

# 2026 ASBrS Resource Guide: Ablative Therapies

Transcutaneous and Percutaneous  
Treatment Protocols for Benign and  
Malignant Breast Tumors

**Clinical Guideline & Decision Matrix**

## Open Surgical Excision



- Leaves visible scarring
- Creates potential distortion on follow-up mammography
- Alters breast contour and size

## Percutaneous & Transcutaneous Ablation



- Minimal to no visible aesthetic changes
- Avoids invasive surgical procedures
- Requires only a small scar for device placement (percutaneous) or zero scars (transcutaneous)

**X-Axis: Regulatory Status (FDA Approved vs. Investigational/Clinical Trial)**

**Y-Axis**  
**Y-Axis: Invasiveness (Percutaneous vs. Transcutaneous)**

**Cryoablation & Vacuum-Assisted Excision**

Standard of care for small fibroadenomas.

N/A for benign in this guide.

No modalities currently approved.

**Focused Microwave Ablation (MWA) & Focused Ultrasound Ablation (FUA)**

MWA needs large trials. FUA safe abroad, currently under FDA-approved clinical trial in US.

**Strict Rule: Must not be performed outside clinical trials.**

# Percutaneous Efficacy Dashboard: Benign Fibroadenomas

Golatta et al. (Cryoablation)

**93%**

Non-palpable and invisible on ultrasound at 1 year (N=60)

97% excellent/good cosmesis; only 2% reported pain.

Li et al. (Vacuum-Assisted)

**1.9%**

Local recurrence rate at 34 months median follow-up (N=1,578)

Risk factors for recurrence include >2 lesions, >1cm size, or procedure-related hematoma.

Fine et al. (Vacuum-Assisted)

**98%**

Lesions non-palpable and patient satisfaction with appearance at 6 months (N=216)

# ASBrS Selection Criteria: Fibroadenoma Cryoablation & Percutaneous Excision



**Imaging Visibility:** The lesion must be easily visualized on ultrasound.



**Histologic Confirmation:** Diagnosis of fibroadenoma must be confirmed on core biopsy prior to treatment.



**Clinical Concordance:** Diagnosis must align seamlessly with imaging findings, patient history, and physical exam.



**Size Boundary:** Lesion must strictly measure <4 cm in largest diameter.



**Operator Requirement:** Must be performed by a physician with considerable ultrasound experience, as precise needle placement dictates technical success.





## Palliative / Poor Surgical Candidates

Historically reserved for patients unable to tolerate surgery. Explored across focused ultrasound, laser, cryotherapy, microwave, and radiofrequency.

## Primary Intent for Early-Stage Disease

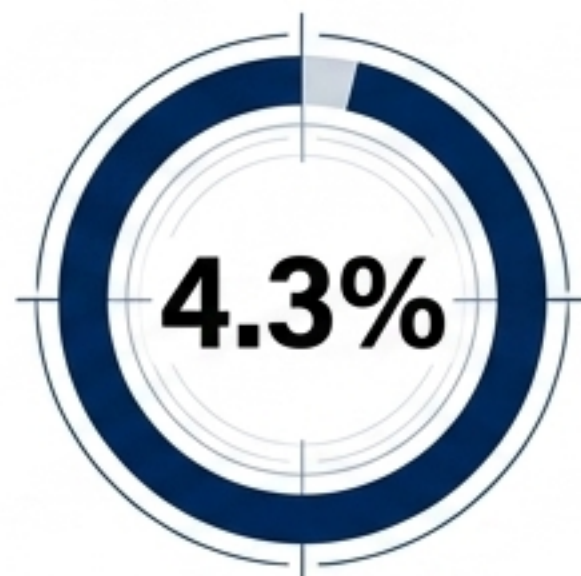
Percutaneous ablative therapy executed without surgical excision for carefully selected, low-risk early-stage breast cancer profiles.

# The ICE3 Trial Dashboard: Malignant Tumor Efficacy

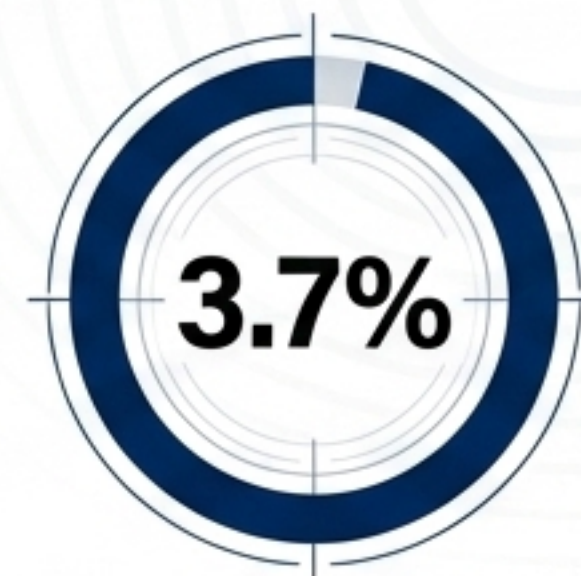
## ICE3 Trial Parameters

- **Cohort:** N=194 women, >60 years old.
- **Tumor Profile:** Unifocal, US-visible Invasive Ductal Carcinoma (IDC),  $\leq 1.5\text{cm}$ , Low/Low/Intermediate grade, ER/PR+, HER2-.
- **Exclusions:** Lobular, EIC, LVI, node-positive.

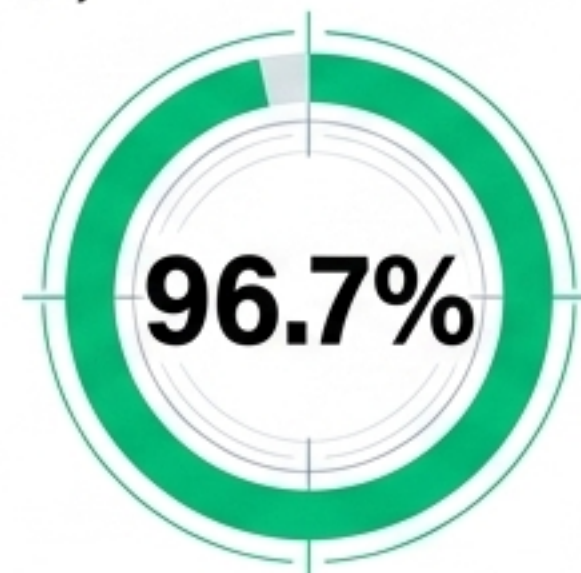
## 5-Year Outcomes at 54.2 Months



Ipsilateral Breast Tumor Recurrence (IBTR)



IBTR for patients receiving endocrine therapy only



Breast Cancer Survival Rate

# CRUCIAL AGE SHIFT

Trial Profile: >60 Years → FDA Indication: ≥70 Years

November  
2024

October  
2025

## FDA General and Plastic Surgery Devices Panel Vote

Voted “Yes” that benefits of cryoablation for low-risk breast cancer outweigh the risks.

## FDA Class II Approval Granted

**Indication:** Local treatment of biologically low-risk  $\leq 1.5\text{cm}$  IDC.

**Condition:** Requires post-market clinical validation testing for long-term recurrence and adverse events.

# The Ideal Malignant Candidate (Go/No-Go)

## The Ideal Candidate - GO

### ✓ INDICATIONS

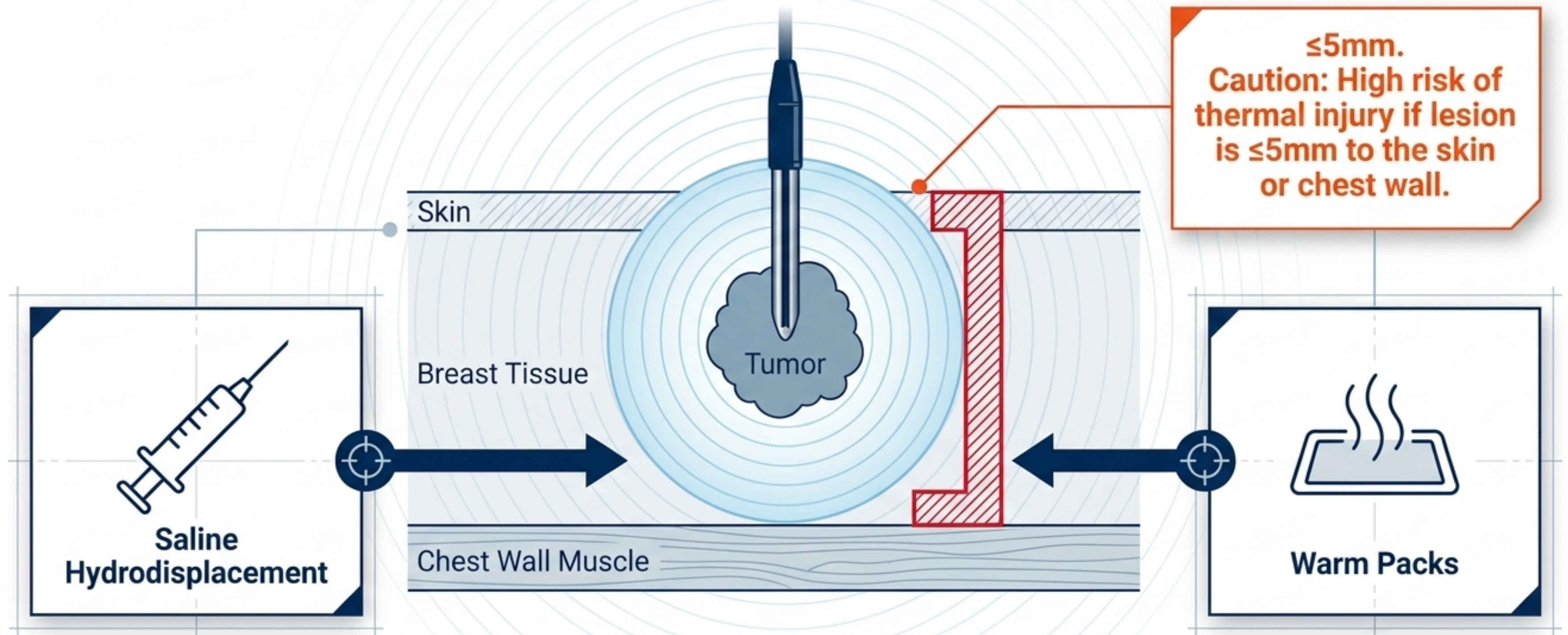
- Age  $\geq 70$  years.
- Tumor  $\leq 1.5$ cm in size.
- US-visible Invasive Ductal Carcinoma (IDC).
- Biologically Low-Risk: Grade 1-2, ER/PR+, HER2-, Ki67  $< 15\%$  (or genomic low-risk).
- Clinically node-negative (confirmed via axillary ultrasound).

## Absolute Exclusions - NO-GO

### ✗ CONTRAINDICATIONS

- Lobular carcinoma.
- Extensive Intraductal Component (EIC  $\geq 25\%$  of neoplasia on core biopsy).
- Multifocal / Multicentric disease or multifocal calcifications on mammogram.
- Evidence of Lymphovascular Invasion (LVI).
- Prior surgical biopsy of index lesion, coagulopathy/thrombocytopenia, or received neoadjuvant therapy.

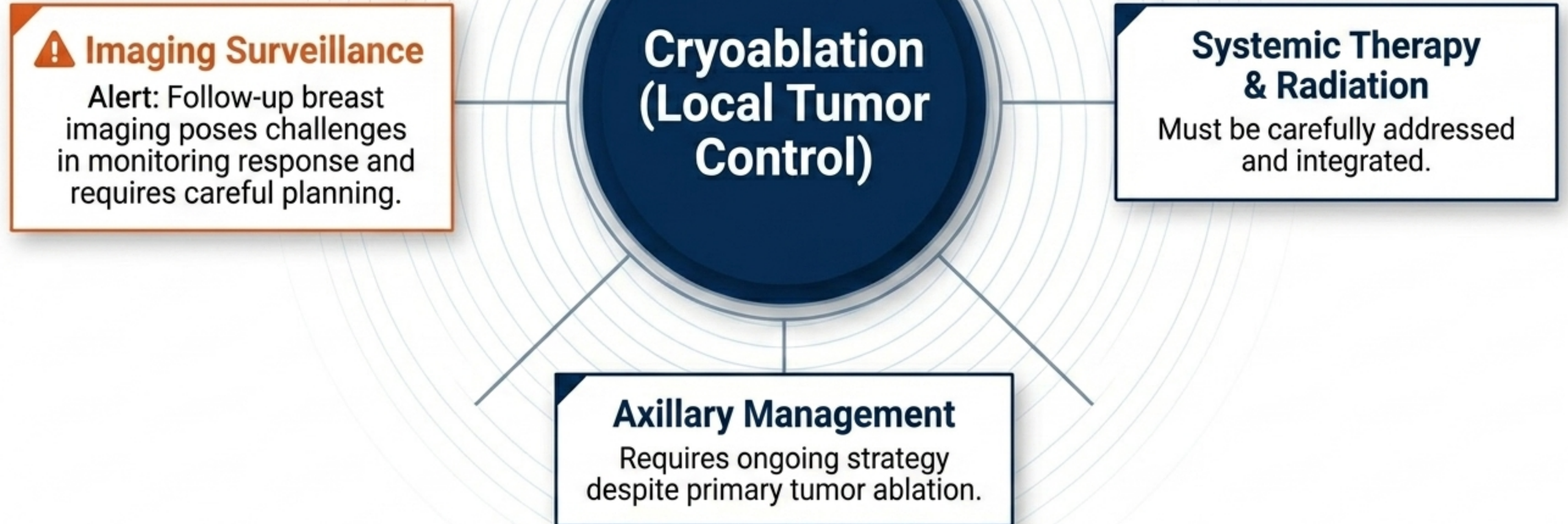
# Technical Safety Schematic: Thermal Injury Prevention



Deploy to protect surrounding structures from hypothermic injury.

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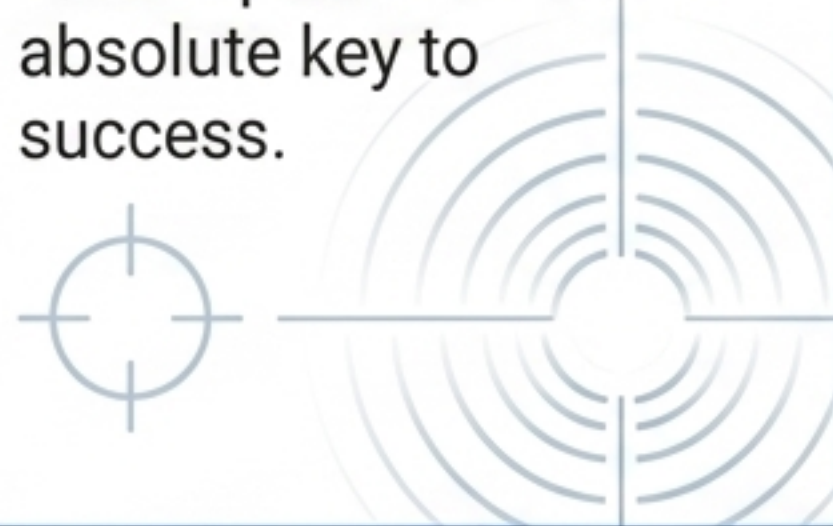
# Integrated Treatment Planning & Management (Cryoablation Context)



# ASBrS Mandate: Implementation & Competency

## The Learning Curve

Significant technical learning curve exists for safe and effective cryoablation. Precise needle placement is absolute key to success.



## Technical Credentialing

Procedure must be performed by a radiologist or surgeon with considerable ultrasound experience via extensive clinical exposure or credentialed courses prior to adoption.



## Registry Participation

As special controls and larger trials emerge, active participation in clinical registries is highly advised to track long-term safety and validate post-market efficacy.

