

Information For Patients

STARmed Thyroid
Radiofrequency Ablation (RFA)

Discover Relief From Thyroid Nodules Without Surgery



Treating your thyroid nodule with STARmed radiofrequency ablation (RFA)

It is important to know what is involved in an RFA procedure, including the benefits and possible risks. We are here to help you understand what thyroid nodules are, how they are normally treated, why an RFA procedure may be right for you, and what to expect before, during, and after your RFA treatment. It is important to continue this discussion with your doctor, but hopefully the information contained here can act as a starting point for such a discussion.

What are thyroid nodules?

Thyroid nodules are an abnormal overgrowth of tissue in the thyroid gland (located in the base of your neck). These nodules can be solid or fluid-filled. Nodules on your thyroid can interfere with the gland's proper functioning. Luckily, only 5% of thyroid nodules are cancerous, but benign (non-cancerous) nodules can cause issues.¹ These issues include swelling at the base of the neck, voice hoarseness, coughing, difficulty breathing and/or swallowing, dizziness, pain, pressure, and appearance concerns.

How are benign thyroid nodules typically treated?

If the thyroid nodule is not causing any symptoms, your doctor may suggest monitoring the nodule. This usually consists of a physical exam, routine thyroid function tests, and ultrasound imaging. If the nodule grows larger, the physician may recommend a needle biopsy of the nodule. If a benign thyroid nodule remains unchanged, you may not require treatment.

If you and your doctor decide that a treatment option is necessary, hormone therapy, surgery, or alcohol ablation are the typical options offered to patients.

Hormone Therapy can be used if your thyroid gland simply cannot make enough thyroid hormone that your body needs. The goal is to closely replicate normal thyroid functions.

Antithyroid Medication can be used if your thyroid makes too much thyroid hormone than what your body needs. These drugs block the formation of thyroid hormone by the thyroid gland.

Surgery can be used to remove the nodule if it is too large and symptomatic. A thyroid surgery can generally be classified as a partial thyroidectomy or a total thyroidectomy. The extent of your thyroid surgery should be discussed between you and your thyroid surgeon based on your conditions. Some patients develop hypothyroidism following a partial thyroid surgery, requiring life-long medication to supply enough thyroid hormone for your body. This is especially true if you had your entire thyroid gland removed.

Alcohol Ablation is another minimally invasive treatment. This involves injecting an amount of alcohol in the thyroid nodule. This treatment is helpful for treating nodules that occur in areas that aren't easily accessible during surgery and good for nodules that contain mainly fluid (cystic). Multiple treatment sessions are often required.

What is radiofrequency ablation (RFA)

Radiofrequency ablation is a minimally invasive procedure that passes an electrical current through a needle electrode to destroy the targeted tissue. STARmed Thyroid RFA utilizes this technique to treat (ablate) your thyroid nodule with heat created at the needle tip. During the procedure, the needle electrode is inserted into your thyroid nodule under ultrasound guidance. Your physician will then allow a carefully controlled amount of radiofrequency energy to flow through the needle electrode into the nodule tissue to destroy the cells. The destroyed tissue cells flow through your body naturally as waste over the course of months, allowing your nodule to decrease in size.

Why am I being offered STARmed Thyroid RFA?

STARmed Thyroid RFA was developed over 15 years ago and tens of thousands of procedures are being performed worldwide. STARmed Thyroid RFA preserves healthy thyroid tissue by target-treating only nodule tissue without compromising normal thyroid functions. It can avoid the risks and long recovery times of surgery as it can be performed under local anesthesia in an outpatient office or in a hospital setting.

To determine if STARmed Thyroid RFA is right for you, you will need to undergo an assessment that will include an ultrasound scan and a fine-needle aspiration (biopsy) where several samples of the nodule will be taken and sent to pathology for microscopic evaluation.

Your doctor will then discuss your treatment options with you. There are benefits and risks related to any treatment option and these will be explained in detail during this discussion.

Benefits of STARmed Thyroid RFA

- Preserves your healthy thyroid tissue
- Allows your thyroid to function normally without the need for a lifetime medication
- Minimally invasive procedure
- Performed under local anesthesia
- Performed as an outpatient procedure in an office or hospital setting
- Shorter recovery times
- No scarring
- Volume reduction over time
- Low complication rate
- Worldwide use
- Quality of life



Scan to view the animation

Risks of STARmed Thyroid RFA

All treatments and procedures have risks and these will be discussed in detail with you by your doctor.

- Minor complications can include skin burn, hematoma, and vomiting.
- Major complications are rare but can include: nodule rupture, nodule rupture causing an infection, and voice change. The risk of permanent injury to the voice box nerve causing alteration in the voice is less than 1% (1 in 100).²
- Larger nodules may require more than one treatment for effective nodule shrinkage. Your doctor will discuss with you the likelihood of needing additional treatments during your initial assessment.

Where will the procedure take place?

The procedure can be performed in either an outpatient facility or a hospital setting.

How do I prepare for STARmed Thyroid RFA?

Your healthcare provider will review any of your current medications and provide further instructions if needed. Other than blood thinners, which you will likely need to stop taking a few days prior to the procedure, most medications do not interfere with the procedure.

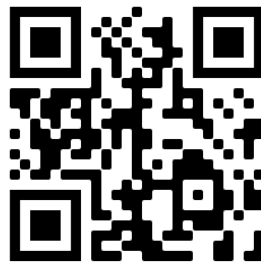
What happens during the STARmed Thyroid RFA procedure?

To begin the procedure, you will be asked to lie your head on a small cushion, with your neck extended. Two grounding pads will be placed on your thighs. Your doctor will clean and prepare the skin and then administer local anesthesia in the area surrounding your thyroid. You will be able to breathe, swallow and speak normally during the entire procedure.

A thin needle electrode will be inserted directly into the nodule and the doctor will allow a carefully controlled amount of energy to flow into the tissue to ablate (treat) the nodule. Ablative changes to the nodule caused by the treatment can be seen in real-time by the doctors performing the procedure. To ensure that you are handling the procedure well, your doctor may ask you how you are doing and whether or not you can feel any pain. They can easily make adjustments, if you are uncomfortable at any time.

With the sustained RFA thermal heat, the affected nodule may be permanently destroyed. Your immune system will break down the affected tissue, shrink the nodule, and then let the affected tissue flow through the body naturally as waste.

When the procedure is complete, a small bandage will be placed on the treatment site, and ice packs may be used to cool your neck.



Scan to view the animation

Will it hurt?

Because local anesthesia is administered before the procedure, very few patients experience pain. Following the procedure, you will be given an ice pack and if you experience pain post procedure, the physician will recommend what medication you should take.

What happens afterwards?

You will be monitored for a short period of time and then discharged. Please check with your physician before the procedure regarding driving as you may need someone to drive you to and from the procedure. You should be able to return to most of your day-to-day activities almost immediately.

How successful is STARmed Thyroid RFA?

In the week following the procedure, the cells of the treated thyroid nodule are removed by the body's immune system. Most patients notice a reduction in nodule size in just 2-3 weeks, with solid nodules taking longer than cystic (fluid-filled) nodules.

The amount of reduction depends on the original size and nature of the nodules. The average is 60-75% reduction after 3 months and approximately 84-90% reduction at one year.³

In the years following the procedure, all that remains in the treated area is scar tissue. While some of the nodules around the scar may remain, this area is significantly smaller after the treatment. The surrounding healthy thyroid gland is preserved and can continue to produce thyroid hormones.

Symptoms like difficulty swallowing, pressure or tightness in the throat, or a bulky appearance of the nodule are typically eliminated or significantly reduced.

Continue this discussion with your doctor

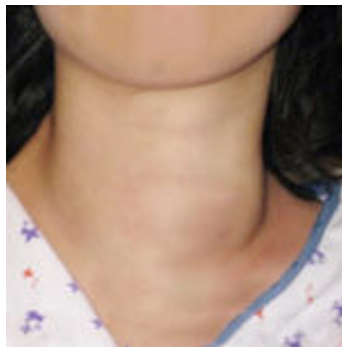
Hopefully, we have answered most of your questions and concerns about STARmed Thyroid RFA, but please remember to discuss all of your treatment options with your doctor. Make sure that you are well-informed and satisfied with your choice before consenting to any treatments or procedures.

Results

Before
STARmed RFA Procedure

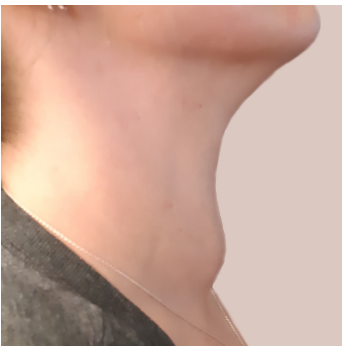


1 Year After
STARmed RFA Procedure

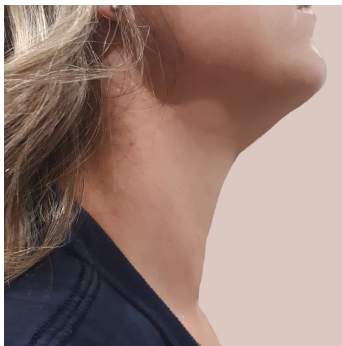


Individual results may vary.
Consult with your physician for more information on STARmed Thyroid RFA
Photos courtesy of Dr. Jung Hwan Baek.

Before
STARmed RFA Procedure



6 Months After
STARmed RFA Procedure



Individual results may vary.
Consult with your physician for more information on STARmed Thyroid RFA

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Patient education and resources help you make the best choice for your condition. Find more information about STARmed Thyroid Radiofrequency Ablation at www.rfaforlife.com

References

1. Source Section of rfaforlife.com
2. Baek JH, Lee JH, Sung JY, et al. Complications encountered in the treatment of benign thyroid nodules with US-guided radiofrequency ablation: a multicenter study. *Radiology*. 2012;262(1):335-342. doi:10.1148/radiol.11110416
3. Jeong WK, Baek JH, Rhim H, et al. Radiofrequency ablation of benign thyroid nodules: safety and imaging follow-up in 236 patients. *Eur Radiol*. 2008;18(6):1244-1250. doi:10.1007/s00330-008-0880-6

Indication:

The VIVA Combo RF Ablation System and star RF Electrode are intended for use in percutaneous and intraoperative coagulation and ablation of tissue.

Contraindications:

There is a risk that error may result due to the radiofrequency current on patients who have pacemakers and other active implants. Do not use the radiofrequency lesion generator and electrode on these patients.

Complications:

The following types of complications may result due to the use of the radiofrequency lesion generator and electrode.

- Tumor recurrence
- Burning by overheating of surgical unit
- Dangers from inexperienced operator's use
- Side effects or cross infection from reuse
- Weakness of liver functions
- Delayed bleeding in the operated body parts
- Symptoms after RFA treatment include (abdominal) pain, fever, nausea, headache, right shoulder joint pain and chest discomfort might occur)
- Ascites/diarrhea
- Ventricular fibrillation

Caution: Federal (USA) law restricts this device for sale by or on the order of a physician. Talk to your doctor about the risks and benefits of treatment options, including safety and cost considerations.

