

2. Indications for focused ultrasound ablation for the treatment of fibroadenoma:

Focused ultrasound ablation for the treatment of fibroadenoma is currently under investigation in the United States, and is not approved by the FDA for this indication. This technique is considered investigational and should not be performed outside the realm of a clinical trial. There is an ongoing FDA-approved clinical trial for “echotherapy” in the treatment of fibroadenomas.

3. Indications for percutaneous and/or transcutaneous ablative treatments of malignant tumors of the breast:

Cryoablation is currently approved for treatment of benign and malignant soft tissue tumors by the FDA. Currently, there are no specific technologies that have FDA approval for breast tumors. Participation in registries and clinical trials evaluating the use of these technologies with and without surgical excision of a breast malignancy is advised as early data emerges on their efficacy.

- References -

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