Ontario
Trillium Gift of Life Network

Quality Process Instruction Manual

Product Recall Process Instruction

1.0 Purpose:

To describe the process that needs to be conducted after a supplier notifies of a product recall.

2.0 Scope:

This process applies to:

- Trillium Gift of Life Network (TGLN)

3.0 Responsibilities:

Director of Quality is responsible for:

- overseeing the product recall process within TGLN
- performing a preliminary investigation for all product recalls
- developing the TGLN response to the recall
- ensuring that no recalled product is inadvertently used in error

Quality Specialist is responsible for:

- gathering the pertinent product manufacturer's product information
- identifying potentially impacted stakeholders
- developing communications correspondence to send to the affected stakeholders
- making contact with pertinent representatives from each of the potentially impacted stakeholders to advise them of the recall and next steps

Employees are responsible for:

- advising Quality Department of the product recall
- providing pertinent details regarding the product including manufacturer's and supplier's information and product lot #'s

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4.0 Process:

4.1. An employee advises the Quality Department of a product recall on a consumable used in either organ or tissue recoveries.

4.2. Director Quality performs a preliminary investigation:

- identifies products involved
- identifies if any organ/tissue recipients have been impacted
- identifies the suppliers involved
- identifies potential area of care of potential organ, tissue and transplant that could be affected, by consulting with the TGLN clinical and transplant teams

4.3. Director Quality assigns the recall to the Quality Specialist, or designate to have further details gathered:

- manufacturer's product brochure
- manufacturer's replacement product brochure, if available
- manufacturer's withdrawal notice, including product lot #'s
- spreadsheet of any potential impacted recipients

4.4. Quality Specialist communicates with transplant programs to learn additional details regarding any recipients impacted, during either their pre-transplant or post-transplant care.

4.5. Quality Specialist develops the following product recall documentation for distribution to the affected organ/tissue transplant programs:

- letter from TGLN to each affected transplant program to advise of the recall
- manufacturer's replacement product brochure, if available
- manufacturer's product recall letter
- manufacturer's product withdrawal notice
- list of potentially affected hospital recipients

4.6. Director Quality reviews the information packages to be sent to each transplant program and makes adjustments, where appropriate.

4.7. Quality specialist responds to any questions or queries from the affected stakeholders.

5.0 Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
TGLN Recall Letter	_____	Quality Department	Quality Department	16 years
Manufacturer's Replacement Product Brochure	_____	Quality Department	Quality Department	16 years
Manufacturer's Product Recall Letter	_____	Quality Department	Quality Department	16 years
Manufacturer's Product Withdrawal Notice	_____	Quality Department	Quality Department	16 years
List of Potentially Affected Recipients	_____	Quality Department	Quality Department	16 years

6.0 References:

- None

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Exhibit 1: Sample TGLN Recall Letter

Trillium Gift of Life Network 483 Bay Street South Tower, 4th Floor Toronto, Ontario M5G 2C9

Dear Ms. Sharpen,

I am writing this letter to inform you that Teva Pharmaceuticals has voluntarily recalled two specific lot numbers of its Viaspan (UW) perfusion solution. Please see the attached recall letter. The reason for the recall was a potential microbial contamination at their European manufacturing site. The contaminating organism is a gram positive bacillus, Bacillus Cereus. See the attached notification from Teva.

Attached is a list of tissue recoveries that were conducted on organ and tissue donors, in which abdominal organs were recovered using Viaspan. Since this recall, TGLN has removed all of the affected Viaspan from its inventory and replaced it with SPS-1 solution. Please see attached a product brochure. While all further communication updates from the pharmaceutical manufacturer will be shared by TGLN, it is recommended that each tissue bank make their own independent phone calls to the pharmaceutical manufacturer to have their pertinent questions answered.

Yours truly,

John Hanright, P. Eng.
Director, Quality Assurance & Performance Improvement
Trillium Gift of Life Network

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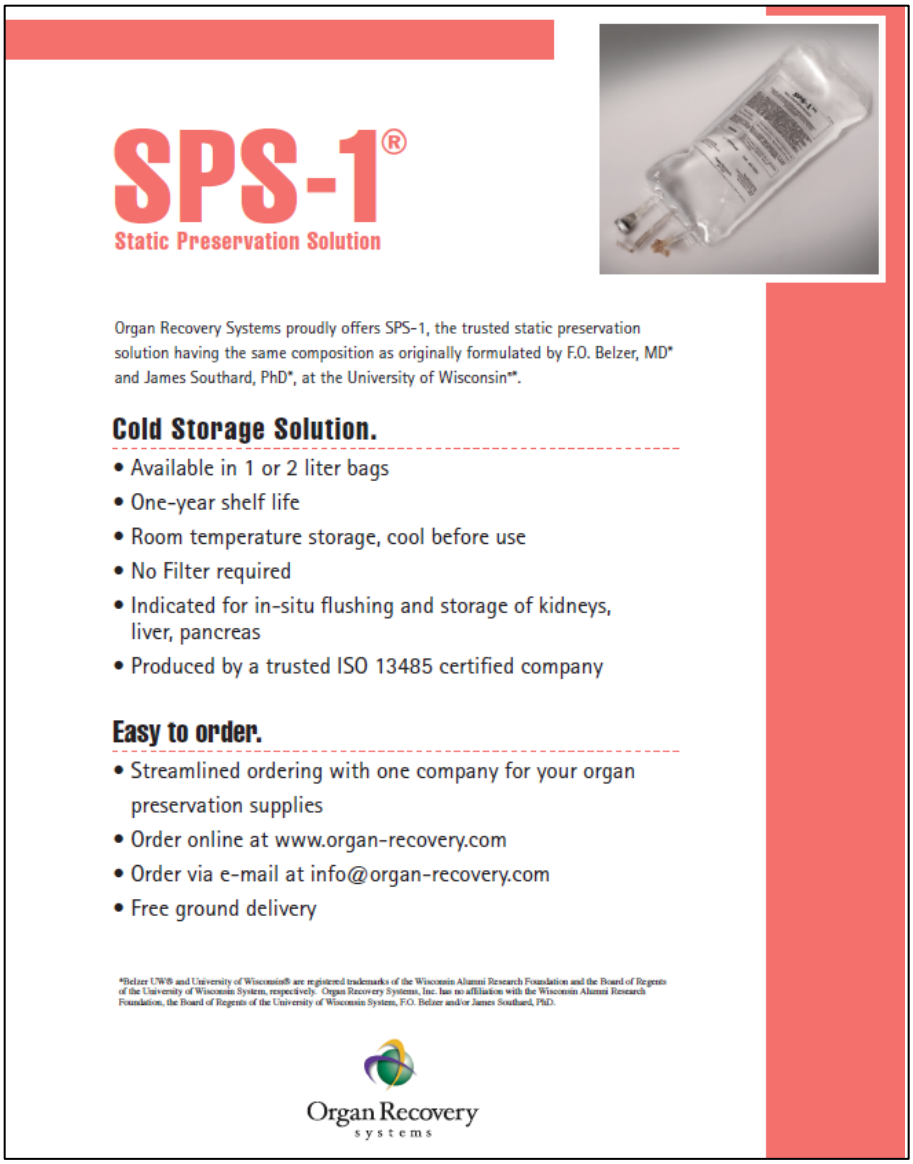
Exhibit 2: Sample Manufacturer's Replacement Product Brochure



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systems

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Exhibit 3: Sample Manufacturer's Product Recall Letter

TEVA Pharmaceuticals

April 6, 2012

Dear Healthcare Professional,

Teva Pharmaceuticals USA (under the Duramed label) would like to inform you of an Urgent Medical Device Recall regarding ViaSpan® solution which has an intended use of flushing and cold storage of organs including kidney, liver, and pancreas at the time of their removal from the donor in preparation for storage, transportation and eventual transplantation into a recipient. This product is manufactured by a third party, Fresenius Kabi Austria, for Teva. Teva distributes this product in the U.S. and Canada only.

Summary

- A potential for ViaSpan contamination by *Bacillus cereus* during the manufacturing process was discovered following routine testing procedures and investigations by the production site.
- At the present time, there is no evidence of contamination in the ViaSpan that has been released to the marketplace. We have also received no adverse events to date.
- Teva Pharmaceuticals (Duramed) has decided, as a precautionary measure to recall all batches/lots of potentially affected ViaSpan in the U.S. and Canada.

Below is a list of affected lots. **These lots were distributed between December, 2011 and March, 2012.**

Lot #	Exp. Date	Product Code	Size
16EK0007	10/2012	1000-46-06	10 x 1000mL Bags
16EK0193	10/2012	1000-46-06	10 x 1000mL Bags

If you have these lots, please refer to the attached Urgent Medical Device Recall that was issued on March 30, 2012 for further instruction.

Teva believes there are alternative solutions for organ preservation available, the selection of which should be based on the appropriate clinical judgment of the healthcare provider. Below follows guidance for those cases where patients recently underwent or will undergo organ transplantation, in which ViaSpan has or will be used as an organ preservation solution. For each individual case the healthcare providers should use appropriate clinical judgment in the care of their patients.

- As a precautionary measure, close medical monitoring is recommended for any patients who recently underwent an organ transplantation in which ViaSpan had been used as an organ preservation solution.

Teva Pharmaceuticals
1090 Horsham Road | North Wales, PA 19454 | Tel. 215.591.3000 | www.tevapharm-na.com

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Exhibit 4: Sample Manufacturer's Product Withdrawal Notice

TEVA your global advantage

VOLUNTARY
MARKET WITHDRAWAL NOTICE

ATTENTION: Retailers / Distributors / Wholesalers

Customer name here

Date:	April 5, 2012
Manufacturer:	Fresenius Kabi Austria
Distributor in Canada:	Barr Laboratories/Duramed
Product Description:	**Viaspan Cold Storage Solution Bags**

Product Name	Size	DIN	Lot Number	Expiry Date	Date of 1st Sale (MM/DD/YYYY)
Viaspan Cold Storage Solution	1000mL	N/A	16EI0222	09/2012	11/03/2011
Viaspan Cold Storage Solution	1000mL	N/A	16EK0007	10/2012	01/04/2012

Reason For Withdrawal: A precautionary measure due to a lack of assurance of sterility

Type of Withdrawal: **Type II**

Special Instructions: Returned Merchandise Authorization not required. Please ensure you send the Withdrawal Return Form with your merchandise being returned.

Return Procedure: **Retailers/Distributors/Wholesalers**:
All further distribution of the above lots must cease. Please return all affected stock immediately marked as **"Product Withdrawal Material – Not for Use" via courier service.** Please contact **Purolator Courier** and quote *account* # 1-0876563 and request a package pick up. Please send your return to the following address:

Barr Laboratories Inc.
c/o Lynden International Logistics Co.
10 Corrine Ct
Vaughan, Ontario
L4K 4T7
Attn: Returns Department

Credit Policy: All product withdrawal stock will receive 100% credit based upon TEVA 's current list price. To facilitate this process we ask that you complete the attached Withdrawal Return Form and include it with your return. Please be advised that product withdrawal stock must be returned to Barr Laboratories/Lynden International Logistics by May 5, 2012

Should you require additional information concerning the return of affected stock, please contact Denise Rodé of Customer Care 905-879-2798, 1-800-268-4937 or drode@lilco.lynden.com.

Should you have any questions regarding the product, please contact Teva Medical Affairs at 215-641-6974.

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Exhibit 5: List of Potentially Affected Recipients

DON ID	RETRIEVAL START DATE	RETRIEVAL END DATE	TRANSPLANT PROGRAM	RECOVERED & TRANSPLANTED ORGAN	TRANSPLANT DATE	RECIPIENT NAME
12345	12/11/2011 11:30:00	12/11/2011 15:00:00	ABC Hospital	Kidney-Right	12/11/2011 23:59:00	Smith, John
67890	12/18/2011 16:36:00	12/18/2011 18:10:00	ABC Hospital	Kidney-Left	12/19/2011 23:59:00	Doe, Joe
11121	12/18/2011 16:36:00	12/18/2011 18:10:00	ABC Hospital	Kidney-Right	12/18/2011 23:59:00	Smeeth, Jon
31415	01/06/2012 13:21:00	01/06/2012 15:00:00	ABC Hospital	Kidney-Right	01/06/2012 23:59:00	Dough, Jo