

# LIFE 18™ apheresis unit Field safety notice

EN

Surveillance gap in the blood leak detection of the LIFE 18™ apheresis system

Dear user,  
we would like to bring to your attention a possible problem that may occur when using the LIFE 18™ apheresis system.

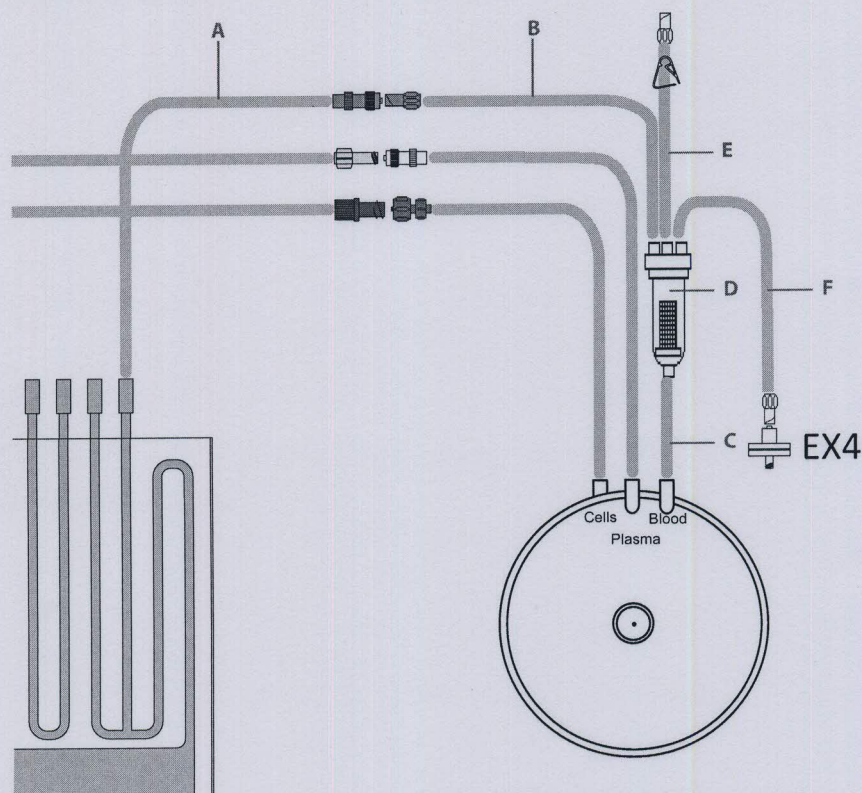


Figure: connection of Disk Separator with Theraline or TPE Line pump cassette.

## Description

During a treatment blood is withdrawn from the venous access of the patient and delivered to the Disk Separator via the tubing lines (depicted as A to C in the figure above) and the Disk Separator drip chamber (depicted as D). The pressure in the drip chamber is monitored by external sensor EX4. This flow path is checked for tightness during the set-up procedure.

If a leak develops in this flow path of the blood during the treatment, usually the pressure will drop and the external pressure sensor EX4 will raise an alarm if the pressure is not fluctuating (or alternating) within a certain range.

Tests in our laboratory have shown the possibility that under certain circumstances the LIFE 18 apheresis unit will not interrupt the treatment and stop all pumps if a blood leak occurs in the tubing of the Disk Separator (anywhere between A and F in the figure above).

If such a phenomenon occurs during treatment and would remain undetected by the user, the patient might lose significant blood volumes.

### Initial action

**Please make sure that the patient connected with the LIFE 18 apheresis unit never remains unattended during the treatment. Please check for tubing set integrity regularly during the treatment.**

### Action by the manufacturer

Our company is working hard to solve this potential problem by a modified software with an improved surveillance of the blood pumps. The development, verification, validation and release of the revised software however will probably require several weeks. In addition, the thorough installation of the revised software on all LIFE 18 apheresis units by our qualified service engineers will also require significant time.

We would like to emphasize that this type of a severe blood leak in the fluid path of the Disk Separator during a treatment has been observed for the first time in more than 30.000 treatments performed with the separator. In this particular case the blood leak was immediately detected by the operator and resolved by stopping the treatment and replacement of the defective separator before any harm to the patient occurred.

The above indicated initial action presents an intermediate preventive action, before the revised software will be able to correct the gap in the blood leak detection of the LIFE 18 apheresis unit.

We thank you for understanding that we are taking these measures to ensure the safety of your patients.

Your sincerely,



14.10.2013



► [www.therasorb.com](http://www.therasorb.com)

**Miltenyi Biotec GmbH** | Robert-Koch-Straße 1 | 17166 Teterow | Germany | Phone +49 3996 158-258 | Fax +49 3996 158-222  
macstec@miltenyibiotec.de | [www.miltenyibiotec.com](http://www.miltenyibiotec.com)

Miltenyi Biotec provides products and services worldwide. Visit [www.miltenyibiotec.com/local](http://www.miltenyibiotec.com/local) to find your nearest Miltenyi Biotec contact.

Unless otherwise specifically indicated, Miltenyi Biotec products and services are for research use only and not for therapeutic or diagnostic use. LIFE 18 and TheraSorb are registered trademarks or trademarks of Miltenyi Biotec GmbH. Copyright © 2013 Miltenyi Biotec GmbH. All rights reserved.