

December 2018

Urgent FIELD SAFETY NOTICE

IV Pole Collar for Spectra Optia® Apheresis System

Type of action: Device Upgrade

Dear Valued Customer,

Terumo BCT is dedicated to providing you with the highest quality support and remains committed to communicating information regarding Terumo BCT products. This letter provides information about the new IV pole collar accessory for the Spectra Optia system.

New Spectra Optia systems will be shipped with an IV pole collar (shown in Figure 1 below). This feature has been added to avoid a pinch point between the IV pole and the machine while lowering the IV pole.

If the operator does not hold onto the IV pole while pressing the IV pole release button, the IV pole may drop in a free fall. If the operator's hand or any other body part is in the path of the free-falling IV pole, the operator could be injured. Because this is an added safety feature, do not remove the collars after they are installed on the IV pole.



Figure 1: Photo of the IV pole collar installed on the Spectra Optia IV pole.

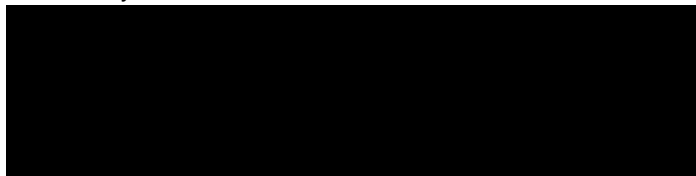


Figure 2: Photo of the IV pole collar prior to installation.

Your local Terumo BCT representatives will work with you to ensure IV pole collars are provided and installed on Spectra Optia systems already in the field. On new machines, service technicians will attach the IV pole collar to the IV pole during installation.

We appreciate your continued support and look forward to serving you. If you have any questions, please contact your Terumo BCT representative or your regional customer support center. Please note that your National Competent Authority has been notified about this Field Safety Notice.

Sincerely,



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