



2026-02-12

**Urgent: Medical Device Recall (Removal)**

Product Name: Erbe Flexible Cryoprobe

Part Number	Part Description	UDI-DI	Lot Numbers
20402-401	Flexible Cryoprobe (OD 1.1mm, L1.15mm) w/ oversheath (OD2.6mm, L817mm)	04050147021778	Reference Attachment 1
20402-402	Flexible Cryoprobe (OD 1.1mm, L1.15mm) w/ oversheath (OD2.6mm, L757mm)	04050147021792	
20402-410	Flexible Cryoprobe (OD 1.7mm, L1.15mm)	04050147021815	
20402-411	Flexible Cryoprobe (OD 2.4mm, L1.15mm)	04050147021839	

Dear Health Care Professional/Provider,

The purpose of this letter is to advise you that ERBE USA is voluntarily recalling (removing) affected Erbe Flexible Cryoprobes. The probes are intended for palliative devitalization (destruction) of tissue during interventional procedures by the application of extreme cold and cryoadhesion for applications such as the removal of foreign bodies, mucus plugs, blood clots, necrotic tissue, tissue tumors (palliative recanalization) and tissue biopsies.

Serious injuries have occurred or could occur due to rupturing/bursting of the cryoprobe during activation. This rupture has only been reported on the outer white tube, the part of the probe which is outside of the patient. We have a report of 5 potential serious injuries in the U.S.

**Reason for Action**

Through complaints, Erbe has been made aware of cases with the affected Cryoprobes rupturing/bursting during activation. The rupture causes a loud sound which could cause tinnitus, temporary hearing loss, or persistent hearing loss. In addition, if the probe is held at the rupture/burst location, minor injuries to the hand and/or fingers could occur. The rupture/burst is caused by an insufficient adhesive application in production leading to excessive input pressure. At the time of this letter, Erbe has received 43 complaints related to this product problem of the concerned lot numbers. The 43 complaints have been identified as adverse events. The concerned lot numbers consist of a total quantity of 90,034 units.

**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 most 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 (i.e., hyperextended fingers, hand hurting, minor burn) were documented.

### **Action Required**

Our records indicate that your facility has purchased an ERBECRYO®2 and therefore could be in possession of one or more of the affected products. Therefore, Erbe requires the following actions:

1. Discontinue use of the products with the affected lot numbers from Attachment 1.
2. Examine your inventory, remove, and quarantine any identified devices with the affected lot numbers from Attachment 1.
3. Ensure all applicable personnel within the vicinity of device activation carefully read the content of this notification. If affected product has been transferred to a different location, please ensure that location and personnel receive a copy of this notification.
4. Please contact Erbe at [fieldaction.us@erbegroup.com](mailto:fieldaction.us@erbegroup.com) or 678-483-8499, to obtain a Return Material Authorization number. Erbe will issue replacement product or credit for unused product once returned. Erbe will pay for shipping costs.
5. Please complete the Response Form and return to Erbe via the following options. Please note: response is required, even if you may not have any affected product on hand.
  - a. Web portal: [Device Removal Response Form](#)
  - b. Email Response Form as attachment to [fieldaction.us@erbegroup.com](mailto:fieldaction.us@erbegroup.com)).
  - c. Call Erbe at 678-483-8499
6. If a response is not received within 4 weeks of this letter, Erbe will provide a second and third reminder in 4-week increments.
7. If you have further distributed this product, identify your locations, and forward this notification to them.

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

- Online: By completing and submitting the report online at: [www.fda.gov/medwatch](http://www.fda.gov/medwatch)
- Regular mail or fax: Download the form from [www.fda.gov/MedWatch/getforms.htm](http://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 800-332-0178



**Actions Taken by Erbe**

Erbe has improved and stabilized the manufacturing process and implemented additional inspection controls to ensure product specifications are met.

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](mailto:fieldaction.us@erbegroup.com) or 678-483-8499.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Tartal".

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

**Attachment 1: Affected Lot List**

<b>Part Number: 20402-401 Affected Lot Numbers</b>						
WO461310	WO461311	WO461312	WO461314	WO461315	WO461829	WO461831
WO461832	WO461833	WO461834	WO461835	WO461842	WO461843	WO461844
WO461847	WO461848	WO462117	WO462118	WO462119	WO462120	WO462121
WO462122	WO462123	WO462124	WO462125	WO462128	WO462129	WO462130
WO462373	WO462374	WO462375	WO462376	WO462377	WO462378	WO462379
WO462380	WO462387	WO462388	WO462389	WO462397	WO462825	WO462826
WO462827	WO462828	WO462829	WO462830	WO462831	WO462838	WO462839
WO462840	WO462841	WO462842	WO462843	WO462844	WO462845	WO462846
WO462847	WO462848	WO462849	WO463308	WO463309	WO463310	WO463311
WO463312	WO463313	WO463314	WO463316	WO463317	WO463390	WO463391
WO463392	WO463393	WO463394	WO463395	WO463396	WO463397	WO463398
WO463399	WO463400	WO463401	WO463402	WO463403	WO463404	WO463405
WO463406	WO463407	WO463408	WO463409	WO464270	WO464271	WO464272
WO464273	WO464274	WO464275	WO464276	WO464277	WO464278	WO464279
WO464699	WO464700	WO464701	WO464702	WO464703	WO464994	WO464995
WO464996	WO464997	WO465021	WO465022	WO465023	WO465024	WO465025
WO465026	WO465027	WO465050	WO465051	WO465052	WO465053	WO465054
WO465055	WO465056	WO465057	WO465066	WO465067	WO465068	WO465069
WO465243	WO465244	WO465245	WO465246	WO465247	WO465248	WO465249
WO465255	WO465256	WO465257	WO465258	WO465259	WO465260	WO465261
WO465262	WO465266	WO465267	WO465268	WO465269	WO467858	WO467859
WO467860	WO467861	WO467862	WO467863	WO467884	WO467885	WO467886
WO468210	WO468211	WO468212	WO468213	WO468214	WO468215	WO468216
WO468217	WO468218	WO468219	WO468220	WO468221	WO468230	WO468231
WO468232	WO468609	WO468610	WO468611	WO468612	WO468613	WO468614
WO468618	WO468619	WO468620	WO468621	WO468622	WO468623	WO468624
WO468625	WO468626	WO468627	WO468628	WO468629	WO468630	WO468631
WO468632	WO468634	WO468635	WO468636	WO468637	WO468638	WO468639
WO468640	WO468641	WO468654	WO468655	WO468656	WO468657	WO468658
WO468659	WO468660	WO468661	WO468662	WO468663	WO468664	WO468665
WO468666	WO468669	WO468670	WO469350	WO469351	WO469352	WO469353
WO469354	WO469357	WO469358	WO469359	WO471335	WO471336	WO471337
WO471338	WO471339	WO471340	WO471341	WO471342	WO471344	W4468495
W4465348	W2469080	W2469062	W2469061	W2469059	W2469058	W2468858
W2465755	W2465609	W2463595	W2463592	W2463591	W2463590	W2463589
W2462285	W2462282	W2462281	W2462280	W2462279	W2459857	W2459856
W2459855						

<b>Part Number: 20402-410 Affected Lot Numbers</b>			
WO459860	WO462187	WO462322	WO462390
WO462391	WO462392	WO462393	WO462396
WO462677	WO462678	WO463323	WO463324
WO463325	WO463326	WO463386	WO463387
WO464280	WO464281	WO464282	WO464283
WO464284	WO465059	WO465060	WO465061
WO465062	WO467876	WO467877	WO467878
WO467879	WO468225	WO468226	WO468227
WO468642	WO468643	WO468644	WO468645
WO468647	WO468671	WO468672	WO468673
WO468674	WO469361	WO469362	WO469363
W2459858	W2459958	W2462283	W2463593
W2465596	W2465623	W2465693	W2465768
W2468859	W2470050	W2470051	W2470052
W4465597			

<b>Part Number: 20402-411 Affected Lot Numbers</b>			
WO461840	WO461846	WO462097	W2462284
WO463327	WO463328	WO463388	W2463594
WO464285	WO464286	WO465063	WO465064
W4465351	W2465601	W2465689	W2465749
W2465769	WO467873	WO467874	WO467875
WO468648	WO468649	WO469364	W2459861
W2459862	W2459863		