الموضوع: إشعار بمتابعة جهاز طبي
Sterile medical device containing multiple components to perform a breast biopsy, Breast Biopsy Tray

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

FDA

بناء على التقرير الصادر عن وكالة ال
الذي يشير إلى وجود بعض المواد الدخيلة قد تؤثر على سلامة الاستعمال، نرجو منكم تعميم هذه
النشرة على جميع المستشفيات المعنية.

مرفق: ربط أ
التقرير الصادر عن وكالة ال

FDA

 البيان:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات
Medical & Radiation Emitting Device Recalls

Class 2 Recall
Breast Biopsy tray

Date Posted: February 07, 2013
Recall Number: Z-0799-2013


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 packaged 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 1-877-845-7747.

Quantity in Commerce: 80 trays

Distribution: USA Nationwide Distribution including the states GA, OH, GA, NC and ME.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. .../cfPMN/pmn.cfm
8. .../cfr/ri.cfm
9. .../CMAUDE/TextSearch.cfm
10. .../CRES/res.cfm
11. .../CFR/CFRS.cfm
12. .../CFR/CFRSearch.cfm
13. .../cfStandards/search.cfm
14. .../cfAssen/assembler.cfm
15. .../Medeu/searchReportText.cfm
16. .../cfCilia/Search.cfm
17. .../cfTPLC/tplc.cfm

Page Last Updated: 05/03/2013

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Medical & Radiation Emitting Device Recalls

Date Posted: February 07, 2013
Recall Number: Z-0797-2013

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: 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.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ./cfPMN/pmn.cfm
8. ./cfRl/rl.cfm
9. ./cfMAUDE/TextSearch.cfm
10. ./cfRES/res.cfm
11. ./cfPMA/pma.cfm
12. ./cfPCD/classification.cfm
13. ./cfStandards/search.cfm
14. ./cfCFR/CFRSearch.cfm
15. ./cfPCD_RH/classification.cfm
16. ./cfAssem/assembler.cfm
17. ./Medsun/searchReportText.cfm
18. ./cfClna/Search.cfm
19. ./cfTPLC/tplc.cfm

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