THERMIva®

FAQ'S

by Red Alinsod, MD

The Thermi Clinical Advisory Council

Thermi was founded on a philosophy of engaging the physician owner in the advancement of his/her specialty area of medicine. Each Thermi physician is invited to participate in our Clinical Advisory Council (CAC), an independent body that encourages collaboration and the free exchange of ideas among peers. This collegial participation accelerates learning while optimizing both clinical and financial success.

ThermiVa FAQ's

At ThermiVa CAC meetings, and on ThermiVa webinars, there is always an opportunity to ask questions of Red Alinsod, MD, Medical Director of South Coast Urogynecology, and Chair of the Thermi Women's Health Clinical Advisory Board.

Between meetings, physicians have posed questions that may be of interest to other ThermiVa users. For that reason, we have compiled a collection of frequently asked questions about ThermiVa. We respectfully request that this document be kept for your practice's reference and not to be utilized for patient distribution. Our intention for this guide it to assist you with a successful start to your exciting new ThermiVa practice.

These responses reflect the professional opinion of Dr. Alinsod, based on his many years of clinical experience. For questions or comments, please contact Dr. Alinsod directly at red@urogyn.org.

The ThermiVa system and probes are FDA cleared (K130689) and indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis; and the creation of lesions in nervous tissue.

Questions Asked:

PRE-TREATMENT

1. Is this procedure permitted if a patient is breastfeeding?
2. Can RF energy affect breast milk?
3. What is the post vaginal delivery recommendation for treatment?
4. Can we treat women who complain of painful intercourse?
5. How should we treat undiagnosed pelvic pain?
6. What is the recommended age range that can be treated?
7. Can patients with a verified proper IUD placement have ThermiVa treatments?
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10. Can you treat a patient that has Lichen Sclerosus?
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15. If a patient has had a previous hysterectomy or has an enterocele, are there any concerns for treating the vaginal apex for bowel injury concerns?
16. Can ThermiVa help to reduce or eliminate vaginal or labial varicose veins?
17. If a patient is being treated with Chemotherapy for any reason, including autoimmune disease, can they be treated with ThermiVa?
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20. We have referred to ThermiVa's informed consent "Possible experiences and/or risks associated with the procedure." Are there any signs or details to take note of DURING the treatment to avoid causing these complications?

ThermiVa FAQ's

WITH DR. RED ALINSOD

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2. Why are some patients experiencing spotting or shedding?
3. Do you see an increase in menstrual cycle after treatment?
4. How are nerves affected by RF?
5. Can it treat episiotomy, hemorrhoids and scar tissue?
6. When treating internally you can sometimes see a white discharge. Is this sloughing or something else? Please explain.
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POST-TREATMENT

1. Results: When should a patient expect to begin their "maintenance" program? Does this differ for internal and external treatments?
2. What results can you see with prolapse? Does the technique change for bladder prolapse?
3. What is the furthest data recorded for ThermiVa patients?
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10. Failure rate. Are there any patients who do not show visible results (vulva) even after completion of 3 treatments?
11. General complications.

PRE-TREATMENT

1. Is this procedure permitted if a patient is breastfeeding?

You can treat all breastfeeding patients.

2. Can RF energy affect breast milk?

It has no effect.

3. What is the post vaginal delivery recommendation for treatment?

6 weeks for an uneventful normal vaginal delivery. By then, any vaginal repair has healed and tissue response to ThermiVa is outstanding.

4. Can we treat women who complain of painful intercourse?

Those with painful intercourse may benefit dramatically from ThermiVa. It all depends on what the pain is stemming from. The patient will need a workup for painful intercourse before treatment. If the cause of painful intercourse is from atrophic vaginitis, then ThermiVa will be an excellent therapy. If painful intercourse is from a pelvic surgery, such as a mesh repair, then that should have a surgical work up. Patients with mesh are considered safe, unless they have had complications. Again, we are early in this knowledge; those with mesh, should be evaluated by an experienced pelvic surgeon. Providers, who do not preform pelvic surgery, should not do ThermiVa on mesh repair patients without medical clearance.

5. How should we treat undiagnosed pelvic pain?

ThermiVa has been an incredible treatment for the following complications; atrophic vaginitis, levator spasms, and even those with introital pain from lichen schlerosis and hyperplastic dystrophy. I would not treat a patient with a vulvar lesion that has not been diagnosed or biopsied. You never want to treat a patient with VAIN/VIN/Precancer of the vulvar or vagina. To be perfectly safe, treat only those with a completely normal visual vulva/vagina.

6. What is the recommended age range that can be treated?

The average age treated is 18 + to infinity, depending on complaint and issue. This is a procedure for both the pre and postmenopausal women.

7. Can patients with a verified proper IUD placement have ThermiVa treatments?

That is perfectly fine. Patients with IUDs are safe to treat because IUDs are in the uterine cavity away from the vaginal cavity with the thick and firm cervix acting as a bank vault door. The only time it may even be an issue is if the uterus with an IUD is prolapsing into the vagina. In that case, it is advised not treating uterine prolapse patients earlier in this FAQ. Even if you did treat a patient with an IUD inside a prolapsing uterus, the uterine wall is of sufficient thickness to be a barrier to RF energy, therefore not affecting the IUD. Mirena IUD has no metal parts and is completely safe to treat. Progestasert and other metal containing IUDs are protected by the cervix and uterine wall that RF energy will not affect.

8. How should the diagnosis of prolapsed uterus be ascertained?

The patient should be cleared from prolapse and have a pelvic exam before treatment. Pelvic exams can come from anyone who does paps/pelvics and are proficient at it. If a doctor does not feel confident in their pelvic exam then the patient can see her primary care and get examined. The treating doctor should then request a report stating the pelvic exam is normal and that there are no vulvovaginal lesions and no uterine prolapse. If there is a bladder or rectal prolapse then that can be treated.

9. Should patients have a recent pap smear?

It is suggested to have a recent physical and or pap smear (when applicable) within the last 2 years (since women without a cervix do not have a pap smear). I believe that ThermiVa treatments are best for those with normal paps. However, I believe it is also acceptable to treat women with low risk HPV subtypes. Those with high risk HPV should be managed and treated before proceeding with ThermiVa treatments. Once you have a normal pap, Thermiva treatments are acceptable.

10. Can you treat a patient that has Lichen Sclerosus?

Yes. Many patients have been treated that state their post treatment skin is less sensitive and irritated. It is thought that treating this skin may thicken it, making it less sympotomatic. It's likely that ThermiVa will become a good option as a future treatment on those with a biopsy proving LS and/or any vulvar dystrophy short of pre cancer. ThermiVa has also been used on those with very thickened vulvar skin that patients complain to be itchy (hyperplastic dystrophy). Previously this condition was treated with topical steroids such as Lidex and Clobetasol Propionate. ThermiVa has helped these patients with symptoms. These symp-toms are not a contraindiction at all.

11. Who suffers from vaginal laxity?

Vaginal Laxity is very common after vaginal delivery. This condition can also be the result of aging, obesity, hormones, chronic constipation, straining, lifting, or any activity that would cause the vagina to stretch beyond its normal capacity.

12. Who are candidates for ThermiVa?

- Women who are experiencing vaginal laxity and a loose or rubbing feeling
- Women who are displeased with the appearance of their labia majora, especially while wearing bathing suits, athletic attire, leggings, jeans, etc.
- Women who are experiencing any sexual dysfunction or orgasmic issues
- Women who are having difficulty retaining tampons or may have pelvic prolapse, such as fallen bladder or fallen rectum
- Women who may suffer from urinary leakage or stress incontinence.
- Women who may suffer from dryness of their vagina or labia (atrophic vaginitis) due to the effects of menopause

13. Do women on hormone replacement therapy need to stop at any time?

No need to stop, change, or alter the way you are taking your hormone replacement therapy. If using vaginal estrogens apply AFTER treatment.

14. Research has shown there is a correlation between vaginal dryness and orgasmic dysfunction in women who have been on birth control for extended periods of time, due to a medical issue such as PCOS. Can ThermiVa help with this issue without having the patient stop the birth control?

Yes, definitely, if the patient had orgasmic dysfunction. ThermiVa can improve sensitivity in all patients, whether they are on hormones or birth control pills. In patients who suffer from orgasmic dysfunction (anorgasmia or taking too long to achieve orgasms), it can reduce the time to reach orgasm by one third to one half. However, if you have no such problem, it will not make you hyper-orgasmic. It only helps those who have orgasmic issues. Those who have normal orgasms when treated with ThermiVa continue to have normal orgasms, but can experience stronger and more coordinated muscular contractions.

15. If a patient has had a previous hysterectomy or has an enterocele, are there any concerns for treating the vaginal apex for bowel injury concerns?

No concern. Hundreds of women have been treated post-hysterectomy. The tip is rounded and blunted, so the risk of perforating the vagina into the bowel/rectum/bladder is none, unless you force the device in with tremendous pressure. We recommend light pressure.

16. Can ThermiVa help to reduce or eliminate vaginal or labial varicose veins?

No, it will not reduce either vaginal or labial varicose veins, these may require surgery such as labia majoraplasty. It is safe to perform ThermiVa treatments over these areas.

17. If a patient is being treated with Chemotherapy for any reason, including autoimmune disease, can they be treated with ThermiVa?

There are no studies to prove safety or to establish this as a contraindication. It is my recommendation that the patient wait until their therapies are completed before being treated with ThermiVa. This has not been studied at this time.

18. Can patients experience a change in their menstrual cycle after a ThermiVa treatment?

Most patients will have no change in their menses. We have reported cases of patients experiencing mild to moderate spotting lasting between 24hrs-72hrs. This is probably secondary to touching the cervix during treatment. Rare patients with very regular cycles may have an onset of an early cycle, but this can be due to many reasons such as stress and emotional issues. If this should occur, they are encouraged to seek professional medical advice from their OB/GYN or Primary Care physician. As always, be sure that the patient has a negative pregnancy test before ThermiVa treatments.

19. Any requirements for pre-treatment examinations when doing ThermiVa for vaginal laxity? E.g. Mandatory pap smears or checks for polyps/lesions, etc., before actual treatment.

My practice in the US is to require a normal Pap within the past 2 years, so you don't accidentally treat cervical pre-cancers or find abnormal pelvis masses, polyps. In Canada, the health system standard of care is every 2-3 years for Pap Smears. Ultimately, the requirement or timeframe for a Pap should be a practice decision. It's my standard of care to perform a pelvic exam before each treatment. You can treat anyone with mild to moderate pelvic prolapse. I personally treat those with cystocele and rectoceles up to a moderate range, meaning the leading edge of the prolapse does not go further than 1 cm pass the hymen.

In general, do not treat any patient with an abnormal Pap until it resolves, do not treat any undiagnosed vulvar lesions, and do not treat when there is visible venereal warts or HSV or molloscum. If the Pap shows low risk lesions or low risk HPV then it is safe to treat. ThermiVa does not make HPV act up, show up, or advance in severity.

Be sure to check a pregnancy test on the appropriate patients before treatment. Assume they are all pregant until proven otherwise.

20. We have referred to ThermiVa's informed consent "Possible experiences and/or risks associated with procedure." Are there any signs or details to take note of DURING the treatment to avoid causing these complications?

No, not that I can quantify. This procedure is extremely safe with rare minor complications and no reported significant complications noted.

TREATMENT

1. How do we explain M.O.A. and results seen in regards to urinary stress incontinence?

This is a very remarkable story. Stress incontinence is from poor support of the mid urethra, resulting typically from stretched out pubocervical fascia that then fails to act like a backboard for the urethra to become compressed from pressure events of stress such as coughing/sneezing/jumping. It can also occur because of damaged/stretched out or poorly contracting urethral muscles. This complex dual mechanism of the urethral muscles and the backboard theory are what provide continence. Anything that effects both, results in leakage or urine with stress. ThermiVa does two things to address these two issues. First, it contracts the pubocervical fascia, tightening it, and provides a firmer floor for the urethra to compress against when the patient coughs or sneezes. Instead of flopping, the firmer pubocervical fascia is now not getting stretched and pushed down now and provides floor pressure upwards to compress the urethra that is getting pushed downward. Next, ThermiVa has healing effects on the muscle and nerves, as well as, the fascial tissue. The healing effect on muscle is well known and is why it is used on damaged or sore muscles by physical therapists in pro sports. So, now radiofrequency heals the torn or damaged muscles, plus the tightening effects, bring these torn and stretched out muscles closer in proximity together and now the individual muscle fibers act like a unit of muscle to increase pressure when contracted. Instead of individual muscle fibers working separately, the more closely tied in units of muscle; work together to improve the continence mechanism of the urethra. Lastly, it's thought that the ThermiVa does have nerve healing effects that may increase the sensitivity of nerves of the urethral muscles and bladder. Nerves are more sensitive in detecting pressure changes and defensively contracting to provide continence. These same nerves that may be too sensitive or easily triggered from traumatic deliveries, menopausal changes, interstitial cystitis are now not "overactive" or spastic. Those with overactive bladder symptoms, typically feel a reduction in need to urinate frequently or sudden uncontrolled urge to urinate by a third to a one half. They feel like they can go longer between voids, they have larger voids, and have a stronger stream, one that they can control better by the ability to stop midstream if they wanted to, when they could not prior to treatment.

2. Why are some patients experiencing spotting or shedding?

Spotting can occur when ThermiVa electrode touches the cervix. We can see the same results with a pap swear. It can also occur if the patient has an untreated vaginitis (bacterial vaginitis, candida vaginitis, trichonomas vaginitis). More serious, is if they have an active/untreated gonorrhea or chlamydia infection. If patients have had a hysterectomy, then treat to the vaginal cuff. If bleeding is repetitive, encourage a pelvic exam be performed for visually inspection, vaginal cultures, GC and Chlamydia testing.

3. Do you see an increase in menstrual cycle after treatment?

No, increased menses has not been reported nor documented. Patients have reported no change in their cycle schedule, length or flow.

4. How are nerves affected by RF?

The RF affects nerves by increasing its release of vasoactive peptides that are then available at the nerve terminals. The increase in neurotransmitter activity at the nerve synapse is not clear. These vasoactive peptides result in vasodilation of the arterioles on the vulva/vagina/clitoral and G-Spot areas. The increased blood flow is similar in effect to Viagra in males. Increased blood flow results in increased plasma transudate from the arteriole through the vessel epithelium and out to the vaginal canal.

5. Can it treat episiotomy, hemorrhoids and scar tissue?

ThermiVa may soften scar tissue. It has been shown to soften skin. It's likely to shrink hemorrhoids. However, for hemorrhoids, the preference is to ablate and destroy them with higher temperature RF, such as the technology of the ThermiRase protocol at 80C.

6. When treating internally you can sometimes see a white discharge. Is this sloughing or something else? Please explain.

The white discharge when treating internally is transudate from stimulation or arousal. Not really vaginal sloughing per se. Very normal. This is actually a good sign that their response to treatment will be outstanding in terms of atrophic vulvovaginitis.

7. Can ThermiVa be combined with other procedures?

ThermiVa can be used with many other vulvovaginal treatments. For example, when treating a labia minoraplasty, ThermiVa treatments on the entire vulvar structures can provide an improved cosmetic appearance and post procedure improved skin softness/fullness/smoothness. For most patients, this is an added and unexpected benefit from ThermiVa. All of your vaginal surgical patients can be presented with ThermiVa as an add-on option that can be done at the same time as their insurance or cash based surgeries.

8. Are anesthetics needed for this procedure?

No. The treatment feels like a comfortable, warm heat and patient feedback is necessary.

9. How long does the procedure take?

Approximately 10-15 minutes for labia majora reduction and 15-20 minutes for vaginal tightening. The protocol consists of 3 treatments recommended one month apart.

10. Is there any contraindiction to longer treatment?

No. But whether anything longer than 5 minutes is better than 3-5 minutes is not known.

11. What would you say at this point would be your maximum treatment times for internal and external areas?

About 5 minutes is my maximum treatment per zone with excellent results.

12. Treatment of the clitoral area or 12 o'clock position. Our competitors have specifically cautioned to avoid these areas due to urethra stricture, do we need similar precautions?

We do not and in fact, this provides us a huge advantage and selling point over our perceived competition. Per our protocol, the clitoral areas, hood and clitoris are all treated to 40-45 degrees, providing increased blood flow and improved sensitivity. The orgasmic dysfunction is aided in many who have problems achieving orgasms or that have decreased sensitivity. Then at the 12 o'clock position and around the urethra, treat the entire anterior compartment and pubocervical fascia and patients experiencing urinary leakage, frequency, and urgency may improve dramatically. Since the alleged G-Spot is said to be located in the same area, orgasmic dysfunction again is aided by increased blood flow.

13. For treatment of urinary incontinence, what's the protocol?

As mentioned above, for mild to moderate stress incontinence and over active bladder, treat the mid urethra and whole anterior compartment for about 5 minutes per treatment and repeat monthly x 3. This treatment has become the basis of my urogynecology practice. It's safe, no slings, no mesh, and with excellent results, similar to slings and anticholinergic medicines. Almost all my treatments include the entire external vulva and internal vagina; rarely is there a patient who only gets the anterior compartment treated. I find most patients want the entire feminine areas treated to obtain the best systemic rejuvenation possible. For those with severe stress incontinence, also called Intrinsic Sphincter Deficiency, you may need to treat the anterior compartment's mid urethra every 2-3 months. If your patient does not respond to ThermiVa for SUI or OAB, then be suspicious for ISD. A urodynamic study would be appropriate to determine if ISD is present. If a patient who has just emptied her bladder is stressed with cough/sneeze/heel bounce and leaks urine then she has an 80-85% chance that her incontinence is severe. These are the poor ThermiVa candidates. On the other hand, the woman who empties her bladder completely and just leaks upon standing from the toilet seat is one who will do very very well with ThermiVa.

POST-TREATMENT

1. Results: When should a patient expect to begin their "maintenance" program? Does this differ for internal and external treatments?

External Treatments:
If the patient has external issues and concerns, after the third treatment they may require additional treatments between 4-6 months. You can give the example of: this treatment is typically going to last as long as a Botox treatment.

Internal Treatments:
The maintenance treatments can be between 6 to 12 months after the 3rd treatment. The internal effects of comfort, moisture, fullness, incontinence and overactive bladder can have longer lasting effects than the external treatments. The results for orgasmic dysfunction can be longer lasting than other comlpaints and may last over 18 months. It's an observation that when the nerves have been sensitized the effects are very enduring in terms of maintained sensitivity.
Always consider the number of treatments the patient has had when educating them on a maintenance program. If the patient has had less than the 3 treatments as recommended; than they may desire additional treatments sooner.

2. What results can you see with prolapse? Does the technique change for bladder prolapse?

If the patient has pelvic prolapse, I would concentrate my treatment time on that particular compartment. Spend at least 5 minutes in the anterior compartment if the prolapse is of the bladder, then at least 5 minutes on the posterior compartment if the prolaspe is the rectum. Ten minutes total if the prolapse is located in both. ThermiVa has worked to reduce symptoms for patients with mild to moderate pelvic prolapse (up to stage 2 where the leading edge can go up to a cm past the hymen), but does not work well in severe prolapse when the tissue is visible and palpable. It will not be beneficial for those patients with uterine prolapse. What I have seen is that with ThermiVa treatments, you can reduce cystocele and rectocele stages by ½ to 1 Stage. This may be enough to avoid surgery in selected patients who have mild to moderate symptoms. It is not recommend-ed for those with severe cystocele, rectocele, uterine prolapse or vaginal prolapse. Please note: ThermiVa reduces vaginal tissue stretched out and has no "tacking" abilities.

3. What is the furthest data recorded for ThermiVa patients?

For external vulvar treatments / introital treatments, patients are out almost two years. Different RF technologies have been used since 2009-2010, so we have RF patients out over 5 years. ThermiVa internal treatments, the patients are now out one year plus. We can report that with RF and ThermiVa we have had no reported serious complications.

4. What are the post op instructions regarding hot tubs and swimming?

Hot tubs and swimming are permitted after treatment. If the patient has had a rare spotting episode with treatment, they should wait a day or two.

5. How soon can Thermiva treatments be repeated?

It is recommended that ThermiVa treatments should be done every 30 days for three treatments. Then start a maintenance program as needed based on results. Treatments have been done at 3-6 weeks. Treating every 2 weeks may be too soon because at 2 weeks is typically when my patients see and feel more dramatic changes occurring.

6. What could patients experience post procedure?

Patients may say that they will feel tighter immediately after treatments, but that it improves even more with time. Another example is with incontinence, where it is not unusual to have patients become dry immediately after their treatment. We often see that a morning ThermiVa treatment, results in no stress incontinence that evening. In regards to vaginal dryness, the moisture starts more dramatically at 2 weeks and it may only be slightly improved after the first treatment and start presenting itself more significantly after the 2nd or 3rd treatment. The doctor and patient should not be concerned that they are not as wet as they want to be after only 1 treatment. After 3 treatments there are no known failures for atrophic vaginitis treatments.

7. What are post-procedure expectations?

Post procedure patient may resume normal daily activities. There are no restrictions for physical or sexual activity. Patients may feel the tightening effects the same day, others will take more time and notice changes at 2 weeks. Immediately there may be mild cramping, but this should resolve within 24 hours. If cramping persists contact your physician. To avoid possible cramping stop when you encounter moderate resistance. Patients should not see an increase or change in discharge. The interpreted increase in discharge is probably the gel used during treatment seeping out. The improvement in vaginal moisture post treatment does not typically show itself in the first week and is seen starting 2 weeks post treatment. In short, the answer is that there is no increase in vaginal discharge with ThermiVa.

8. When can women resume sexual activity?

Women can resume their normal activities of daily living. This includes resuming sexual activity the same day as long as no abnormal bleeding is reported.

9. Is there any measurement or quantification with regards to success in treatment of vaginal laxity?

We do not have a scale to quantify this treatment other than patient satisfaction measured by the VLQ and SSQ and FSFI validated questionnaires. If there are doctors with the equipment and desire to quantify the tightening effects of ThermiVa, they are very welcome to do the studies. Volume and pressure studies would be ideal, probably best done by a urogynecologist with a urodynamic studies equipment. We are currently working on a Visual Analog Scale to quantify the external tightening effects.

10. Failure rate. Are there any patients who do not show visible results (vulva) even after completion of 3 treatments?

In my practice it is very rare. We have found that almost everyone gets some tightening effect, especially if they had significant laxity. The patients with the least visible tightening are younger patients with good tight skin to start. Those who have not had vaginal births or are not suffering from laxity do not get much tighter. There is a limit reached in tightness, but those who need the tightening almost always improve. In our experience, over 95% of patients have satisfactory improvement in tightening. If there are, do we have any statistics for that? The statistics for atrophic vaginitis are even better. In my practice 100% of patients who suffered from atrophic vulvovaginitis have claimed a return of moisture to normal levels after 3 treatments. I have found you can treat those severely stenotic vaginas quite successfully. There are no contraindications to treat those ladies who are significantly tighter from menopause and our electrode was specifically designed to be tolerated by all patients being treated. With ThermiVa treatments, the new collagen comes in very soft and pliable and the tissues are now more moist and adaptable to intercourse. There is one thing that ThermiVa cannot help and that is if there is an apical or uterine prolapse. The tissue shrinkage is not enough to address those severe issues. It can help in mild to moderate cystocele and rectocele, but not in apical or uterine prolapse.

11. General complications.

We have had no serious adverse problems or complications. I personally have never seen a UTI, blisters or burns from the treatment. I have never seen any infections, perforations or urethral strictures. There can be an occasional hot spot if the probe lingers too long at one spot, but this is easily avoidable and still tolerated by the patient. Sporadic patients have reported a very rare transient loss of sensitivity for a few days that returned to normal and giving way to improved sensitivity and orgasmic response. Conversely, there can also be transient hypersensitivity of the vulvar and clitoral structures, but women who experience this find it mostly pleasing in nature.