Independence Medical®

1810 Summit Commerce Park
Twinsburg, Ohio 44087
p 1-800-860-8027
f 330-963-6516
w www.indemed.com

BOARDMAN MEDICAL
ATTN: RECALL COORDINATOR
300 NORTH STATE STREET
GIRARD, OH 44420-2538

URGENT - PRODUCT RECALL

Medline

For select lots of

Kits and/or Packs Containing H&P Povidone Iodine Products

September 30, 2011

Dear Valued Customer:

Medline is conducting a recall on select lots of procedure trays containing povidone iodine products produced by H&P Industries. These products were recently recalled by the manufacturer due to manufacturing systems and conditions at H&P Industries which present a risk of infection in patients undergoing medical and surgical procedures.

Our records indicate that we may have drop shipped affected product, on your behalf, to patients on the enclosed sheet. Please refer to the enclosed list of Medline items and lot numbers potentially affected, contact your patients and ask them to check their stock immediately. If they find they have affected product, advise them to discontinue use and return the product to you. Upon receipt, contact Independence Medical Customer Service at 1-800-860-8027 for return instructions.

Thank you for your assistance in this matter.

Sincerely,

Independence Medical

Medline Industries Inc
One Medline Place
Mundelein, IL 60060-4486

1-847-643-4678
Toll Free: 1-866-359-1704
Fax: 1-866-767-1290

September, 2011

H&P Industries

(Triad, Triad+ & Major Pharmaceutical)

Sub-Recall Notification

IMMEDIATE ACTION REQUIRED
Povidone Iodine Products

Dear Medline Customer:

H&P Industries, Inc is voluntarily recalling all Povidone Iodine Products. This recall was initiated because products were manufactured without having in place a system for microbial testing at the time of release, without having a system for testing of incoming components, and without having procedures designed and established to prevent objectionable microorganisms in these drug products. The use of these products manufactured under these conditions presents a risk of infection in patients undergoing medical and surgical procedures.

Accounts that purchased kits and/or packs containing the recalled component since 2008 are being notified.

On the back of this letter you will find a list of products you purchased.

REQUIRED ACTION:

1. Immediately check your stock for affected kits. Any affected components identified at the time the kit is being used should be removed and discarded. Another appropriate product should be substituted. The other non Triad components within the kit are not affected and may be used.

2. Please complete and return the attached Verification Form in its entirety to avoid future notifications. Indicate the number of stickers on this form that are needed to label your existing inventory of affected product. The form may be scanned and emailed to Recalls@Medline.com or faxed to 866-767-1290.

3. Promptly notify any customers to whom you may have distributed affected product.

Note: By signing and returning the Verification Form you acknowledge that you received and understand this notification.

Should you have any questions please contact our Recall Department at 1-866-359-1704. As a distributor of this product, we sincerely regret the inconvenience. We, like you, place the health and safety of your patients first and foremost.

Sincerely,

Kathy Dunne
Recall Coordinator

Items/Lots Potentially Affected By Recall

Please note that this recall affects only specific lot ranges. If you have any of the trays listed below, locate the lot # on the packaging to determine if the tray is affected by the recall. All lots starting with 08, 09, or 10 are affected by this recall. In addition, any specific lot numbers listed below are also affected by the recall. If the lot number ends with JD or contains a Z, it is not affected by this recall.

Medline Item Number	Indpendence Item Number	Product Description	Lot Numbers Affected
DYNC1810	601810	TRAY, FOLEY INSERTION W/10ML SYRINGE	lots beginning 08, 09, or 10, plus lots 11AA1268, 11AA1290
DYNC1815	601815	TRAY, FOLEY INSERTION W/30ML SYRINGE, PVP	lots beginning 08, 09, or 10, plus lot 11BA0659
DYNC1820	601820	TRAY, CATHETER, URETHRAL, VINYL, PVP, 14FR	lots beginning 08, 09, or 10
DYNC1810	6001810	TRAY, FOLEY INSERTION W/10ML SYRINGE	lots beginning 08, 09, or 10, plus lots 11AA1268, 11AA1290
DYNJ02001	6002001	CENTRAL LINE DRESSING CHANGE KIT	lots beginning 08, 09, or 10
DYNJ03033	6003033	CENTRAL VENOUS CATH KIT	lots beginning 08, 09, or 10, plus lot 11BB4194
DYNJ03300	6003300	WOUND DRESSING CHANGE TRAY, GLOVES/DRAPES/STERILE	lots beginning 08, 09, or 10
DYND10150	6010150	TRAY, FOLEY CATH, SIL-ELAST, NO BG, 16FR 10ML	lots beginning 08, 09, or 10
DYND10160	6010160	TRAY, FOLEY INSERTION, PVP, 10ML, LF, PVP	lots beginning 08, 09, or 10
DYND10200	6010200	TRAY, FOLEY INSERTION, PVP, 30ML SYRINGE	lots beginning 08, 09, or 10, plus lot 11BB3271
DYND10300	6010300	STERILE CATH TRAY W/14FR VINYL CATHETER	lots beginning 08, 09, or 10
DYND10305	6010305	TRAY, URETHRAL, NO-CATHETER, PVP	lots beginning 08, 09, or 10, plus lots 11BA0434, 11BA0559
DYND10350	6010350	TRAY, URETHRAL, CATHETER, RED-RUBBER, 15FR	lots beginning 08, 09, or 10
DYND10400	6010400	TRAY, URETHRAL, CLOSED SYSTEM, VINYL, 14FR	lots beginning 08, 09, or 10, plus lot 11BB1910
DYND10402	6010402	TRAY, URETHRAL, PRE-CONN, VINYL, 14FR	lots beginning 08, 09, or 10
DYND11860	6011860	FOLEY 16FR 5CC PRE-CONNECTED TRAY W/DRAINAGE BAG	lots beginning 08, 09, or 10
DYND11865	6011865	FOLEY TRAY, 18FR 5CC, DRAIN BAG, GLOVES, DRAPE, STERILE	lots beginning 08, 09, or 10
DYND11908	6011908	PRE-CONNECTED FOLEY TRAY W/COATED CATH, 18FR, 5CC	lots beginning 08, 09, or 10
DYND18200	6018200	TRAY, URETHRAL, CATHETER, VINYL, 14FR	lots beginning 08, 09, or 10
DYNC1816	60DYNC1816	RED RUBBER LATEX CATHETER TRAY, 15FR	lots beginning 08, 09, or 10
DYND11008	60DYND11008	TRAY, FOLEY CATH, SIL-ELAST, 18FR, 10ML, BG	lots beginning 08, 09, or 10, plus lot 11BB3741
DYND11095	60DYND11095	FOLEY INSERTION TRAY W/O CATH, W/DRAIN BAG & JELLY	lots beginning 08, 09, or 10
DYNJ08835	60DYNJ08835	DEBRIDEMENT TRAY WITH SAFETY SCALPEL - CASE	lots beginning 08, 09, or 10, plus lot 11CB0347
DYNJ08835H	60DYNJ08835H	DEBRIDEMENT TRAY WITH SAFETY SCALPEL - EACH	lots beginning 08, 09, or 10, plus lot 11CB0347

Minor Procedure Trays / Non-Sterile Kits

This recall affects specific lot ranges. If you have any of the trays listed below, locate the lot number on the packaging to determine if it is affected by the recall. Should you find any affected product on hand, affix a sticker to the outside of each tray/kit to instruct your personnel not to use the Triad component. At the time of use, discard the Triad component as the tray/kit is opened. For the products listed below, unless a specific lot number is provided, use the following criteria to determine if the product is affected.

- Trays that are not expired and have lot numbers beginning with 08, 09 and/or 10 **are** affected by the recall.
- If the lot number ends with a JD or contains a Z, it is not affected by the recall.

MATERIAL	Description	
DYNC1815	TRAY,FOLEY INSERTION,W/30ML SYRINGE,PVP	11BA0659
DYNC1815	TRAY,FOLEY INSERTION,W/30ML SYRINGE,PVP	All Lots meeting criteria
DYNC1820	TRAY,CATHETER,URETHRAL,VINYL,PVP,14FR	All Lots meeting criteria
DYND10200	TRAY,FOLEY INSERTION,PVP,30ML SYRINGE	11BB3271
DYND10200	TRAY,FOLEY INSERTION,PVP,30ML SYRINGE	All Lots meeting criteria
DYND10300	TRAY,CATHETER,URETHRAL,VINYL,14FR	All Lots meeting criteria
DYND18100	TRAY,FOLEY INSERTION,PVP,10ML SYRINGE	All Lots meeting criteria