

Miltenyi Biotec B.V. & Co. KG, Friedrich-Ebert-Str. 68, 51429 Bergisch Gladbach

Bergisch Gladbach, 2024-08-30

Field Safety Notice: Use of a central venous catheter with the TheraSorb® LIFE 21® therapeutic apheresis platform.

Dear customer,

Ensuring patients' safety is our top priority, and we aim to keep you informed about potential risks with our medical devices. We are writing to provide important safety information concerning the use of a central venous catheter in conjunction with the TheraSorb® LIFE 21® therapeutic apheresis platform.

Affected Products

Product Name	Catalogue Number	GTIN (UDI-DI)
LIFE 21 apheresis unit for sale	330-000-621	04049934006449
LIFE 21 apheresis unit for lease	330-000-622	04049934006456

Safety information and recommended actions

The LIFE 21 apheresis unit is classified as being in protection class I, and touchable metal parts are classified as applied part B (based on EN IEC 60601-1). The instrument is therefore not designed and suitably safe for direct cardiac application, i.e. the use with central venous catheters inside the right atrium.

The blood lines to and from the patient (applied parts) can hypothetically establish an electrical contact with the patient through instrument leakage currents. Conducting solutions in or around the tubing set could cause a current to flow between the LIFE 21 and the patient's vascular access. If the tip of a conducting catheter touches the right atrial wall, this can cause fibrillation by a microshock.

Therefore, do not place the tip of a central venous catheter inside the right atrium. If a central venous catheter is used, make sure that the tip is located outside the right atrium.

EN IEC 60601-2-16 considers this risk and the associated hazardous sequence of events as being of a very low probability. In more than 20 years of use of the LIFE apheresis units, no incidence of an actual or suspected cardiac fibrillation has been reported.

Thank you for your attention to this safety information. We are committed to providing safe and reliable healthcare solutions and appreciate your cooperation in maintaining the highest standards of patient care.

We kindly ask you to confirm that you have received and understood the safety information above by completing the attached **response form**.

If you have any questions about this matter, please contact your Miltenyi Biotec representative or visit <https://www.miltenyibiotec.com/support/technical-support.html>.

Sincerely,
Miltenyi Biotec B.V. & Co. KG

Miltenyi Biotec B.V. & Co. KG

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Field Safety Notice: Use of central venous catheters with the TheraSorb® LIFE 21® therapeutic apheresis platform.

Response form

Please send this response form to the following e-mail address as soon as possible, but no later than 30 days after receiving this letter: GlobalComplaints_MDR@miltényi.com

Thanks you for your cooperation.

Customer/facility

Address

Name (contact person)

Position

Telephone number

E-mail

- ☐ I confirm that I have received and understood the safety information.
- ☐ I confirm that all users of the device were and will be informed about the safety information

Date / Signature

Miltényi Biotec B.V. & Co. KG

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