



2005 Midway Road Suite A
Menasha, WI 54952

Informed Consent

diVa™ Vaginal Laser Therapy

I, _____, authorize
 _____, and / or a designated practitioner of
 _____ to perform a diVa laser vaginal therapy treatment on the
 following area(s) of my body

The diVa hybrid fractional vaginal laser therapy uses hybrid technology of 1470 nm non-ablative laser and 2940 nm ablative laser to create controlled zones of coagulation to chosen depths into the vaginal mucosa and fractionally vaporize (ablate) micro laser channels.

Review of facts about laser therapy

- The 2940 nm Erbium YAG laser wavelength of diVa is delivered through a focused vaginal delivery device that precisely removes channels of mucosal tissue by vaporizing (heating to high temperature) the water within tissue. The device has the ability to create micro channels while leaving the area around the channels intact.
- The 1470 nm laser wavelength of diVa is delivered immediately after the 2940 nm wavelength through the same vaginal delivery device to create a microscopic layer of wounded tissue.
- Laser treatment procedures may produce a pattern visible on the vaginal mucosa. This event usually fades while in the healing phase.
- Light from a laser can be harmful to eyes and wearing special safety eyewear is necessary at all times during the procedure.
- A topical anesthetic may be used to lessen the sensation of the laser as it interacts with the mucosa. The sensation, while being treated, may feel like pin pricks, or bursts of heat or similar to a sunburn. The type of topical is at the discretion of the practitioner. There are known severe allergic reactions to ingredients in topical anesthetics. Patient's with known allergies to anesthetics will list them here: _____

Pre-treatment considerations

- No one pregnant may have this procedure.
- No one who has a history of bleeding disorders may have this procedure.
- If you previously suffered from Herpes simplex sores or human papillovirus (HPV) warts, there is a risk that this treatment could contribute to a recurrence.
- No one who has taken the medication Accutane or its generic forms within the last year may have this procedure.
- Estrogen therapy programs may be used before and after laser treatments in order to enhance the results.

Treatment considerations

- The diVa laser with single-use dilator will be inserted in the vaginal canal. The laser energy will be delivered through the handpiece circumferentially along the length of the vaginal canal.
- The diVa laser vaginal therapy may produce pinpoint bleeding in the area of the micro laser channels. This event usually subsides in a few minutes to a few hours. More uncommon it can persist up to 24 hours.
- Discharge and cramping may be associated with this procedure and may last from 3-4 days depending on the depth and concentration (percentage) of the laser channels of the treatment performed.
- The diVa laser vaginal therapy treatment necessitates a post therapy care regime that must be followed. You will be able to return to your daily routine; however, you will be asked to refrain from sexual intercourse for up to 48 hours depending on the depth and concentration (percentage) of laser channels of the treatment performed.

Common side effects and risks

- Edema (swelling) of the vaginal mucosa may occur.
- Urticaria (itching) often times occurs as the old tissue is shed and the new tissue is being formed.

- If any of the above symptoms intensify, your clinician should be notified. A cool compress placed on the area provides comfort. The treated area should be cared for delicately.
- Limited activity may be advised, as well as, no hot tub, swimming, or douching.
- Discomfort, especially a sunburn feeling, may persist for a few days.
- Infection is not usual after therapy; however herpes simplex virus infections around the mouth can occur following treatments. This applies to both individuals with a past history of the virus or individuals with no known history. Other signs of an infection can be a fever, purulent (pus) material, severe redness, swelling in the area, and skin that is hot to touch. Should these symptoms occur, the clinician must be notified to prescribe appropriate medical care.
- Allergic reaction is uncommon from treatment. Some persons have localized reactions to topical preparations. Systemic reactions are rare.
- The potential complications of diVa are:
 - Scarring- hypertrophic and non-hypertrophic
 - Burns- from superficial to full thickness
 - Extensive tissue destruction
 - Ulceration
 - Induced bruising or petechiae formation
 - Severe edema

Additional Treatment or Surgery Necessary - There are many variable conditions which influence the long-term result of laser therapy. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with these procedures. Other complications and risks can occur but are even more uncommon. Should complications occur, procedures, surgery or other therapy may be necessary. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied on the results that may be obtained.

FINANCIAL RESPONSIBILITIES - The cost of laser treatment involves several charges for the services provided. This includes fees charged by your doctor, the cost of pre and post-operative care medications, surgical supplies, laser equipment and personnel, laboratory tests, and possible outpatient hospital charges, depending on where the procedure is performed. It is unlikely that elective surgery costs would be covered by an insurance plan. Even if there is some insurance coverage, you will be responsible for necessary co-payments, deductibles and charges not covered. Additional costs may occur should complications develop from the therapy.

Disclaimer: Informed consent documents are used to communicate information about the proposed therapy of a disease or condition along with disclosure of risks and alternative forms of therapy. The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your physician may provide you with additional or different information which 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 all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

- The potential risks and benefits have been explained of the diVa hybrid fractional vaginal laser therapy along with alternative methods. I choose to have diVa hybrid fractional vaginal laser therapy.
- I understand that compliance with pre and post care instructions is crucial for success of diVa hybrid fractional vaginal laser therapy and to prevent unnecessary side effects or complications.
- I understand that there are many variable conditions which influence the long-term result of diVa hybrid fractional vaginal laser therapy. The practice of medicine and surgery and the subsequent use of laser is not an exact science. Although good results are expected, there is no guarantee, expressed or implied, on the results that may be obtained.
- I understand that the diVa hybrid fractional vaginal laser therapy treatment involves payment and the fee structure has been explained to me.

Photography

I do _____ or do not _____ consent to photographs and other audio-visual and graphic materials before, during, and after the course of my therapy to be used for medical, marketing, and education purposes. Although the photographs or accompanying material will not contain my name or any other identifying information, I am aware that I may or may not be identified by the photos.

I have read and understand all information presented to me before signing this consent form. I have been given an opportunity to have all of my questions answered to my satisfaction. I understand the procedure and accept the risks. I agree to the terms of this agreement.

Patient's Name (Printed): _____

Signature: _____ Date: _____

Witness: _____