



رقم المحفوظات: ٤٩/٢٥  
رقم الصادر: ١٢/١/١٨٣٩٩  
بيروت، في: ٧ - تشرين الثاني ٢٠١٢

جانب نقيب الاطباء في الشمال/طرابلس

الموضوع: إشعار بمتابعة جهاز طبي

Povidine – Iodine prep solution / Povidine prep pads

الجهاز المعنى بالمتابعة:

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

بناء على التقرير الصادر عن وكالة ال FDA

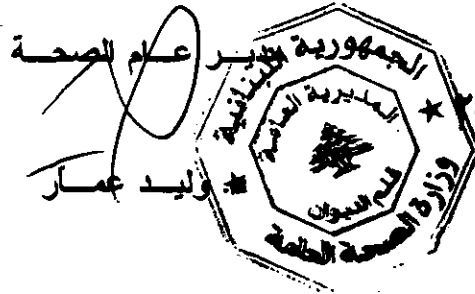
الذي يحذر فيه من استعمال الصنف المذكور أعلاه لما له من مضاعفات خطيرة على المريض ،  
نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن  
الشركة المصنعة.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



وثيقة مطابقة للأصل  
بيروت في ٩ تشرين الثاني ٢٠١٢  
بمس قسّم الدروس والنظايا  
العلاقات الصحية والدولية  
عبد صومط





رقم المحفوظات: ٤٠/٢٥  
رقم الصادر: ١٨٣٩٩  
بيروت، في: ٧ - تموز ٢٠١٢

جانب نقيب الاطباء في لبنان/بيروت

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مرفق ربطا:

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يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات



وثيقة مُعلّاة بتمه لأرسل  
بيروت في ٩ تموز ٢٠١٢  
بمس قسر الدروس والتشاي  
العلاقات الصحية والدولية  
عيد ضووط



Home Medical Devices Medical Device Safety Medical Device Recalls

**Medical Devices**

**Custom Medical Specialties, Inc., Custom HSG Tray, Hysteroscopic Sterilization Pack, Custom Vein Tray, Custom Amnio 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:**

<b>Product Name</b>	<b>Lot Number and Expiration Date</b>
1. CMS-4501-R1: Custom HSG Tray containing 2 oz. PVP Prep Bottle	LN: 20182-1006 Exp. Date: 03/2013
2. CMS-4975: HSG Tray containing 4 oz. bottle PVP Prep Solution	LN: 19134-1004 Exp. Date: 05/2011
3. CMS-8457: Hysteroscopic Sterilization Pack containing 4 oz. bottle PVP Prep	LN: 15011-0904 Exp. Date: 01/2011
	LN: 16363-0908 Exp. Date: 03/2011
4. BR980-9600: Hysteroscopy Sterile Procedure Kit containing 2 oz. bottle PVP Prep Solution	LN: 14255-0901 Exp. Date: 09/2011
	LN: 15287-0905 Exp. Date: 02/2011
5. CMS-4316: Custom Vein Tray containing 4 oz. bottle PVP Prep Solution	LN: 15974-0906 Exp. Date: 03/2011
	LN: 17052-0910 Exp. Date: 03/2011
	LN: 14161-0901 Exp. Date: 10/2010
6. CMS-8450-R1: Custom Vein Tray containing 4 oz. bottle PVP Prep Solution	LN: 15924-0906 Exp. Date: 07/2011
7. CMS-8495-R5: Custom Vein Tray containing 4 oz. bottle PVP Prep Solution	LN: 16975-0910 Exp. Date: 03/2011
	LN: 17709-0912 Exp. Date: 08/2011
	LN: 19702-1005 Exp. Date: 03/2013
8. CMS-2586: Custom Amnio Tray containing 2 oz. bottle PVP Prep Solution	LN: 20144-1006 Exp. Date: 03/2013
	LN: 14163-0901 Exp. Date: 10/2010
9. CMS-8162-R1: Fox Chase Specials Pack containing 2 oz. bottle PVP Prep Solution	LN: 14267-0901 Exp. Date: 10/2010
10. CMS-8325-R2: Abington Radiology Drainage Pack containing 4 oz. bottle PVP Prep Solution	LN: 14452-0902 Exp. Date: 10/2011
	LN: 15205-9904 Exp. Date: 02/2011
	LN: 16147-0907 Exp. Date: 03/2011
11. CMS-8325-R3: Abington Radiology Drainage Pack containing 4 oz. bottle PVP Prep Solution	LN: 16690-0909 Exp. Date: 04/2011
	LN: 17431-0911 Exp. Date: 08/2011

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: 18345-1002 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

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<sup>1</sup> 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.

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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



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U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

FDA Home Medical Devices Databases



510(k)<sup>7</sup> Registration & Listing<sup>8</sup> Adverse Events<sup>9</sup> Recalls<sup>10</sup> PMA<sup>11</sup> Classification<sup>12</sup> Standards<sup>13</sup>  
 CFR Title 21<sup>14</sup> Radiation-Emitting Products<sup>15</sup> X-Ray Assembler<sup>16</sup> Medsun Reports<sup>17</sup> CLIA<sup>18</sup> TPLC<sup>19</sup>

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**Class 1 Recall**  
**Povidine-Iodine prep**  
**solution/Providine prep pads**



<b>Date Posted</b>	September 20, 2012
<b>Recall Number</b>	Z-2355-2012
<b>Product</b>	CMS-8325-R2 Abington Radiology Drainage Pack and CMS-8325-R3 Abington Radiology Drainage Pack containing 4 oz. bottle PVP Prep Solution Product Usage: The PVP contained in the kit is used in skin prep
<b>Code Information</b>	14267-0901, 14452-0902, 15205-0904, 16147-0907, 16690-0909, 17431-0911, 17708-0912, 17913-1001, 18240-1002, 18308-1002, 18345-1002, 18511-1002, 18739-1003, 18829-1003
<b>Recalling Firm/ Manufacturer</b>	Custom Medical Specialties, Inc. 330 East Main Street Pine Level, North Carolina 27568
<b>For Additional Information Contact</b>	Diane McAlinn 919-202-8462 Ext. 205
<b>Reason for Recall</b>	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.
<b>Action</b>	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.
<b>Quantity in Commerce</b>	195 cases
<b>Distribution</b>	US Nationwide Distribution including the states of CO, FL, KS, MA, MI, NJ and PA.

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