AABIP Member Communication: ERBE Cryoprobe Safety Notice

The American Association for Bronchology and Interventional Pulmonology is aware of recent FDA reports and an expanded manufacturer recall involving ERBE flexible cryoprobes.

The recall identifies a risk of probe rupture or bursting during activation, attributed to manufacturing issues with adhesive integrity leading to excessive internal pressure. Although the rupture has been reported in the portion of the probe external to the patient, it produces a loud explosive sound and has been associated with tinnitus, temporary or persistent hearing loss, and minor physical injuries (e.g., hand injuries, burns) to nearby personnel.

To date, 58 complaints and adverse events have been reported, prompting expansion of the recall to include additional lot numbers across multiple probe sizes. Affected devices should be removed from use immediately.

Patient and provider safety remains our highest priority. The AABIP is actively monitoring the situation and engaging with the manufacturer and clinical experts.

Pending further guidance, members should exercise heightened caution:

- Assess the necessity of cryoprobe use on a case-by-case basis
- Consider alternative diagnostic or therapeutic approaches where appropriate
- **Immediately discontinue and quarantine affected lot numbers**
- Adhere to manufacturer guidance and institutional safety protocols
- Remain vigilant for potential complications and ensure appropriate procedural safeguards

Facilities should follow manufacturer instructions for inventory review, product quarantine, and return/replacement.

We recognize that cryotechnology plays a critical role in interventional pulmonology, including applications such as transbronchial cryobiopsy and endobronchial tumor management. Given the seriousness of the reported events, thoughtful clinical judgment is warranted regarding when and whether to proceed with its use during this period of uncertainty. However, we have been informed by ERBE executives that more recent manufacturing of the probes includes a component that significantly mitigates the risk of the probes bursting and all probes distributed by Erbe-USA include this component with sufficient support to meet clinical demands.

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The AABIP will continue to provide updates as additional information becomes available. We encourage members to report any adverse events through appropriate institutional channels and to the FDA's MedWatch program to support ongoing safety surveillance.

https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/medical-product-safety-information

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