



Tuesday, February 7, 2012

Dear Valued Customer:

URGENT RECALL NOTICE
CareFusion Skin Prep Trays containing Povidone-Iodine

Table 1. Affected CareFusion Skin Prep Trays

Catalog Numbers	Description
4420	Wet PVP-I Small Procedure Preoperative Skin Prep Tray (2 oz. 10% PVP-I, 2 oz. 7.5% PVP-I)
4468	Wet PVP-I Preoperative Skin Prep Tray (3 oz. 10% PVP-I, 3.7 oz. 7.5% PVP-I)
4469A	Wet PVP-I Vaginal Preoperative Skin Prep Tray (3 oz. 10% PVP-I, 3.7 oz. 7.5% PVP-I)

The purpose of this letter is to notify you of a voluntary field removal (recall) initiated by CareFusion regarding CareFusion Skin Prep Tray Catalog Numbers 4420, 4468, and 4469A, as noted in Table 1, above. (Please reference attached list of all affected lot numbers.)

CareFusion has identified a potential patient safety risk with the CareFusion Preoperative Skin Prep Trays containing povidone-iodine, specifically catalog numbers 4420, 4468, and 4469A manufactured between January 01, 2011 and October 21, 2011. CareFusion Preoperative Skin Prep Trays are medical device convenience kits containing two bottles with PVP-I solutions along with other medical device items such as sponges, gloves and drapes. Povidone-iodine bottles with loose caps or failed seals may result in PVP-I solution leakage, soiling other components within the kit (gloves, sponges, surgical drapes). Additionally, bottles with loose caps or failed seals may lead to elevated levels of ethylene oxide (EO) sterilant and/or by-products within the PVP-I solution, which may represent a patient safety risk. Individual bottles of PVP-I solution sold independently are not affected.

Because containers with leaking or loose caps may not be detected until the kit is in use, CareFusion is removing from market all related Preoperative Skin Prep Trays with PVP-I solution (Catalog Numbers 4420, 4468, and 4469A) to reduce the risk to health which may be posed by the device or its components. CareFusion is advising its distributors and customers not to use these products and to destroy or return them for destruction.

Please forward this letter to all customers that currently utilize product codes 4420, 4468 and 4469A to make them aware of this recall. **The product must not be used.** We require that you perform a 100% physical inventory to verify if any of the affected lot numbers are in stock. CareFusion does not require that the product be returned, although we will accept returned product. Destroy any affected product you may have on hand at your facilities; please follow your facility's disposal protocol or return the affected product back to CareFusion.

Please note that product codes 4420, 4468 and 4469A have been backordered for several months and continue to be on backorder today. For assistance with appropriate substitute options and/or replacement product, please contact CareFusion Customer Support Department at (800) 523-0502, extension 53576.

Please fill out the information on page three (3) of this letter acknowledging that you have received this notification and that you will communicate this letter to your customers who utilize product codes 4420, 4468 and 4469A.

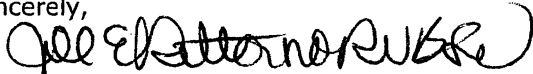
This voluntary recall notification is being conducted with knowledge of FDA in accordance with US regulations. Any adverse reactions experienced with the use of this product, and or quality problems, should also be reported to the FDA's MedWatch Program by:

- Web: MedWatch website at www.fda.gov/medwatch
- Phone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178, or by
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

CareFusion appreciates your immediate attention to this urgent matter. Contact the person named below immediately if any adverse reactions are experienced with the use of this product.

Should you have any questions related to the product directly, please contact Mary Wilson at (913) 345-3504 or at mary.wilson@carefusion.com. Should you have any questions related to this recall, please feel free to contact me directly at (847) 473-1500 or Jill.Rittorno@carefusion.com.

Sincerely,



Jill E. Rittorno, RN, BSN
Customer Advocacy Manager

Attachment

**RE: Report of Recall Notice/Distributor Notification
CareFusion Skin Prep Trays containing Povidone-Iodine (PVP-I)**

REQUIRED INFORMATION TO BE PROVIDED BY YOUR COMPANY

Company Name: _____

Required Action For Distributors

1. Please destroy/discard or return any affected product you may have in-stock at your facility. **Do not further distribute these products.**
2. Forward this **URGENT RECALL NOTICE** to any customers to whom affected products have been sold, notifying them of the potential risk. (Reference attachment for affected production lot numbers.) End users must be advised to discard or return any CareFusion Skin Prep Tray with the noted product/lot number. End users must **NOT** use these products.
3. Complete and return this Acknowledgement Form indicating that you have received this **URGENT RECALL NOTICE** and that you have communicated the Recall Notice to all customers who have purchased CareFusion Preoperative Skin Prep Tray catalog numbers 4420, 4468, and 4469A. Please complete the following reconciliation table and return this form to CareFusion.
4. Contact CareFusion Customer Service for details on return and/or replacement of stock.

PLEASE COMPLETE THE FOLLOWING TABLE:

PRODUCT CODE	DESCRIPTION	INVENTORY QTY	QTY DESTROYED	QTY RETURNED
4420	Small Procedure Prep Tray (2oz. 10% PVP-I, 2oz. 7.5% PVP-I)			
4468	Preoperative Skin Prep Tray (3oz. 10% PVP-I, 3.7oz. 7.5% PVP-I)			
4469A	Vaginal Prep Tray (3oz. 10% PVP-I, 3.7oz. 7.5% PVP-I)			

My signature below certifies acknowledgement of this letter pertaining to CareFusion Skin Prep Tray catalog numbers 4420, 4468, and 4469A. (Reference attached list of all affected lot numbers). I also certify and can document that my company has presented this information to all customers to whom these affected lots were distributed.

Print Name: _____

Signature: _____

Date: _____

Please return completed form via e-mail to judy.ebbert@carefusion.com via fax to (847) 473-7774.

Attachment: List of Affected Lot Numbers

4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000319389
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000321446
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000323733
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000326090
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000328468
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000330882
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000333747
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000336418
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000336443
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000340606
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000344792
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000349464
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000354078
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000354079
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000358785
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	0000367470
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	Y11C1711
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	Y11C2202
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	Y11C3733
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	Y11C3751
4420	PREP TRAY WET PVP-I SMALL PRCDR, W/GLOVE	Y11D0544

4468	PREP TRAY WET PVP-I W/GLOVE	0000310407
4468	PREP TRAY WET PVP-I W/GLOVE	0000310409
4468	PREP TRAY WET PVP-I W/GLOVE	0000310411
4468	PREP TRAY WET PVP-I W/GLOVE	0000310413
4468	PREP TRAY WET PVP-I W/GLOVE	0000312077
4468	PREP TRAY WET PVP-I W/GLOVE	00000312080
4468	PREP TRAY WET PVP-I W/GLOVE	0000312081
4468	PREP TRAY WET PVP-I W/GLOVE	0000313225
4468	PREP TRAY WET PVP-I W/GLOVE	0000313227
4468	PREP TRAY WET PVP-I W/GLOVE	0000313229
4468	PREP TRAY WET PVP-I W/GLOVE	0000313233
4468	PREP TRAY WET PVP-I W/GLOVE	0000313523
4468	PREP TRAY WET PVP-I W/GLOVE	0000314761
4468	PREP TRAY WET PVP-I W/GLOVE	0000314762
4468	PREP TRAY WET PVP-I W/GLOVE	0000315476
4468	PREP TRAY WET PVP-I W/GLOVE	0000315477
4468	PREP TRAY WET PVP-I W/GLOVE	0000315478
4468	PREP TRAY WET PVP-I W/GLOVE	0000315480
4468	PREP TRAY WET PVP-I W/GLOVE	0000317227
4468	PREP TRAY WET PVP-I W/GLOVE	0000317229
4468	PREP TRAY WET PVP-I W/GLOVE	0000317230
4468	PREP TRAY WET PVP-I W/GLOVE	0000317231
4468	PREP TRAY WET PVP-I W/GLOVE	0000318349
4468	PREP TRAY WET PVP-I W/GLOVE	0000318350
4468	PREP TRAY WET PVP-I W/GLOVE	0000318351
4468	PREP TRAY WET PVP-I W/GLOVE	0000318352
4468	PREP TRAY WET PVP-I W/GLOVE	0000319401
4468	PREP TRAY WET PVP-I W/GLOVE	0000319402
4468	PREP TRAY WET PVP-I W/GLOVE	0000319403
4468	PREP TRAY WET PVP-I W/GLOVE	0000319404
4468	PREP TRAY WET PVP-I W/GLOVE	0000319405
4468	PREP TRAY WET PVP-I W/GLOVE	0000321997
4468	PREP TRAY WET PVP-I W/GLOVE	0000321998
4468	PREP TRAY WET PVP-I W/GLOVE	0000321999
4468	PREP TRAY WET PVP-I W/GLOVE	0000322000
4468	PREP TRAY WET PVP-I W/GLOVE	0000322001
4468	PREP TRAY WET PVP-I W/GLOVE	0000323739
4468	PREP TRAY WET PVP-I W/GLOVE	0000323740
4468	PREP TRAY WET PVP-I W/GLOVE	0000323741

4468	PREP TRAY WET PVP-I W/GLOVE	0000326095
4468	PREP TRAY WET PVP-I W/GLOVE	0000326097
4468	PREP TRAY WET PVP-I W/GLOVE	0000326099
4468	PREP TRAY WET PVP-I W/GLOVE	0000326100
4468	PREP TRAY WET PVP-I W/GLOVE	0000326101
4468	PREP TRAY WET PVP-I W/GLOVE	0000326103
4468	PREP TRAY WET PVP-I W/GLOVE	0000326104
4468	PREP TRAY WET PVP-I W/GLOVE	0000328472
4468	PREP TRAY WET PVP-I W/GLOVE	0000328473
4468	PREP TRAY WET PVP-I W/GLOVE	0000328474
4468	PREP TRAY WET PVP-I W/GLOVE	0000328475
4468	PREP TRAY WET PVP-I W/GLOVE	0000328497
4468	PREP TRAY WET PVP-I W/GLOVE	0000328502
4468	PREP TRAY WET PVP-I W/GLOVE	0000328504
4468	PREP TRAY WET PVP-I W/GLOVE	0000330880
4468	PREP TRAY WET PVP-I W/GLOVE	0000330881
4468	PREP TRAY WET PVP-I W/GLOVE	0000330884
4468	PREP TRAY WET PVP-I W/GLOVE	0000330885
4468	PREP TRAY WET PVP-I W/GLOVE	0000330886
4468	PREP TRAY WET PVP-I W/GLOVE	0000333712
4468	PREP TRAY WET PVP-I W/GLOVE	0000333754
4468	PREP TRAY WET PVP-I W/GLOVE	0000333755
4468	PREP TRAY WET PVP-I W/GLOVE	0000333756
4468	PREP TRAY WET PVP-I W/GLOVE	0000333757
4468	PREP TRAY WET PVP-I W/GLOVE	0000333758
4468	PREP TRAY WET PVP-I W/GLOVE	0000333759
4468	PREP TRAY WET PVP-I W/GLOVE	0000333761
4468	PREP TRAY WET PVP-I W/GLOVE	0000333762
4468	PREP TRAY WET PVP-I W/GLOVE	0000336431
4468	PREP TRAY WET PVP-I W/GLOVE	0000336433
4468	PREP TRAY WET PVP-I W/GLOVE	0000336434
4468	PREP TRAY WET PVP-I W/GLOVE	0000336435
4468	PREP TRAY WET PVP-I W/GLOVE	0000336437
4468	PREP TRAY WET PVP-I W/GLOVE	0000336439
4468	PREP TRAY WET PVP-I W/GLOVE	0000336442
4468	PREP TRAY WET PVP-I W/GLOVE	0000336448
4468	PREP TRAY WET PVP-I W/GLOVE	0000336449
4468	PREP TRAY WET PVP-I W/GLOVE	0000336450
4468	PREP TRAY WET PVP-I W/GLOVE	0000336451
4468	PREP TRAY WET PVP-I W/GLOVE	0000336452

4468	PREP TRAY WET PVP-I W/GLOVE	0000336453
4468	PREP TRAY WET PVP-I W/GLOVE	0000342781
4468	PREP TRAY WET PVP-I W/GLOVE	0000342782
4468	PREP TRAY WET PVP-I W/GLOVE	0000342783
4468	PREP TRAY WET PVP-I W/GLOVE	0000342785
4468	PREP TRAY WET PVP-I W/GLOVE	0000342786
4468	PREP TRAY WET PVP-I W/GLOVE	0000342787
4468	PREP TRAY WET PVP-I W/GLOVE	0000342788
4468	PREP TRAY WET PVP-I W/GLOVE	0000342789
4468	PREP TRAY WET PVP-I W/GLOVE	0000342790
4468	PREP TRAY WET PVP-I W/GLOVE	0000344054
4468	PREP TRAY WET PVP-I W/GLOVE	0000344798
4468	PREP TRAY WET PVP-I W/GLOVE	0000344800
4468	PREP TRAY WET PVP-I W/GLOVE	0000344810
4468	PREP TRAY WET PVP-I W/GLOVE	0000344811
4468	PREP TRAY WET PVP-I W/GLOVE	0000344812
4468	PREP TRAY WET PVP-I W/GLOVE	0000347086
4468	PREP TRAY WET PVP-I W/GLOVE	0000347087
4468	PREP TRAY WET PVP-I W/GLOVE	0000347088
4468	PREP TRAY WET PVP-I W/GLOVE	0000347089
4468	PREP TRAY WET PVP-I W/GLOVE	0000347090
4468	PREP TRAY WET PVP-I W/GLOVE	0000347091
4468	PREP TRAY WET PVP-I W/GLOVE	0000347093
4468	PREP TRAY WET PVP-I W/GLOVE	0000347094
4468	PREP TRAY WET PVP-I W/GLOVE	0000347095
4468	PREP TRAY WET PVP-I W/GLOVE	0000347096
4468	PREP TRAY WET PVP-I W/GLOVE	0000349465
4468	PREP TRAY WET PVP-I W/GLOVE	0000349466
4468	PREP TRAY WET PVP-I W/GLOVE	0000349467
4468	PREP TRAY WET PVP-I W/GLOVE	0000349473
4468	PREP TRAY WET PVP-I W/GLOVE	0000349812
4468	PREP TRAY WET PVP-I W/GLOVE	0000351290
4468	PREP TRAY WET PVP-I W/GLOVE	0000351684
4468	PREP TRAY WET PVP-I W/GLOVE	0000351687
4468	PREP TRAY WET PVP-I W/GLOVE	0000354085
4468	PREP TRAY WET PVP-I W/GLOVE	0000354087
4468	PREP TRAY WET PVP-I W/GLOVE	0000354089
4468	PREP TRAY WET PVP-I W/GLOVE	0000354091
4468	PREP TRAY WET PVP-I W/GLOVE	0000354096
4468	PREP TRAY WET PVP-I W/GLOVE	0000354100

4468	PREP TRAY WET PVP-I W/GLOVE	0000356292
4468	PREP TRAY WET PVP-I W/GLOVE	0000356294
4468	PREP TRAY WET PVP-I W/GLOVE	0000356296
4468	PREP TRAY WET PVP-I W/GLOVE	0000356299
4468	PREP TRAY WET PVP-I W/GLOVE	0000356300
4468	PREP TRAY WET PVP-I W/GLOVE	0000361254
4468	PREP TRAY WET PVP-I W/GLOVE	0000361255
4468	PREP TRAY WET PVP-I W/GLOVE	0000361284
4468	PREP TRAY WET PVP-I W/GLOVE	0000615475
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S1567
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S2362
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S2363
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S2370
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S2371
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S2372
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S2402
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S2436
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S2988
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S2989
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S2990
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S3008
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S3011
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S3012
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S3118
4468	PREP TRAY WET PVP-I W/GLOVE	Y10S3119
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A0340
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A0341
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A0347
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A0349
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A1125
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A1139
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A1147
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A1148
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A1155
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A1270
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A1980
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A1981
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A1982
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A2013
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A2014

4468	PREP TRAY WET PVP-I W/GLOVE	Y11A2637
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A2638
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A2639
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A2729
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A2733
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A2734
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A3238
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A3239
4468	PREP TRAY WET PVP-I W/GLOVE	Y11A3240
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B0276
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B0279
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B0290
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B0411
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B0603
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B0949
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B0959
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B0960
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B0961
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B1240
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B1241
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B1427
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B1651
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B2564
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B2566
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B2925
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B2927
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B2928
4468	PREP TRAY WET PVP-I W/GLOVE	Y11B2932
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C0274
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C0275
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C0283
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C0284
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C0318
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C0319
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C0320
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C1275
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C1276
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C1277
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C1278
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C1280

4468	PREP TRAY WET PVP-I W/GLOVE	Y11C1976
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C1977
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C2146
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C2147
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C2865
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C3085
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C3086
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C3103
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C3104
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C3105
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C3141
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C3142
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C3744
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C3745
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C3746
4468	PREP TRAY WET PVP-I W/GLOVE	Y11C3752
4468	PREP TRAY WET PVP-I W/GLOVE	Y11D0541
4468	PREP TRAY WET PVP-I W/GLOVE	Y11D0542
4468	PREP TRAY WET PVP-I W/GLOVE	Y11D0777
4468	PREP TRAY WET PVP-I W/GLOVE	Y11D0778
4468	PREP TRAY WET PVP-I W/GLOVE	Y11D0783
4468	PREP TRAY WET PVP-I W/GLOVE	Y11D0784
4468	PREP TRAY WET PVP-I W/GLOVE	Y11D0785
4468	PREP TRAY WET PVP-I W/GLOVE	Y11D0786
4468	PREP TRAY WET PVP-I W/GLOVE	Y11D0787

4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000312078
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000312079
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000313237
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000315474
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000317224
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000317225
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000317226
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000319388
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000319398
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000319399
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000319400
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000321995
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000326091
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000330888
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000331259
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000331933
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000333748
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000333749
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000333750
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000336430
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000336454
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000340623
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000342778
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000342779
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000342780
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000344796
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000347085
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000348120
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000351690
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000354083
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000356290
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	0000361072
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y10S1161
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y10S1568
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y10S2006
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y10S2007
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y10S2364
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y10S2993
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11A1149

4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11A2470
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11A3023
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11B0434
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11B0955
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11B1613
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11B2924
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11C0276
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11C1279
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11C1855
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11C3087
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11D0543
4469A	PREP TRAY WET PVP-I VAGINAL W/GLOVE	Y11D0779



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CareFusion Skin Prep Tray Recall Q&A

CareFusion is committed to providing safe and effective products for customers, and patient safety is of the utmost priority. As part of this commitment and through its quality testing procedures, CareFusion identified a problem with some Pre-operative Skin Prep Trays containing povidone-iodine that could potentially result in a risk to patient safety. As a result, CareFusion has issued a voluntary recall of Patient Pre-operative Skin Prep Trays containing povidone-iodine, specifically catalog numbers 4420, 4468 and 4469A, manufactured between January 1, 2011 and October 21, 2011. CareFusion stopped shipping the affected prep trays in October of 2011.

The Q&A below may help answer some of your questions; should you have any other questions, please contact the CareFusion Customer Support Department at (800) 523-0502, extension 53576.

Q&A

1. Why is CareFusion recalling the Pre-operative Skin Prep Trays containing povidone-iodine?

Our Quality Management System detected a signal, based on a spike in customer reports related to leaking bottles within these kits. A project team was assembled and they determined that bottles may have loose caps or failed seals, which may result in PVP-I solution leakage, soiling other components within the kit (gloves, sponges, surgical drapes). As a result, CareFusion stopped shipping the affected prep trays in October of 2011.

As part of the investigation, CareFusion conducted an evaluation of the effects that the sterilization cycle would have on these leaky or loose capped bottles. This testing confirmed that ethylene oxide (ETO), which is a sterilant, and/or by products may penetrate the bottles or enter through failed seals, and the level of ETO found was above the specifications for this chemical. Elevated levels of ETO sterilant and/or by products within the PVP-I solution may cause increased irritation/sensitization when applied to patients' skin.

Based on this finding, and in alignment with its commitment to quality products, CareFusion felt the best approach for customers and their patients was to issue a voluntary recall of catalog numbers 4420, 4468 and 4469A, manufactured between January 1, 2011 and October 21, 2011.

2. What are the risks associated with elevated levels of ETO?

The current bottle configurations may not prevent ethylene oxide (ETO), a sterilant, and/or by products from penetrating the PVP-I solution contained within the bottles. As a result, elevated levels of ETO may be found in the PVP-I solution. This level of ETO exceeds CareFusion's specifications and therefore

is not acceptable. Despite more than 200 complaints of leaking bottles, to date there have been no reports of adverse events related to the PVP-I solution or these prep trays.

3. Do I need to stop using the product?

Yes. Because bottles with leaking or loose caps or failed seals may not be detected until the kit is in use, the Patient Pre-operative Skin Prep Trays covered by this voluntary recall should not be used.

4. If I've used the affected product on my patients, are they are risk?

CareFusion is not aware of any reported adverse health effects for patients, but if you have any concerns, or an adverse event does arise please contact the CareFusion Customer Support Department at (800) 523-0502, extension 53576.

Any adverse reactions experienced with the use of this product, and or quality problems, should also be reported to the FDA's MedWatch Program by:

- Web: MedWatch website at www.fda.gov/medwatch
- Phone: 1-800-FDA-1088
- Fax: 1-800-FDA-0178, or by
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787

5. What should I do with the affected products?

The affected products should not be used. Any affected product should be destroyed in accordance with your facility's disposal protocol. Alternatively, the product can be returned to CareFusion. For questions regarding disposal or financial reimbursement of trays covered by this recall, please contact the CareFusion Customer Support Department at (800) 523-0502, extension 53576.

6. What will happen to my order, which has been placed for the backordered product?

While we are working on resolving this problem, we cannot at this time predict when we will resume shipping. Therefore, all current orders for backordered prep trays will be cancelled within our system. CareFusion does have several alternative solutions available to you. For assistance with appropriate substitute options, please contact the CareFusion Customer Support Department at (800) 523-0502, extension 53576.

7. Will CareFusion provide any alternative products?

Yes, CareFusion offers several alternative solutions. These may include use of another product such as ChloroPrep® or a dry sterile prep tray, plus two non-sterile bottles of PVP-I scrub and one bottle of PVP-I paint. These bottles of PVP-I scrub and paint, which is sold individually are not affected by the recall and may be used to provide safe and effective patient preoperative skin prep.

Other patient prepping items are available from CareFusion. For assistance with appropriate substitute options, please contact the CareFusion Customer Support Department at (800) 523-0502, extension 53576.