

STARmed Thyroid RFA

Advanced Radiofrequency Ablation System



Safe | Precise | Minimally-Invasive



Patient Centric Innovation

About STARmed

TaeWoong Medical USA is the exclusive distributor for STARmed

2009 GLOBALLY RECOGNIZED

In the percutaneous radiofrequency ablation (RFA) field and for our passion to continuously enhance patient quality of life through unceasing innovations.

TODAY

2020

VIVA II RF Electrode



2017

VIVA combo RF Generator

VIVA+
combo
RF Generator



Indication for Use

The VIVA combo RF System is intended for use in percutaneous and intraoperative coagulation and ablation of the tissue.

VIVA+
combo
RF System

- VIVA combo RF Generator
- star RF Electrode
- VIVA Pump

2014

VIVA multi RF Generator

VIVA+
multi RF Generator



2011

VIVA RF Electrode



VIVA+
RF Generator

1st Gen VIVA RF Generator



2010

star RF Electrode



2009



STARmed Thyroid RFA

Safe and Reliable Alternative For Benign Thyroid Indications

According to American Thyroid Association, approximately 20 million Americans possess some form of thyroid disease.¹ It is conservatively estimated 150,000 thyroidectomies are performed annually in the USA with 63% of the cases performed on benign indications.^{2,3}

Patients are seeking **a safe alternative for their benign thyroid symptoms** to avoid losing their thyroid gland and submitting themselves to **surgery-related risks, aesthetically unappealing scar on the neck, and long-term medication dependence.**

STARmed Thyroid RFA is the clinically proven solution

15
YEARS

of proven thyroid radiofrequency ablation performance* with over 100,000 procedures performed globally

95+

thyroid RFA clinical articles have been published worldwide with STARmed Thyroid RFA System**

Volume Reduction Rate (VRR)



for non-functioning benign thyroid nodule (NFBTN) at 60 months^{5,6}

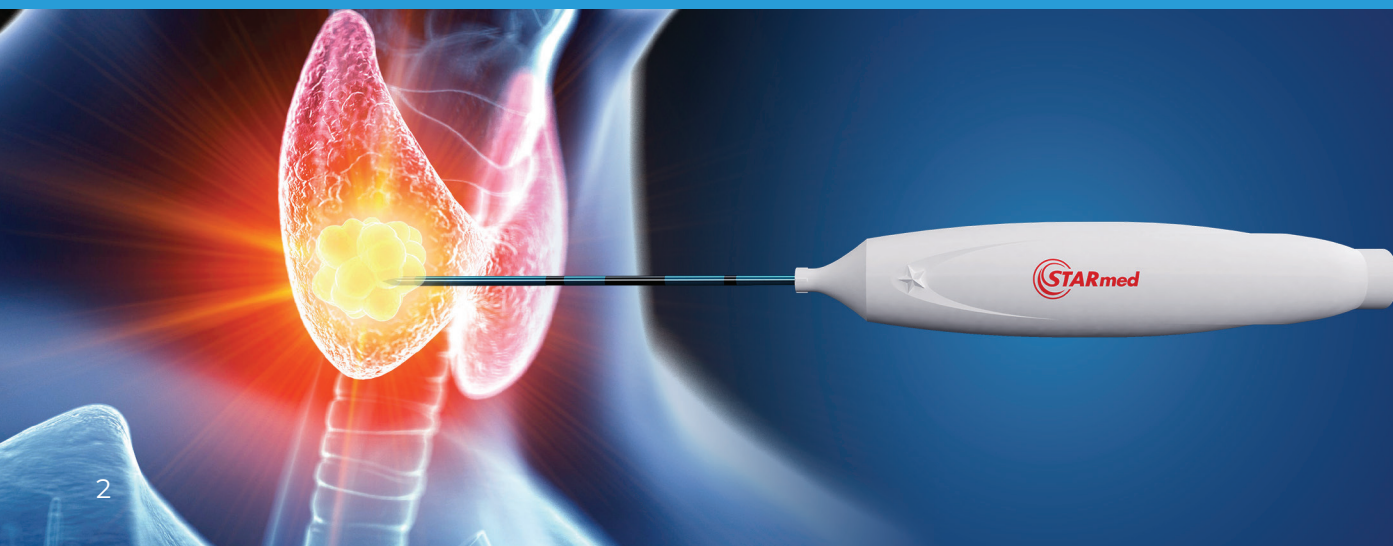


for autonomously functioning thyroid nodules (AFTN) at 12 months^{4,5}

STARmed Thyroid RFA offers predictable and reliable radiofrequency ablation performance and seamless therapy delivery with the exceptional ease of technical operation.

* Based on long-term volume reduction rate observed in clinical articles

** Data on file



Real Results From STARmed Thyroid RFA

The Benefits Proven by Science

As the market leader in thyroid radiofrequency ablation, STARmed Thyroid RFA offers a minimally invasive solution for your patients. Discover the many reasons why STARmed Thyroid RFA treatment should be your therapy of choice.

No surgical incision⁷

No post-operative scar⁷

Low complication rate⁸

Compressive symptoms relieve⁷

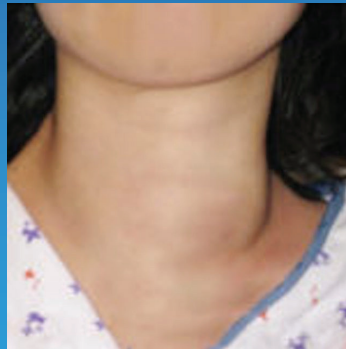
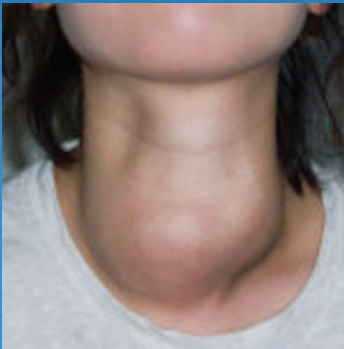
Short operative and recovery time⁷

No or minimal effect on thyroid gland's functionality (hypothyroidism)⁷

Transient and mild pain, most frequently during procedure only⁷

Female, 30's
Pre-procedure

12 Months
Post-procedure



Female, mid-30's
Pre-procedure

6 Months
Post-Procedure

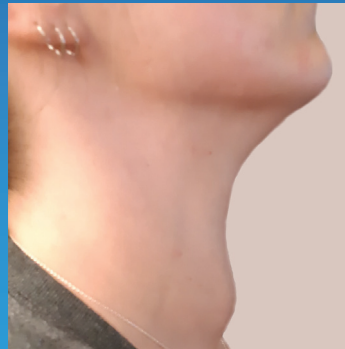


Photo Courtesy of Dr. Jun Hwan Baek
Results May Vary

“ *Radiofrequency ablation was effective and safe for treating benign thyroid nodules* ”

VIVA combo RF System

Ideal for percutaneous ultrasound-guided radiofrequency ablation (RFA) procedures

The industry-leading VIVA combo RF Generator is designed to deliver and sustain the optimal temperature range in the desired area to effectively ablate soft tissue with precision. It enables a minimally invasive approach with reliable and predictable performance.

VIVA combo RF Generator

- **Continuance Mode** generates radiofrequency power output continuously to support the “moving-shot” technique, works with **real-time Impedance Monitoring System** to ensure safe ablation processes
- **Up to 200W capacity** to accommodate a variety of indications and nodules of varying sizes and compositions
- **Easy-to-read, intuitive user interface** to allow easy monitoring of the procedure progress in real-time
- **Audible alert tones** and **automatic shutoff** to ensure a safe procedure process and prevent over-ablation
- **Compact footprint** to allow for the easy mobilization of the console
- **Optional footswitch** to enable hands-free generator output control during the procedure



Weight: 13lb

Specifications

Order Number	VCS10
RF Power	0~200watt at 50Ω load
Operating Frequency	480kHz
Temperature Monitor	5°C~95°C
Impedance Monitor	10~800Ω

VIVA Pump

- **Internal cooling system** circulates saline through the electrode to lower the temperature around the active tip of the electrode
- **Efficient partner** of the Continuance Mode to achieve maximum ablative margin while minimizing tissue charring - all with **ONE** electrode insertion.

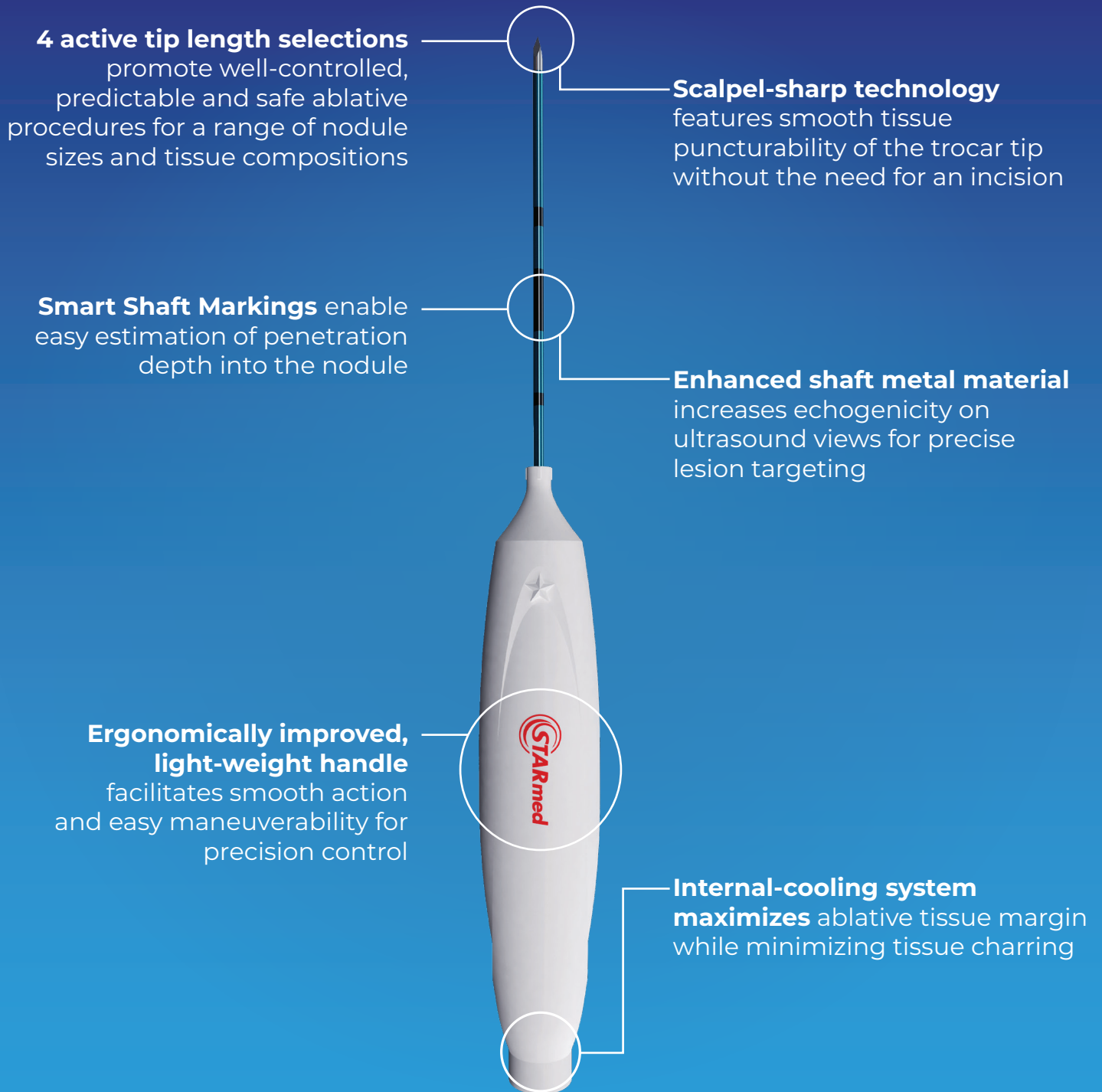


VP01-1

star RF Electrode

Single-use electrode for predictable, well-controlled, and consistent ablation zone

The monopolar star RF Electrode is the very FIRST electrode on the market designed to address thyroid diseases. It offers the largest selection of electrode gauge, shaft length, and active tip length to provide uncompromised treatment for a variety of neck indications, making a difference between a challenging procedure and an efficient one.



Ablation Zone Reference Value

Excellent ablation performance in a range of ellipsoid-shaped ablation zone sizes

Predictability is crucial to clinical success. Hence, we believe providing clinically relevant ablation reference values from a rigorous testing protocol will help you achieve and maintain control of your patient's disease.

Active Tip (mm):

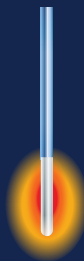
4mm

5mm

7mm

10mm

19 Gauge



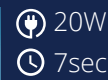
0.38
cm

0.72 cm



0.45
cm

0.88 cm



0.75
cm

1.10 cm



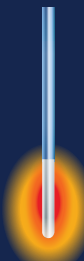
4mm

5mm

7mm

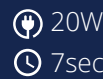
10mm

18 Gauge



0.55
cm

0.79 cm



0.84
cm

1.07 cm



0.92
cm

1.23 cm



DISCLAIMER

Ablation zone areas are observed using ex-vivo tissue model with a fixed technique by holding the electrode fixed in the area and ablate for the set amount of time.

Bovine ex-vivo ablation results may vary from in-vivo test or clinical results due to different conditions. Animal data is not indicative of human clinical outcomes.


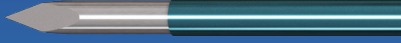


Ablation size is dependent upon tissue vascularization, type, temperature, impedance and user techniques.

star RF Electrode Portfolio

Portfolio of electrodes to deliver precise radiofrequency energy to the desired area

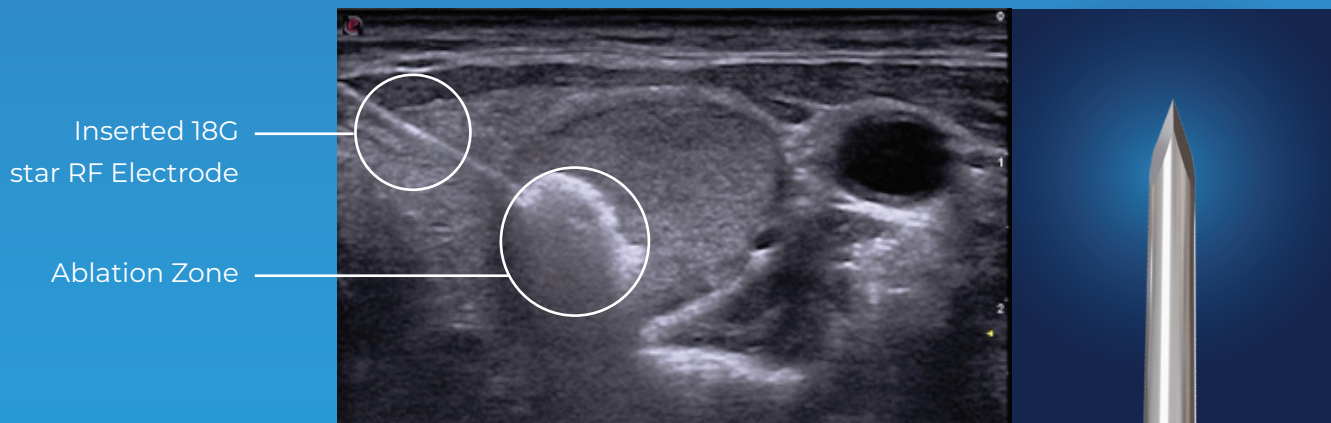
Product Specifications

Electrode Handle Length: 9.9cm

Active Tip Length	Shaft Length (cm)	Guage	Order Number	
4 mm	7	18	18-07s04F	
		19	19-07s04F	
	10	18	18-10s04F	
		19	19-10s04F	
5 mm	7	18	18-07s05F	
		19	19-07s05F	
	10	18	18-10s05F	
		19	19-10s05F	
7 mm	7	18	18-07s07F	
		19	19-07s07F	
	10	18	18-10s07F	
		19	19-10s07F	
10 mm	7	18	18-07s10F	
		19	19-07s10F	
	10	18	18-10s10F	
		19	19-10s10F	

PRODUCT INDICATIONS

The VIVA Combo RF System is intended for use in percutaneous and intraoperative coagulation and ablation of the tissue.



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IMPORTANT SAFETY INFORMATION / DISCLAIMER

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 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
- Weakness of liver functions
- Symptoms after RFA treatment includes (abdominal) pain, fever, nausea, headache, right shoulder joint pain and chest discomfort might occur

LEARN MORE



Only TaeWoong Medical USA offers a complete package of products, training, and extensive support. Contact your TaeWoong Medical USA representatives to learn more about how we can help you with your patient outreach effort.

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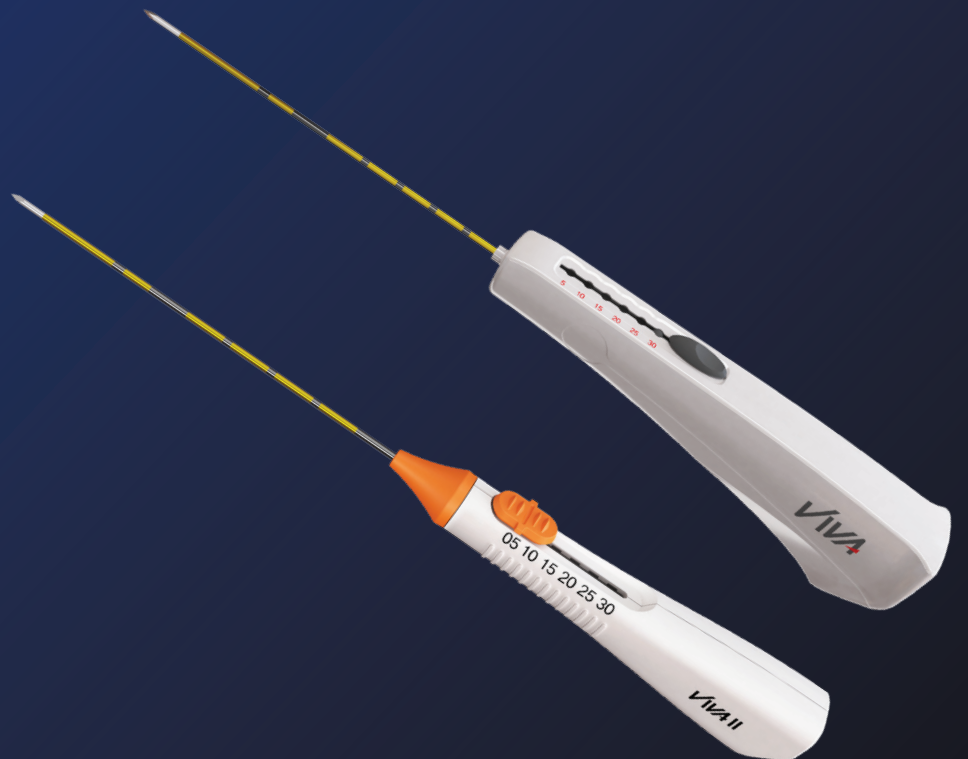
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“

When a patient is treated using RFA instead of surgery the optimal result overtime shall be guaranteed... together with the low frequency of complications recorded in these studies, represents high-level evidence which allows us to consider a non-surgical thermal treatment as a real alternative to surgery⁹

”



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