

# Information For Patients

STARmed Thyroid

Radiofrequency Ablation (RFA)

**Discover Relief From Thyroid Nodules Without Surgery**



# Your journey to recovery, starts with knowledge and ends with you feeling better.

## 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're 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 (benign) thyroid nodules?

Thyroid nodules are an abnormal overgrowth of tissue in the thyroid gland (located in your neck). These nodules can be solid or fluid-filled. Nodules on your thyroid, however common, can interfere with this gland's proper functioning. Luckily, only about 5% of thyroid nodules end up being cancerous, but even benign (non-cancerous) ones can cause issues, such as: swelling at the base of the neck, a hoarse voice, coughing, difficulty breathing and swallowing, dizziness, pain and pressure and they can become quite large and unsightly.

### How are benign thyroid nodules typically treated?

If the thyroid nodule is not causing any symptoms, your doctor may suggest simply keeping an eye on your condition. This usually means having a physical exam and thyroid function tests at regular intervals. It may also include an ultrasound. You are also likely to have another biopsy if the nodule grows any larger. If a benign thyroid nodule remains unchanged, you may never require treatment.

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

*Hormone therapy* can be used if your thyroid gland simply cannot make enough thyroid hormone for your body's needs. The goal is to closely replicate normal thyroid functioning.

*Surgery can be used to remove the nodule, often along with most of the thyroid tissue — a procedure called a near-total thyroidectomy. After a thyroidectomy, you'll need a lifelong treatment with levothyroxine to supply your body with normal amounts of thyroid hormone.*

*Alcohol Ablation* is another minimally invasive treatment. This involves injecting a small 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. Multiple treatment sessions are often required.

### **What is radiofrequency ablation (RFA)?**

STARmed Thyroid RFA is a 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.

### **Why am I being offered STARmed RFA?**

STARmed Thyroid RFA was developed over 15 years ago and about 7,000 procedures are performed worldwide, each year. STARmed Thyroid RFA preserves healthy thyroid tissue and only nodules are treated without compromising the thyroid function. 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 of medication
- Minimally invasive procedure
- Performed under local anesthesia
- Performed as an out-patient procedure, which means no downtime or hospitalization
- Shorter recovery times
- No scarring
- Volume reduction
- Low complication rate
- Worldwide use
- Quality of life

## Risks of STARmed Thyroid RFA

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

- Serious complications are rare. The main risks are: bleeding, hoarse voice due to nerve bruising, skin burns and infection. Infection can be a delayed problem and present with swelling, pain and redness.
- Rare serious complications can include: damage to the food pipe (esophagus), wind pipe (trachea) and nerves to the voice box (vocal cords). The risk of permanent injury to the voice box nerve leading to alteration in the voice is less than 1% (less than 1 in 100).
- Larger nodules could require more than one treatment for effective nodule shrinkage. Your doctor will discuss the likelihood of needing additional treatments with you 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 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 happens during the STARmed Thyroid RFA procedure?

To begin the procedure, a topical numbing agent will be applied under the skin surrounding your thyroid gland. Once you are relaxed and your neck is numb, your doctor will locate the nodule using ultrasound-guided imaging. The thin 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 the nodule.

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.

The ablation changes to the nodule caused by the treatment can be seen in real time by the doctors performing the procedure.

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

With the sustained RFA thermal heat, the nodule is degenerated. This degenerated tissue is then able to flow through the body, naturally, as waste.

## Will it hurt?

Because local anesthesia is administered before the procedure, very few patients experience any pain at all. Following your treatment, you will be given ice packs and pain medication, if needed.

## What happens afterwards?

You will be monitored for a short period of time, and then discharged. Please check with your doctor before you drive, 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 nodules.

Part or all of the affected thyroid nodule may be permanently destroyed during the procedure. Immune cells of the body break down the affected tissue, shrinking the nodules.

The amount of reduction depends on the original size and nature of the nodules. The average is 40-60% reduction after 3 months and approximately a 60-90% reduction after one year.

In the years following the procedure, all that remains in the treated area is scar tissue. While some of the nodule around the scar may remain, this area is significantly smaller after treatment. The surrounding healthy thyroid gland is preserved and can continue to produce thyroid hormone. Blood hormone levels completely normalized in 82% of patients and medication was no longer required.

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.

# 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://www.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.