

2026-06-26

Urgent: Medical Device Correction Update

Product Name: ERBECryo 2 Cryosurgical Unit

Part Number	Part Description	UDI-DI
10402-000	ERBECRYO® 2 Cryosurgical Unit	04050147013797

Dear Health Care Professional/Provider,

The purpose of this letter is to advise you that Erbe USA is updating the voluntary recall of the affected Erbe Flexible Cryoprobes to include a corrective action on the ERBECRYO 2 Cryosurgical Unit. This update is to notify the market that a mandatory ERBECRYO® 2 Software Update is required. This update modifies the system's parameters when detecting increased gas flow conditions. If abnormal gas flow is identified, the Cryosurgical Unit will stop activating to prevent the continual use of a potentially malfunctioning Cryoprobe and will display Error code K-59.

Through our investigation we have identified that a strong pull force on the white hose can lead to a pneumatic short circuit between the gas inlet and connector. If this happens, there is a potential that the high-pressure CO₂ leaks into the return path, leading to excessive input pressure on the external tube, causing the Cryoprobe to rupture.

The original Recall Letter sent on February 12, 2026, informed the market that serious injuries have occurred or could occur due to Cryoprobe rupturing/bursting during activation. A second Recall Letter was sent on May 04, 2026, informing the market that the original recall was expanding to include additional lots of Cryoprobes. Reference FDA Recall Number RES 28429.

Risk to Health

The rupturing/bursting of the Cryoprobe can affect patients, healthcare professionals, or any person near the device when activated. The device failure produces a loud noise that can cause tinnitus, temporary hearing loss, or persistent hearing loss. Other potential injuries could include physical injuries from the burst, such as hand injuries and potential minor burns.

- In several reported cases, tinnitus and/or temporary hearing loss were documented.
- In one reported case, persistent hearing loss was documented.
- In four reported cases, minor injuries (e.g., hyperextended fingers, hand hurting, minor burns, etc.) were documented.

Required Software Update (Correction)

Erbe USA Inc. is updating all ERBECRYO® 2 Units to software Version (V)1.0.4. The software update will be completed by September 2026. This software update includes the following corrective measures:

- CO₂ Flow Monitoring: CO₂ flow value monitoring has been enhanced, resulting in improved system response time.

- Error K-59 Messaging Update: The display text associated with Error Code K-59 has been revised to include instructions for instrument exchange. If this Error Code is displayed, users are to remove the existing instrument and restart the Cryosurgical Unit. Following restart and insertion of a new Cryoprobe, the procedure may be continued. If the error persists after instrument replacement and device restart, please contact Erbe USA's Technical Services Department.

With this software update, there is no change of the Cryosurgical Unit's intended use or performance. Please continue to follow all warnings, instructions, guidelines, etc. involved with the Unit and Cryoprobe.

As stated above, this update modifies the system's parameters when detecting increased gas flow conditions. If abnormal gas flow is identified, the Cryosurgical Unit will stop activating to prevent the continual use of a potentially malfunctioning Cryoprobe and will display Error code K-59.

Customer Action Required

Our records indicate that your facility has purchased an ERBECRYO®2 requiring the mandatory update. Therefore, we request the ERBECRYO®2 Unit be made available to the Erbe Representative to install the (V)1.0.4 Software. The Erbe Representative will perform all tasks required to update the software; we require the following customer action:

1. Confirm acknowledgement with Erbe Representative on-site.
2. Share this notice with all users within your facility.

While awaiting software update, there is no change of the Cryosurgical Unit's intended use or performance. Please continue to follow all warnings, instructions, guidelines, etc. involved with the Unit and Cryoprobe.

If a Cryoprobe needs to be exchanged due to the Cryosurgical Unit registering this Error Code, please contact Erbe USA's Technical Services Department (Phone Number: 1-800-778-3723, Email: technicalservice.us@erbegroup.com).

Erbe requests you to report any complaints, including any instances of rupturing/bursts, to our Technical Service Department at 770-955-4400. Adverse events experienced with the use of this product may also be reported to FDA's MedWatch Adverse Event Reporting program:

- Online: By completing and submitting the report online at: www.fda.gov/medwatch
- Regular mail or fax: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 1-800-332-0178

Erbe fully appreciates your prompt assistance in addressing this removal action. If you require additional information, please contact our field action team at fieldaction.us@erbegroup.com or 678-483-8499.

Sincerely,



John Tartal
Senior Director of Quality and Regulatory Affairs
ERBE USA, Inc.