

# Efficacy and Sterility of Swabbable-Valve Transfer Set

## For Management of Bulk Contrast and Saline in Accordance with USP Guidelines

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### Introduction

Bulk pharmaceutical packaging has become a common format for packaging contrast agents, as it is more economical than individual small contrast vials. With the utilization of bulk pharmaceutical packaging, new requirements for safely dispensing the contrast agent must be considered. Attention should be paid to the manner in which bulk pharmaceuticals are successfully packaged without contaminating the bulk supply and without contaminating the fluid delivered. Similar methods should be employed for the packaging and dispensation of contrast fluid.

### USP Requirements

The USP (United States Pharmacopeial Convention) discusses the requirements for multiple dosing from bulk containers in Section <I>. This section requires that injection container closures for multiple dose vials must maintain the sterility of the container's contents. In USP Section <797>, risk categories for compounding and dispensing of multi-dose pharmaceuticals are established and the need for aseptic handling is strongly emphasized. Risk categorization for a device may be changed based on the handling techniques or environmental conditions of dispensing.

Examination of these guidelines indicates that the ideal transfer set for bulk contrast containers would preserve the sterility of the contrast media remaining in the bulk container. Also, the ideal transfer set connection would be simple to aseptically clean and then couple to multiple syringes, thus allowing fluid dispensing in less stringent environments than described in USP <797> under the low risk category.

### SVTS Overview

The SVTS is a transfer set with a spike at the bulk connection end and a plastic tube that runs from the spike to a Halkey-Roberts swabbable, luer-compatible connection. The SVTS transfer set was designed and tested with USP requirements in mind. The concept of the SVTS transfer set is to provide a closed system set that can be utilized to fill syringes with minimal contamination risks. The SVTS meets all the normal sterile device requirements for validation of sterilization process (per ISO 11135), validation of packaging (per



ISTA-2A), and assurance of biocompatibility of the materials used in its construction (per ISO 10993-1 for limited exposure indirect blood path contact with the patient-Class II device).

To address the special requirements for bulk contrast dispensing into multiple syringes, the SVTS transfer set incorporates a Halkey-Roberts swabbable valve at the syringe connection point. The Halkey-Roberts valve is designed to be an "easy to clean" entry method into a sterile fluid environment. The prior uses of this valve have been to provide entry into IV set-ups and other fluid delivery systems that require intermittent multiple entries into the system.

### Test Protocol

To ensure that the technology of the Halkey-Roberts valve would function to preserve the sterility of a bulk contrast container with multiple fluid dispensing, a series of bacterial challenge studies were performed. These challenges used worst case conditions under the following scenarios: the use of bacterial growth media as the fluid used in the container/SVTS system; the use of a very small mobile bacteria to challenge the integrity of the valve; the use of a very high bacterial population as the challenge; the number of times the device was activated; and the time interval over which each set was tested. The time of use for each transfer set was twelve hours (the labeled time of use period for the SVTS transfer set). The bacteria contaminate used for the challenges was selected because it is a very small organism capable of movement against fluid currents. The timeframe and chosen microorganism made an especially severe challenge for the device. Other portions of the contamination testing collected the fluid dispensed from the transfer set/bulk container:

**The contamination testing performed during the development of the SVTS transfer set demonstrated no bacterial contamination of the transfer set or the bulk fluid container under any of the test conditions.**

Therefore, analysis of the contamination pattern demonstrated that the SVTS with the Halkey-Roberts valve is capable of mitigating the contamination potentials to a degree that allows the filling of multiple syringes from a bulk contrast container in a less than Class 100 laminar flow hood with a high degree of confidence.

### **Conclusion**

The contamination studies demonstrated that the SVTS transfer set with the Halkey-Roberts swabbable valve is capable of maintaining the sterility of the contents of the bulk contrast container over the prescribed time interval and number of uses described in the product labeling.

**SVTS Swabbable-Valve Transfer Set**  
**50 per box**  
**Compatible with all Medrad CT and MR syringes**



### **Standards and Guidance Referenced in this paper are:**

1. United States Pharmacopeia No.27, 2004.
  - a. Section <1> Injections page 2108.
  - b. Section <797> Pharmaceutical Compounding-Sterile Preparations page 2350.
  - c. Section <1211> Sterilization and Sterility Assurance of Compendial Articles page 2616.
2. United States Pharmacopeia No 27. Supplement No.1 2004.
  - a. Section <797> Pharmaceutical Compounding-Sterile Preparations page 23121.
3. ISO/AAMI 11135 Medical Devices-Validation and Routine Control of Ethylene Oxide Sterilization.
4. ISO/AAMI 10993-1 Biological Evaluation of Medical Devices-Part 1 Guidance on Selection of Tests.
5. ISTA-2A International Safe Transit Association test method 2-A.

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