UPDATED - URGENT MEDICAL DEVICE RECALL

Description	List	Lot(s)
Extension Set For Bladder Irrigation or Urinary Drainage, Compatible with T-U-R Flow-Pouch™ Reservoir, List 6542	4693-01	Refer to Table 1 for lots distributed.
T-U-R Y-Set Nonvented Set for Transurethral Resection Procedures	6543-01	
Cystoscopy/Irrigation Set Nonvented, 77 inch (195 cm) for Constant or Intermittent Bladder Irrigation	6544-01	
Large Bore Y-Irrigation Set Nonvented Set	6599-01	
4-Lead T-U-R Irrigation Set Nonvented Set for Transurethral Resection Procedures	15239-01	

28 March 2014

To: Risk Manager/Material Manager/Pharmacy

Hospira Inc. (Hospira) is voluntarily notifying you that the packages containing the sets listed above may not be completely sealed during the manufacturing process. **Please ensure that all potential users in your facility are made aware of this notification and the recommended actions.**

Issue: The Tyvek cover may not be completely sealed to the rest of the package allowing openings at the edge of the sterile package. Hospira has received complaints of the sterile pack not sealed properly or the Tyvek cover sheet not centered on the bottom tray of the pack. None of the reported complaints have resulted in death or serious injury.

Risk to Health: The open packaging of the affected product provides the opportunity for infectious agents and particulate matter to enter into the irrigation system and be transferred into the urinary tract. The greatest risk of harm in the population at most risk, immunocompromised patients, is that from infection. The risk of serious injury from infection is highly unlikely and harm is most reasonably expected to be reversible with medical intervention. Adverse health consequences of a temporary nature may occur, such as mild discomfort or low grade fever, however these symptoms are reasonably expected to resolve without medical intervention and would be difficult to separate from the typical symptoms experienced after such a procedure. Serious injury from the affected product is unlikely in all populations.

Affected Product: Refer to Table 1

Instructions:

1. **Please check your inventory and immediately quarantine any affected product.**
2. *Complete the attached reply form and return it to the fax number or e-mail address on the form*, even if you do not have the affected product.
3. Inform potential users of this product in your organization of this notification.
4. Return affected product to Stericycle using labels provided with this letter. If you have not received a return label or reply form or require additional assistance, please contact Stericycle at 1-877-377-5128 (M-F, 8am - 5pm ET). The return labels are for single use only. Please do not reproduce. Please visit http://expertezlabel.com to request additional labels for returning affected product.
5. To ensure proper and timely credit, follow the instructions on the return label for returning products.

If you have distributed the product further, please notify your accounts that may have received the product from you of this notification and ask them to contact Stericycle at 1-877-377-5128 (M-F, 8am - 5pm ET) to obtain a reply form.

Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com

Product Correction: The root cause has been identified and is being addressed and Hospira is currently shipping the above list numbers after a 200% inspection has been completed.

Please contact Hospira Customer Care at 1-877-946-7747 (M-F, 7am to 6pm CT) or your Hospira representative regarding product availability and for questions regarding this field action.

For further inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Complaint Management	1-800-441-4100 (M-F, 8am-5pm CT) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 or medcom@hospira.com (Available 24 hours a day/7 days per week)	Medical inquiries

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Please be assured that maintaining a high level of safety, quality and service is Hospira's highest priority. We appreciate your cooperation.

Sincerely,

Christopher Ganser
Corporate Vice President, Device Quality

Juergen Schmider, MD, PhD
Vice President, Global Pharmacovigilance & Product Safety

Table 1 – Affected Product Distributed February 2012 through March 2014

Description	List	Lots
Latex-Free Extension Set For Bladder Irrigation or Urinary Drainage, Compatible with T-U-R Flow-Pouch™ Reservoir, List 6542	4693-01	16119NS 17186NS 21134NS 25129NS
Latex-Free T-U-R Y-Set Nonvented Set for Transurethral Resection Procedures	6543-01	13106NS 13170NS 13251NS 14261NS 14262NS 15139NS 16117NS 17131NS 17132NS 17184NS 18110NS 18111NS 18182NS 19133NS 20122NS 20123NS 20124NS 20205NS 22146NS 22147NS 22148NS 22149NS 23103NS 23104NS 23105NS 23106NS 24156NS 25130NS 25131NS 27109NS 27253NS 27286NS 28136NS 28137NS 29094NS 29095NS 29096NS 30194NS 30195NS 30196NS 31042NS 31043NS 32229NS 32230NS 33138NS 33139NS 33140NS 34286NS 35117NS
Latex-Free Cystoscopy/Irrigation Set Nonvented, 77 inch (195 cm) for Constant or Intermittent Bladder Irrigation	6544-01	13107NS 13108NS 13171NS 13172NS 15141NS 15142NS 15143NS 16113NS 16114NS 16115NS 16116NS 16174NS 16175NS 16176NS 17134NS 18112NS 19130NS 19131NS 19132NS 20119NS 20120NS 20121NS 21130NS 21131NS 21207NS 22144NS 22145NS 23107NS 23108NS 23109NS 23110NS 23111NS 23112NS 24194NS 24204NS 25133NS 25254NS 27110NS 27111NS 27155NS 28192NS 28271NS 28272NS 29097NS 29170NS 29171NS 30197NS 30198NS 30199NS 30200NS 31044NS 31045NS 32231NS 32232NS 32319NS 33328NS 34170NS 34171NS 34287NS 35115NS 35116NS 35250NS 36160NS
Latex-Free Large Bore Y-Irrigation Set Nonvented Set	6599-01	12145NS 12146NS 16120NS 17130NS 18113NS 19134NS 20196NS 21132NS 24120NS 25134NS 25211NS 27112NS 28273NS 28274NS 29098NS 31040NS 32296NS 33142NS 34143NS
Latex-Free 4-Lead T-U-R Irrigation Set Nonvented Set for Transurethral Resection Procedures	15239-01	13259NS 17185NS 18181NS 23102NS 27108NS 28275NS 29093NS 31041NS

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UPDATE - Urgent Medical Device Recall Reply Form – RESPONSE REQUIRED
Irrigation Sets – Tyvek cover may not be completely sealed
28 March 2014

Check your inventory and complete the information below, even if you do not have the affected product.
Failure to complete all sections of this page may result in improper, delayed or denied credit.

Fax the completed form to 1-866-324-3732 or email it to Hospira6633@stericycle.com. *The return label provided in this notification is for single use only, please DO NOT reproduce.* Please visit *http://expertezlabel.com* to request additional labels for returning affected product. If you have questions about this form please call Stericycle at 1-877-377-5128 (M-F, 8am - 5pm ET).

Customer Information

Business Name _____ Hospira Customer # (if applicable) _____

Address/City/State/Zip _____

Contact Name/Phone/E-mail Address _____

Completed by: Printed Name/Signature/Date _____

☐ I have **NO** affected product (fill out and return this form to Stericycle at the fax/e-mail above).

☐ **YES**, I have affected product (fill out and return this form to Stericycle via the fax/e-mail above and return the product per the instructions on the return label).

If affected product is not being returned, please explain:

- Have you distributed the product further to the retail level? YES___ NO___
  - If yes, have you notified your retail customers? YES___ NO___ (if no, explain below)

List and Lot Number	Quantity to be returned	Wholesaler/Distributor Name If you purchased from Wholesalers/Distributors include name, address, city, state, zip, quantity from each, and invoice number. If you purchased directly from Hospira leave this section blank.	PO, debit memo or invoice
		1.	
		2.	
		1.	
		2.	

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