

# TimeWalker IntimaLaser™

### TIMEWALKER® LASER LINE

# **Intima**laser<sup>™</sup>

### **Technology optimized for**

Gynecology applications

### **Integrated G-Runner**

Robotic scanner

### **Dual wavelength**

Er:YAG & Nd:YAG lasers

### Easy-to-use, guided

User interface

Green pointer

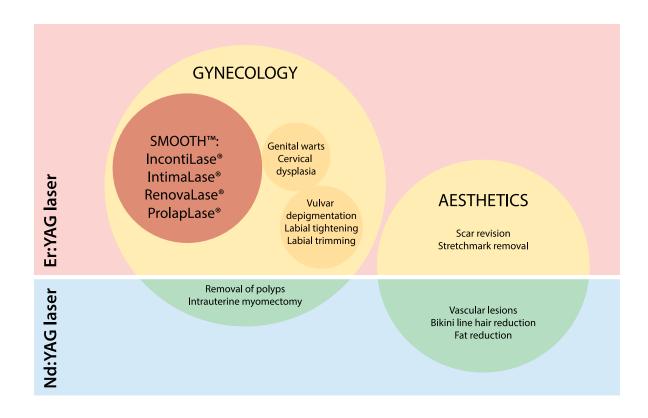
Wireless foot switch





### A true gynecological laser

- Revolutionary, patented & clinically evaluated non-invasive procedures for treating pelvic floor disorders
- High-precision clinical, aesthetic and surgical procedures
- Two complementary laser wavelengths (Er:YAG and Nd:YAG) for exceptional versatility – from gentle ablative to non-ablative thermal treatments
- Minimally invasive with quick recovery and high patient satisfaction



### **G-Runner** Robotic Scanner

### **Integrated scanner**



- Automatic delivery of laser energy
- Optimal accuracy and precision of laser beam delivery
- Optimized treatment time
- Increased comfort and convenience for the operator

# S P E C I A L I Z E D Innovative handpieces



- Highest quality bio-compatible materials such as titanium and gold
- Fotona's innovative handpiece technology optimizes the delivery of laser pulses to the treatment area.

### TIMEWALKER® LASER LINE



### The laser specialized for gynecological treatments

# Innovative non-invasive treatments with proprietary Fotona SMOOTH® technology

- IncontiLase® Laser for treatment of Stress Urinary Incontinence
- IntimaLase® Laser for treatment of Vaginal Relaxation Syndrome
- RenovaLase® Laser for treatment of Vaginal Atrophy/GSM
- ProlapLase® Laser for treatment of Pelvic Organ Prolapses

### Ablative Er:YAG procedures

- Condyloma
- Episiotomy scars
- C-section scars
- Labiaplasty
- Depigmentation
- Traumatic Scars



### Non-ablative Nd:YAG procedures

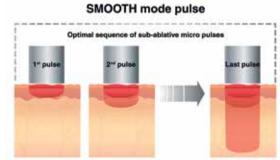
- Vascular lesions
- Hair removal
- Surgical treatments: polyp removal, intrauterine myomectomy
- Photobiomodulation for pain reduction
- Mucosa and skin wound healing

# Unmatched Fotona Technology

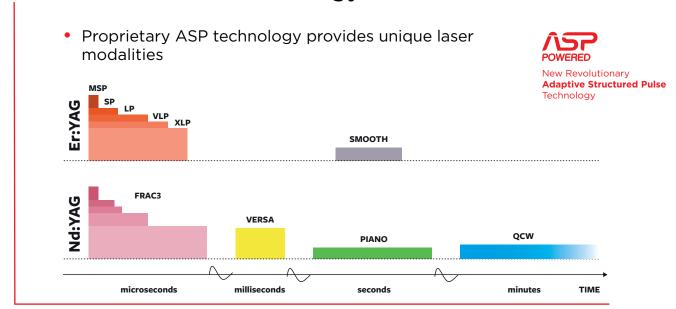
### Unique Fotona SMOOTH® mode

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

The 2.94 µm wavelength, in conjunction with Fotona's 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.



### Third Generation ASP Technology



### **Top-Hat Beam Profile**

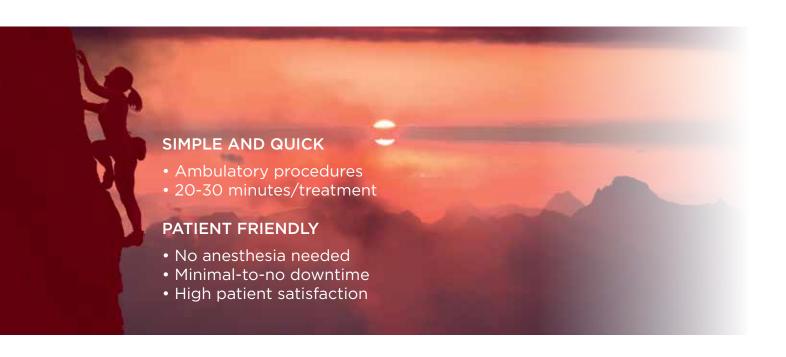
- Uniform treatments
- Predictable results

#### Multi-Channel Feedback Control

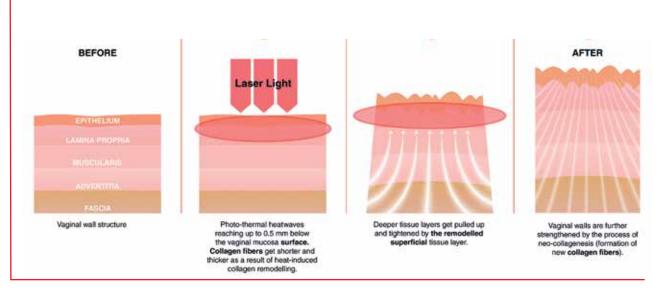
 The system double checks the energy and regulation of each pulse for safe and reproducible treatments

### Fotona SMOOTH® Procedures

- Non-invasive, non-ablative laser procedures
- Patented laser technology to send mild heat pulses to the vaginal walls
- Resulting in functional strengthening of connective tissue inside the vaginal wall
- Increases in vaginal wall thickness and functional improvement in the mucosal tissue



### Mechanism of action



# **Inconti**Lase®

### Stress urinary incontinence treatment

- Non-ablative Fotona 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
- For mild and moderate stress urinary incontinence patients, with very good results in severe stress urinary incontinence as well



Fotona SMOOTH® mode treatment of the anterior vaginal wall



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

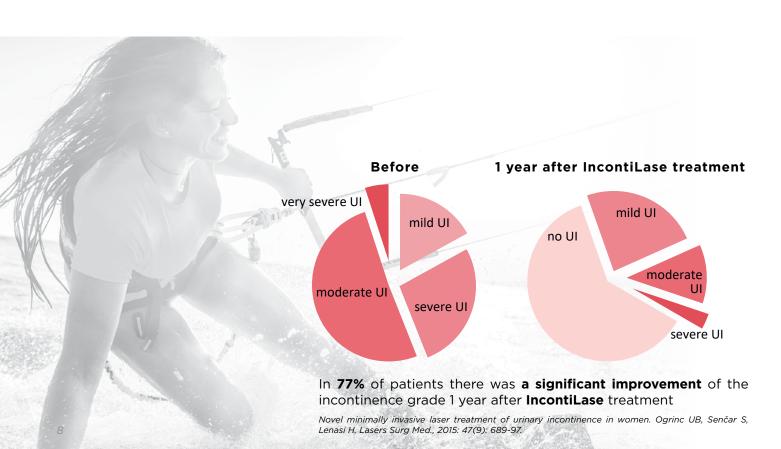
Dr Sabina Sencar



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

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



# IncontiLase® Intra

# Treatment for SUI due to intrinsic sphincter deficiency and urinary symptoms of GSM

- Revolutionary non-invasive Fotona SMOOTH® intraurethral treatment
- For treatment of type III stress urinary incontinence



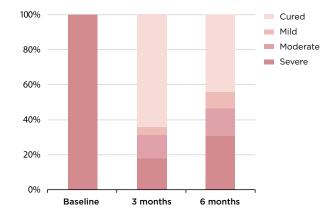


R09-2Gu

# Significant improvement was observed in 82% of type III SUI patients



Gaspar, A. & Brandi, H., 2017. Nonablative erbium YAG laser for the treatment of type III stress urinary incontinence (intrinsic sphincter deficiency). Lasers in Medical Science, 32(3), pp.685-691.



ICIQ-UI SF evaluation of SUI after Incontilase Intra before treatment (baseline), at 3 and at 6 months following treatment.

Gaspar, A. & Brandi, H., 2017. Non-ablative erbium YAG laser for the treatment of type III stress urinary incontinence (intrinsic sphincter deficiency). Lasers in Medical Science, 32(3), pp.685-691.

A. Gaspar, S. Maestri, J. Silva, H.Brandi, D. Luque, N. Koron, Z. Vizintin, Intraurethral Erbium: YAG Laser for the Management of Urinary Symptoms of Genitourinary Syndrome of Menopause: A Pilot Study, Laser in Surgery and Medicine, 50:802–807, 2018

LV Jian-Wei, LV Ting-ting, SI Jun-wen, Fang Wei-Lin, Jiang Chen, Leng Jing, Xue Wei: Non-ablative transurethral Erbium YAG laser in treatment of female stress urinary incontinence, Journal of Modern Urology, 2018

### **IntimaLase®**

### Vaginal tightening treatment

- Photothermally tightens the vaginal canal
- Mechanism of action is based on shrinking and thickening of the connective tissue in the vaginal wall
- For women with increased vaginal laxity due to childbirth and/or ageing



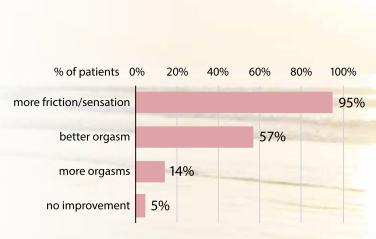
IntimaLase® treatment



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. Journal of Laser and Health Academy, 2012(1); 46-58.



Patients' assessment of sexual gratification improvement after IntimaLase® treatment.

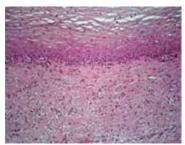
Gaviria J, Lanz J. Laser Vaginal Tightening (LVT) - evaluation of a novel noninvasive laser treatment for vaginal relaxation syndrome. Journal of Laser and Health Academy, 2012(1); 46-58.



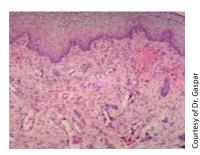
### RenovaLase®

# Treatment for genitourinary syndrome of menopause / vaginal atrophy

- Non-ablative gentle photothermal treatment of the vaginal canal causing mild hyperthermia and inducing microvascularisation and tissue regeneration
- Restores normal vaginal mucosa structure and function
- Eliminates the need for long-term estrogen treatment



Atrophied vaginal mucosa



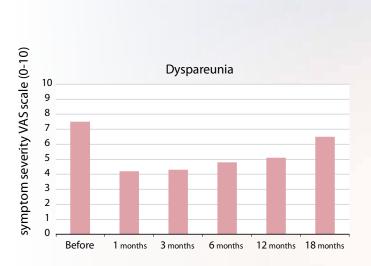
Vaginal mucosa after RenovaLase® treatment



RenovaLase® treatment induces a significant improvement of genitourinary syndrome of menopause, including vaginal dryness and dyspareunia. Additionaly, 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.



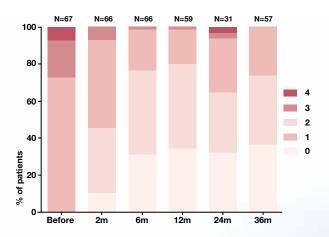
RenovaLase® significantly improves GSM symptoms, including vaginal dryness and dyspareunia, in breast cancer survivors.

Gambacciani, Marco, and Marco Levancini. "Vaginal erbium laser as secondgeneration thermotherapy for the genitourinary syndrome of menopause: a pilot study in breast cancer survivors." Menopause 24.3 (2017): 316-319.

# **Prolap**Lase®

### Pelvic organ prolapse treatment

- 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



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", April 2018

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, September 2016

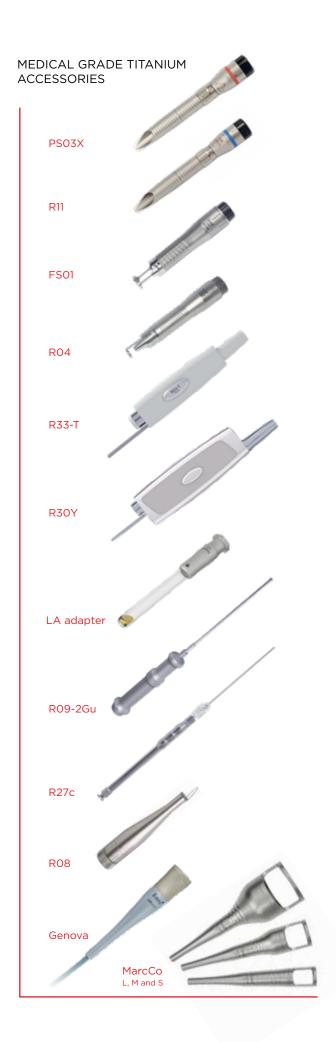


### TIMEWALKER® LASER LINE

# **Intima**laser<sup>™</sup>







# Scientifically proven results

### Scientific research using Fotona SMOOTH®

#### STRESS URINARY INCONTINENCE

T, Erel, L. Carazo Fernandez, D. Inan, M. Makul: Er:YAG laser treatment of urinary incontinence after failed TOT/TVT procedures. European Journal of Obstetrics & Gynecology and Reproductive Biology 252 (2020) 399–403

N.Okui, Efficacy and safety of non-ablative erbium:YAG laser treatment as a novel surgical treatment for overactive bladder syndrome: comparison with anticholinergics and β3-adrenoceptor agonist, World Journal of Urology, https://doi.org/10.1007/s00345-019-02644-7 (published online 28. January 2019)

A. Kuszka, M. Gamper, C. Walser, J. Kociszewski, V. Viereck: Erbium:YAG laser treatment of female stress urinary incontinence: midterm data. Int Urogynecol J. 2019 Dec 11. doi: 10.1007/s00192-019-04148-9.

N.Okui, Comparison between erbium-doped yttrium aluminum garnet laser therapy and sling procedures in the treatment of stress and mixed urinary incontinence, World Journal of Urology,

A. Gaspar, S. Maestri, J. Silva, H.Brandi, D. Luque, N. Koron, Z. Vizintin, Intraurethral Erbium:YAG Laser for the Management of Urinary Symptoms of Genitourinary Syndrome of Menopause: A Pilot Study, Laser in Surgery and Medicine, 50:802–807, 2018,

N. Okui, Mixed and Stress Urinary Incontinence treatment with vaginal Erbium laser - comparison of laser treatment with TVT and TOT in Asian women with MUI and SUI, 12 months follow-up, Progress in Medicine. Vol.38. No.3. 321-326. 2018

M. Blaganje, D.Scepanovic, L. Zgur, I. Verdenik, F. Pajk, A. Lukanovic, Non-ablative Er:YAG laser therapy effect on stress urinary incontinence related to quality of life and sexual function: A randomized controlled trial, European Journal of Obstetrics, Gynecology and Reproductive Biology, May 2018, Volume 224, Pages 153–158,

N. Okui, Comparison of Erbium-YAG laser treatment with TVT and TOT in Asian women with SUI, Geriat. Med. 55(4), 421-423, 2017

Tien YW, Hsiao SM, Lee CN, Lin HH, Effects of laser procedure for female urodynamic stress incontinence on pad weight, urodynamics, and sexual function. International Urogynecology Journal, 2017, 28(3):469-76.

Fistonic N, Fistonic I, Findri Gustek S, Sorta Bilajac Turina I, Franic D, Vizintin Z, Kazic M, Hreljac I, Perhavec T, Lukac M: Minimally invasive, non-ablative Er:YAG laser treatment of stress urinary incontinence in women – a pilot study. Lasers in Medical Science, 2016: vol. 31 (4) pp 635-43.

Ogrinc UB, Senčar S, Lenasi H. Lasers, Novel minimally invasive laser treatment of urinary incontinence in women. Surg Med., 2015: 47(9): 689-97.

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.

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

### VULVOVAGINAL ATROPHY / GENITOURINARY SYNDROME OF MENOPAUSE

M. Gambacciani, M. Levancini, E. Russo, L. Vacca, T. Simoncini and M. Cervigni, Long-term effects of vaginal erbium laser in the treatment of genitourinary syndrome of menopause, Climacteric, 2018 Apr;21(2):148-152. doi: 10.1080/13697137.2018.1436538. Epub 2018 Feb 13

M.Gambacciani, S. Palacios, Laser therapy for the restoration of vaginal function, Maturitas 99 , 10–15 (2017)

Gambacciani M, Levancini M, Vaginal erbium laser as secondgeneration thermotherapy for the genitourinary syndrome of menopause: a pilot study in breast cancer survivors. Menopause, 2017, 24(3):216-210

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.

Gambacciani M, Levancini M, 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. It. J. Gynaecol. Obstet. 2015, 27: 9-11.

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

#### **VAGINAL RELAXATION SYNDROME**

M. Mitsuyuki, U. Stok, I. Hreljac, K. Yoda, Z. Vizintin: Treating Vaginal Laxity Using Nonablative Er:YAG Laser: A Retrospective Case Series of Patients From 2.5 Years of Clinical Practice, Sexual Medicine, Published online: February 7, 2020,

Pardo JI, Solá Dalenz V, Laser Vaginal Tightening with Non-ablative Er:YAG for Vaginal Relaxation Syndrome. Evaluation of Patient Satisfaction. LAHA Journal of the Laser Health Academy, 2016(1):12-17.

Gaviria J, Korosec B, Fernandez J, Montero G, Up to 3-Year Follow-up of Patients with Vaginal Relaxation Syndrome Participating in Laser Vaginal Tightening. LAHA Journal of the Laser Health Academy, 2016(1):6-11

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.

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

#### PELVIC ORGAN PROLAPSE

Bizjak Ogrinc U, Sencar S, Non-ablative vaginal erbium YAG laser for the treatment of cystocele. It. J. Gynaecol. Obstet. 2017, 29:19-25.

Bizjak Ogrinc U, Sencar S, Laser Treatment of Higher Grade Cystocele. LAHA Journal of the Laser and Health Academy, 2013 (1); S22.

Vizintin Z, Lukac M, Kazic M, Tettamanti M: Erbium Laser in Gynecology. Climacteric. 2015, 18(1):4-8.

#### OTHER GYNECOLOGICAL INDICATIONS

U. Bizjak-Ogrinc, S. Sencar: Effectiveness and safety of ablative Er:YAG laser treatment for external genital warts. Zdrav. Vestn. 2020;89(7–8):357–64.

U.B. Ogrinc, S. Sencar,B. Luzar, A. Lukanovic: Efficacy of Non-ablative Laser Therapy for Lichen Sclerosus: A Randomized Controlled Trial, Journal of Obstetrics and Gynecology Canada, 2019

M. Gómez-Frieiro, E. Laynez-Herrero: Use of Er:YAG laser in the treatment of vulvar lichen sclerosus, International Journal of Women's Dermatology, available online 4 June 2019.

Erel T, Vulvodynia treated with Erbium:YAG laser, European Journal of Obstetrics, Gynecology and Reproductive Biology, 2018, Volume 231, Pages 280-281.

Download a compendium of scientific studies proving the safety and efficacy of noninvasive gynecology treatments using Fotona SMOOTH® technology.





# **Training & Education**

### Regular clinical workshops - make a SMOOTH start!

# Comprehensive workshops and online trainings

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

The extensive live and online workshops, where participants engage in live demonstrations and gain in-depth uderstanding of laser physics and laser tissue interaction, provide the needed insight into the fundamentals of non-invasive gynecological treatments and other procedures.



# 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.



#### 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



### 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





Committed to Engineering

The Highest Performance, Best Made Laser Systems in the World

since 1964

#### WHY DOCTORS CHOOSE FOTONA



"Fotona procedures are very safe. The SMOOTH (technology) is intrinsically safe. After the use of Fotona lasers, seeing a few patients, I did realize, right away, that these procedures are very safe, very effective and rewarding also from an economical point of view."

- Dr. Marco Gambacciani, Italy



"So has the laser changed my practice? Absolutely! To be a good well-rounded clinician you need to be good or have a knowledge, certainly, of all aspects of treatment and investigations and the way we look after our patients. So, for me, you need to be able to offer everything to be a good urogynecologist. And a laser for me is another option outside of surgery."

— Dr. Barry O'Reilly, Ireland



"The Fotona laser is definitely my choice because it's established worldwide. And from my experience I'm a happy user. I'm very excited to have my second unit installed very soon."

— Dr. Koh Kai Yee, Malaysia



"I began to work with a very effective method which gives me the opportunity to help my patients without operations have a very good result."

— Dr. Svetlana Stulova, Russia



"The decision to purchase the Fotona came after I've checked all existing systems provided. Fotona was the only one, definitely the most user-friendly and, especially, the support. The support was very, very important for me because I need the support. I need to know that somebody's behind me. It's the best thing I've ever, ever purchased. Ever!"

- Dr. Liora Bunzl, Austria



"There are all sorts of lasers now out there. But my rationale was that the Fotona lasers are extremely safe and safety is what we should strive for."

— Dr. Aleksandra Novakov Mikić, Serbia

Fotona, LLC 2307 Springlake Road #518 Dallas, TX 75234 USA Fotona, d. o. o. Stegne 7 1000 Ljubljana Slovenia FU Fotona GmbH Hohlbachweg 2 73344 Gruibingen, Germany FU Fotona Beauty Light, (Suzhou) Medical Devices Co, Ltd. No 2, Zengfu Road, Guli Town Changshu City, Jiangsu Province CHINA. 215515 Fotona France SARL 47 Boulevard de Courcelles 75008 Paris France FU

All Fotona medical lasers are CE marked and approved to be sold in the EU. For countries where specific national approvals or clearances are required, some of the products and/or applications may not yet have been approved. Please check with Fotona, your local Fotona distributor or your national regulatory body about whether a specific product or application has been approved to be marketed and sold in your country.

