Urgent Safety Notice (FSN)

Subject:	Mandatory Replacement of the Solenoid Valve
Product:	IceCube MED Freezer (11/14/17)
Affected unit serial number at your location:	See email

Dear Sir or Madam,

As a responsible manufacturer of medical devices, the safety and reliability of our devices are our top priority. We are writing today to inform you of a proactive safety corrective action regarding the solenoid valve of the above-mentioned freezer. The competent federal authority, BASG, has received a copy of this Urgent Safety Notice.

1. Background and Cause

During a technical modification in 2023, a deviation occurred in one of our supplier's manufacturing processes that could lead to the retaining ring coming loose over the solenoid valve's extended service life. This could result in the valve becoming stuck in the **closed** position.

Further in-depth investigations as part of our ongoing product monitoring have also shown that, with high usage frequency, an adverse effect on long-term performance cannot be entirely ruled out, which could cause the valve to become stuck in the **open** position. However, the functional failure rate in the field has been very low to date relative to the installed base.

To absolutely rule out any impairment of temperature stability and any potential impact on your stored goods, we are implementing this proactive corrective measure. According to our service records, a potentially affected component is installed in the unit you are operating.

2. Important Measure to Minimize Risk (Effective Immediately)

Please ensure that all individuals in your organization who need to be aware of this measure are informed of this notice. Instruct your staff to strictly adhere to the following until the solenoid valve is physically replaced:

- The freezer must not be left unattended **at any time** during operation.
- The entire **alarm chain** of the unit (including any alarm outputs, external dialing systems, or internal laboratory monitoring systems) must be checked immediately to ensure it is functioning properly. It must be ensured that alarms are relayed without interruption to the on-call staff.
- This continuous monitoring ensures that any potential **malfunction** is immediately detected by the operating personnel.
- Should the valve become blocked, the operator's internal emergency plan for sample and patient safety (e.g., relocation of samples) must be initiated **immediately** to effectively prevent damage.

3. On-site Replacement Procedure

The replacement of components will be carried out in a risk-based phased approach starting from the factory. Due to their direct proximity to patients, medical facilities and clinics will be prioritized starting in the **second half of August 2026**.

Scheduling and on-site modifications will be implemented on a rolling basis until all affected devices have been updated. The quality-tested components will be provided directly through our authorized service partners.

Cost Policy:

- We will provide the solenoid valve component free of charge.
- If the valve replacement is performed as a separate service call, we will cover the full costs for travel and labor.

- If the valve replacement is combined with a scheduled maintenance visit in accordance with your regular maintenance interval, we will charge the cost of the regular maintenance (including travel). The valve replacement itself remains free of charge.

4. Appointment

Our technical customer service team or our service partner will contact you directly in the next few days to schedule a service appointment at short notice. Despite the summer vacation period, we aim to complete this as quickly as possible. We sincerely thank you for your cooperation and are available at any time to answer your questions.

Sincerely,

[redacted]

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5. RESPONSE FORM

Subject: Mandatory Replacement of the Solenoid Valve
Product: IceCube MED Freezer (11/14/17)

Please complete and sign this form and return it by email **no later than 7 days after receipt** to service@sylab.com **(for Austria only)** or to the address **provided by your local service partner**.

- **Receipt Confirmed:** We confirm that we have received the Urgent Safety Notice and have understood its contents.
- **Precautionary measure:** We will ensure close monitoring of the freezer and the freezing process until the valve is replaced.
- **Technician visit:** Please contact us to schedule an appointment for the free replacement of the solenoid valve by our technical service team.

Affected units at our location:

Serial number(s) of the devices:	
Name of the clinic / department:	
Name of the contact person:	
Phone number for scheduling an appointment:	
Date:	
Signature:	

Note: You can fill out, sign, and save this document directly in Adobe Reader and return it via email. Alternatively, you can print it out, sign it by hand, and scan it.