



Miltenyi Biotec



FIELD SAFETY NOTICE/CUSTOMER INFORMATION FOR:

Product name: LIFE 18™ - Theraline pro

REF: 330-000-651

Intended purpose: The LIFE 18 - Theraline pro is used for channelling of blood, plasma and solutions. For connection of the different components of the LIFE 18 apheresis system (e.g. separator, solutions and adsorber) and the patient for applications run on the LIFE 18 apheresis unit.
The LIFE 18 - Theraline pro is an accessory to the LIFE 18 apheresis unit and may only be used in conjunction with the other accessories of the TheraSorb product line.

Potential Defect: Miltenyi Biotec GmbH as the manufacturer is aware of a misconnection of fluid paths in 1 of 15,000 tubing sets. A reoccurrence is improbable but cannot be completely excluded.

Hazard: If instructions for use are not followed, the safe and effective use of the device cannot be guaranteed. Solutions used for the treatment might be applied in the wrong order.

Actions to be taken: Please make sure that the tubing set installation process – Part 2 is performed as indicated on the screen of the LIFE 18 apheresis unit and described in chapter 6.4 of the LIFE 18 apheresis unit user manual (Adsorption therapy with multiple-pass adsorbers).
If an alarm occurs during this process please make sure to follow the appropriate troubleshooting instructions on the screen and in the LIFE 18 apheresis unit user manual (General instructions and troubleshooting).
Do not continue the installation process without handling all upcoming alarms adequately. Under no circumstances connect all solutions simultaneously.

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Customer information: LIFE 18™ - Theraline pro

Dear customer,

The safety and effectiveness of TheraSorb products is of utmost importance for Miltenyi Biotec. Therefore, we want to inform you about a potential but improbable impairment of the LIFE 18™ - Theraline pro.

Miltenyi Biotec GmbH is aware of a single case of misconnected fluid paths in 15,000 sold units. This production-related defect in combination with a handling error might lead to an unsafe and ineffective treatment.

As a precaution we want to inform you about this potential impairment of Theraline pro tubing sets. The use of such a defective tubing set is prevented by exactly following the instructions for use.

- Please always strictly follow the instructions on the screen of the LIFE 18 apheresis unit and in the product specific manuals and package inserts.
- Please take special care that the NaCl solution bag is connected properly in order to assure an optimal rinsing of the tubing set and the adsorbers during preparation and treatment.
- Please make sure to adequately handle upcoming alarms. Please never continue with installation unless all errors are resolved. In case an error cannot be resolved please consult one of our application specialists, discard the tubing set and restart with a new tubing set.

We thank you for your understanding that we take this measure as a precaution to ensure the performance and safety of our products.

Dr. Werner Schmidt

16. March 2018

Safety Officer Medical Devices according to §30 MPG

QA-Global Complaints/MDR