THYROID NODULE TREATMENT CENTER

Richard J. Harding, MD, FACS
Endocrine & General Surgeon
Board Certified Medical Director

TNTC PATIENT PACKET

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WELCOME

As medical director of the Thyroid Treatment Center, I would like to welcome you to our center. I sincerely hope to make your procedure a very pleasant experience for you. The mission of the TNTC is preservation of normal thyroid function while treating benign symptomatic thyroid nodules using the most advanced minimally invasive treatments available.

Every day new thyroid nodules are discovered by their physicians, family, friends, and even their hairdressers! Some people have symptoms related to the size of the nodules, which directs them to seek medical consultation. Others have no symptoms but learn about these nodules after undergoing radiologic testing for different reasons. The proper evaluation of these nodules is very routine. Much of the evaluation is predicated on the size of the nodule. Once nodules measure about 15 mm, we generally recommend an ultrasound guided biopsy. If there are some concerning features seen on ultrasound, a biopsy can be performed even if the size criteria are not met. Additionally, an enlarging nodule should be sampled under ultrasound guidance. Very small nodules under 6 mm do not require a biopsy under most conditions.

The presence of a nodule does not alter thyroid function. If a patient is hypothyroid, they should be thoroughly evaluated by their primary physician or an endocrinologist. Hypothyroidism is not caused by nodules. Occasionally, some nodules are autonomous and do not respond to the hormonal regulatory system that keeps the thyroid hormone levels in a normal range. These over-functioning nodules cause symptoms of fatigue, insomnia, and heat intolerance. Frank hyperthyroid symptoms include nervousness that makes people tremulous and shaky. Additionally, these patients feel hot and have a racing heart. Long term heart disease is a common consequence of this disorder. If this condition exists, these patients need an endocrinologist who will prescribe medications to regulate and suppress the thyroid function down to normal levels. Once properly regulated, further therapies can be considered.

Most thyroid nodules are benign. The most readily available modality for evaluating these is ultrasound. The test is easily performed without any concern for radiation exposure. The physician performed exam is much better than reviewing stationary images saved from prior examinations. The neck ultrasound study is easily repeated with no potential harm to the patient. There are several features in benign nodules that we like to identify to consider a lesion low risk of malignancy. When some of these features are absent, the nodule would be considered indeterminate, or potentially at risk for malignancy. These nodules will be tested using a needle biopsy to help the physician guide therapy. Not all nodules have favorable ultrasound characteristics, although they may prove benign on biopsy. Additionally, a small percentage of nodules can have favorable findings on ultrasound yet can be found to have papillary thyroid cancer. It is for these reasons that routine surveillance ultrasound is initiated once a nodule

grows to about 15 mm in largest dimension.

The treatment of these thyroid nodules varies depending on the nature of the nodules as well as the symptoms produced. Any malignancy will need to be removed if it is over 15 mm. Some smaller malignancies are now being followed without surgery. These are followed utilizing strict criteria and under research- based protocols. This mode of therapy in avoiding surgery and monitoring the patient has been very successful.

Small nodules tend not to create symptoms, whereas large nodules can create many problems such as difficulty with breathing when lying flat, difficulty with swallowing solid food (pills), and even a chronic cough. Nodules with compression symptoms can be removed with surgery. If they are not cancer and not suspicious for the possibility of cancer, then a minimally invasive, ultrasound guided therapy is very effective applying energy directly into the nodule. This treatment applies energy directly to heat it up to the point of tissue death. Once the tissue is devitalized, the body walls off and slowly reabsorbs the treated tissue.This method leaves the adjacent normal tissue unharmed and thus preserves the thyroid function. Unfortunately, surgery removes the entire side (lobe) due to safety concerns. This unavoidably removes the abnormal and normal tissue on the entire side. Approximately 60-75% of these patients will require thyroid hormone supplementation. Surgeons have been performing this treatment routinely for over 100 years.

If a biopsy raises a concern for the possibility of cancer, then surgery is recommended to allow for proper analysis of the tissue by pathologist. The surgery should be performed by a surgeon very familiar with thyroid operations, and who performs them regularly. The definition of a high-volume thyroid surgeon is currently established at 25 operations annually.

The Thyroid Nodule Treatment Center is available to navigate the numerous diagnostic and therapeutic options with you. Patients with normal thyroid function can present immediately to review treatment options regarding symptomatic thyroid nodules or nodules which they can see and feel because the nodules are so large. The most innovative therapy may be available to you. The immediate and long-term results with thyroid radiofrequency ablation are excellent. The overall satisfaction of this therapy has been uniformly high.

Sincerely,

Dr. Richard J. Harding

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INVOICE

THYROID NODULE TREATMENT CENTER
TIN 85-0986673
2320 N 3RD STREET
PHOENIX, AZ 85004

RECEIPT

Date:

Treating Physician: Richard J Harding MD Endocrine Surgeon

	Description	
76536	COMPREHENSIVE NECK ULTRASOUND	
64999	CERVICAL PLEXUS BLOCK	
76490	ULTRASOUND GUIDANCE RADIOFREQUENCY PROCEDURE	
60660	RADIOFREQUENCY THYROID NODULE	
C1889	SURGICAL SUPPLIES RFA PROBE	
60661	RADIOFREQUENCY SECOND THYROID NODULE	
	Credit Card Expense Fee 3%	
	Total	$
	Payment	
	Payment Due: TOTAL	

PRE-OP INSTRUCTIONS

5-7 Days Before Your Procedure

Blood Thinners & Supplements

Discontinue the following medications or supplements as they may increase bleeding or interfere with anesthesia:

- Aspirin or aspirin-containing products (e.g. Alka-Seltzer, BC powder, unless otherwise advised by your physician).
- Baby Aspirin 81mg needs to be stopped 1 day prior to procedure
- Coumadin, Plavix or other blood-thinning agents.
- Supplements, herbal remedies, and vitamins (e.g. Vitamin E, Omega 3, Fish Oil, Flax
- Seed Oil, Garlic Pills, Black Cohosh, Ginseng, Ginkgo, Fen-phen, Saw Pimento, St. John's Wort, etc.)

Day of Procedure

Medications

- Mild anxiety medications are recommended and can be prescribed for you to take 15 minutes before the procedure. If requested, prescription will be sent to your pharmacy of choice at least one day in advance of your procedure for you to bring with you.
- Bring Ibuprofen or Tylenol with you to take after the procedure, if needed.

General

- Do not wear jewelry or makeup on day of procedure
- Wear loose cotton clothing. Shirt must have an open collar/neck line. Wear an old shirt as there is a possibility that the orange sterile prep used prior to the procedure could stain clothing.
- Wear or bring a pair of loose shorts with you as there will be grounding pads placed on your skin above the knee cap.
- Bring a hair tie (non-metallic) to eliminate any hair from touching your neck.
- Ice packs are very helpful after the procedure for minimizing discomfort.
- Be prepared to stay in our office for an hour after the procedure for observation.
- Pre-op pictures of the neck will be taken prior to the procedure unless refused by the patient.

*If you have any questions, please call our office at (602) 889-2924 and ask for the medical assistant.

PATIENT INFORMED CONSENT

Operation or procedure and alternatives:

I, _____, authorize Dr. Richard Harding, and assistants of his choosing to perform the procedure: Radiofrequency Ablation of thyroid nodule(s) (Left) (Right). I understand the reason for the procedure is to treat large benign nodules in order to shrink the size of nodule(s), destroy nodule function, and decrease symptoms.

Alternatives include:

1. Thyroid surgery which has potential complications of nerve injury, hoarseness, scar on neck, loss of thyroid function, hypocalcemia, anesthesia, hospital admission.
2. To not undergo procedure(s) listed which will not improve symptoms or condition, and the disease may progress.

Patient Initials _____

Risks: This authorization is given with the understanding that any operation or procedure involves some risks and hazards. Some of the significant risks of this particular procedure are: pain, injury to thyroid, injury to surrounding structures, recurrent laryngeal nerve injury with temporary or permanent hoarseness, need for ongoing medical treatment of disease, bruising, complicate further surgery, failure to treat undiagnosed cancer, failure to improve existing symptoms, temporary pain at injection site during administration, prolonged numbness and tingling, accidental vascular injection, tumor regrowth, burn caused by the overheated electrodes, local bleeding at site of the ablation, nodule rupture. **Any compromise in airway concerns may warrant a transfer to the hospital for further therapy.**

I also understand that the more common risk of any procedure include: infection, bleeding, nerve injury, blood clots, heart attack, allergic reaction, and pneumonia. **These risks are serious and possibly fatal.**

Patient Initials _____

Anesthesia: the administration of anesthesia also involves serious risks, most importantly a rare risk of reaction to medication causing death. This medication can cause nausea, drowsiness, and dizziness. I consent to the use of such anesthetics as may be considered necessary by the person responsible for these services.

Patient Initials _____

Additional procedure: if Dr. Harding discovers an unsuspected condition at the time of the procedure such as bleeding, I authorize him to perform such other procedures as deemed necessary except _____.

Patient Initials _____

Results not guaranteed: I understand that no guarantee or assurance has been made as to the results of the procedure and that it may not cure the condition. Repeat treatment may be indicated for recurrent growth of some nodules.

Patient Initials _____

Patient consent: I have read and fully understand this consent form. I understand I should not sign this form if all items, including my questions, have not been explained or answered to my satisfaction or if I do not understand any of the terms or words contained in this consent form. I have no further questions.

Patient Initials _____

IF YOU HAVE ANY QUESTIONS AS TO THE RISKS OR HAZARDS OF THE PROPOSED PROCEDURE OR ANY QUESTIONS CONCERNING THEM, ASK DR RICHARD HARDING BEFORE SIGNING THIS FORM.

DO NOT SIGN UNLESS YOU HAVE READ AND THOROUGHLY UNDERSTAND THIS FORM

Patient name:_____

Patient signature:_____ DOB:_____

Today's date:_____

Witness:_____

Physician declaration: I have explained the contents of this document to the patient and have answered all the patient's questions; to the best of my knowledge, the patient has been adequately informed. The patient has been consented.

Physician signature: _____ Today's date:_____

PREPARATION CHECKLIST

->Read, fill in and/or check each statement as appropriate:

___ I am not pregnant
___ I am not wearing any makeup, lipstick
___ I have removed all jewelry and piercings
___ I am not wearing any metal fasteners (zippers, buttons, belts…)
___ I do not have a pacemaker

MEDICATIONS
___ I do not take any blood thinners
___ I am not taking any coumadin or antiplatelet therapy
___ I have not taken thyroid medication

___Typically, no change to medication is necessary unless you are on anticoagulants (instructions to be discussed)
___No antibiotics or pain medications are typically needed other than Tylenol or Ibuprofen

Sedative
___If I want to take a sedative prior to the procedure, I understand that I must

1. Inform our office staff at least 24 hours in advance of your procedure
2. Inform our office staff at least 24 hours in advance of your procedure
3. Bring the prescription with you to the office to take 20 minutes before procedure

___I understand that If I do NOT take a sedative, I should be able to drive home and resume normal activity following the procedure

___ I have not had prior thyroid surgery
___ I have presented two FNA biopsies that are benign, one for autonomous functioning thyroid nodule

___My symptom score from 1-5 (five being severe) is_____
___My cosmetic score from 1-4 (four being severe) is_____

___ I understand a popping sound in my neck is possible and normal with this procedure
___ I understand the goal is to obtain 50% reduction over the next several months
___ I understand that more than one procedure may be necessary for desired results
___ I understand the possibility of regrowth of treated nodule and that additional treatments may be necessary
___ I understand patients may experience various degrees of discomfort during ablation
___ I understand complications as listed in the consent
___ I understand a diagnosis of Hashimotos increases my risk of developing hypothyroidism
___ I understand that hyperfunctioning thyroid nodules that are cured with procedure may also increase risk of hypothyroidism at a rate of 3%
___ I understand that a semi-permanent marker will be used on my neck for proper placement of probe
___ I understand that since there is no anesthesia, there will be no monitoring of vitals during the procedure

___ I understand that no exercise is permitted on the day of procedure and normal activities/exercise can resume the following day

___ I understand I must return to be examined by ultrasound to demonstrate volume reduction at the following milestones:

1. 1 month (30 days) after the procedure
2. 3 months after the procedure
3. 6 months after the procedure

___ I understand that further observation or admission may be required following the procedure, depending on condition after ablation

Signed:
_____

Patient Name
_____

DATE
_____

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DYSPHAGIA HANDICAP INDEX (DHI)

Patient Name _____ DOB _____

Today's Date _____

		Never	Sometimes	Always
1P	I cough when I drink liquids.			
2P	I cough when I eat solid food.			
3P	My mouth is dry.			
4P	I need to drink fluids to wash food down.			
5P	I've lost weight because of my swallowing problem.			
1F	I avoid some foods because of my swallowing problem.			
2F	I have changed the way I swallow to make it easier to eat.			
1E	I'm embarrased to eat in public.			
3F	It takes me longer to eat a meal than it used to.			
4F	I eat smaller meals more often due to my swallowing problem.			
6P	I have to swallow again before food will go down.			
2E	I feel depressed because I can't eat what I want.			
3E	I don't enjoy eating as much as I used to.			
5F	I don't socialize as much due to my swallowing problem.			
6F	I avoid eating because of my swallowing problem.			
7F	I eat less because of my swallowing problem.			
4E	I am nervous because of my swallowing problem.			
5E	I feel handicapped because of my swallowing problem.			
6E	I get angry at myself because of my swallowing problem.			
7P	I choke when I take my medication			
7E	I'm afraid that I'll choke and stop breathing because of my swallowing problem.			
8F	I must eat another way (e.g., feeding tube) because of my swallowing problem.			
9F	I've changed my diet due to my swallowing problem.			
8P	I feel a strangling sensation when I swallow.			
9P	I cough up food after I swallow.			

Date of Procedure: _____

Initial size of nodule: _____mL

1 month: _____mL

VRR:_____

3 months: _____mL

VRR:_____

6 months: _____mL

VRR:_____

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2	3	4	5	6
Normal		Moderate Problem		Severe Problem

Please circle the number that matches the severity of your swallowing difficulty (1 = no difficulty at all; 4 = somewhat of a problem; 7 = the worst problem you could have)

Place a check in the box that describes your swallowing difficulty

Total	_____
P (Physical)	_____
F (Functional)	_____
E (Emotional)	_____

Values are given as mean ± SD

Normal, n - 35; Mild n - 65; Moderate, n - 93; Severe, n - 20

Table 4 Subscales by self-perceived dysphagia severity for dysphagia group

Subscale	Normal	Mild	Moderate	Severe
Total	7.89±7.75	15.69±9.77	34.86±16.0	63.20±23.38
Physical	4.74±3.66	8.68±3.80	13.85±5.55	21.50±7.70
Functional	2.34±4.27	4.58±5.28	13.68±8.51	24.00±10.68
Emotional	0.80±2.53	2.43±2.90	7.33±5.74	17.70±8.37

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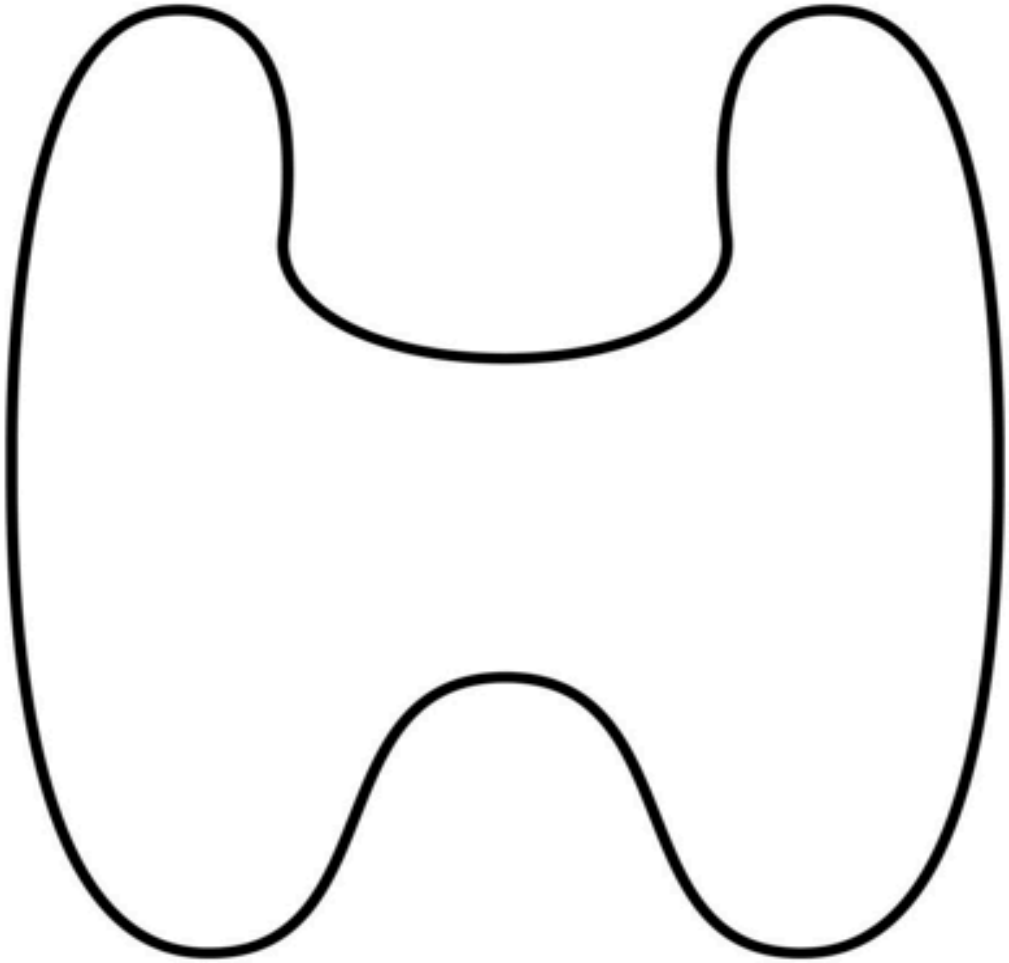
Toxic nodule | Non-toxic nodule



RIGHT | LEFT

Office: 602-889-2923 | Fax: 602-889-2926
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PATIENT FINANCIAL RESPONSIBILITY FORM

TNTC provides minimally invasive thyroid nodule procedures using advanced equipment designed to preserve thyroid function. These procedures **may not have standard AMA procedure codes** and may **not be recognized by insurance companies or Medicare** for direct billing.

TNTC is an out-of-network, self-pay provider.

- TNTC does **not** bill insurance or submit prior authorizations.
- Payment for TNTC procedures is **due at the time of service**.
- TNTC will provide documentation if you wish to submit a claim to your insurance. Reimbursement varies by individual plan and is not guaranteed.

Services Billed Through Arizona Endocrine Surgery (AES): AES is an OON provider and **may submit claims to your insurance** for evaluation-related services. Coverage depends on your specific plan's coverage. Your **initial consultation**, diagnostic evaluation, and any procedures performed during that evaluation are provided by **Arizona Endocrine Surgery (AES)** may include:

- Office visit evaluation
- Diagnostic ultrasound
- Fine-needle aspiration (if needed)
- Other diagnostic procedures performed during your evaluation

Services Provided by TNTC on the Day of Treatment: The minimally invasive thyroid procedure itself is performed and billed **exclusively through TNTC** as a self-pay service. Treatment procedures may include::

- Comprehensive neck and thyroid ultrasound
- Cervical plexus block
- Ultrasound guidance
- Radiofrequency ablation (RFA) of the thyroid nodule

Additional procedures, such as **ultrasound-guided drainage of a thyroid cyst**, may be required. When appropriate, these may be billed through AES and submitted to insurance, even if performed on the same day.

Patient Acknowledgement: I understand which services are billed through AES, which services are billed through TNTC, and which services require self-payment. I have had the opportunity to ask questions.

Patient Name:_____ **Date:**_____

AUTHORIZATION LETTER FOR RADIOFREQUENCY ABLATION OF THE THYROID GLAND

The management of thyroid nodules has changed dramatically in the last twenty years worldwide. With the introduction of fine needle biopsy over 40 years ago, we can characterize nodules as either benign, indeterminate, and potentially malignant with an in-office biopsy. A symptomatic nodule determined to be benign now can be treated with multiple options.

Of course, the most definitive option is surgery, which has the advantage of eliminating the entire nodule completely. The **downside of surgery**, however, is that the entire thyroid lobe is removed, including functional thyroid tissue, thus predisposing to hypothyroidism and a **lifetime of medication**. The hospital charges alone for this procedure are approximately $30,000-$40,000. This does not include the additional surgeon's, anesthesiologist's, and pathologist's charges. Long term costs for management of permanent hypothyroidism is also not factored in these charges. Although surgical risks for thyroidectomy are low, complications are frequent enough to increase the morbidity to the patient and create considerable cost for management and therapy. Most of the thyroid surgery in the United States is performed by low volume surgeons, who have a higher complication rate compared to high volume surgeons. Fortunately, nonoperative approaches are now available for which the complication rate for is easily one tenth or less than for open surgery.[1,2]

Thyroid radiofrequency ablation (RFA) was introduced in Korea in 2002 and has become the most common mode of managing benign thyroid nodules throughout Asia, Europe, and the United Kingdom for the past decade. This treatment modality has become so common that entire sets of guidelines have been established and even updated. An International Multidisciplinary Consensus Statement of the Head and Neck Society states that radiofrequency ablation should now be recognized as the first modality of treatment if available.[3]

Radiofrequency Ablation of soft tissue received U.S. FDA clearance in late 2018 and has been slowly introduced to the endocrine, surgical, and head and neck community of physicians. This intervention requires a water-cooled RF probe which can be specifically directed to the vascular margins of the target nodule. The water-cooled RF probe focused energy safely and effectively destroys the abnormal tissue and vascular supply. The equipment is expensive, and the length of the procedure takes much longer than laser thermal ablation. With the laser treatment, a laser fiber is introduced in the middle of the nodule and the heat dissipates radially.

*The studies comparing the two treatments document the **superiority of RFA** over laser in terms of better outcomes. The nodules decrease more in volume with RFA and the requirement for secondary procedures is only 5% as compared to 10% seen with laser. This superiority of RFA has been documented in multiple studies including the 12-month Randomized (LARA II Study) Trial.*[4]

The significant difference in the procedure regarding skill required, time of the procedure, cost of the equipment, and effectiveness of therapy, makes applying the Category III CPT code assigned for Laser ablation of thyroid nodules inappropriate. **RFA thyroid nodules are equivalent to interventions performed by an interventional radiologist for RF Ablation of liver and renal tumors**.

These procedures require image guided complete thermal ablation of solid tumors in other complex areas of the body. The procedure codes for these procedures are

- 47382 which has a work RVU assignment of 14.9, and
- 50592 which has a work RVU of 6.55.

Hospital charges for these procedures range from $45,000 to $25,000 respectively.

The indications for thyroid RFA are the same as for thyroid surgery. Visual deformity and compressive symptoms (such as foreign body sensation, pressure, dysphagia, hoarseness, and choking sensation) are relieved within weeks of RFA as the ablated nodule shrinks in volume.

Additionally, RFA thyroid has completely changed the management of autonomous thyroid nodules. No longer is costly radioactive iodine exposure necessary. Radioactive iodine not only destroys the specific lesion, but also the adjacent healthy thyroid tissue, more often rendering the recipient hypothyroid. The surgical option of thyroid lobectomy requires removal of healthy thyroid tissue around the toxic nodule. **With RFA thyroid nodules, only the abnormal tissue is treated**, thus allowing for prompt restoration of normal thyroid function.

With the success of RFA in treatment of autonomous thyroid nodules, those of us in the Thyroidology community envision a change in the upcoming guidelines to consider RFA thyroid as the first line of therapy for this disease process.

Each of the following, recent references refer to decades of articles of successful RFA well recognized and accepted in World literature. Where noted, the full article can be downloaded from the Thyroid Nodule Treatment Center website.

Research

1. Kandil, E., Omar, M., Aboueisha, M., Attia, A. S., Ali, K. M., Abu Alhuda, R. F., Issa, P. P., Wolfe, S., Omari, S., Buti, Y., Abozaid, O., Toraih, E., Shama, M. A., Lee, G., Tufano, R. P., & Russell, J. O. (2022). *Efficacy and Safety of Radiofrequency Ablation of Thyroid Nodules: A Multi-institutional Prospective Cohort Study. Annals of surgery*, 276(4), 589–596. https://doi.org/10.1097/SLA.0000000000005594 Download from TNTC:

2. Hussain I, Zulfiqar F, Li X, Ahmad S, Aljammal J. *Safety and Efficacy of Radiofrequency Ablation of Thyroid Nodules-Expanding Treatment Options in the United States*. J Endocr Soc. 2021;5(8):bvab110. Published 2021 Jun 10. doi:10.1210/jendso/bvab110 Download from TNTC

3. Orloff LA, Noel JE, Stack BC Jr, et al. *Radiofrequency ablation and related ultrasound-guided ablation technologies for treatment of benign and malignant thyroid disease: An international multidisciplinary consensus statement of the American Head and Neck Society Endocrine Surgery* Section with the Asia Pacific Society of Thyroid Surgery, Associazione Medici Endocrinologi, British Association of Endocrine and Thyroid Surgeons, European Thyroid Association, Italian Society of Endocrine Surgery Units, Korean Society of Thyroid Radiology, Latin American Thyroid Society, and Thyroid Nodules Therapies Association. Head Neck. 2022;44(3):633-660. doi:10.1002/hed.26960 Download from TNTC

4. Cesareo R, Manfrini S, Pasqualini V, et al. *Laser Ablation Versus Radiofrequency Ablation for Thyroid Nodules: 12-Month Results of a Randomized Trial (LARA II Study)*. J Clin Endocrinol Metab. 2021;106(6):1692-1701. doi:10.1210/clinem/dgab102 Download from TNTC

5. Zielske, Dr., Broek, RE. Radiofrequency ablation, cryoablation, irreversible electroporation, and other ablation procedures. *Interventional Radiology Coding Reference; Radiofrequency Ablation, Cryoablation, Irreversible Electroporation, and Other Ablation Procedures*. *Dr. Z's Medical Coding Series: Interventional Radiology Coding Reference*. 20th ed. Brentwood, TN:ZHealth Publishing: 2023: 549-559. https://www.zhealthpublishing.com/coding-products/books-and-ebooks/interventional-radiology-coding-reference-2023

6. L. Yan, X.Y. Li, Y. Li and Y. Luo. *Ultrasound-Guided Radiofrequency Ablation versus Thyroidectomy for the Treatment of Benign Thyroid Nodules in Elderly Patients: A Propensity Matched Cohort Study*. American Journal of Neuroradiology June 2023, 44 (6) 693-699; DOI: https://doi.org/10.3174/ajnr.A7890. Download from TNTC