الموضوع: إشعار بمتابعة جهاز طبي
Povidine – Iodine prep solution / Povidine prep pads

الجهاز المعني بالمتتابعه:

Povidine – Iodine prep solution / Povidine prep pads
Trade Mark: Custom Medical Specialties, Inc.
Local Representative:

FDA بناء على التقرير الصادر عن وكالة ال
الذي يحظر فيه استعمال الصنف المذكور أعلاه لما له من مضاعفات خطيرة على المريض ،
نرجو منكم متابعة هذا الموضوع مع الأطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن
الشركة المصنعة.

مرفق ربط:

FDA التقرير الصادر عن وكالة ال

بلغ:

- دائرة البرنامج والمشاريع
- المستشفيات الحكومية
- المستعفيات
الموضوع: إشعار بمتابعة جهاز طبي

Povidine – Iodine prep solution / Povidine prep pads

بناء على التقرير الصادر عن وكالة ال FDA الذي يحذر فيه من استعمال الصفن المذكور أعلاه لما له من مضاعفات خطيرة على المريض، نرجو منكم متابعة هذا الموضوع مع الأطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

مرفق ربط:

- التقرير الصادر عن وكالة ال FDA

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات
Medical Devices

Custom Medical Specialties, Inc., Custom HSG Tray, Hysteroscopic Sterilization Pack, Custom Vein Tray, Custom Amnic Tray, Fox Chase Specials Pack, Abington Radiology Drainage Pack, Custom CT Biopsy Tray, HSG Tray, Custom Myelogram Tray, and Hysteroscopy Sterile Procedure Kit

Recall Class: Class I

Date Recall Initiated: September 30, 2011

Products:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Lot Number and Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CMS-4501-R1: Custom HSG Tray containing 2 oz. PVP Prep Bottle</td>
<td>LN: 20182-1006 Exp. Date: 03/2013</td>
</tr>
<tr>
<td>2. CMS-4975: HSG Tray containing 4 oz. bottle PVP Prep Solution</td>
<td>LN: 19134-1004 Exp. Date: 05/2011</td>
</tr>
<tr>
<td>4. BR980-9600: Hysteroscopy Sterile Procedure Kit containing 2 oz. bottle PVP Prep Solution</td>
<td>LN: 16363-0908 Exp. Date: 03/2011</td>
</tr>
<tr>
<td>5. CMS-4316: Custom Vein Tray containing 4 oz. bottle PVP Prep Solution</td>
<td>LN: 14255-0901 Exp. Date: 09/2011</td>
</tr>
<tr>
<td>6. CMS-8450-R1: Custom Vein Tray containing 4 oz. bottle PVP Prep Solution</td>
<td>LN: 15287-0905 Exp. Date: 02/2011</td>
</tr>
<tr>
<td>7. CMS-8495-R5: Custom Vein Tray containing 4 oz. bottle PVP Prep Solution</td>
<td>LN: 15974-0906 Exp. Date: 03/2011</td>
</tr>
<tr>
<td></td>
<td>LN: 17052-0910 Exp. Date: 03/2011</td>
</tr>
<tr>
<td></td>
<td>LN: 14161-0901 Exp. Date: 10/2010</td>
</tr>
<tr>
<td></td>
<td>LN: 15924-0906 Exp. Date: 07/2011</td>
</tr>
<tr>
<td></td>
<td>LN: 16975-0910 Exp. Date: 03/2011</td>
</tr>
<tr>
<td></td>
<td>LN: 17709-0912 Exp. Date: 08/2011</td>
</tr>
<tr>
<td>8. CMS-2586: Custom Amnic Tray containing 2 oz. bottle PVP Prep Solution</td>
<td>LN: 19702-1005 Exp. Date: 03/2013</td>
</tr>
<tr>
<td></td>
<td>LN: 20144-1006 Exp. Date: 03/2013</td>
</tr>
<tr>
<td></td>
<td>LN: 14452-0902 Exp. Date: 10/2011</td>
</tr>
<tr>
<td></td>
<td>LN: 15205-9904 Exp. Date: 02/2011</td>
</tr>
<tr>
<td></td>
<td>LN: 16690-0909 Exp. Date: 04/2011</td>
</tr>
<tr>
<td></td>
<td>LN: 17431-0911 Exp. Date: 08/2011</td>
</tr>
</tbody>
</table>

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm320774.htm 10/16/2012
LN: 17708-0912  Exp. Date: 08/2011
LN: 17913-1001  Exp. Date: 09/2011
LN: 18240-1002  Exp. Date: 10/2011
LN: 18308-1002  Exp. Date: 10/2011
LN: 18345-1802  Exp. Date: 11/2011
LN: 18511-1002  Exp. Date: 11/2011
LN: 18739-1003  Exp. Date: 01/2012
LN: 18829-1003  Exp. Date: 01/2012
LN: 16661-0909  Exp. Date: 01/2012
LN: 16662-0909  Exp. Date: 01/2012
LN: 17272-0910  Exp. Date: 10/2012
LN: 17566-0911  Exp. Date: 10/2012
LN: 17923-1001  Exp. Date: 09/2012
LN: 18188-1001  Exp. Date: 10/2012
LN: 18195-1001  Exp. Date: 10/2012
LN: 18793-1003  Exp. Date: 11/2012
LN: 19158-1004  Exp. Date: 06/2011
LN: 19850-1006  Exp. Date: 01/2013

12. CMS-4873: Custom CT Biopsy Tray containing 4 oz. bottle PCP Prep Solution

13. CMS-4873-R1: Custom CT Biopsy Tray containing 4 oz. bottle PVP Prep Solution

14. CMS-5284: Custom Myelogram Tray containing 2 oz. bottle PVP Prep Solution

Use: The PVP (Povidone Iodine Prep) contained in the kit is used in skin prep.

Recalling Firm:
Custom Medical Specialties, Inc.
330 East Main Street
Pine Level, North Carolina 27568

Manufacturer of the Povidone Iodine Prep Solution:
H & P Industries, Inc.
700 W. North Shore Dr.
Hartland, Wisconsin 53029-8358

Reason for Recall: The custom surgical kits contain Povidone Iodine Prep solution that had previously been recalled by H & P Industries, Inc. The manufacturer did not conduct any microbial testing and the products did not meet proper finished specifications. These products may cause serious adverse health consequences, including death.

Public Contact:
Custom Medical Specialties, Inc.
(919) 202-8462

FDA District: Atlanta District Office

FDA Comments: Recall letters were sent on September 27, 2011 to advise them of the recall of Povidone Iodine Prep Solutions manufactured by H & P Industries and distributed by Triad Group. The letter requested that they inspect inventory and return any remaining products.

Class I recalls are the most serious type of recall and involve situations in which there is a

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm320774.htm 10/16/2012
reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program either online, by regular mail or by FAX.

Page Last Updated: 09/25/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Accessibility Contact FDA Careers FDA Basics FOIA No Fear Act Site Map Transparency Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

For Government For Press
Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals

U.S. Department of Health & Human Services

Links on this page:

1. /Safety/MedWatch/default.htm

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm320774.htm 10/16/2012
Class I Recall
Povidone-Iodine prep
solution/Providine prep pads

Date Posted
September 20, 2012

Recall Number
Z-2355-2012

Product
CMS-8325-R2 Abington Radiology Drainage Pack and CMS-8325-R3 Abington Radiology Drainage Pack containing 4 oz. bottle PVP Prep Solution Product Usage: Usage: The PVP contained in the kit is used in skin prep

Code Information
14267-0901, 14452-0002, 15205-0904, 16147-0907, 16890-0908, 17431-0911, 17708-0912, 17913-1001, 18240-1002, 18308-1002, 18345-1002, 18511-1002, 18739-1003, 18928-1003

Recalling Firm/M
Manufacturer
Custom Medical Specialties, Inc.
Pine Level, North Carolina 27758

For Additional
Information Contact
Diane McAlpin
919-202-8462 Ext. 205

Reason for Recall
The firm saw on the FDA web site a recall by the manufacturer of the Povidone Iodine Prep Solution due to no microbial testing and product did not meet proper finished goods specifications.

Action
Custom Medical Specialties sent an Urgent Medical Device Recall letter dated September 27, 2011 and a follow-up letter dated September 4, 2012 to all affected customers. The letter identified the affected product, problem, and actions to be taken. The letter requested that customers inspect inventory, discontinue use and return any remaining affected products. A Return Authorization Number and shipping number will be given to customer by calling 919-202-8462 ext 205. Customers were instructed to complete and return the attached Acknowledgement and Return Product form.

Quantity in Commerce
195 cases

Distribution
US Nationwide Distribution including the states of CO, FL, KS, MA, MI, NJ and PA.