



رقم المحفوظات: ٣٨١٢٥
رقم الصادر: ١٣/١١٤٤٤٥
بيروت، في:

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Sterile medical device containing multiple components to perform a breast biopsy, Breast Biopsy Tray

الجهاز المعنى بالمتابعة:

- Sterile medical device containing multiple components to perform a breast biopsy, Breast Biopsy Tray
- Trade Mark: Custom Healthcare System
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

الذي يشير الى وجود بعض المواد الدخيله قد تؤثر على سلامة الأستعمال ، نرجو منكم تعميم هذه

النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

التقرير الصادر عن وكالة ال FDA

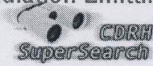
يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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الجمهورية اللبنانية

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Medical & Radiation Emitting Device Recalls

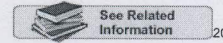


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**Class 2 Recall
Breast Biopsy tray**



Date Posted	February 07, 2013
Recall Number	Z-0796-2013
Product	Custom Breast Biopsy Tray, Catalog # B 9-16261, packaged in bags, 1 tray/bag, 20 bags/case. Product Usage: A sterile medical device containing multiple components utilized by physician to perform a breast biopsy.
Code Information	LOT NO. 100212 EXPIRES: 06/2013
Recalling Firm/ Manufacturer	Custom Healthcare Systems, Inc. 4205 Eubank Rd Richmond, Virginia 23231-4328
For Additional Information Contact	R. Michael Chou 804-421-5959
Reason for Recall	Surgical procedure trays are packed with pharmaceuticals for injection that may contain particulate matter.
Action	Custom Healthcare Systems, Inc. sent an Urgent Recall Letter dated November 19, 2012 to all affected customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to check inventory, quarantine affected product and return affected product to Stericycle using the label provided with the letter. Customer were also requested to complete and return the enclosed recall response form. For questions contact Hospira Customer Care at 1-877-946-7747.
Quantity in Commerce	80 trays
Distribution	USA Nationwide Distribution including the states GA, OH, GA, NC and ME.

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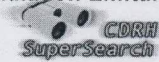
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Medical & Radiation Emitting Device Recalls

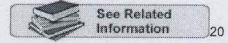


510(k)⁷|Registration & Listing⁸|Adverse Events⁹|Recalls¹⁰|PMA¹¹|Classification¹²|Standards¹³
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Class 2 Recall
Breast Biopsy Kit



Date Posted	February 07, 2013
Recall Number	Z-0797-2013
Product	Custom Breast Biopsy Tray w/Sodium Chloride, Catalog # B9-15263A, packaged in bags, 1 tray/bag, 20 bags/case. Product Usage: A sterile medical device containing multiple components utilized by physician to perform a breast biopsy.
Code Information	LOT NO. 60812 EXPIRES: 11 /2012
Recalling Firm/Manufacturer	Custom Healthcare Systems, Inc. 4205 Eubank Rd Richmond, Virginia 23231-4328
For Additional Information Contact	R. Michael Chou 804-421-5959
Reason for Recall	Surgical procedure trays are packed with pharmaceuticals for injection that may contain particulate matter.
Action	Custom Healthcare Systems, Inc. sent an Urgent Recall Letter dated November 19, 2012 to all affected customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to check inventory, quarantine affected product and return affected product to Stericycle using the label provided with the letter. Customer were also requested to complete and return the enclosed recall response form. For questions contact Hospira Customer Care at 1-877-946-7747.
Quantity in Commerce	80 trays
Distribution	USA Nationwide Distribution including the states GA, OH, GA, NC and ME.

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