



Extracorporeal photopheresis drive tube leak due to end-user misload

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A 10-year-old boy (44 kg, 3520 mL total blood volume) with chronic graft-versus-host disease after allogeneic stem cell transplant was undergoing extracorporeal photopheresis using the Cellex instrument when something unexpected happened. The procedural kit was loaded according to standard operating procedures and the system was primed successfully. After 150 mL of whole blood was processed, the instrument showed high pressure system alarm error 18, which was quickly followed by a “pop” and blood leakage into the centrifuge chamber (see figure). The procedure was aborted and blood was not returned to the patient due to the loss of sterility from the leak. The estimated blood loss was approximately 200 to 300 mL, which accounted for the blood in the tubing and centrifuge bowl. Given the patient’s preprocedure hematocrit (Hct) of 27.2% and stable vital signs (before—blood pressure 135/72, pulse 103 bpm, temperature 36.4°C; after—blood pressure 127/72, pulse 112 bpm, temperature 36.1°C) no blood was transfused. His Hct the following day was 28.4%.

An investigation by Therakos showed no machine or procedural kit malfunctions. Examination of the drive tube revealed wear marks on the outside of the drive tube near the upper bearing stop that were consistent with a misload. Wear of the upper bearing likely occurred because the bearing stop was moving while touching something fixed.

There are at least five reports to Therakos or the FDA¹ of a drive tube leak using the Cellex since 2010. Possible reasons for blood leakage into the centrifuge chamber may include a defective drive tube or centrifuge bowl misload by the end-user. When installing the centrifuge bowl, it is important to verify that the bearings and drive tube are not damaged and the drive tube bearings are fully seated in their retainer clips.

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CONFLICT OF INTEREST

The authors have disclosed no conflicts of interest.

REFERENCE

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