

Fotona[®]
choose perfection



FotonaSmooth[®]

Revolutionary non-surgical
laser for vaginal health

www.fotona.com

FotonaSmooth®: In-Office Based Non-Invasive Laser Therapy for Vaginal Health*

Pelvic floor dysfunction

Symptoms of age- and childbirth-related pelvic floor dysfunction, such as urinary incontinence and pelvic floor prolapse, affect hundreds of millions of women worldwide.

- 60-80% of women over 50 will experience atrophy in their lifetime
- 40% of women suffer from some form of urinary incontinence

Conservative treatments such as pelvic floor muscle therapy (Kegel exercises) often fail because of patients' lack of compliance. Surgical options, although effective, suffer from a high rate of adverse effects and are typically a patient's last resort.

Revolutionary non-surgical laser treatment

Connective tissue in the vaginal walls is an important factor in pelvic organ support. Symptoms of pelvic floor dysfunction mainly arise from laxity in the vagina or its supporting ligaments, due to increasing age and vaginal childbirth.

Fotona's SMOOTH™ is a non-invasive non-ablative laser procedure for functional strengthening of connective tissue inside the vaginal wall, improving the pelvic floor support and diminishing symptoms of pelvic floor dysfunction.

What is the SMOOTH™ mode of action?

SMOOTH™ gynecological procedures are based on the discovery that the delivery of an optimal sequence of heat pulses to the vaginal mucosa results in strengthening and rejuvenation of the vaginal wall. FotonaSmooth® is a gynecological laser system developed specifically for performing SMOOTH™ treatments.

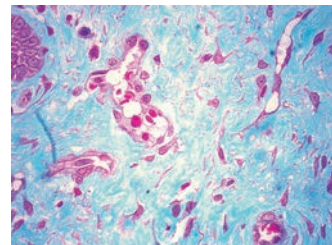
FOTONA'S SMOOTH TREATMENTS INCLUDE:

IncontiLase® – Stress Urinary Incontinence

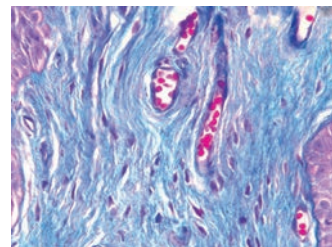
IntimaLase® – Vaginal Relaxation Syndrome

RenovaLase® – Vaginal Atrophy / Genitourinary Syndrome of Menopause

GOMORI TRICHROME STAIN



Vaginal mucosa sample before IntimaLase® treatment.

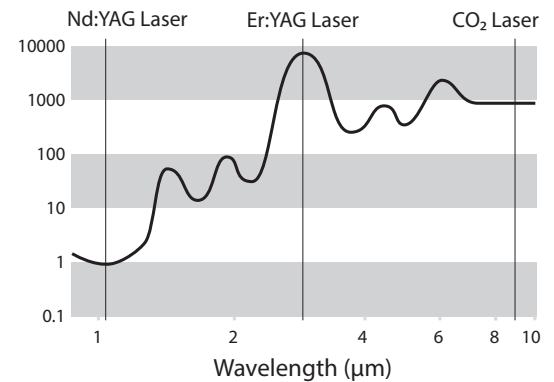


Vaginal mucosa sample 6 months after IntimaLase® treatment showing increased collagen density.

Courtesy of J. Gaviria, MD

Optimal Er:YAG laser wavelength

FotonaSmooth® operates at the optimal infrared Er:YAG laser wavelength (2.94 μm) that coincides with the maximal absorption peak of the mucosal tissue. This ensures that the laser light is delivered to the tissue in a controlled superficial manner without the risk of affecting deeper-lying structures.



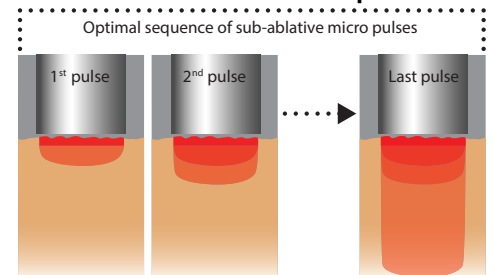
The Er:YAG wavelength sits at the highest peak of the absorption spectrum of water and is therefore completely absorbed within a few microns of mucosal tissue.

Unique SMOOTH™ mode

FotonaSmooth® delivers patented sequential Er:YAG SMOOTH™ mode laser pulses to the vaginal wall mucosa, generating controlled and optimal distribution of heat within the tissue, enabling collagen remodelling and neo-collagenesis.

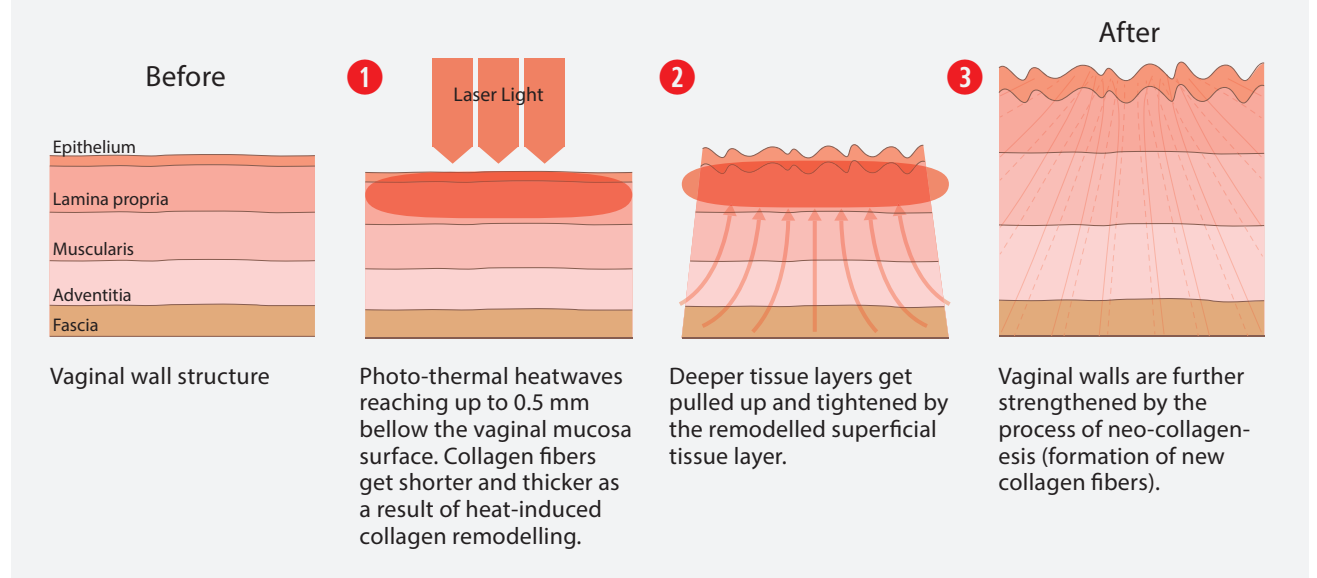
The 2.94 μm wavelength, in conjunction with its patented SMOOTH mode delivery, allows for a highly controlled, safe procedure with no impact to any critical structures, including any penetration or disruption of the mucosal lining.

SMOOTH™ mode pulse



Unique sequential SMOOTH mode Er:YAG laser pulses generate an optimal structure of heat waves.

MECHANISM OF ACTION



FotonaSmooth® – Non-surgical Er:YAG Laser for Vaginal and Pelvic Floor Health

Patient and physician-friendly

- Simple, fast in-office procedure
- Outstanding results, peer-reviewed
- No anesthesia required, non-ablative
- Minimal discomfort or downtime
- Excellent return on investment
- Multiple additional applications



Er:YAG treatments



Nd:YAG treatments

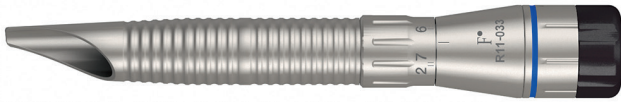
Easy to use

- Large touchscreen with intuitive graphical user interface
- Easily accessible presets for all applications
- Lightweight, ergonomic articulated arm delivery system

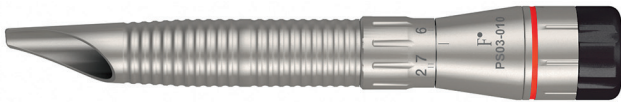


Tools for gynecological treatments

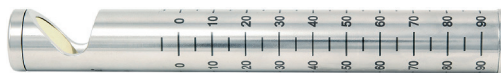
G-SET™ – INTRAVAGINAL ACCESSORY SET



R11 full-beam titanium handpiece



PS03 patterned titanium handpiece



IncontiLase treatment: 90° angular golden mirror titanium adapter



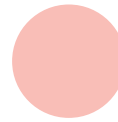
IntimaLase treatment: 360° circular golden mirror titanium adapter



SClear speculum



Wired laser speculum



FULL-BEAM AND PATTERNED HANDPIECES



- Zoom optics with spot sizes from 2-7 mm offers a wide range of treatments
- Collimated beam enables precise delivery of laser energy
- Titanium technology ensures robustness and durability
- Additional handpiece options for cervical treatments and soft tissue cutting



G-RUNNER – FOR AUTOMATED OPERATION



- Automatic delivery of laser energy to the vaginal canal
- Improvement in accuracy and precision of laser delivery – more homogenous coverage of vaginal mucosa - better results!
- Optimized treatment time
- Increased comfort and convenience for the operator

G-Runner™ - proprietary Fotona's scanning technology

Wide Range of Treatments

FotonaSmooth® is more than a SMOOTH laser

Additional non-surgical Er:YAG gynecological procedures

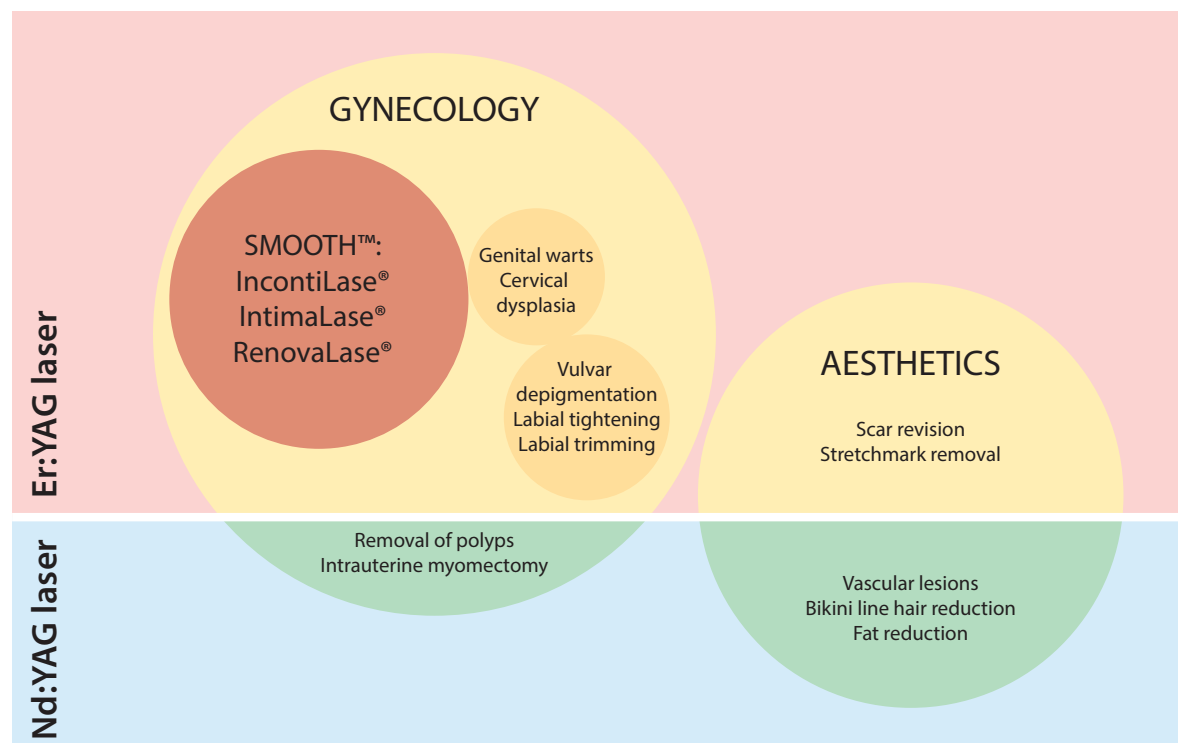
The Er:YAG laser incorporated in FotonaSmooth® allows the user to perform other non-surgical treatments, such as:

- Vulvar depigmentation
- Labial and vulvar tightening

Surgical Er:YAG gynecological procedures

In addition, FotonaSmooth® can also be used for various surgical gynecological procedures, such as:

- Genital warts removal
- Cervical dysplasia vaporisation
- Labial trimming



Expand your practice

Additional Nd:YAG wavelength

FotonaSmooth® capabilities can be expanded with an additional Nd:YAG laser source. The Nd:YAG laser wavelength of 1.064 µm exhibits the most homogeneous absorption in human tissue and thus represents a complementary wavelength to the Er:YAG wavelength with the shortest penetration depth in human tissue. Together, these golden-standard wavelengths are well suited for handling an exceptionally wide range of aesthetic and clinical procedures.

Key aesthetic treatments

Er:YAG

Skin resurfacing, stretchmarks
Scar revisions
Lesions removal
Acne scar treatments

Nd:YAG

Vascular lesion removal
Removal of unwanted hair
Wrinkle reduction
Active acne treatments

Fotona Er:YAG and Nd:YAG laser system models

		Er:YAG GYNECOLOGY	Nd:YAG GYNECOLOGY	Er:YAG AESTHETICS	Nd:YAG AESTHETICS
GYNECOLOGY MODELS					
FotonaSmooth® XS	20 W Er:YAG	YES	NO	Optional	NO
FotonaSmooth® SP	20 W Er:YAG 30 W Nd:YAG	YES	YES	Optional	Optional
FotonaSmooth® SP+	20 W Er:YAG 80 W Nd:YAG	YES	YES	Optional	Optional
GENERAL USE MODELS					
XS Dynamis®	20 W Er:YAG	Optional	NO	YES	NO
SP Spectro®	20 W Er:YAG 30 W Nd:YAG	Optional	Optional	YES	YES
SP Dynamis®	20 W Er:YAG 80 W Nd:YAG	Optional	Optional	YES	YES

FotonaSmooth[®] treatments

1

IncontiLase[®]

A minimally invasive solution for stress urinary incontinence

How does IncontiLase[®] work?

- Fotona's 2.94 μm Er:YAG non-ablative laser with proprietary SMOOTH[™] mode technology
- Improves urethral support by photothermal strengthening of the vaginal wall
- Works on connective tissue in the vaginal mucosa with emphasis on the anterior vaginal wall



Fotona SMOOTH[™] mode treatment of the anterior vaginal wall

WHO IS ELIGIBLE FOR INCONTILASE[®]?

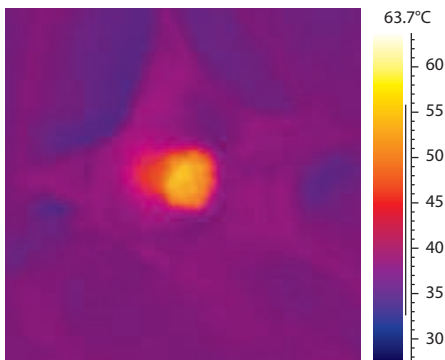
- The treatment works best in mild and moderate stress urinary incontinence patients with very good results in severe stress urinary incontinence as well
- Mixed incontinence patients get relief in stress symptoms

SIMPLE AND QUICK

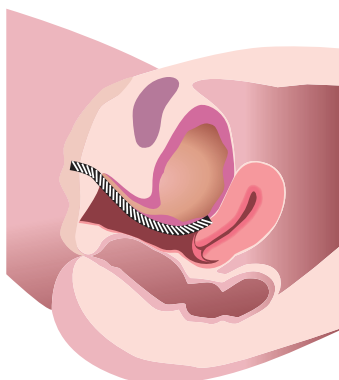
- Ambulatory procedure
- 20-30 minutes/treatment

PATIENT FRIENDLY

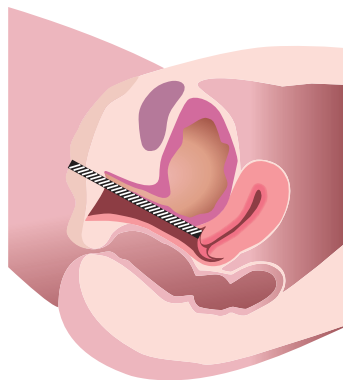
- No anesthesia
- No downtime
- High patient satisfaction



Thermal camera images of the introitus show that SMOOTH[™] pulses achieve the optimal peak temperature range (60-65°C) for collagen remodelling and initiation of neo-collagenesis.



Mild and moderate stress and mixed urinary incontinence



After IncontiLase® treatment

Tissue \ Invasiveness	Non invasive methods	Invasive methods
Pelvic floor muscles	Kegel exercises Vaginal cones Electrostimulation	Surgical repair
Connective tissues	IncontiLase®	Anterior repair Sling procedures (TVT, TOT)



One year following the IncontiLase treatment, we found significant improvement in 77% of patients diagnosed with SUI.

Dr Sabina Senčar



Apart from non-invasiveness, the main advantage of IncontiLase over surgery is that it can be applied as an ambulatory procedure, which means a lower economic burden.

Dr Urska Bizjak Ogrinc

Ogrinc UB, Senčar S, Lenasi H. Novel minimally invasive laser treatment of urinary incontinence in women. Lasers Surg Med. 47(9):689-97.

FotonaSmooth® treatments

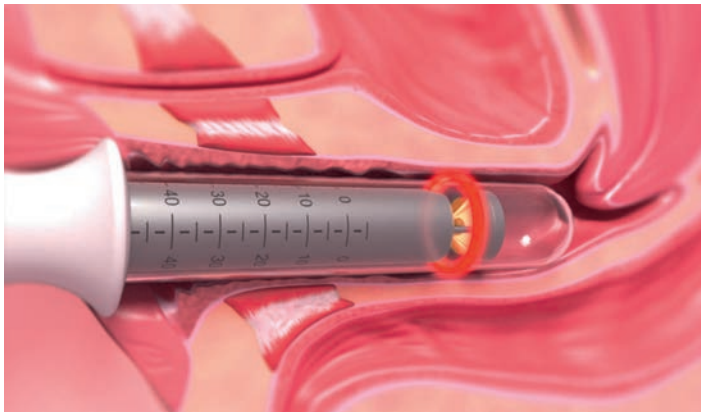
2

IntimaLase®

A true incisionless laser treatment for vaginal relaxation syndrome

How does IntimaLase® work?

- Photothermally tightens the vaginal canal
- Mechanism of action is based on shrinking and thickening of the connective tissue in the vaginal wall



WHO IS ELIGIBLE FOR INTIMALASE®?

- Women with increased vaginal laxity due to childbirth and/or ageing

SIMPLE AND QUICK

- Ambulatory procedures
- 20-30 minutes/treatment

PATIENT FRIENDLY

- No anesthesia
- No downtime
- High patient satisfaction



95% of my patients assess vaginal tightness and sexual gratification as strongly or moderately improved after IntimaLase treatment.

Dr Jorge Gaviria

Gaviria J, Lanz J. Laser Vaginal Tightening (LVT) – evaluation of a novel noninvasive laser treatment for vaginal relaxation syndrome. LAHA Journal of Laser and Health Academy, 2012(1); 46-58.

3

RenovaLase® Gentle laser treatment of vaginal atrophy / genitourinary syndrome of menopause

How does RenovaLase® work?

- Non-ablative gentle photothermal treatment of the vaginal canal using very low energies that cause mild hyperthermia and induce microvascularisation and tissue regeneration without shrinking the collagen
- Restores normal vaginal mucosa structure and function
- Eliminates the need for long-term estrogen treatment



RenovaLase treatment induces a significant improvement of genitourinary syndrome of menopause, including vaginal dryness and dyspareunia. Additionally, this treatment can

be proposed in postmenopausal women who cannot be treated with hormones.

Dr Marco Gambacciani

Gambacciani M, Levancini M, Cervigni M. Vaginal erbium laser: the second-generation thermotherapy for the genitourinary syndrome of menopause. *Climacteric*. 2015, 18(5):757-763.



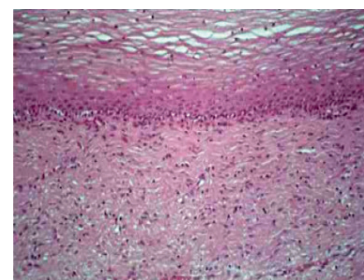
We observed significant improvement of symptoms and also regeneration of normal mucosal structure. Better and more lasting results compared to local estriol therapy.

Dr Adrian Gaspar

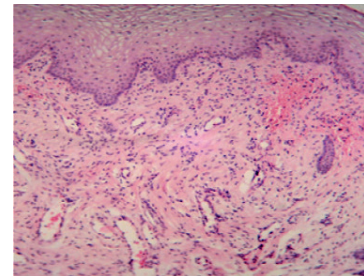
Gaspar A . Comparison of new minimally invasive Er:YAG laser treatment and hormonal replacement therapy in the treatment of vaginal atrophy . *Climacteric* 2014 ; 17(Suppl 1) : 48 – 108 , P 124 (Abstr)

WHO IS ELIGIBLE FOR RENOVALASE®?

- Women suffering from vaginal atrophy symptoms such as vaginal dryness, irritation and dyspareunia



Atrophied vaginal mucosa



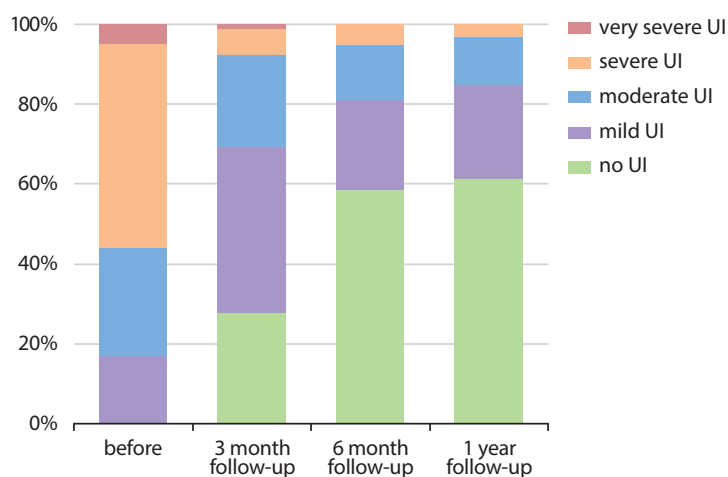
Vaginal mucosa after RenovaLase treatment

Courtesy of Dr. Gaspar

Scientifically proven results

Publications in peer-reviewed journals

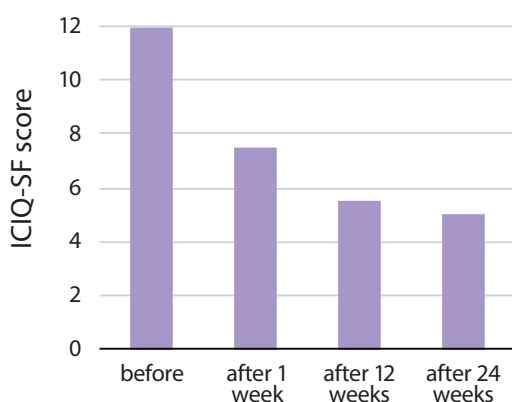
IncontiLase® treatment



One year after the treatment, significantly improved continence was reported in 77% of SUI patients.

The effect of IncontiLase therapy on the improvement of the grade of urinary incontinence (UI). Figure shows the distribution of patients (in %) with regard to the grade of incontinence (mild, moderate, severe, very severe) before treatment, at 2 months, six months and one year after the procedure.

Data presented in Lasers Surg Med. 47(9):689-97.

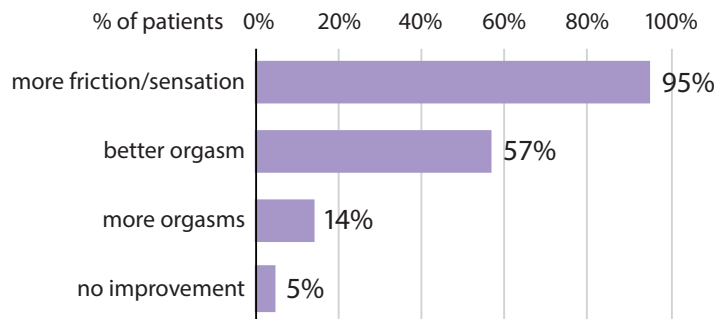


Significant decrease in ICIQ-SF incontinence score.

Effect of IncontiLase therapy on International Consultation on Incontinence Questionnaire (ICIQ-SF score) in postmenopausal women suffering from stress urinary incontinence.

Data presented in Climacteric. 2015, 18(5):757-763.

IntimaLase® treatment

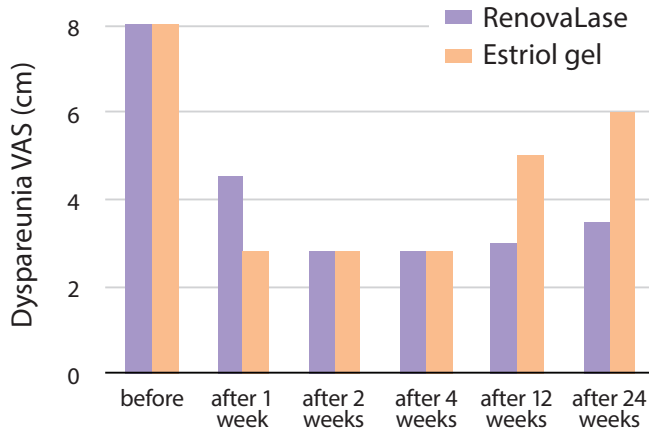


Patients' assessment of sexual gratification improvement after IntimaLase treatment.

Data presented in *J. LA&HA*, 2012(1); 46-58.

95 % of patients reported an improvement of sexual gratification.

RenovaLase® treatment



Effect of RenovaLase therapy on dyspareunia using the visual analog score (VAS) on a 10-point scale for the women receiving laser treatment and the women receiving estriol. In the estriol group, a reduction of efficacy can be seen 12 weeks after the end of treatment. Conversely, the RenovaLase group maintained the same positive results throughout the entire study period up to the 6-month follow-up.

Data presented in *Climacteric*, 18(5):757-763.

Significant improvement in clinical symptoms of vaginal dryness and dyspareunia. An alternative to estriol therapy.

Long-lasting improvement in vaginal atrophy symptoms and histology of vaginal mucosa observed 18 months after RenovaLase treatment.*

* Gaspar A. et al. Efficacy of Erbium:YAG Laser Treatment Compared to Topical Estriol Treatment for Vaginal Atrophy Symptoms - submitted for publication in *Lasers in Surgery and Medicine*.

Training & Education

Regular clinical workshops – make a SMOOTH start!

Comprehensive workshops

Training is provided in cooperation with the Laser and Health Academy under the guidance of experts in medical laser technology.

The extensive workshops, where participants engage in live demonstrations and gain in-depth understanding of laser physics and laser tissue interaction, provide the needed insight into the fundamentals of non-invasive gynecological treatments and other procedures that can be performed with the FotonaSmooth® system.

THE WORKSHOPS COVER:

- Laser safety and physics
- Laser-tissue interaction
- Extensive theoretical and hands-on application training
- A visit to a clinic for live patient demonstrations



Fotona and the Laser & Health Academy

Fotona has partnered with the Laser & Health Academy (LA&HA) to help support the professional growth of medical practitioners. To get the most out of your Fotona laser system, our practitioner workshops, co-organized with LA&HA (www.laserandhealth.com), provide hands-on demonstrations of our lasers by international clinical experts.

ANNUAL INTERNATIONAL LASER & HEALTH ACADEMY SYMPOSIUM

- Attended by several hundred physicians every year
- Newest research and treatments in different fields of laser medicine, including gynecology
- For more information, contact info@laserandhealth.com

Sound Scientific Background

Scientific research using FotonaSmooth®

STRESS URINARY INCONTINENCE

Novel minimally invasive laser treatment of urinary incontinence in women. Ogrinc UB, Senčar S, Lenasi H. *Lasers Surg Med.* 47(9):689-97.

Vaginal erbium laser: the second-generation thermotherapy for the genitourinary syndrome of menopause. Gambacciani M, Levancini M, Cervigni M. *Climacteric.* 2015, 18(5):757-763.

Minimal Invasive Laser Treatment for Female Stress Urinary Incontinence. Khalafalla MM, Elbiaa AM, Abdelazim IA, Hussain M (2015). *Obst&Gyn Int. Journal*, 2015, 2(2) 00035.

First assessment of short-term efficacy of Er:YAG laser treatment on stress urinary incontinence in women: prospective cohort study. Fistončić N, Fistončić I, Lukanović A, Guštek ŠF, Turina IS, Franić D. *Climacteric.* 2015 Oct;18 Suppl 1:37-42.

Minimally invasive laser procedure for early stages of stress urinary incontinence (SUI). Fistončić I, Findri-Guštek Š, Fistončić N. *LAHA Journal of Laser and Health Academy*, 2012(1); 67-74.

Novel Minimally Invasive VSP Er:YAG Laser Treatments in Gynecology. Vizintin Z, Rivera M, Fistončić I, Saracoğlu F, Guimares P, Gaviria J, Garcia V, Lukac M, Perhavec T, Marini L, *LAHA Journal of Laser and Health Academy*, 2012(1); 46-58.

Minimally invasive, non-ablative Er:YAG laser treatment of stress urinary incontinence in women. Fistončić N, Fistončić I, Findri Gustek S, Sorta Bilajac Turina I, Franić D, Vizintin Z, Kazic M, Hreljac I, Perhavec T, Lukac M. *Lasers in Medical Science*, 2016.

VULVOVAGINAL ATROPHY / GENITOURINARY SYNDROME OF MENOPAUSE

Vaginal erbium laser: the second-generation thermotherapy for the genitourinary syndrome of menopause. Gambacciani M, Levancini M, Cervigni M. *Climacteric.* 2015, 18(5):757-763.

Vaginal Erbium Laser: the Second Generation Thermotherapy for the Genitourinary Syndrome of Menopause (GSM) in Breast Cancer Survivors. A preliminary report of a pilot study. Gambacciani M, Levancini M. *It. J. Gynaecol. Obstet.* 2015, 27: 9-11.

Short-term effect of vaginal erbium laser on the genitourinary syndrome of menopause. Gambacciani M, Levancini M. *Minerva Ginecol.* 2015 Apr;67(2):97-102.

Laser Treatment of Vaginal Atrophy in Post-menopause and Post-gynecological Cancer Patients. Bojanini JF, Mejia AM. *J. LA&HA*, Vol. 2014, No.1; pp.65-71.

VAGINAL RELAXATION SYNDROME

Laser Vaginal Tightening (LVT) – evaluation of a novel noninvasive laser treatment for vaginal relaxation syndrome. Gaviria J, Lanz J. *LAHA Journal of Laser and Health Academy*, 2012(1); 46-58.

Novel Minimally Invasive VSP Er:YAG Laser Treatments in Gynecology. Vizintin Z, Rivera M, Fistončić I, Saracoğlu F, Guimares P, Gaviria J, Garcia V, Lukac M, Perhavec T, Marini L, *LAHA Journal of Laser and Health Academy*, 2012(1); 46-58.

SINCE 1964

Founded in 1964, only four years after the invention of the very first laser, Fotona is one of the most experienced developers of high-technology laser systems. Fotona today is a world-leading medical laser company recognized for its innovative, award-winning laser systems for applications in gynecology, dentistry, surgery and aesthetics & dermatology. Based in the US and EU, with corporate headquarters in Dallas, Texas, and Ljubljana, Slovenia, Fotona's business philosophy is to continuously choose perfection to ensure the maximum performance and efficacy of its medical devices.

COMMITTED TO ENGINEERING
THE HIGHEST PERFORMANCE, BEST MADE LASER SYSTEMS IN THE WORLD



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ISO 9001:2008, EN ISO 13485:2003,
MDD 93/42 EEC Annex II excluding
(4), ISO 13485:2003 (CMD CAS).

