

Customer number:

Dortmund, 2018 August

**Urgent safety information SLK Varilymph 12 Pro**

BfArM - case number 02604/18

Dear Sir or Madam,

For a given reason, we would like to inform you about the following corrective action.

**Identification of the affected medical devices:**

SLK Varilymph 12 Pro, serial numbers AIK000001 to AIK003883.

**Description of the problem including the identified cause:**

The supplied power cord is equipped on the device with a IEC connector in protection class I version and on the power supply with a mains plug of protection class II. Proper and intended use in conjunction with the Varilymph 12 Pro compression device is not hazardous as the housing of the Varilymph 12 Pro is insulated (protection class II).

There is a risk if another, non-insulated electrical device (protection class I) with an IEC connection (C14 socket) is operated with the cable. In this case, the Varilymph 12 Pro mains cable would not provide any connection of all metallic touchable parts to the protective conductor.

What measures should be taken by the addressee?

Please inform users about the risks described above!

Have an exchange done by a mains cable provided by us free of charge, which eliminates the described risk. Please use the attached confirmation form.



SLK Medical GmbH  
Lindenhorster Straße 38-40  
44147 Dortmund  
Tel. 0800 - 755 00-55  
Fax 0800 - 755 00-66

[www.slk-medical.de](http://www.slk-medical.de)

— Please destroy the affected power cable (eg by cutting the cable) and document this. Please inform us about the implementation of the measure and the corresponding serial numbers of the devices.

The Varilymph 12 Pro product can continue to operate safely with the affected power cord until the power cord is replaced.

Timetable for implementation: 3 months

Passing on the information described here:

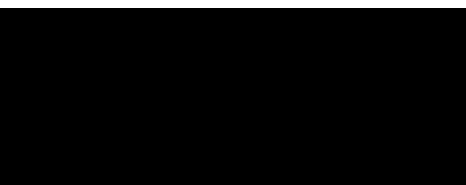
Please make sure in your organization that all users of the o. G. Products and other persons to be informed of this urgent safety information. If you have given the products to third parties, please forward a copy of this information.

— Please retain this information at least until the action has been completed.

The Federal Institute for Drugs and Medical Devices has received a copy of this "Urgent Safety Information".

We regret the inconvenience this entails.

— If you have any further questions, please contact Sales Assistant Ms Jasmin Petzsch on 0231-92 53 60-278.



SLK Medical GmbH

**Attached**  
delivery note

Return Form "Confirmation about Replacement Power Cord"  
  
power cord