

# Your Journey STARmed Thyroid Radiofrequency Ablation (RFA)

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RFA For Life



Discover  
Relief  
From  
Thyroid Nodules  
Without  
Surgery





REGINE BOUCARD

“It’s a relief to know that this procedure exists and works... it reduced it [her thyroid nodule] by 80%.”

STARmed Thyroid RFA Patient

# RESULTS

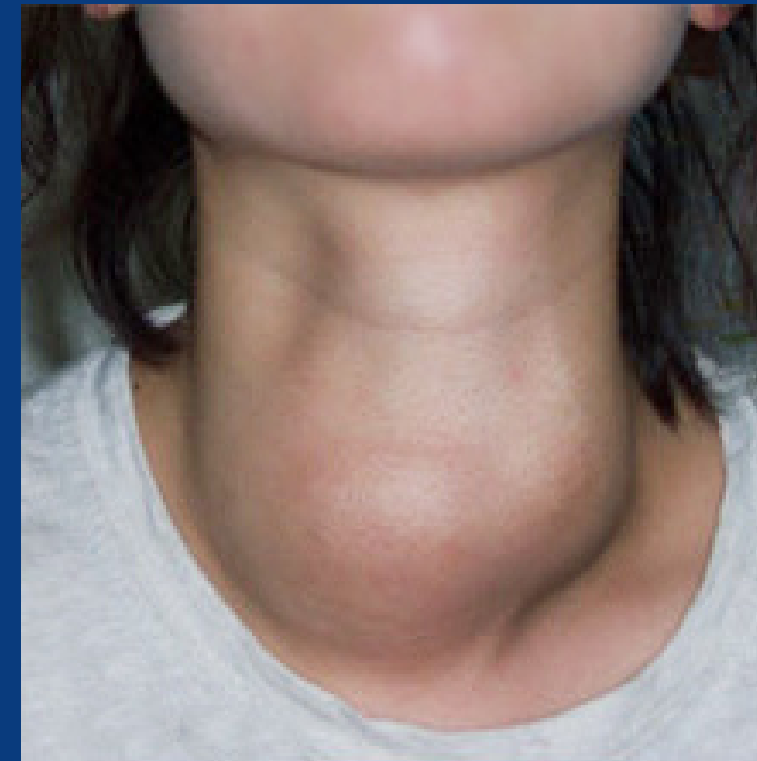
Before  
STARmed RFA Procedure



6 Months After  
STARmed RFA Procedure



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.





# Introduction - Thyroid Overview

The thyroid is a small, butterfly-shaped gland that regulates your heart rate, blood pressure, temperature, and metabolism. Nodules in the thyroid gland can affect how the thyroid functions. Nodules may or may not cause symptoms.

The majority of nodules are benign and non-life-threatening, but they can still cause problems. Some symptoms include: discomfort, difficulty or pain when swallowing, production of excess thyroid hormone, as well as, swelling and enlargement in the neck.

Traditionally, the only treatments available for problematic thyroid nodules were thyroid surgery or radioactive iodine therapy. Today, patients who want an alternative to surgery or radiation have another option.

While thyroid surgery is a relatively safe procedure, it is an invasive surgery. It requires hospitalization, general anesthesia, a lifetime of medication, and causes more pain and a longer recovery time. Additional risks, specific to thyroid surgery include: bleeding, scarring, hypothyroidism, damage to the vocal cord nerve, and calcium deficiency. Thyroid surgery also results in a visible scar on the neck.

Radioactive iodine therapy also presents challenges. Precautions must also be taken after therapy to protect others from exposure to the radiation, particularly children. Short-term side effects for radioactive iodine therapy include: nausea, swelling and tenderness in the neck area, dry mouth, and a lingering metallic taste.

After surgery or radioactive iodine treatment, lifetime thyroid hormone medication is often required. You will need to have regular blood tests as your doctor determines the proper thyroid hormone dosage for you, and it may take some time before you feel your best. In the United States, surgery and radioactive iodine treatments have been the only options to treat thyroid nodules — until now.



# Thyroid Nodule Symptoms

Symptoms vary from person-to-person, but may include



**SWELLING AT THE  
BASE OF THE NECK**



**HOARSE VOICE**



**COUGHING**



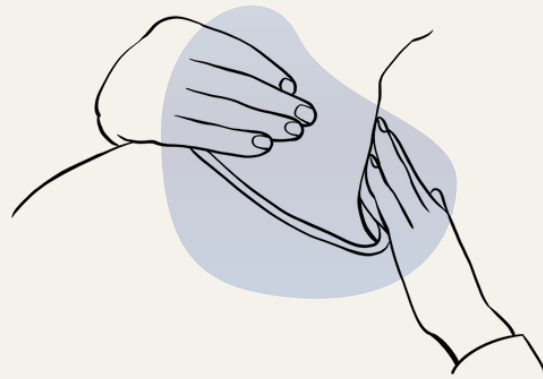
**DIFFICULTY  
BREATHING AND  
SWALLOWING**



**DIZZINESS**

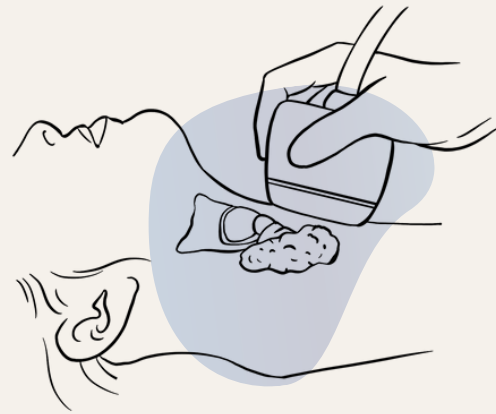


# How are Thyroid Nodules Diagnosed?



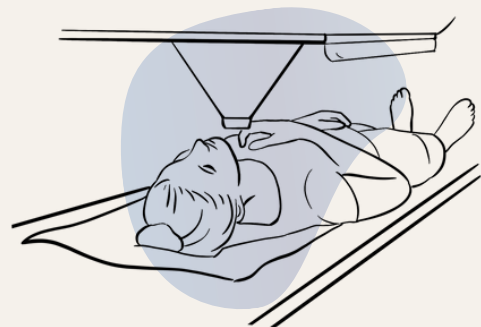
## EXAM

Your doctor can detect a thyroid nodule by examining your neck to feel your thyroid gland.



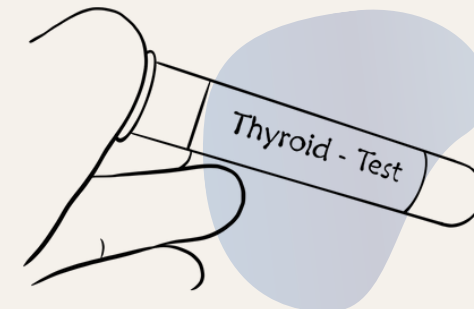
## ULTRASOUND

Thyroid ultrasound uses sound waves to produce images of the thyroid gland within the neck. It is commonly used to evaluate lumps or nodules. Your doctor may also use ultrasound as a guide when performing a fine-needle aspiration biopsy.



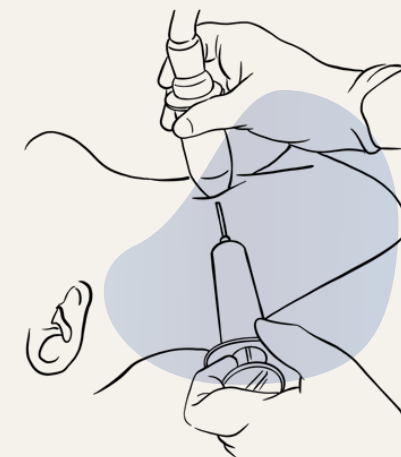
## THYROID SCAN

A thyroid scan is a specialized imaging procedure for examining your thyroid. The scan works with nuclear medicine to evaluate the way your thyroid functions.



## THYROID FUNCTION TEST

Your doctor may take a blood sample to measure levels of T3 and T4—the thyroid hormones and thyroid-stimulating hormone (TSH). TSH is a hormone made by the pituitary gland to regulate the thyroid's production of T3 and T4. These blood tests cannot detect if a thyroid nodule is cancerous, but will help rule out other thyroid conditions.



## FINE-NEEDLE ASPIRATION

Using ultrasound to guide needle placement, your doctor takes several samples of the nodule. The samples are sent to pathology for microscopic evaluation.





## STARmed THYROID RFA

STARmed Thyroid RFA was developed over 15 years ago and about 7,000 procedures are performed worldwide each year. This treatment is now available for patients in the United States who want a non-surgical, non-radiation option for treating thyroid nodules.

With STARmed Thyroid RFA, these thyroid nodules are treated without compromising the thyroid function. STARmed Thyroid RFA treatment preserves healthy thyroid tissue and avoids the risks and long recovery times of surgery.

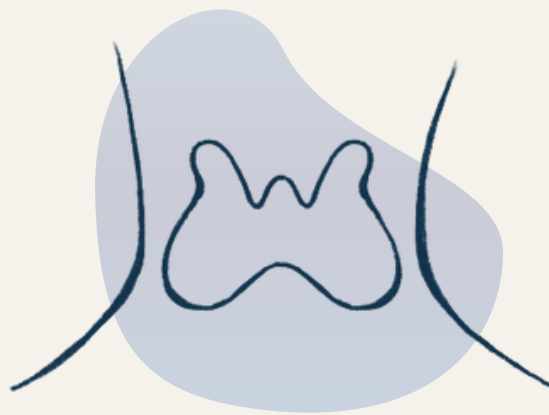
## What Is STARmed Thyroid RFA?

STARmed Thyroid RFA is a relatively painless, minimally invasive medical procedure that treats thyroid nodules. Using ultrasound-guided imaging, the nodule is located, allowing the treatment to focus solely on the targeted nodule area. Using a radiofrequency generator, your doctor allows a carefully controlled amount of energy to flow through the electrode into the tissue to ablate the nodule. With the sustained RFA thermal heat, the nodule is degenerated, allowing the degenerated tissue to flow through your body naturally as waste over the course of a few months.



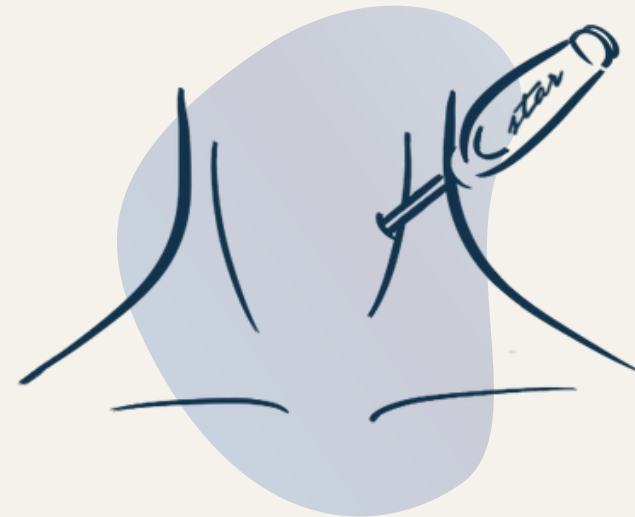
# Benefits of STARmed Thyroid RFA

STARmed Thyroid RFA is a minimally invasive option used to treat benign thyroid nodules. RFA is a quick, non-surgical procedure that allows most patients to resume their normal day-to-day activities immediately following treatment.



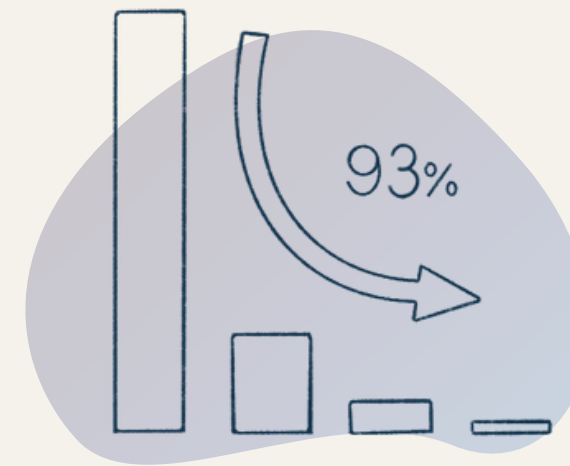
## SAVE YOUR THYROID

Preserves your healthy thyroid tissue, helping the thyroid to function normally without the need for lifetime medication.



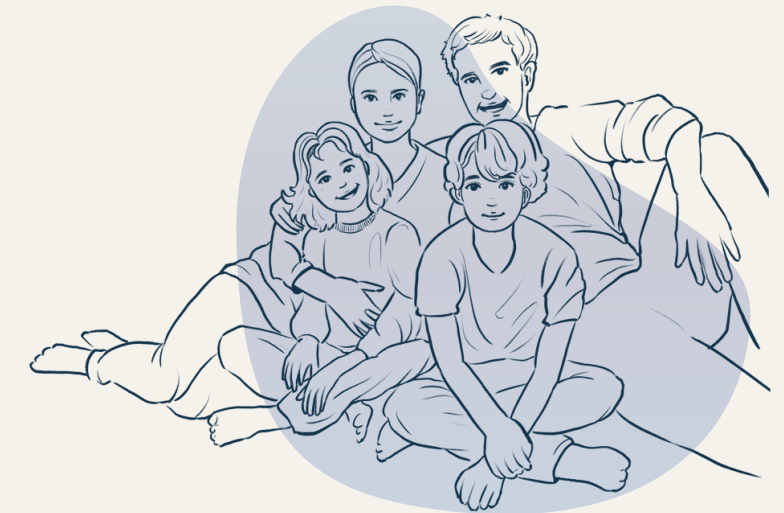
## MINIMALLY INVASIVE

A thin needle is used to avoid any surgical scars. No general anesthesia is required, which means no downtime or hospitalization.



## VOLUME REDUCTION

A major clinical study showed that non-functioning benign nodules shrunk 73% in the first 6 months and up to 93% within 4 years.



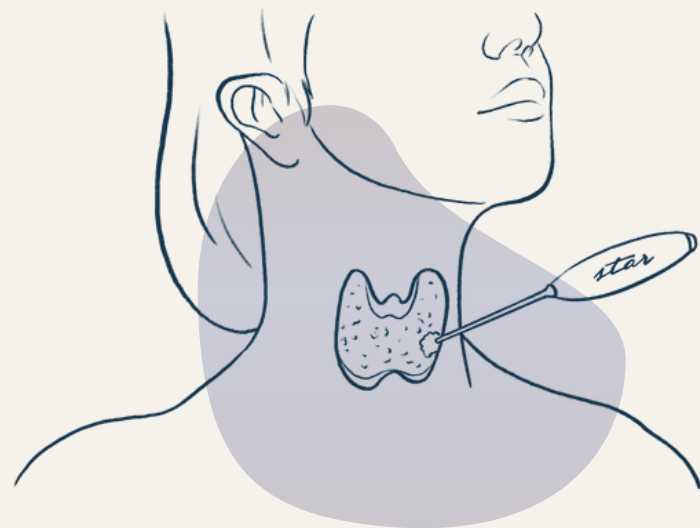
## QUALITY OF LIFE

Tens of thousands of patients across the globe have chosen STARmed Thyroid RFA to successfully treat their thyroid disease.



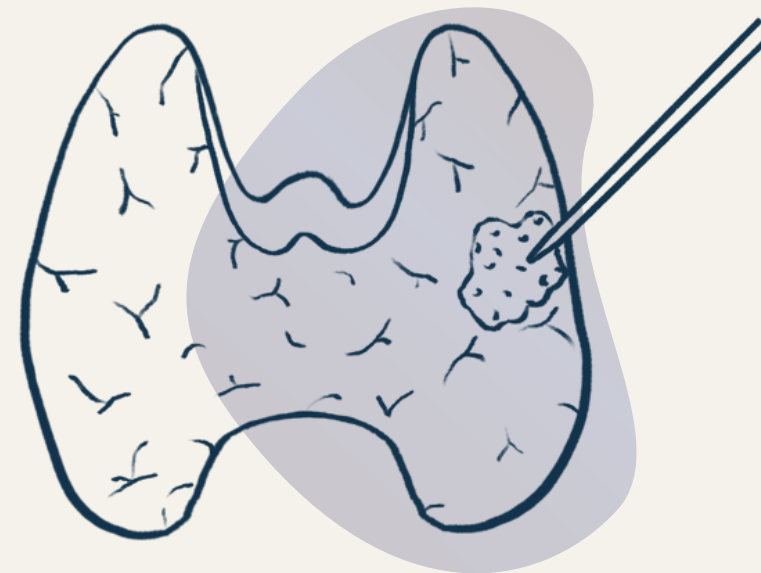
# How STARmed RFA Works

To begin the procedure, a numbing medicine will be applied under the skin and around the thyroid gland. Once you're relaxed, and your neck is numb, a thin electrode is inserted and directed into the nodule. Radiofrequency energy emitted from the electrode causes very precise destruction of the targeted tissue. The electrode is systematically guided through the entire nodule and the process is repeated until the nodule is completely treated.



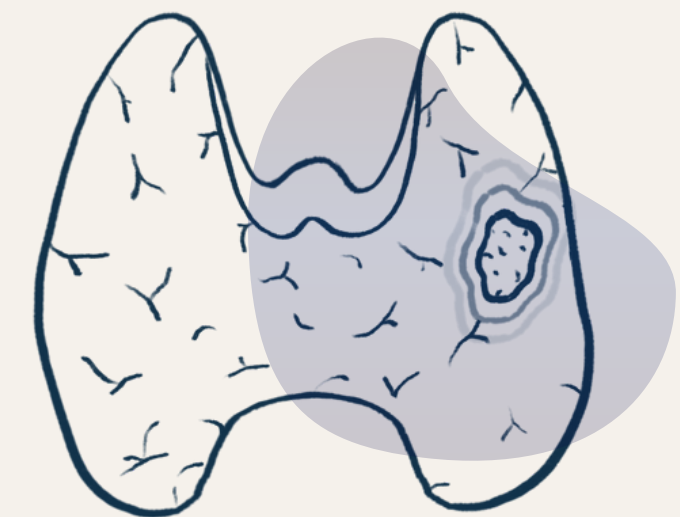
## TARGET

Using ultrasound, your doctor will locate the nodule and insert a thin electrode into the affected area. This method ensure that the treatment is focused solely on the targeted nodule area.



## HEAT

Using a VIVA RF generator, your doctor will allow energy to flow through the electrode into the nodule. The radiofrequency ablates the nodule and the heat is sustained for a safe, pre-determined length of time, usually just a few minutes.



## REDUCE

With the sustained RFA thermal heat, the nodule is degenerated and flows through the body as waste. Most patients notice a reduction in nodule size in just 2-3 weeks.

# STARmed Thyroid RFA Procedure Experience

## Preparing for STARmed Thyroid RFA

Your healthcare provider will review any current medications you are taking 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 to expect during STARmed Thyroid RFA

You will be able to breathe, swallow and speak normally during the entire procedure. You will be asked to lie your head on a small cushion, with your neck extended.

Your doctor will clean and prepare the skin and administer local anesthesia in the area surrounding your thyroid. Two grounding pads will be attached to your thighs. 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.

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

## What to Expect After the STARmed Thyroid RFA

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





## What Happens to the Nodules After Procedure

After 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 to 3 weeks, with solid nodules taking longer than cystic nodules.

The amount of reduction depends on the original size and nature of the nodules. The average is 40% to 60% reduction after three months, and about 60% to 90% reduction after one year.

Years after the procedure, only the scar tissues will remain in the treated area. The nodule around the scar may still remain, but this area will be minimized after the procedure. The surrounding healthy thyroid gland will be preserved and will continue to produce thyroid hormone.

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





## Is the procedure painful?

Because local anesthesia is administered before the procedure, very few patients experience any pain at all. During the RFA, it's normal to feel pushing and pressure in the neck, but the procedure generally does not cause pain. Patients occasionally feel heat or discomfort in the neck that may radiate to the ear or jaws. Following your procedure, you will be given ice packs and pain medication, if needed. For more questions related to the procedure, please consult directly with your doctor.

## Will the procedure leave a scar?

No. The procedure is delivered using a thin needle. There may be small markings on your neck from the needle for 1-2 days following the procedure, but it will not leave any visible scarring.

## How many treatments are necessary?

One procedure will sufficiently decrease the size of the nodules and improve symptoms, but If the treated nodules are close to vocal cord nerves or nodules are very large, additional procedure may be necessary to significantly decrease the nodule. The untreated areas of nodules may impede the improvement of thyroid function, so complete ablation may be required and more than one procedure may be needed.

## How effective is the procedure?

For benign nodules, clinical trials have shown an average Radiofrequency ablation of benign cold nodules showed volume reductions of 32.7-58.2% at 1 month and 50.7-84.8% at 6 months, while reducing symptoms and cosmetic problems. In a long-term follow-up study, RFA was effective over a four year period, with nodules consistently decreasing by 93.5%.





# Discover Your Relief Today



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](http://www.rfaforlife.com).

References on Source Section of [rfaforlife.com](http://rfaforlife.com)

#### 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
- Burn due to the over-heating of the the surgical equipment
- Dangerous situation due to the unskilled equipment control
- Cross-infection or complications due to the re-use of the inappropriate electrode ascites/diarrhea
- Bleeding of the coagulated part
- 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.

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