



[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

Class 2 Device Recall ERBECRYO 2 Cryosurgical Unit



[510\(k\)](#)⁷ [DeNovo](#)⁸ [Registration & Listing](#)⁹ [Adverse Events](#)¹⁰ [Recalls](#)¹¹ [PMA](#)¹² [HDE](#)¹³ [Classification](#)¹⁴ [Standards](#)¹⁵
[CFR Title 21](#)¹⁶ [Radiation-Emitting Products](#)¹⁷ [X-Ray Assembler](#)¹⁸ [Medsun Reports](#)¹⁹ [CLIA](#)²⁰ [TPLC](#)²¹

[New Search](#)

[Back to Search Results](#)

Class 2 Device Recall ERBECRYO 2 Cryosurgical Unit



Date Initiated by Firm	June 26, 2026
Date Posted	August 12, 2026
Recall Status ¹	Open ³ , Classified
Recall Number	Z-2938-2026
Recall Event ID	99341 ²³
510(K)Number	K190651 ²⁴
Product Classification	Unit, cryosurgical, accessories ²⁵ - Product Code GEH ²⁶
Product	ERBECRYO 2 Cryosurgical Unit Model/Catalog Number: 10402-000
Code Information	UDI-DI 04050147013797/ Serial Numbers: All serial numbers up to 11608268 Software Version: 1.0.3
FEI Number	1000140388
Recalling Firm/ Manufacturer	Erbe USA Inc 2225 Northwest Pkwy SE Marietta GA 30067-8764
For Additional Information Contact	Customer Service 770-955-4400 Ext. 133
Manufacturer Reason for Recall	A strong pull on the high-pressure transfer hose of cryosurgical unit may lead to pneumatic short circuit between he gas inlet and the connector resulting in CO2 leaking into the return path, leading to excessive pressure causing the cryoprobe to rupture.
FDA Determined Cause ²	Device Design
Action	On June 26, 2026, Erbe USA issued a Urgent: Medical Device Correction update notification to affected consignees via multiple methods (Email/Website/Hand delivery). ERBE ask consignees to take the following actions: 1. 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. 2. Confirm acknowledgement with Erbe Representative on-site. 3. Share this notice with all users within your facility. 4. 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.
Quantity in Commerce	1126 units
Distribution	US Nationwide distribution including in the states and territories of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania,

Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming.

Total Product Life Cycle [TPLC Device Report](#)²⁷

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)²⁸.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database

[510\(K\)s with Product Code = GEH](#)²⁹

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <https://www.fda.gov/>
4. <https://www.fda.gov/Medical-Devices>
5. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
12. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
15. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
19. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
20. </scripts/cdrh/cfdocs/cfCla/Search.cfm>
21. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm>
22. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports>
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=99341
24. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K190651>
25. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GEH>
26. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GEH>
27. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm?id=GEH>
28. <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall>
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=GEH&number=&applicant=Erbe%20Elektromedizin%20GmbH

Page Last Updated: 08/31/2026

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [العربية](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [فارسی](#) | [English](#)

[Accessibility Contact](#) [FDA Careers](#) [FDA Basics](#) [FOIA No FEAR Act](#) [Nondiscrimination](#) [Website Policies / Privacy](#)



U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Ph. 1-888-INFO-FDA (1-888-463-6332)

[Contact FDA](#)



[For Government For Press](#)

[Combination Products Advisory Committees](#) [Science & Research](#) [Regulatory Information](#) [Safety](#) [Emergency](#) [Preparedness](#)
[International Programs](#) [News & Events](#) [Training and Continuing Education](#) [Inspections/Compliance](#) [State & Local Officials](#)
[Consumers](#) [Industry Health Professionals](#) [FDA Archive](#) [Vulnerability Disclosure Policy](#)



U.S. Department of **Health & Human Services**

Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
3. <https://www.fda.gov/>
4. <https://www.fda.gov/Medical-Devices>
5. <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
11. </scripts/cdrh/cfdocs/cfRES/res.cfm>
12. </scripts/cdrh/cfdocs/cfPMA/pma.cfm>
13. </scripts/cdrh/cfdocs/cfHDE/hde.cfm>
14. </scripts/cdrh/cfdocs/cfPCD/classification.cfm>
15. </scripts/cdrh/cfdocs/cfStandards/search.cfm>
16. </scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm>
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
19. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
20. </scripts/cdrh/cfdocs/cfClia/Search.cfm>
21. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm>
22. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports>
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=99341
24. </scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K190651>
25. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GEH>
26. </scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=GEH>
27. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm?id=GEH>
28. <https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall>
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=GEH&knumber=&applicant=Erbe%20Elektromedizin%20GmbH