

June 2024

**VOLUNTARY MEDICAL DEVICE SAFETY ALERT**

**SPECTRA OPTIA™ APHERESIS SYSTEM  
Reminder to Prime Blood Warmers**

Dear Valued Customer:

The purpose of this letter is to remind Spectra Optia system users of a potential safety hazard when using a blood warmer attached to a Spectra Optia tubing set and to reinforce the actions required to mitigate this risk. If the blood warmer is not primed before use, air could be delivered to a patient.

Many Spectra Optia procedures include the option to use a blood warmer. The Spectra Optia operator's manual instructs operators how to connect and prime a blood warmer when one is used. The operator's manual also includes warnings about the risk of delivering air to a patient if a blood warmer is not primed. These warnings appear throughout the manual: in the "General procedural warnings" section in the Preface of the operator's manual and in the instructions for priming the lines before connecting the patient for each procedure for which a blood warmer is an option.

If an operator did not observe this warning and/or did not follow the instructions in the operator's manual, this safety hazard could occur.

**REASON FOR THE SAFETY ALERT**

Terumo Blood and Cell Technologies has received complaints where air was returned to a patient due to an unprimed blood warmer. A blood warmer that is not primed and is connected to the Spectra Optia tubing set return line could cause a risk.

A blood warmer can be attached to the tubing set either at the beginning of a procedure or during a procedure.