

## YOUR HEALTH. YOUR CHOICE.

There are several options to manage a fibroadenoma. Talk with your doctor about which option may be right for you.



### Watchful waiting

You may choose to observe your fibroadenoma over time, and feel your breast for changes. Your doctor may request follow-up visits every 6-12 months and ultrasound or other imaging to check for any changes such as enlargement of the tumor or discomfort.



### Surgery

Fibroadenomas can be removed surgically. Performed in an operating room, the fibroadenoma is surgically removed through an incision and sutured (stitched) closed. Depending on the size of the fibroadenoma and location in the breast, healing may result in an indentation or change in the shape and size of the breast. In addition, the size of the skin scar will vary depending on the size of the fibroadenoma.



### Office-Based Cryoablation

Cryoablation is FDA-cleared for destroying fibroadenomas by freezing, offering a minimally invasive option to surgery. Tumors are destroyed by applying extremely cold temperatures to freeze them. Cryoablation technology has been used for decades to destroy benign and cancerous lesions.

*"Patients have been really satisfied with this procedure. It's an office-based procedure and avoids a trip to the operating room. It has great cosmetic results, with virtually no scarring, and no down time from surgery."*

Dr. Karen Columbus, Cincinnati, Ohio, USA

## CHOOSE PROSENSE™

The ProSense™ cryoablation procedure empowers women with the choice of a minimally invasive option to surgery that maintains breast shape and minimizes scarring. As a simple and quick ultrasound-guided procedure performed conveniently in a physician's office, ProSense™ alleviates the anxiety of hospitalization and anesthesia needed for other types of tumor treatment.



of women who underwent cryoablation for their fibroadenoma rated cosmetic results as excellent or good.<sup>1</sup>

<sup>1</sup>Golatta, Michael & Harcos, Aba & Pavlista, David & Danes, Jan & Klein, Rafi & Simovich, Paola & Gruber, Ines & Hahn, Markus. (2014). Ultrasound-guided cryoablation of breast fibroadenoma: a pilot trial. Archives of gynecology and obstetrics. 291. 10.1007/s00404-014-3553-5.

## ABOUT ICECURE MEDICAL

IceCure offers the choice of a minimally invasive cryoablation treatment option for some select benign and malignant breast tumors. The FDA-cleared and CE-marked ProSense® System uses liquid-nitrogen to generate ultra cold temperatures to destroy tumors by freezing them, offering a minimally invasive alternative to traditional surgery. The ProSense® system is also indicated as a cryosurgical tool for fibroadenomas and for use in the fields of general surgery, oncology, gynecology, and proctology.



## It's My Choice



## THE CHOICE OF CRYOABLATION

A minimally invasive outpatient procedure for fibroadenoma

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## WHAT IS A FIBROADENOMA?

Fibroadenomas are the most common type of breast tumor affecting up to 10% of women in their lifetime. They are solid (not fluid-filled) masses, with clearly-defined edges and are typically round or oval in shape. Fibroadenomas are benign, which means they are not cancerous, and do not turn into cancer. They may increase in size with time, particularly with hormonal changes.

Fibroadenomas may be palpable (able to be felt) in the breast. While some remain unchanged for many years, they may grow to a size larger than a golf ball over time. Some women find these lumps or masses uncomfortable and bothersome, and may have associated pain or tenderness. In some cases, fibroadenomas can physically deform the breast.

## HOW IS A FIBROADENOMA DIAGNOSED?

Fibroadenomas are usually found during a breast self-examination, or a clinical breast exam performed by a physician. Breast imaging, such as mammography, ultrasound, or MRI, will be taken and a definitive diagnosis can be made by taking a biopsy (tissue sample). While fibroadenomas tend to have a typical appearance on physical exam and imaging, the diagnosis must be confirmed - no imaging study can fully ensure that a lump is indeed benign.



## WHAT ARE THE BENEFITS OF CRYOABLATION FOR FIBROADENOMA?

**Maintain breast shape:** No tissue is removed and there is minimal scarring.

**Short, office-based procedure:** Average procedure time is between 30 - 45 minutes with no hospital waiting or overnight stay; only local anesthesia is injected to the area

**Quick recovery:** Patients can return to normal activity with little downtime

**Minimal pain and discomfort:** Cold numbs the area

## WHAT HAPPENS AFTER CRYOABLATION?

Patients who have undergone cryoablation for breast tumors have reported mild-to-moderate pain, edema (swelling), and bruising. Other adverse events can include the risk of incomplete ablation (not fully treating the tumor area) and skin burns to nearby tissue which can be mitigated by injected saline.

You will have a palpable mass (area that can be felt) while your body naturally reabsorbs the destroyed cells. The size of the mass typically reduces over time, depending on the initial size of the mass and other factors.

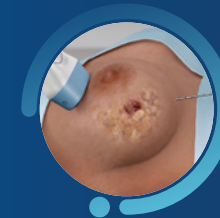
The mass may not completely resolve. Be sure to share with your breast imaging specialists that you have had cryoablation when you have follow up imaging (e.g., mammography, ultrasound, MRI).

## PROSENSE™ CRYOABLATION: STEP-BY-STEP

During the minimally invasive ProSense™ cryoablation procedure, your doctor will inject local anesthesia and use ultrasound (sonographic) imaging to guide a small cryoprobe (thin hollow needle) into the breast tumor.

Once the cryoprobe is placed, it undergoes a freeze-thaw-freeze cycle, where extremely cold temperatures (lower than -170° C) destroy the breast tumor by creating an ice ball around the targeted tissue. The tissue destroyed by the ice ball is naturally reabsorbed by the body over time and adjacent tissue is left unharmed.

The procedure is monitored in real-time by ultrasound to ensure the ice ball is growing sufficiently around the tumor, including a margin (area of tissue surrounding the tumor, similar to surgery), and to avoid damage to the skin or muscle.



1 The cryoprobe is inserted into the tumor at a small incision site.



2 The tumor is enveloped by an ice ball. The extreme cold kills the tumor tissue.



3 The cryoprobe is removed and a Steri-Strip is applied, requiring no stitches.



To learn more about cryoablation for Fibroadenoma, visit our website at [icecure-medical.com/clinical-applications/fibroadenomas/](https://www.icecure-medical.com/clinical-applications/fibroadenomas/)