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
- Almost 50% of parous women suffer from some degree of pelvic organ prolapse

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 SMOOTH™ mode?

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.
**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.

![Graph showing wavelength comparison between Nd:YAG, Er:YAG, and CO2 lasers](image)

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.

![Diagram showing mechanism of action](image)

**MECHANISM OF ACTION**

1. **Before**
   - Epithelium
   - Lamina propria
   - Muscularis
   - Adventitia
   - Fascia

   Vaginal wall structure

2. **Laser Light**
   - Photo-thermal heatwaves reaching up to 0.5 mm below the vaginal mucosa surface. Collagen fibers get shorter and thicker as a result of heat-induced collagen remodelling.

3. **After**
   - Deeper tissue layers get pulled up and tightened by the remodeled superficial tissue layer.
   - Vaginal walls are further strengthened by the process of neo-collagenesis (formation of new collagen fibers).
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

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

- **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

- **IncontiLase® and ProlapLase® treatment**
  - 90° angular golden mirror titanium adapter

- **IntimaLase®, RenovaLase® and ProlapLase® treatment**
  - 360° circular golden mirror titanium adapter

- **SClear speculum**

- **Wired laser speculum**

G-SET™ - Fotona’s proprietary scanning technology

- **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™ - Fotona's proprietary 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 1064 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

<table>
<thead>
<tr>
<th>Er:YAG</th>
<th>Nd:YAG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin resurfacing, stretchmarks</td>
<td>Vascular lesion removal</td>
</tr>
<tr>
<td>Scar revisions</td>
<td>Removal of unwanted hair</td>
</tr>
<tr>
<td>Lesions removal</td>
<td>Wrinkle reduction</td>
</tr>
<tr>
<td>Acne scar treatments</td>
<td>Active acne treatments</td>
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</table>

Fotona Er:YAG and Nd:YAG laser system models

<table>
<thead>
<tr>
<th>GYNECOLOGY MODELS</th>
<th>Er:YAG GYNECOLOGY</th>
<th>Nd:YAG GYNECOLOGY</th>
<th>Er:YAG AESTHETICS</th>
<th>Nd:YAG AESTHETICS</th>
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</thead>
<tbody>
<tr>
<td>FotonaSmooth® XS</td>
<td>20 W Er:YAG</td>
<td>YES</td>
<td>NO</td>
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</tr>
<tr>
<td>FotonaSmooth® SP</td>
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<tr>
<td>FotonaSmooth® SP+</td>
<td>20 W Er:YAG 80 W Nd:YAG</td>
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</table>

<table>
<thead>
<tr>
<th>GENERAL USE MODELS</th>
<th>Er:YAG GYNECOLOGY</th>
<th>Nd:YAG GYNECOLOGY</th>
<th>Er:YAG AESTHETICS</th>
<th>Nd:YAG AESTHETICS</th>
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<tbody>
<tr>
<td>XS Dynamis®</td>
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<td>SP Spectro®</td>
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<tr>
<td>SP Dynamis®</td>
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</tr>
</tbody>
</table>
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

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

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.

<table>
<thead>
<tr>
<th>Invasiveness</th>
<th>Non invasive methods</th>
<th>Invasive methods</th>
</tr>
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<tbody>
<tr>
<td>Tissue</td>
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<tr>
<td>Pelvic floor muscles</td>
<td>Kegel exercises Vaginal cones Electrostimulation</td>
<td>Surgical repair</td>
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<tr>
<td>Connective tissues</td>
<td><strong>IncontiLase®</strong></td>
<td>Anterior repair Sling procedures (TVT, TOT)</td>
</tr>
</tbody>
</table>
One year following the IncontiLase® treatment, we found significant improvement in 77% of SUI patients.

Dr. Sabina Sencar

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

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, 6 months and 1 year after the procedure.


IncontiLase® treatment significantly reduced leakage quantity measured by 1h pad test.

FotonaSmooth® treatments

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

IntimaLase® treatment

<table>
<thead>
<tr>
<th>% of patients</th>
<th>0%</th>
<th>20%</th>
<th>40%</th>
<th>60%</th>
<th>80%</th>
<th>100%</th>
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</thead>
<tbody>
<tr>
<td>more friction/sensation</td>
<td></td>
<td></td>
<td></td>
<td>95%</td>
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<tr>
<td>better orgasm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>57%</td>
<td></td>
</tr>
<tr>
<td>more orgasms</td>
<td></td>
<td>14%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no improvement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5%</td>
<td></td>
</tr>
</tbody>
</table>


WHO IS ELIGIBLE FOR INTIMALASE®?
• Women with increased vaginal laxity due to childbirth and/or ageing

95% of patients reported an improvement of sexual gratification.


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

Dr Jorge Gaviria

How does ProlapLase® work?

- Photothermal tightening of the tissue and contraction of the vaginal canal stimulating collagen remodeling and the synthesis of new collagen fibers
- A safe and non-invasive alternative to traditional methods
- Incisionless and virtually painless, with no cutting, bleeding or sutures
- Suitable also for higher grade prolapse

WHO IS ELIGIBLE FOR PROPLASLASE®?

- Women suffering from pelvic organ prolapse

The effect of ProlapLase® on cystocele grade distribution at baseline and follow-ups. The figure shows the effects of 2-7 laser treatments on 67 patients over a period of 3 years.

Erbium/YAG laser treatment of pelvic organ prolapses: 3 years follow-up. Sencar S., Bizjak-Ogrinc U., Vizintin

Significant reduction of average pelvic organ prolapse (POP) grade was already observed after the first treatment session. POP grade reduction continued to improve with additional treatments.

Data presented at IMS: 15th World Congress on Menopause.

“...in most of the patients the improvement occurred after the first treatment, with patients reporting better prolapse containment inside of the vaginal canal and less frequent occurrence of the prolapse falling out of vaginal canal.”

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

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

Non-ablative gentle photothermal treatment of the vaginal canal using mild hyperthermia via SMOOTH™ mode.

Enhanced synthesis of new proteoglycan and hialuronic acid molecules, which improves tissue water content and collagen structure.

The result is improved vascularisation and trophism of the vaginal wall and restored normal structure and function of the vaginal mucosa.

RenovaLase® significantly decreased the severity of dyspareunia in breast cancer survivors suffering from GSM, the effect lasting more than 12 months after treatment.

RenovaLase® significantly improves GSM symptoms, including vaginal dryness and dyspareunia, in breast cancer survivors.


RenovaLase® had a significantly better effectiveness in relieving GSM symptoms.

Comparison between RenovaLase® treatment and local estriol on severity of vaginal dryness up to 18 months after treatments.

Scientifically proven results
Scientific research using FotonaSmooth®

STRESS URINARY INCONTINENCE


VAGINAL RELAXATION SYNDROME


PELVIC ORGAN PROLAPSE


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.

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

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
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.