

AVIVA-minimally invasive scarless labiaplasty to restore function and appearance of vulva right in the office!

AVIVA alone- 3000

AVIVA with Morpheus8 RF vulvar remodeling- 4000

<p>APPROPRIATELY</p>		<p>APPROPRIATELY INSUFFICIENTLY</p>	
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2.2 Sample Informed Consent

BELOW ARE **SAMPLES** OF INFORMED CONSENT FORM AND TREATMENT FORMS FOR REGULAR PATIENTS OR FOR VOLUNTEER PATIENTS FOR TRAINING. INMODE PROVIDES THESE FORMS FOR DEMONSTRATION ONLY AND DOES NOT ACCEPT ANY LIABILITY FOR THEIR CONTENTS. IT IS ESSENTIAL THAT EACH CLINIC CUSTOMIZE THE CONSENT FORMS ACCORDING TO TREATMENT PROCEDURE, LOCAL SPECIFIC REQUIREMENTS AND LANGUAGE.

AVIVA SAMPLE INFORMED CONSENT

Patient Name: _____ DOB: _____ Date: _____

I request and authorize _____, or designated person, to perform a procedure on me known as: Aviva utilizing temperature-controlled Radio Frequency technology. This procedure is being used to treat my condition/medical diagnosis of: Laxity

Areas to be treated: _____

Please initial each item:

_____ The areas for treatment have been reviewed with me today and I am in agreement. I have been thoroughly and completely advised regarding the objectives of the procedure. I understand that the practice of medicine and surgery is not an exact science and although these procedures are effective in most cases, no results have been guaranteed. I acknowledge that imperfections might ensue and that the operative result may not live up to my expectations. I understand that skin tightening may not be fully apparent for 6-12 months after this procedure, that tissue tightening varies from individual to individual and results are age-dependent.

_____ The treatment will involve applying heat to the tissue and dermis using radiofrequency for therapeutic purposes and may be combined with Liposuction.

_____ I am aware of the following possible experiences and/or risks associated with the procedure:

- I consent to the administration of local and tumescent anesthesia. I understand that all forms of anesthesia involve risks and the possibility of complications, injury, or death.
- Discomfort may be experienced during and/or after the treatment.
- Some bruising and/or swelling may occur following the procedure. However, it should resolve in days, weeks, or months.
- Temporary redness (erythema) and swelling of the treated area can occur.
- Nerve Injury:
 - Nerve branch injury – weakness of affected areas
 - Hyperactivity – temporary change in smile or any facial expression
 - Temporary numbness/tingling in the area treated.
- Scarring is rare, but is a possibility if the skin surface is disrupted.
- Although uncommon, burns can occur.
- Infection is rare, but should it occur, treatment with antibiotics and/or surgical intervention may be required. Infection can further increase the risk of scarring. Proper wound care is important in the prevention of infection. If signs of infection such as pain, heat, blisters, or surrounding redness develop, call the office immediately.

- I understand the importance of the pre and post treatment instructions and that the failure to comply with these instructions may increase the possibility of complications.

_____ I understand that lipoaspiration may be used in conjunction with the Radio Frequency treatment, if _____ determines it is necessary to do so. I understand that skin irregularities may occur with any lipoaspiration treatment.

_____ I consent to having clinical photographs taken before, during and after my procedure. I understand that these photographs are an important part of my medical record. In addition, I consent to the use of these photographs, without my identity being revealed, for the education of future patients, professional clinical presentations and medical journals.

_____ The nature and effects of the procedure, the risks, the ramifications, complications, as well as alternative methods of treatment have been fully explained to me by the physician or designated person and I understand them. I am aware that this device is FDA cleared for soft tissue coagulation. The benefits of the proposed procedure, along with the probability of success have also been discussed with me. I have been given the opportunity to ask questions and have received satisfactory answers. I certify that I have read the above authorization and that I fully understand it.

DISCLAIMER

Informed Surgical Consent Forms are used to communicate information about the proposed treatment of a condition along with disclosure of risk and alternative treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

What the surgical and office staff have discussed with you and has been included in this consent are the material risks both common and uncommon that the doctor feels a reasonable person would want to know, understand and consider in deciding if the proposed treatment of a condition is something they would like to proceed with.

However, Informed Surgical Consent should not be considered all-inclusive in defining other methods of care and risk encountered. The staff may provide you with additional or different information that is based on all the facts in your particular case and the state of medical knowledge. Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve. It is important that you read the above information contained on this and all preceding pages carefully and have all of your questions answered by the doctor before signing the consent on the last page.

I CONSENT TO THE PROCEDURE AND/OR TREATMENT AND THE ABOVE LISTED ITEMS.

I AM SATISFIED WITH THE EXPLANATION

Patient or Person Authorized to Sign for Patient

Please Print Name Here

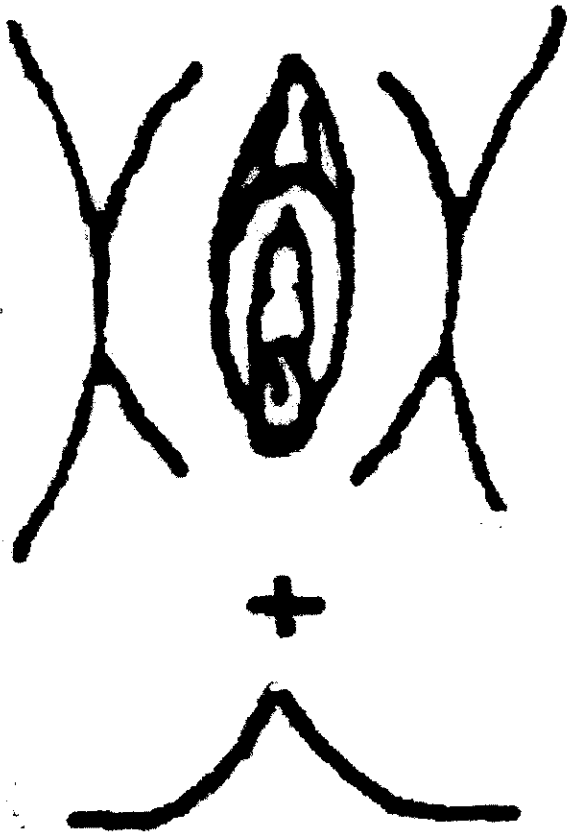
Date

Witness

TREATMENT FORM

Patient Name: _____ DOB: _____ Date: _____

Time	Tumescent solution/ Volume infiltrated	Medications Administered	Local 1% lido with epi



Aviva Zones	kJ per Zone
Internal cutoff	
External cutoff	
Time	
Total KJ delivered	
Fractional RF Fractora/M8 Energy	
#Pulses	

AVIVA SAMPLE POST CARE INSTRUCTIONS

BELOW IS A **SAMPLE** OF POST CARE INSTRUCTION FOR REGULAR PATIENTS OR FOR VOLUNTEER PATIENTS FOR TRAINING. INVASIX/INMODE PROVIDES FORMS FOR DEMONSTRATION ONLY AND DOES NOT ACCEPT ANY LIABILITY FOR THEIR CONTENTS. IT IS ESSENTIAL THAT EACH CLINIC CUSTOMIZE POST CARE INSTRUCTIONS ACCORDING TO TREATMENT PROCEDURE, LOCAL SPECIFIC REQUIREMENTS AND LANGUAGE.

1. Immediate cooling of the treatment area with saline-soaked gauze can reduce discomfort and excessive skin response.
2. Treatment areas will have Dressings and/or a pressure garment to be removed in 48 hours. According to the physician's instructions, wear the garment in the evening and while sleeping for at least two weeks or until swelling subsides. The garment ideally should be worn for 12 hours per day for the first 2 weeks.
3. For small isolated treatment areas, compression garments may not be necessary. After the procedure, the incisions will be loosely sutured to allow for draining. The doctor may decide to leave drainage ports in the incisions to allow for draining of fatty liquid during the first 12 – 24 hours after the treatment. You will be given instructions on the care of the treatment area and things to avoid.
4. Wound care: Let soapy water wash over the incision sites (do not scrub) then apply antibiotic ointment to the incision points twice daily for one week while the skin is healing after initially removing the pressure garment. Tiny scabs may appear during the healing process. Please do not pick at the scabs.
5. Cleanse the treated areas gently with mild soap such as Cetaphil or Cerave and water after 48 hours. Avoid drying or irritating products for 3 weeks after the procedure. Do not rub or irritate the area.
6. Although these effects are rare and temporary, redness and swelling may last up to 3 weeks and are a part of a normal reaction to the treatment. Bruises occur in some people and last 1 to 2 weeks and are a normal reaction to the treatment. Some patients report a burning sensation, tingling or a tightening sensation in the treatment area for up to 3 months.
7. Limit physical activity and exposure to excessive heat and UV light for 2 wks.
8. Avoid intercourse for 2 weeks post Aviva procedure.
9. If treatment was done on hair-bearing areas, shaving should only be done with an electric razor for the first week.
10. Burns and changes in pigmentation are rare although may occur. If you notice small white bumps, they may take a few weeks to resolve.
11. Only take prescribed pain medication or Tylenol for pain relief (not both) after your procedure, unless instructed otherwise. Other pain relievers such as Aspirin or NSAIDs (i.e. Advil, Motrin, Ibuprofen, Naproxen, Aleve, etc.) can thin the blood and cause bleeding or bruising. The only exception to this rule is if your primary care doctor has prescribed you to take a daily Aspirin, NSAID, or other blood thinner. Your next dose of pain medication should be at: _____. Take all antibiotics unless instructed otherwise.
12. Do NOT drink alcohol for several days as instructed by the doctor after this procedure. Drinking alcohol can negatively affect healing and can cause thinning of the blood, bleeding, crusting and/or bruising.
13. Remember, although the skin has initially healed, it takes 3-6 months before any changes in skin tightening can be perceived AND twelve months before final results in skin tightening can be appreciated.
14. If you experience any questions or experience fever, chills, drainage, discharge, or extreme discomfort, please contact _____. If you are calling after hours, the answering service will page the doctor for you.

Aviva Scarless Labiaplasty Patient Information Sheet

Preop- Congratulations! You have taken an important and brave step in deciding to let us assist you with your functional and anatomical vulvar concerns. The procedure will take place in the office. Please shave the treatment area 2 days before the procedure. Do not take any blood thinning agents such as aspirin, ibuprofen, nsaid's for at least ten days before the procedure. Make sure that you have a ride to and from the procedure. Even though this procedure will be performed under local anesthesia, we will be giving you prescriptions to take an hour before that may make you sleepy and we want you to be safe and refrain from driving. The technique that Dr. Katz will use will depend on whether your procedure involves your labia minora, labia majora, suprapubic area, or all three. You will receive prescriptions for three medications to be taken 90 minutes before your procedure: halcion .25mg, zofran 8mg, and percocet 10 mg. These are to help you with any pain, anxiety, or nausea associated with your procedure, in addition to the tumescent anesthesia that you will receive.

Postop- Wear tight-fitting underwear, leggings or spandex in the evening and while sleeping for at least two weeks or until swelling subsides. As far as wound care, there will be no incisions, but there will be injection sites. Let soapy water wash over these sites **WITHOUT** scrubbing and then apply antibiotic ointment twice a day for one week while the skin is healing. There may be some scabbing. Please do not pick at the scabs. Cleanse the skin gently with a mild soap like Cetaphil after 48 hours. Do not use any soaps with any fragrance for at least the first three weeks.

You may get redness or swelling for up to three weeks. You may get some bruising and this can last for several weeks as well. There is a

possibility of a burning/tingling/tightening sensation for up to three months.

No shaving for at least one week

No tanning, exposure to excessive heat, hot tubs or sexual activity for two weeks.

You may take tylenol for pain relief

Take 1000mg of vitamin C daily to increase healing and to promote collagen and elastin production.

Do not take aspirin or NSAIDS because these may cause bleeding.

Do not drink alcohol for several days after the procedure

Even after your skin heals, it may take 3 to 6 months before you notice any changes and up to 12 months before the final result is achieved.

IF you have any fever, chills, foul discharge, hematoma, drainage or significant discomfort, please contact Dr. Katz immediately. If it is during business hours, she may be reached at the office at 7342425588. If it is after hours, she may be reached at 734 240-8400 through the Promedica Monroe Hospital Operator.

Aviva patient prescription list

Halcion .25mg- take one tab 90 minutes before procedure

Zofran 8mg- take one tab 90 minutes before procedure

Percocet 10mg- take one tab 90 minutes before procedure

Bacitracin ointment- apply bid for one week