

Important Information about SPS-1[®] Static Preservation Solution

Updated: January 12, 2017

Organ Recovery Systems, Inc. became aware yesterday (Wednesday, January 11) of an uncharacteristic odor suggesting a potential contamination of SPS-1[®], Static Preservation Solution product from **Lot Number PBR-0074-337**. In addition, we learned that SPS-1 product from **Lot Number PBR-0060-386** was reported as being present when an odor was noticed, although no odor was specifically identified as coming from this product. While we are certain that the units from both Lots met our product's stringent release criteria upon shipment, we are in the process of conducting a comprehensive investigation of this information.

During our solution manufacturing process and prior to shipping, we conduct rigorous quality testing of our products including sterility testing. These testing procedures include a comprehensive protocol of endotoxin, cytotoxicity, and chemical analysis. Products are released only after verification that they have met all product release criteria. We have verified that **Lot Number PBR-0074-337 and Lot Number PBR-0060-386** met all product release criteria upon shipment.

Although we are confident in our quality control process and believe this is an isolated situation, out of an abundance of caution, **we are temporarily suspending production of SPS-1** and will not be making further shipments of **Lot Number PBR-0074-337 and Lot Number PBR-0060-386** pending the conclusion of our investigation.

Our decision to temporarily suspend production and stop shipping the Lots under investigation is a voluntary and precautionary measure. We are coordinating closely with the FDA and other governmental agencies throughout this process. We will update the market on the results of our investigation and the re-start of production when such information becomes available.

For now, we request that you please **quarantine in place** all SPS-1, Static Preservation Solution from **Lot Number PBR-0074-337 and Lot Number PBR-0060-386**. Please do not dispose or return product to us at this time. As we gather additional information, we will provide you further instructions in the coming weeks.

We highly value our relationship with you, and thank you for your prompt attention to this request.

Should you have additional questions or comments, please do not hesitate to contact me via e-mail: mcopithorne@organ-recovery.com or your account representative.