017, Lot # J4C197, Exp. Date 6-2017, Lot # J4C17Y, Exp. Date 6-2017, Lot # J4C19M, Exp. Date 6-2017, Lot # J4C225, Exp. Date 6-2017, Lot # J4C22H, Exp. Date 6-2017, Lot # J4C358, Exp. Date 6-2017, Lot # J4C35C, Exp. Date 6-2017, Lot # J4C36T, Exp. Date 6-2017, Lot # J4C427, Exp. Date 7-2017, Lot # J4C42D, Exp. Date 7-2017, Lot # J4C44P, Exp. Date 7-2017, Lot # J4C51U, Exp. Date 7-2017, Lot # J4C51W, Exp. Date 7-2017, Lot # J4C56E, Exp. Date 7-2017, Lot # J4C56A, Exp. Date 7-2017, Lot # J4C56Z, Exp. Date 7-2017, Lot # J4C56P, Exp. Date 7-2017, Lot # J4C58J, Exp. Date 7-2017, Lot # J4C58V, Exp. Date 7-2017, Lot # J4C65M, Exp. Date 7-2017, Lot # J4C66A, Exp. Date 7-2017, Lot # J4C66L, Exp. Date 7-2017, Lot # J4C758, Exp. Date 7-2017, Lot # J4C768, Exp. Date 7-2017, Lot # J4C85H, Exp. Date 7-2017, Lot # J4C85W, Exp. Date 7-2017, Lot # J4C906, Exp. Date 7-2017, Lot # J4C96P, Exp. Date 8-2017, Lot # J4C96Z, Exp. Date 8-2017, Lot # J4C879, Exp. Date 7-2017, Lot # J4CA4X, Exp. Date 8-2017, Lot # J4CA4Y, Exp. Date 8-2017, Lot # J4CC01, Exp. Date 8-2017, Lot # J4CC2G, Exp. Date 8-2017, Lot # J4CC4J, Exp. Date 8-2017, Lot # J4CD0C, Exp. Date 8-2017, Lot # J4CE10, Exp. Date 8-2017, Lot # J4CE16, Exp. Date 8-2017, Lot # J4CF0J, Exp. Date 8-2017, Lot # J4CF66, Exp. Date 9-2017, Lot # J4CJ0L, Exp. Date 9-2017, Lot # J4CJ5Z, Exp. Date 9-2017, Lot # J4CJ6J, Exp. Date 9-2017 and Lot # J4CK1K, Exp. Date 9-2017. Product Code

NSLG2C45, Lot # H44W26, Exp. Date 10-2013, Lot # H44W25, Exp. Date 10-2013, Lot # H44W27, Exp. Date 10-2013, Lot # J4A19D, Exp. Date 12-2013, Lot # J4AR6G, Exp. Date 4-2017, Lot # J4AU2R, Exp. Date 5-2017, Lot # J4AV5U, Exp. Date 5-2017, Lot # J4AZ53, Exp. Date 6-2017, Lot # J4C042, Exp. Date 6-2017, Lot # J4C122, Exp. Date 6-2017, Lot # J4C18F, Exp. Date 6-2017, Lot # J4C23J, Exp. Date 6-2017, Lot # J4C270, Exp. Date 6-2017, Lot # J4C32F, Exp. Date 6-2017, Lot # J4C62J, Exp. Date 7-2017, Lot # J4C62P, Exp. Date 7-2017, Lot # J4C816, Exp. Date 7-2017, Lot # J4C90E, Exp. Date 7-2017, Lot # J4C90F, Exp. Date 7-2017, Lot # J4C99K, Exp. Date 8-2017, Lot # J4CA8M, Exp. Date 8-2017, Lot # J4CD6Z, Exp. Date 8-2017, Lot # J4CJ73, Exp. Date 9-2017 and Lot # J4CK5E, Exp. Date 9-2017. Product Code NSLG2S14, Lot # H44Z5R, Exp. Date 11-2013, Lot # J4C312, Exp. Date 6-2017, Lot # J4C639, Exp. Date 7-2017 and Lot # J4CG7Z, Exp. Date 9-2017. Product Code NSLG2S25, Lot # H44Z57, Exp. Date 11-2013, Lot # J4AU2W, Exp. Date 5-2017, Lot # J4AW4P, Exp. Date 5-2017, Lot # J4AW4N, Exp. Date 5-2017, Lot # J4AX4W, Exp. Date 5-2017, Lot # J4AZ5M, Exp. Date 6-2017, Lot # J4C09V, Exp. Date 6-2017, Lot # J4C18R, Exp. Date 6-2017, Lot # J4C22J, Exp. Date 6-2017, Lot # J4C27C, Exp. Date 6-2017, Lot # J4C34E, Exp. Date 6-2017, Lot # J4C34F, Exp. Date 6-2017, Lot # J4C34K, Exp. Date 6-2017, Lot # J4C37R, Exp. Date 6-2017, Lot # J4C49E, Exp. Date 7-2017, Lot # J4C49G, Exp. Date 7-2017, Lot # J4C576, Exp. Date 7-2017, Lot # J4C577, Exp. Date 7-2017, Lot # J4C63W, Exp. Date 7-2017, Lot # J4C67U, Exp. Date 7-2017, Lot # J4C75N, Exp. Date 7-2017, Lot # J4C75X, Exp. Date 7-2017 and Lot # J4C92G, Exp. Date 7-2017. Product Code NSLG2S35, Lot # H44Y6N, Exp. Date 11-2013, Lot # H44Y8A, Exp. Date 11-2013, Lot # H44Y8K, Exp. Date 11-2013, Lot # H44Z65, Exp. Date 11-2013, Lot # H44Z6J, Exp. Date 11-2013, Lot # J4A164, Exp. Date 12-2013, Lot # J4AR9C, Exp. Date 4-2017, Lot # J4AT1U, Exp. Date 4-2017, Lot # J4AT22, Exp. Date 4-2017, Lot # J4AT4H, Exp. Date 4-2017, Lot # J4AU2X, Exp. Date 5-2017, Lot # J4AW31, Exp. Date 5-2017, Lot # J4AW36, Exp. Date 5-2017, Lot # J4AW9D, Exp. Date, 5-2017, Lot # J4AW9H, Exp. Date, 5-2017, Lot # J4AX62, Exp. Date, 5-2017, Lot # J4AX8Y, Exp. Date, 5-2017, Lot # J4AX9F, Exp. Date, 5-2017, Lot # J4C100, Exp. Date, 6-2017, Lot # J4C109, Exp. Date, 6-2017, Lot # J4C15H, Exp. Date, 6-2017, Lot # J4C18W, Exp. Date, 6-2017, Lot # J4C209, Exp. Date, 6-2017, Lot # J4C20A, Exp. Date, 6-2017, Lot # J4C23K, Exp. Date, 6-2017, Lot # J4C27E, Exp. Date, 6-2017, Lot # J4C27H, Exp. Date, 6-2017, Lot # J4C32G, Exp. Date, 6-2017, Lot # J4C34M, Exp. Date, 6-2017, Lot # J4C435, Exp. Date, 7-2017, Lot # J4C43J, Exp. Date, 7-2017, Lot # J4C537, Exp. Date, 7-2017, Lot # J4C53G Exp. Date, 7-2017, Lot # J4C53T, Exp. Date, 7-2017, Lot # J4C57N, Exp. Date, 7-2017, Lot # J4C57P, Exp. Date, 7-2017, Lot # J4C64N, Exp. Date, 7-2017, Lot # J4C64U, Exp. Date, 7-2017, Lot # J4C73T, Exp. Date, 7-2017, Lot # J4C73X, Exp. Date, 7-2017, Lot # J4C914, Exp. Date, 7-2017, Lot # J4C90W, Exp. Date, 7-2017, Lot # J4C92Z, Exp. Date, 7-2017, Lot # J4CE93, Exp. Date, 8-2017 and Lot # J4CC02, Exp. Date, 8-2017. Product Code NSLG2S45, Lot # J4A12R, Exp. Date 12-2013, Lot # J4AV6G, Exp. Date 5-2017, Lot # J4AV6T, Exp. Date 5-2017, Lot # J4AX9V, Exp. Date 5-2017, Lot # J4C15V, Exp. Date 6-2017, Lot # J4C30V, Exp. Date 6-2017, Lot # J4C37T, Exp. Date 6-2017, Lot # J4C67E, Exp. Date 7-2017, Lot # J4C67J, Exp. Date 7-2017, Lot # J4C67M, Exp. Date 7-2017, Lot # J4C74T, Exp. Date 7-2017 and Lot # J4CC9G, Exp. Date 8-2017.