

# FDA Warns Of Potentially Contaminated SPS-1 Static Preservation Solution Distributed by Organ Recovery Systems, Inc.: FDA Safety Communication

**Date Issued:** March 9, 2017

**Audiences:**

- Organ and tissue procurement organizations
- Organ and tissue transplantation centers
- Health Care Providers who conduct organ and tissue transplant procedures
- Health Care Providers who care for organ and tissue transplant recipients
- Operating Room Managers, Directors and Staff
- Risk Managers
- Patients considering organ or tissue transplantation
- Organ and tissue recipients

**Medical Specialties:** Transplant surgeons, Nephrologists, Hepatologists, Infection Control, Infectious Disease Physicians

**Product:** SPS-1 Static Preservation Solution (SPS-1), manufactured by Organ Recovery Systems, Inc., is a clear to light yellow, sterile solution intended for the flushing and cold storage of kidney, liver, and pancreas at the time of organ removal from the donor in preparation for storage, transportation, and eventual transplantation into a recipient.

**Purpose:**

The FDA wants to heighten awareness about the potential for bacterial contamination of SPS-1, and provide recommendations to health care facilities to help mitigate potential patient exposure to infectious bacteria.

In addition, the FDA is calling attention to Organ Recovery Systems' recall of specific SPS-1 lots and the company's temporary suspension of production and distribution of all SPS-1 products.

**Summary of Problem and Scope:**

On Dec. 14, 2016, staff at a health care facility notified the FDA of an uncharacteristic odor from SPS-1 encountered during an organ procurement operation. Laboratory results from fluid samples and cultures from the SPS-1 used for this operation confirmed contamination with *Pantoea* and *Enterococcus* (intrinsically vancomycin-resistant) bacteria.

While it is not yet known how the SPS-1 used for this operation became contaminated, Organ Recovery Systems immediately initiated a **voluntary removal** (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=151877>) of two lots of SPS-1: Lot Numbers PBR-0060-392 and PBR-0074-330.

On Jan. 12, 2017, Organ Recovery Systems **notified** (<http://www.organ-recovery.com/december-18-2016-update-archive/>) (<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>) customers of another report of an uncharacteristic odor from SPS-1 from a different lot, Lot Number PBR-0074-337, suggestive of potential contamination. Additionally, SPS-1 from Lot Number PBR-0060-386 was reported as being present when an odor was noticed, although the report did not identify any odor coming directly from this product.

Since then, Organ Recovery Systems temporarily suspended production and distribution of all SPS-1 products, and added Lot Numbers PBR-0074-337 and PBR-0060-386 to their recall.

On March 8, 2017, Organ Recovery Systems **updated** (<http://www.organ-recovery.com/news-and-events>) (<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)

customers on the voluntary removal of SPS-1 and stated that additional sterility testing of randomly selected bags of SPS-1 should be completed by March 31, 2017.

To date, there have been no reports to the FDA of any post-operative infections or other adverse events directly linked to the identified products.

Recommendations for Organ and Tissue Procurement Organizations and Transplant Facilities:

In addition to following the standard precautions, the FDA recommends facilities and staff:

- Be aware that Organ Recovery Systems has **recalled** (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=151877>) SPS-1 Lot Numbers PBR-0060-392, PBR-0074-330, PBR-0074-337, and PBR-0060-386.
  - Inspect your shelves and immediately remove these products from your inventory.
  - Return the affected lots to Organ Recovery Systems.
  - If there are questions about this recall, contact Organ Recovery Systems at 847-824-2421.
- Consider quarantining existing lots of SPS-1 not included in the recall and use an alternative FDA-cleared product until Organ Recovery Systems provides additional assurance of product safety through additional sterility testing.
  - Be aware that while contaminated SPS-1 to date has been associated with an uncharacteristic odor, the absence of an odor does not rule out the potential for bacterial contamination.
- If your facility does not have an alternative organ preservation solution immediately available, the FDA does not believe that organs exposed to SPS-1 should be excluded from transplantation. Rather, the small risk of infection should be balanced with the benefits of transplantation in each potential recipient.
- Pay attention to the quality of any organ preservation solution used. If there are concerns about odor, cloudiness, precipitation, or any other physical characteristics that could indicate contamination, carefully consider the benefits and risks.
- Report any adverse events or suspected contamination of organ preservation solution to the **FDA** ([/Safety/MedWatch/HowToReport/ucm2007306.htm](http://www.fda.gov/Safety/MedWatch/HowToReport/ucm2007306.htm)) and the manufacturer.

**Recommendations for Patients considering organ or tissue transplantation procedures:**

- Be aware that there are benefits and risks associated with all medical procedures. Ask your doctor about what to expect after an organ or tissue transplantation procedure including possible complications.

**Recommendations for Organ and Tissue Recipients:**

- If you have already undergone an organ or tissue transplantation procedure, *continue with your routine follow-up with your health care provider as recommended.*

**FDA Activities:**

The FDA is working with the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and state public health departments to actively investigate the potential for contamination in Organ Recovery Systems' SPS-1.

Our ongoing activities include:

- Evaluating information about documented and potential infections from multiple sources, including **medical device adverse event reports**

([/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm](#)) submitted to the FDA, federal partners, state public health departments, and international public health agencies.

- Collaborating with CDC and HRSA to **notify** (<https://optn.transplant.hrsa.gov/news/most-recent-update-jan-29-on-the-bacterial-contamination-of-sps-1/>) all Organ Procurement Organizations and transplant centers about the potential for bacterial contamination of Organ Recovery Systems' SPS-1.
- Working with Organ Recovery Systems to reduce the risk of release of contaminated product, confirm the sterility of previously released product, and confirm appropriate quality control procedures.

The FDA will keep the public informed as significant new information becomes available.

#### Reporting Problems to the FDA:

Device manufacturers and user facilities must comply with the applicable **Medical Device Reporting (MDR) regulations**

([/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm](#)).

Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements**

([/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm](#)) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with the use of medical devices. Health care providers should submit voluntary reports of infection transmission associated with organ preservation solutions to the Agency via the **Medical Device Reporting (MDR)** ([/MedicalDevices/Safety/ReportaProblem/ucm2005291.htm](#)) process. If a health care provider suspects contamination of the organ preservation solution before or following use, we encourage the health care provider to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program** ([/Safety/MedWatch/HowToReport/ucm2007306.htm](#)). User facilities participating in the FDA's Medical Product Safety Network (MedSun) should report all of their device-related adverse events through the MedSun reporting site, not through MedWatch.

#### Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at [DICE@FDA.HHS.GOV](mailto:DICE@FDA.HHS.GOV) (<mailto:DICE@FDA.HHS.GOV>), 800-638-2041 or 301-796-7100.

#### Additional Resources

- **Organ Recovery Systems, Inc. SPS-1 Voluntary Product Removal Update. March 8, 2017** (<http://www.organ-recovery.com/news-and-events/>)  
([/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm](#))
- **Organ Procurement & Transplantation Network: Most recent update (Jan. 29) on the bacterial contamination of SPS-1** (<https://optn.transplant.hrsa.gov/news/most-recent-update-jan-29-on-the-bacterial-contamination-of-sps-1/>)
- **Organ Recovery Systems, Inc. Important Information about SPS-1 Static Preservation Solution. January 12, 2017** (<http://www.organ-recovery.com/december-18-2016-update-archive/>)  
([/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm](#))
- **Organ Recovery Systems, Inc. FAQs About Voluntary Product Removal of SPS-1 Lot PBR-0074-330 & Lot PBR-0060-392. December 22, 2016** (<http://www.organ-recovery.com/frequently-asked-questions/>)  
([/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm](#))
- **Organ Recovery Systems, Inc. Customer Notification. Important Information Regarding Two Separate Lots of SPS-1, Static Preservation Solution. December 18, 2016** (<http://www.organ-recovery.com/important-information-regarding-two-separate-lots-of-sps-1-static-preservation-solution/>)  
([/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm](#))

More in **Safety Communications**  
([/MedicalDevices/Safety/AlertsandNotices/default.htm](#))