Löwenstein Medical - Arzbacher Straße 80 - 56130 Bad Ems

Medical device safety
<<adr_1>>
<<adr_2>>
<<adr_3>>
<<adr_4>>
<<Adr_5>>

E-Mail: <<email>>

Customer number: <<KNR>>

08.05.2025

Urgent safety information

FSCA2025015 - Leoni plus transport -RECALL-

Dear Sir or Madam,

At Löwenstein Medical, quality and patient safety are our top priorities. For this reason, we are issuing the following urgent safety information regarding a potential hazard associated with certain Leoni Plus Transport ventilators.

Manufacturer:

Löwenstein Medical SE & Co KG, Arzbacher Straße 80, 56130 Bad Ems

Description of the Problem

We delivered 15 *Leoni Plus Transport* devices that include components which were later found not to meet our internal quality standards.

Identification of the affected devices

Product: *Leoni Plus Transport* (PN 0217400)
Affected Serial Numbers:
0217400hul99990065 / 0217400hul99990066 / 0217400hul99990067 / 0217400hul99990068 / 0217400hul99990070 / 0217400hul99990071 / 0217400hul99990072 / 0217400hul99990073 / 0217400hul99990074 / 0217400hul99990075 / 0217400hul99990076 / 0217400hul99990081 / 0217400hul99990082 / 0217400hul99990084 / 0217400hul99990085

Risk assessment:

The *Leoni Plus Transport* is designed for use during patient transport. Some components in the affected units may malfunction under transport conditions. This could cause the device to stop working and may pose a risk to patients.

Action Required by End Customers and Users

- **Stop using any affected device immediately** to ensure patient safety.

Action Required by Dealers

- **Please forward this safety information** without delay to all customers who received affected devices.
- **Please confirm receipt** of this letter by completing the form provided in *Annex A*.

Action by the Manufacturer

- The affected devices will be **removed from the market**
- We sincerely apologize for any inconvenience this recall may cause. At present, there are no alternative solutions available.

We are very sorry for the trouble this recall may cause. Right now, we do not have any other solution.

Yours sincerely

Medical Device Safety Representative (PRRC)

Annex A: Confirmation of Receipt
Annex B: Customer-specific list of affected devices

<<FSCA>>2025-05-08

Löwenstein Medical SE & Co. KG
Arzbacher Straße 80
56130 Bad Ems, Deutschland
T. +49 2603 9600-0
F. +49 2603 9600-50
info@loewensteinmedical.com
loewensteinmedical.com

Handelsregister
Amtsgericht Koblenz
HRA 20732
IK-Nr. 590711157
St.-Nr. 30/201/00291
USt-IdNr. DE 270737704

Bankverbindungen
Commerzbank Koblenz
BIC COBADEFFXXX
IBAN DE45 5704 0044 0200 1352 00
Volksbank Rhein-Lahn-Limburg
BIC GENODE51DIE
IBAN DE14 5709 2800 0200 4739 06

Komplementärin
Löwenstein Verwaltungs SE
Sitz: Bad Ems
Geschäftsführende Direktoren:
Reinhard Löwenstein
Benjamin Löwenstein
Amtsgericht Koblenz, HRB 28045

Annex A

Confirmation of acknowledgement to Löwenstein Medical

to safety information FSCA2025015 - Leoni plus transport

The original letter was sent to:

<<adr_1>>
<<adr_2>>
<<adr_3>>
<<adr_4>>
<<adr_5>>

Please complete this feedback form and send it to RecallMD@loewensteinmedical.com. Please do not forward this feedback form to any other organisation.

e-mail: RecallMD@loewensteinmedical.com

Löwenstein Medical
Medical device safety
Arzbacher Street 80
56130 Bad Ems
Germany

Please complete in full in block capitals:

- ✓ I hereby confirm that I have received this letter and that I have read and understood its contents.
  All users of the product and other persons to be informed will be notified of this letter.

- ✓ We will immediately ensure that the affected devices are taken out of service.

_____
Date, signature

_____
Name (in block capitals)

_____
Position (in block capitals)

_____
E-mail (in block capitals)

<<FSCA>>2025-05-08 <<KNR>>

Annex A

FSCA2025015 - Leoni plus transport -RECALL-

Customer-specific list of the affected devices that Löwenstein Medical has supplied to you:

Pos	Trade name	Serial number	Delivery date