



2026-05-04

Urgent: Medical Device Recall Expansion

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
20402-410	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 expanding the voluntary recall (removal) of the affected Erbe Flexible Cryoprobes. On February 12, 2026, the Recall Letter informed the market that 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.

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.

Reason for Expansion

Through new complaints, Erbe has identified additional affected Cryoprobe lot numbers that may cause the same failure mode (i.e., rupturing/bursting during activation). Based on these new complaints, Erbe has identified further lot numbers associated with this issue (reference highlighted lots in Attachment 1) and has expanded the recall accordingly. These lots should be removed from use immediately.

As of the date of this letter, Erbe has received a total of 58 complaints related to this product problem, resulting in 58 adverse events. This includes 10 new complaints associated with the expanded lot numbers, which resulted in 10 additional events.

Reason for Recall (Removal)

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. The concerned lot numbers consist of a total quantity of 125,190 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 (e.g., hyperextended fingers, hand hurting, minor burns, etc.) 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 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.
 - 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



- 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 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.

More recent manufacturing of Cryoprobes not included in this removal action now includes a component that mitigates the possibility of rupture.

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,

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

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

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Attachment 1: Recall Affected Lot List (New Lots Highlighted)

Part Number: 20402-401 Affected Lot Numbers						
New Lot Numbers						
WO471345	WO471346	WO471347	WO471348	WO471349	WO472537	WO472538
WO472539	WO472540	WO472594	WO472595	WO472596	WO472597	WO472598
WO472599	WO472600	WO472601	WO472602	WO472603	WO472617	WO472618
WO472619	WO472620	WO472621	WO472622	WO472623	WO472624	WO472625
WO472626	WO472627	WO472628	WO472629	WO472630	WO472631	WO472632
WO472633	WO472634	WO472635	WO472636	WO472642	WO472643	WO472644
WO472647	WO472648	WO472649	WO473613	WO473614	WO473615	WO473616
WO473617	WO473618	WO473619	WO473646	WO473647	WO473648	WO473649
WO473650	WO473651	WO474289	WO474290	WO474291	WO474292	WO474580
WO474581	WO474582	WO474583	WO474584	WO474585	WO474586	WO474587
WO474588	WO475359	WO475360	WO475361	WO475362	WO475363	WO475364
WO475368	WO475369	WO475370	WO475371	WO475372	WO475373	WO475374
WO475375	WO475376	WO475377	WO475378	WO475382	WO475383	WO475384
WO475385	WO475386	WO476017	WO476018	WO476019	WO476020	WO476021
WO476226	WO476227	WO476228	WO476229	WO476230	WO476231	WO476232
WO476233	WO476234	WO476235	WO476273	WO476274	WO476275	WO476690
WO476691	WO476692	WO476693	WO476694	WO476695	WO476696	WO476697
WO476698	WO477070	WO477071	WO477072	WO477073	WO477497	WO477498
WO477499	WO477500	WO477501	WO477502	WO477503	WO477504	WO477505
WO477506	WO477507	WO477508	WO477686	WO477687	WO477688	WO477689
WO477979	WO477980	WO477981	WO477982	WO477983	WO477984	WO477985
WO477986	WO477987	WO477988	WO477989	WO477990	WO478178	WO478179
WO478180	WO478181	WO478182	WO478183	WO478184	WO478185	WO478186
WO478187	WO478188	WO478952	WO478953	WO478954	WO478955	WO478957
Initial Lot Numbers						
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

Part Number: 20402-401 Affected Lot Numbers						
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						

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Part Number: 20402-410 Affected Lot Numbers			
New Lot Numbers			
WO472495	WO472496	WO472497	WO472612
WO472613	WO472614	WO473666	WO473667
WO473668	WO473669	WO473670	WO473791
WO476977	WO476978	WO476979	WO476980
WO477011	WO477012	WO477031	WO477511
WO477512	WO477661	WO477662	WO477663
WO477664	WO478276	WO478277	WO478278
WO478279	WO478313	WO478845	WO478846
WO479954	WO479955	WO479956	WO480079
Initial Lot Numbers			
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			

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Part Number: 20402-411 Affected Lot Numbers			
New Lot Numbers			
WO472498	WO472499	WO472615	WO472616
WO473794	WO473795	WO474908	WO474909
WO474910	WO475357	WO475358	WO477030
WO477513	WO477514	WO478643	WO478646
WO478647	WO478648	WO478843	WO478844
Initial Lot Numbers			
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		