



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.

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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.

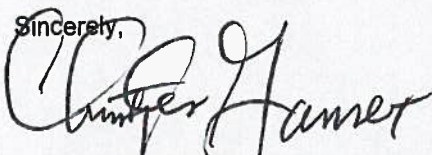
Hospira Contact	Contact Information	Areas of Support
Hospira Global Complaint Management	1-800-441-4100 (M-F, 8am-5pm CT) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 or medcom@hospira.com (Available 24 hours a day/7 days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

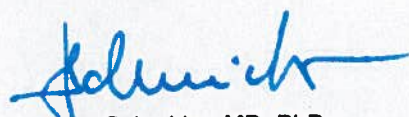

 Juergen Schmitter, MD, PhD
 Vice President, Global Pharmacovigilance & Product Safety



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				

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 <small>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.</small>	PO, debit memo or invoice
	1.		
	2.		
	1.		
	2.		