



Dynamis Laser Overview

Combining high performance and convenience hand in hand: The Dynamis is a true revenue producer for your practice

Key Benefits:

- High precision, tissue-selective treatments
- Intuitive, easy-to-use parameter selection
- Broad range of treatment modes
- Impressive line of advanced accessories
- Minimally invasive, safe treatments, and short downtime
- Great patient comfort and satisfaction

Provides technology for expanded range of treatments

High-Resolution Intuitive GUI

Easy-to-use medical illustrations

Dual Monitor EFC Energy Control

Ensures the precision and consistency of laser output

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■ | Rotoflex Arm

Ergonomically designed for lightweight operation

Handpieces and Scanners

A complete range for supreme versatility

Top-Hat Beam Profile Optics

For uniform treatments with predictable results

Preprogrammed Procedures

Instantly gain access to procedures via a large display

Proprietary VSP Power Supply

Provides a full spectrum of treatment modes

Wireless Footswitch

Offers easy access

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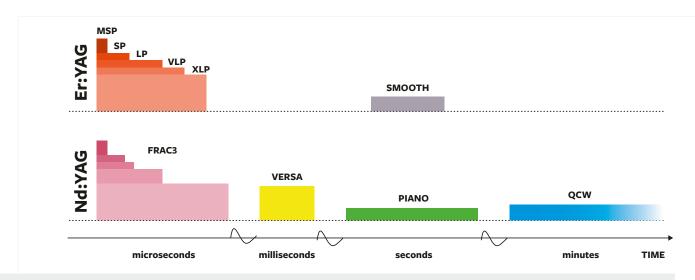


Leading Technology

Two complementary wavelengths with proprietary VSP technology

At the heart of Dynamis Pro laser system are two complementary laser wavelengths, with patented ultra performance technology: Nd:YAG with the most homogeneous penetration for effective deep thermal treatments, and Er:YAG with the highest absorption for ablative and non-ablative superficial treatments.





Innovative pulse modes from patented technologies for higher performance: SMOOTH®, FRAC3®, PIANO

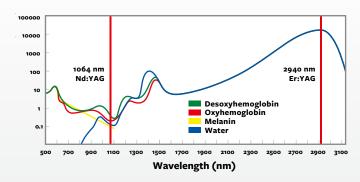
A combination of Superior Wavelengths for Most Major Applications

Proprietary VSP Technology for a Broad Range of Treatment Modes

Best wavelengths

"When it comes to patient results, the Dynamis' Er:YAG and Nd:YAG have proven to be, for me, the best wavelengths to minimize complications and shorten recovery times while providing outstanding clinical results."

— C. Pidal, Argentina





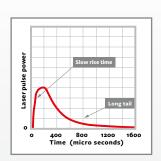
Fotona's VSP technology enables variable pulse durations and shapes (from microseconds to longer than one second) to optimize the effect of the laser on the tissue

Both laser sources feature Fotona's proprietary VSP (Variable Square Pulse) technology that enables an unprecedented range of treatment modes, from extremely short microsecond pulses for intense targeting of selected areas, to very long, sub-second-to-second pulses for gentler bulk tissue treatments.

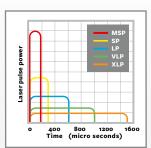
Why an Er:YAG & Nd:YAG laser combination?

The Dynamis' VSP (Variable Square Pulse) Er:YAG laser inherently ablates skin more precisely than other laser wavelengths. Er:YAG energy is highly absorbed in water — the main target chromophore for skin resurfacing — and can thus vaporize skin with micron–precision and very little thermal conduction. This keeps undesired effects such as hypopigmentation and persistent erythema, as well as recovery time, to a minimum. The VSP Er:YAG laser in Dynamis systems can be accurately tuned from varying "cold" and "hot" ablative to non–ablative thermal ratios. Full customizability allows you to precisely attain the clinical outcomes your patients desire.

The Nd:YAG laser perfectly complements the Er:YAG laser's ablative action with its ability to penetrate deeply into the skin to create thermal effects without damaging the skin surface. Its homogeneous absorption in the skin and low absorption in melanin allow it to be safely used on all skin types. Compared to conventional technologies, the VSP Nd:YAG pulses of Dynamis lasers create virtually instantaneous FRAC3® temperature increases, limited to the targeted structures only.



Standard laser technology



Fotona VSP technology



More Applications for your Practice

Award-winning, broad range of applications

SP Dynamis is a uniquely capable and full-featured system offering the power of ultra high performance Er:YAG and Nd:YAG lasers.

Key Treatments:

- **Fotona4D®**
- **TightSculpting®**
- SmoothEye[™]
- NightLase®
- **Active Acne**
- **Benign Lesions Removal**
- Coagulation of Mucosal Tissue
- Full Beam & Fractional Treatments
- Gynecology
- **Hair Removal**
- **Onychomycosis**
- **Pigmented Lesions**
- Scars
- Skin Resurfacing
- Surgical Applications: Laser Lipolysis, Endo Venous Laser Ablation
- Treatment of Wrinkles
- Vascular Lesions
- **Veins**
- **■** Warts



Dynamis Pro System Specs

Laser Type	Er:YAG	Nd:YAG		
Wavelength	2940 nm	1064 nm		
Fluence Range	0.1 – 95 J/cm2	10 to 600 J/cm2		
Pulse repetition rate (frequency)	2 to 50 Hz	0.5 to 100 Hz		
Power	20 W	80 W		
Energy	3 J	50 J		
Pulse Width	Variable with 8 modalities	Variable from 0.1 up to 60 s		
Modalities	MSP Mode: 100 microseconds SP Mode: 300 microseconds LP Mode: 600 microseconds VLP Mode: 1000 microseconds XLP Mode: 1500 microseconds SMOOTH mode: 250 milliseconds V-SMOOTH mode with L-Runner; 100, 200, 300, 400 and 500 milliseconds	FRAC3® VERSA PIANO QCW		
Scanner	TURBO Mode T-Runner, S-Runner, F-Runner	L-Runner, S11		



A highly innovative workstation

"Fotona's Dynamis laser is a highly innovative workstation, which represents a complete ablative skin resurfacing solution capable of providing a wide variety of treatment options."

— Ming–Li Tseng, Taiwan

Ease of Use

With interactive touch screen and medical illustrations

Key Features:

- Easy-to-use medical illustrations and intuitive user interface puts an entire range of applications at your finger tips
- Simple, logical procedure groups with presets and additional expert mode
- User interface intelligently guides you through all applications
 - 1 Select a wavelength



3 Select a type of treatment



2 Select a group of applications



4 Press ready and work





Nd:YAG - for Deep Penetration

The Fotona proprietary Nd:YAG laser

The Nd:YAG laser is characterized by its homogeneous penetration up to 10 millimeters deep and selective absorption in tissue chromophores.

These two features allow Nd:YAG laser light to reach deep skin structures without damaging the epidermis, regardless of skin type.



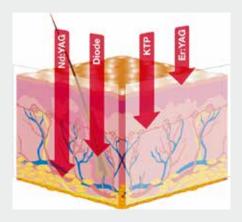


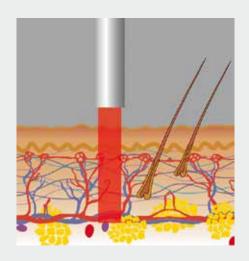
"The advantages of the unique characteristics of the Fotona Nd:YAG laser can be summarized as follows: effective, quick, reliable, cost effective, and no unnecessary consumables. Our patients are very satisfied with the treatment because it is safe, effective, quick and easy."

- R. Gansel, Germany

Key Benefits:

- Deepest Tissue Penetration
- Safer For All Skin Types
- High Reliability





Extreme versatility of treatments with different pulse modes

■ Versa

■ PIANO®

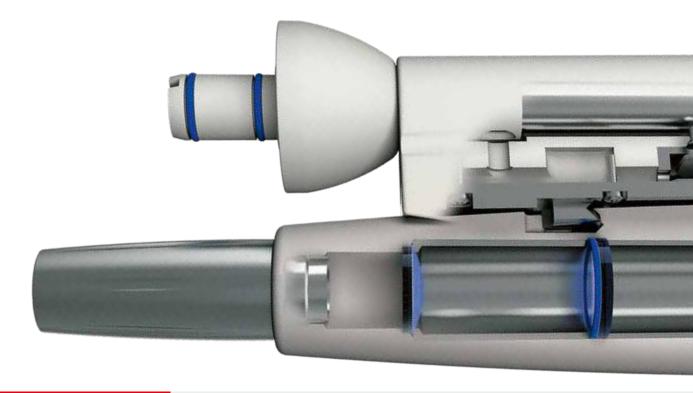
■ FRAC3®

■ QCW



Versa LP

Safety and efficacy in a proprietary Fotona millisecond Nd:YAG pulse



Key Treatments:

- Veins
- **Vascular Lesions**
- Acne
- **■** Warts
- Onychomycosis
- Skin Rejuvenation (Treatment of wrinkles)

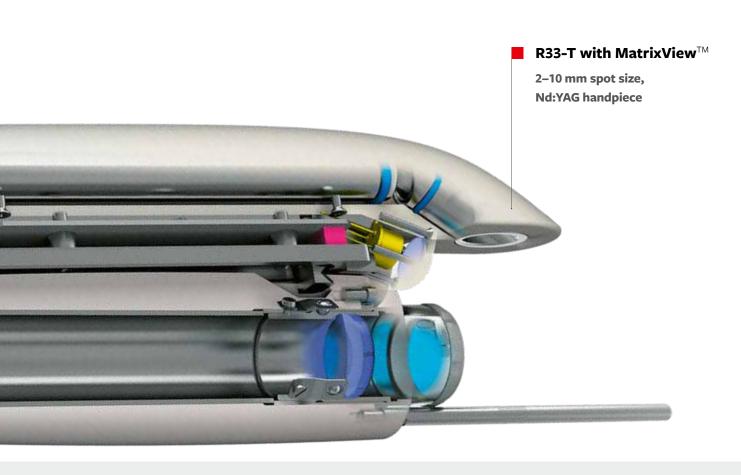








urtesy of R. Sult





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Vascular Lesions

Versa LP: The Perfect Vascular Solution



courtesy of R. Sult



courtesy of R. Sult



courtesy of R. Sult



Vascular Lesions

The Dynamis' long-pulse Nd:YAG laser, penetrating up to a depth of 5-6 mm into the skin, provides a highly effective solution for treating many types of vascular lesions. Independent research shows that over 75% of patients with deep hemangiomas that are treated with Nd:YAG see a dramatic regression in the lesion.

Key Treatments:

- **■** Hemangiomas
- Port-wine stains
- **Telangiectasias**
- Venous lakes
- Angiomas

FRAC3®

Selective targeting of skin imperfections

FRAC3®

A novel non-ablative, three-dimensional fractional modality for skin treatments. FRAC3® utilizes the short pulse duration and high peak power density of Fotona VSP™ generated Nd:YAG laser pulses to produce a three-dimensional fractional pattern in the epidermis and dermis, with damage islands that are predominantly located at the sites of targeted skin imperfections.



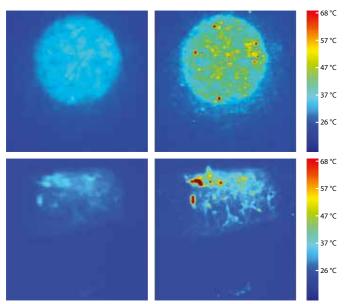
FRAC3® Three-Dimensional fractional skin treatment



courtesy of R. Gansel

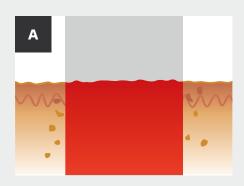
Key Treatments:

■ Skin rejuvenation with selective targeting of skin imperfections (Treatment of wrinkles)

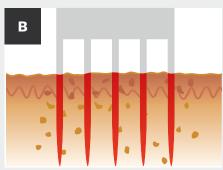


Skin surface temperature thermal image following a long pulse and FRAC3® Nd:YAG laser pulse. Temperature fractionality can be observed following illumination with a FRAC3® pulse.

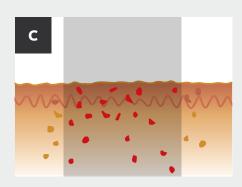
Laser-induced damage islands as healing centers:



a) standard uniform laser treatment

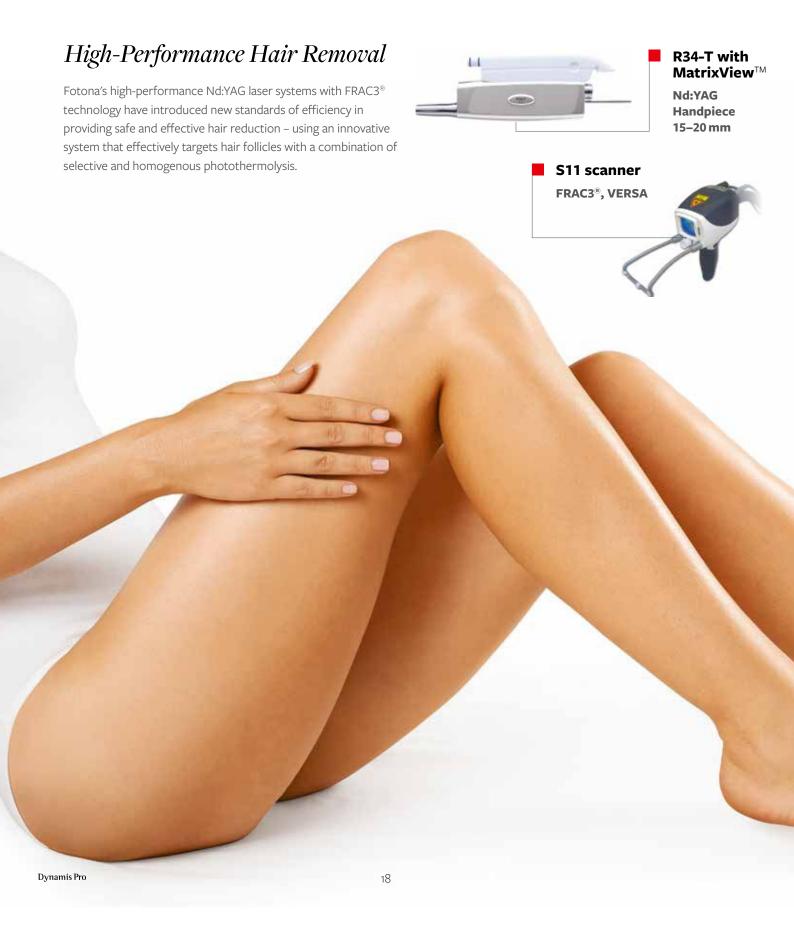


b) standard two-dimensional fractional treatment



c) Three-dimentional FRAC3[®] laser treatment

Permanent Hair Reduction



Safe for All Skin Types

Fotona's Nd:YAG lasers incorporate revolutionary pulse-control technology and a proprietary three-dimensional treatment pattern (FRAC3®) to provide safe and effective hair reduction. Unlike other wavelengths, only Nd:YAG is safe to use on all skin types. Fotona's innovative system effectively targets surface treatment areas while leaving surrounding tissues unaffected.

The success of hair reduction treatments depends largely on a patient's skin and hair type, as well as the skills and treatment insight of the practitioner. Most patients can expect a significant reduction in unwanted hair, and any future hair growth will usually be thinner and lighter, and thus much less pronounced than before.

High-Performance Hair Removal

Combined with the special high-performance L-Runner scanner from Fotona, you can **quickly, comfortably and efficiently treat large areas** such as the legs, back and chest, making laser treatments one of the most cost-effective solutions for long-term hair reduction. Fotona's high peak-power laser pulses provide the speed and efficiency needed to uniformly cover large scanning areas. Depending on the size of the treatment area, between three to five sessions, six to eight weeks apart will lead to a significant aesthetic and clinical result.







PIANO

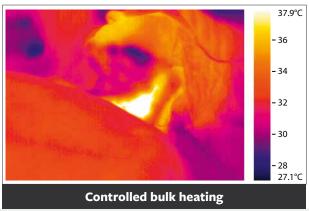
Be in tune with PIANO mode





PIANO

This new, super-long modality extends the duration of Nd:YAG treatments to the seconds regime. This is much longer than the thermal relaxation time of the epidermis or any other skin structures, and does not cause high initial temperature peaks in the epidermis. It is therefore indicated for treatments where overall homogeneous, bulk heating of the dermis is desired.



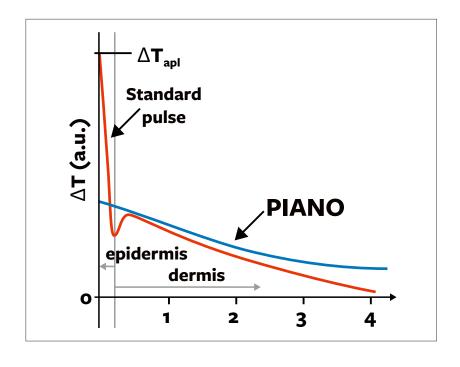
QCW

Enhance body shapes with surgical QCW

QCW

Fotona's Nd:YAG laser has a particular affinity for absorption in hemoglobin, making it an ideal choice for endovenous laser treatments. Its high performance, selectivity and precision (limiting thermal effects to the target tissue), allow for minimal discomfort, exceptional success rates and shortened recovery times.







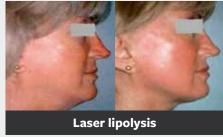
courtesy of M. Taylor



courtesy of M. Taylor

Key Benefits:

- Intended for homogeneous photothermal treatments of the dermis
- Designed to bypass high absorption within the epidermis



courtesy of D. Maletic



courtesy of A. Sikovec



courtesy of D. Maletic

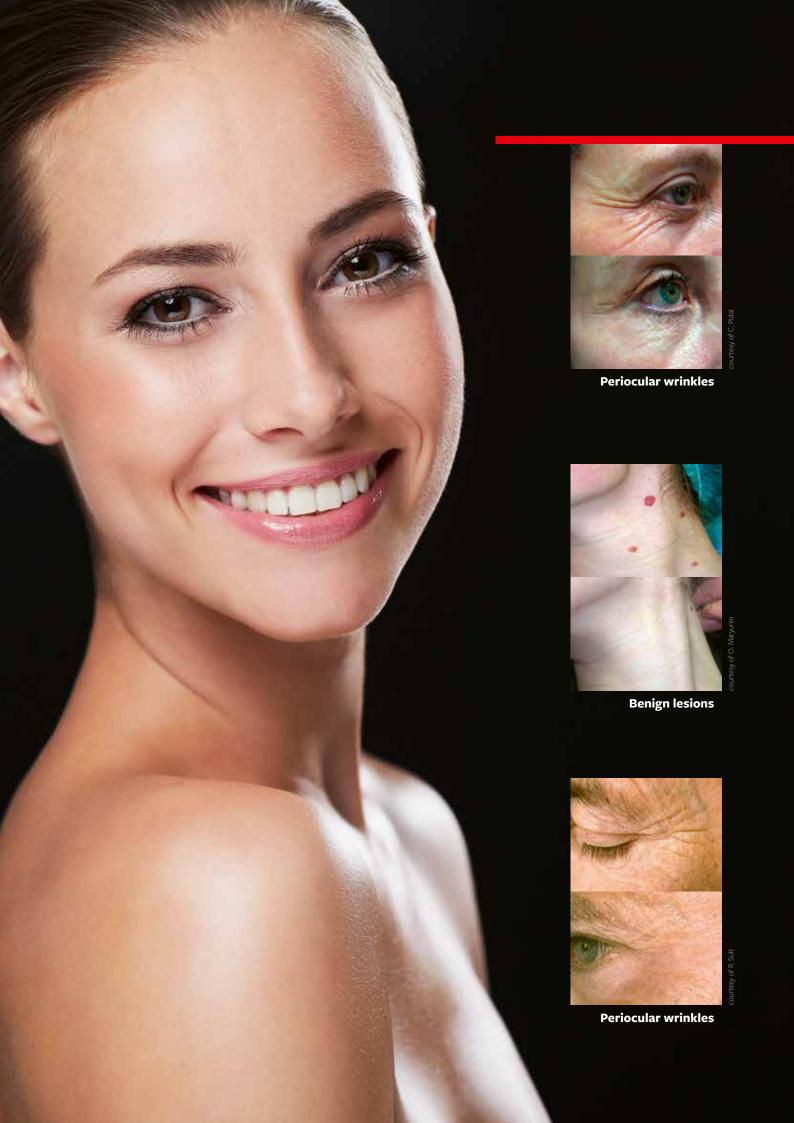
Key Benefits:

- Fast and efficient procedures
- Significantly reduced recovery times
- For body sculpting
- Antiaging treatments from the inside-to-out:

Laser lipolysis

Endovascular treatments

Fibroma removal



Er:YAG - Superior Absorption

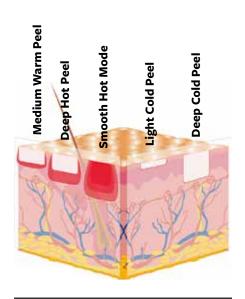
The Fotona proprietary Er:YAG laser

Er:YAG

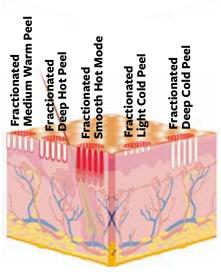
Er:YAG laser utilizes a unique wavelength that is absorbed within a few microns of tissue, thus avoiding any damage to deeper-lying tissues.

VSP

VSP technology enables the operator to easily adjust the laser treatment modality from micro-short (MSP) to extra-long (XLP) pulses in order to precisely balance the removal of epidermis with thermal effects on collagen.



Selection of different available VSP Er:YAG laser treatment regimes



Selection of different available fractional laser treatment regimes

Key Features:

- **Superior absorption**
- Most efficient ablation
- VSP to control the ablation/ coagulation ratio
- From mild-cold to deep-hot ablation
- Full beam and fractional resurfacing
- Special TURBO and SMOOTH® mode

Versatility of Treatments

- From light-cold to deepwarm peels
- **Fractional treatments**
- SMOOTH® mode

The Ideal balance between efficiency and downtime, with the lowest risk of PIH

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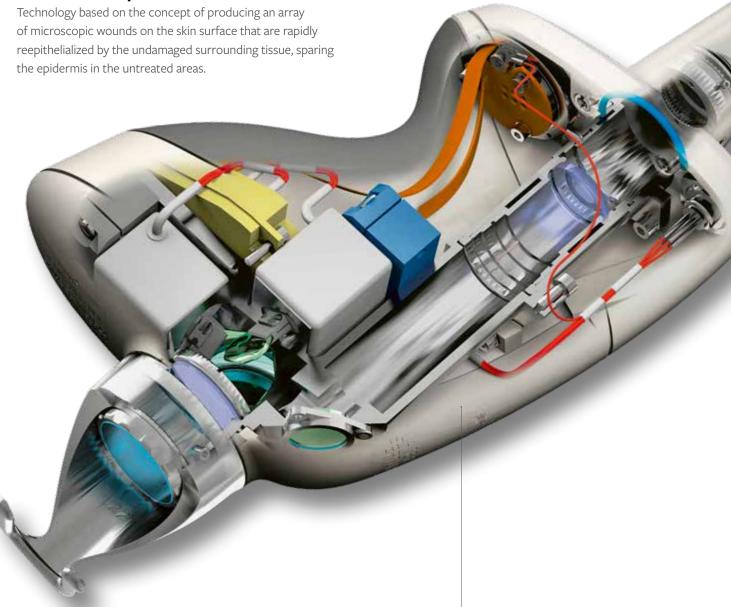
"Dynamis Er:YAG is a very effective tool for resurfacing treatments, in terms of the balance between efficiency and downtime, with the lowest risk of PIH (post-inflammatory hyperpigmentation)."

— A.S.Lun, Hong Kong

VSP Er:YAG Fractional Treatments

When less becomes more

Fractional handpieces



Key Benefits:

- Less invasive skin resurfacing
- Accelerates recovery
- Enhanced wound healing
- Superior for scar healing

F-Runner

- Computer-controlled scanning
- Unrivaled accuracy and uniformity over large areas
- Intense fractional treatments
- 250 µm microspot size
- Adjustable scanning field coverage

FS01 Fractional Handpiece

- Sharp fractional treatments
- 250 µm microspot size
- Fast, effective treatments

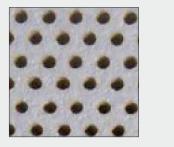














TURBO mode

A unique technology feature which sequences identical pulses within the same treatment spot on the skin, thus enhancing ablation depth and creating more accurate and sharply defined micro-channels.

SMOOTH® Mode

A gentle touch with SMOOTH® Mode

Non-ablative VSP Er:YAG is a unique modality for non-invasive thermal-only treatments.

SMOOTH® Mode

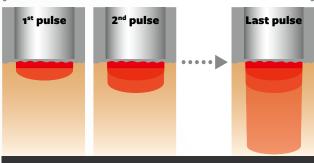
Treats the skin in a smooth, almost "feather-like" non-ablative manner, without bleeding and with precisely controlled temperature deposition. The optical energy is delivered in a unique, sub-second long pulse sequence which prevents temperature build-up at the surface and achieves homogeneous heating within several hundred micrometers of the tissue.



SmoothLiftin[™]

SMOOTH Mode pulse

Optimal sequence of sub-ablative micro pulses



Thermal non-ablative treatment without any bleeding risk or damage to deeper-lying tissues

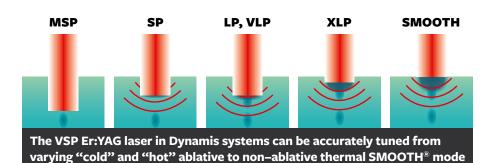
courtesy of Jong-Gu Kim SmoothEye™

Skin resurfacing

Ideal For Non-Ablative Er:YAG Skin Resurfacing

SMOOTH® Mode enables non-ablative laser skin remodeling based on controlled induction of thermal injury of the collagen while preserving the epidermis. In addition to an immediate effect resulting in the shrinkage of collagen fibers, the initiation of neocollagenesis occurs causing the generation of new collagen. The effects result in an overall improvement of laxity and elasticity in the treated tissue.





R11 Variable Spot Size Er:YAG Handpiece

2-7 mm spot size Er:YAG handpiece





FotonaSmooth®

Gynecological treatments

IncontiLase®

- A minimally invasive solution for stress urinary incontinence
- Improves urethral support by photothermal strengthening of the vaginal wall
- The treatment works best in mild and moderate stress urinary incontinence patients with very good results in severe stress urinary incontinence as well



Mild and moderate stress and mixed urinary incontinence

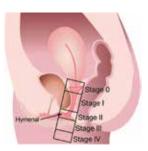


After IncontiLase® treatment

ProlapLase®

- A safe and non-invasive treatment for pelvic organ prolapse (POP)
- Precisely controlled laserinduced photo-thermal effects of the Er:YAG laser in mucosa tissue, stimulating collagen remodeling and the synthesis of new collagen fibers.
- Shrinkage and tightening of the vaginal canal without removal of any tissue.
- Suitable also for higher grade prolapse





The overall impact and burden on the patient's organism is minimal, as opposed to more invasive classical surgical procedures.

IntimaLase®

- A true incisionless laser treatment for vaginal relaxation syndrome
- Photothermal tightening of the vaginal canal based on shrinking and thickening of the connective tissue in the vaginal wall



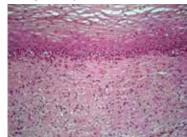


Scientific results show great improvements in vaginal tightness and sexual gratification.

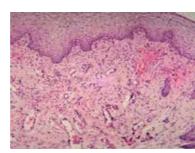
RenovaLase®

- Gentle laser treatment of vaginal atrophy / genitourinary syndrome of menopause
- 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

Courtesy of A. Gaspar



Atrophied vaginal mucosa



Vaginal mucosa after RenovaLase treatment

Tools for gynecological treatments

G extstyle -SET - intravaginal accessory set



R11 full-beam titanium handpiece



PS03 patterned titanium handpiece



Gynecological treatments: 90° angular golden mirror titanium adapter



Gynecological treatments: 360° circular golden mirror titanium adapter



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



SClear speculum

G-RUNNERTM - FOR AUTOMATED OPERATION



- 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

Fotona NightLase® Therapy



NIGHTLASE®

Fotona's NightLase®* therapy is a non-invasive, patient-friendly laser treatment for increasing the quality of a patient's sleep. NightLase can reduce the effects of and decrease the amplitude of snoring by means of a gentle laser treatment of the mucosa tissue.

Simple, Safe and Effective

Fotona's patented laser modality optimizes the length of laser pulses, allowing for the safe penetration of heat into the oral mucosa tissue. It is gentle enough to be used on the sensitive tissue inside the mouth, but strong enough to provide clinically efficacious heating.

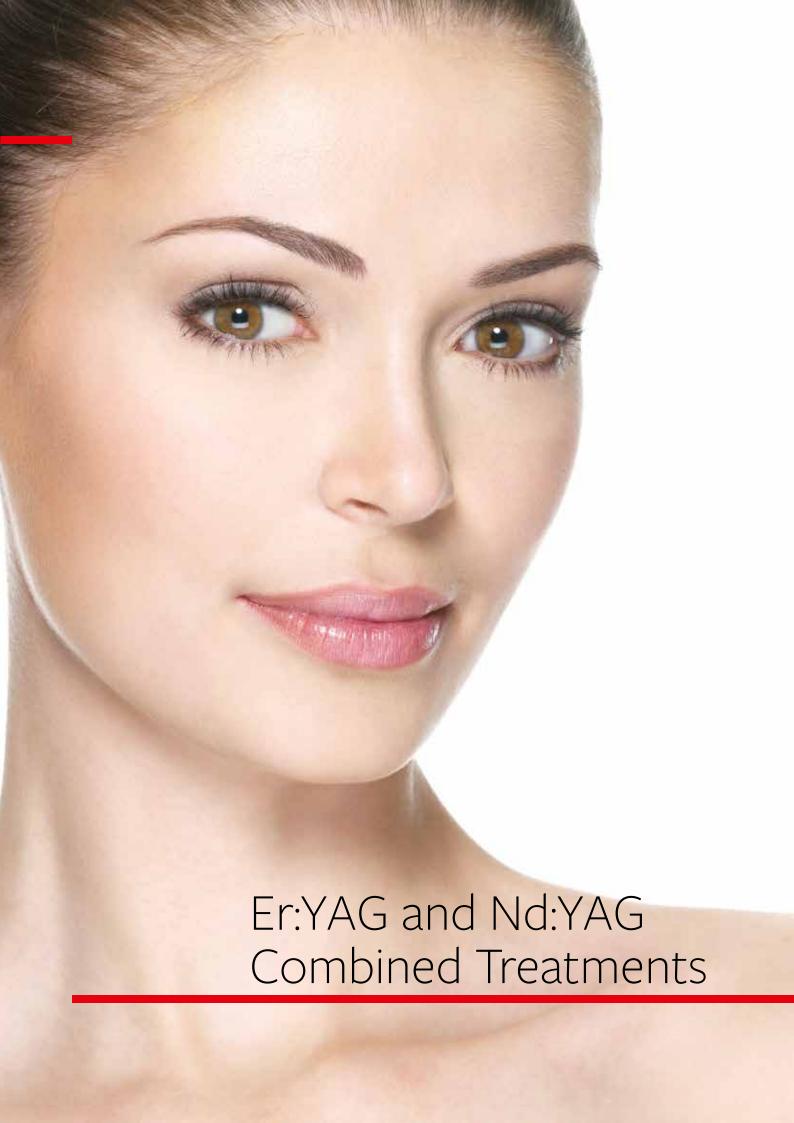
With proper training NightLase has a high success rate in producing a positive change in sleep patterns. Research has shown that NightLase can reduce and attenuate snoring, in an effective, non-invasive way.

A Patient Friendly Solution

A full course of NightLase consists of three separate treatment sessions over a two-month period. The final results of the treatment have been shown to last up to a year, and the therapy can be repeated.

Patients find NightLase to be a highly comfortable and satisfying solution. NightLase requires no device to be worn during sleep and involves no chemical treatment. It's a gentle and easy way for your patients to regain a good night's rest.

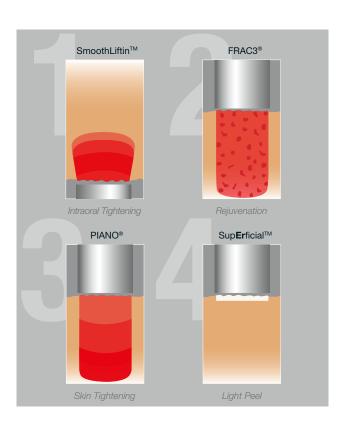
excision and incision, and laser assisted uvulopaletoplasty (LAUP).



Fotona 4D®

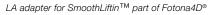
SYNERGISTIC TREATMENTS FROM TWO WAVELENGTHS WORKING TOGETHER

Enabled by the expanded capabilities of the Nd:YAG and Er:YAG wavelengths, the Dynamis provides up to four dimensions of treatment, including a novel SmoothLiftin™ intraoral laser treatment vector. Fotona's complementary Er:YAG and Nd:YAG wavelengths are synergistically applied in 4 different modes: SMOOTH®, FRAC3[®], PIANO[®] and SupErficial™ to work on deeper, medial and superficial connective structures of the skin, while simultaneously targeting different skin imperfections. Fotona's 4D laser treatment of both the exterior facial and interior oral cavity enables full-thickness contraction of collagen for persistent, no-downtime tightening and volumization without injectables. Combining these 4 unique modes and two complementary wavelengths results in a respectable facelifting treatment.









Best possibilities for patients

"Combining the four Fotona skin treatment modes of Dynamis gives the physician a new, powerful non-invasive treatment. Together these unique four laser modalities provide a full thickness penetration laser treatment that can really impress."

— Dr. M.C.Lee, USA



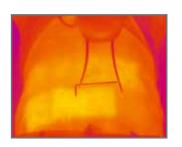
LASER BODY SCULPTING AND SKIN TIGHTENING

- Dual-wavelength laser procedure combining unique PIANO® and SMOOTH® technologies for deep as well as superficial skin tightening and fat reduction
- Non-invasive and comfortable procedure with no downtime
- Safe and effective on all body areas
- No consumables
- TightSculpting® is just one of over 40 applications that are available on the SP Dynamis platform

HIGH PERFORMANCE ACCESSORIES FOR FASTER AND MORE PRECISE TREATMENTS

Fotona's innovative MatrixView S™ temperature monitor ensures effective and controlled treatments with ultimate patient comfort and safety. The scanner-supported TightSculpting® procedure allows for simultaneous large body area treatments using adjustable scanner-area shapes and sizes.







Multiple treatment modalities range from the 2-dimensional TwinLight® procedure to the 4-dimensional Fotona4D® procedure and unique dual-wavelength, non-invasive TightSculpting®.



SmoothEye™

A NON-ABLATIVE FOTONA SMOOTH® MODE TREATMENT FOR TIGHTENING OF THE PERIOCULAR REGION

SmoothEyeTM treatment reduces the appearance of periorbital wrinkles from the inside out, which significantly tightens loose and aging skin of the eyelids and periocular region with little-to-no downtime and maximum patient comfort, making this a very sought after non-invasive cosmetic procedure. After a few treatment sessions, the result is improved skin elasticity, overall structure, and volume with significant wrinkle reduction in the periocular region.



The PSo₃ handpiece is a variable spot size handpiece, with fixed pixel-size, independent of the selected spot size. Spot sizes range from 2 to 7 mm with a fixed pixel structure within the laser spot; when the spot size is changed, the number of pixels inside the spot changes.







A breakthrough treatment

"It works extremely well. Reducing eye bags usually requires invasive surgery and there are side effects. The advantage of this laser-based approach is the non-invasive aspect, which can reduce eye bags safely. This is really a breakthrough treatment that is unlike anything we have seen before for this indication."

— Dr. Pham Huu Nghi, Vietnam



Nd:YAG Accessories







R33T

Nd:YAG Spot size 2-10 mm MatrixView™

R34T

Nd:YAG Spot size 15, 20 mm MatrixView™

R27

Nd:YAG Surgical HP For 600, 1000 micron

R27C

Nd:YAG Small surgical HP For 600, 1000 micron

S11 scanner

Spot size 3,6,9 mm Area 65 mm x 65 mm Frac3®, VERSA



L-runner Pro

Spot size 3,6,9,11 mm Area 65 mm x 65 mm Frac3[®], VERSA, PIANO MatrixView S™

Er:YAG Accessories



Er:YAG Full beam Smooth® mode Spot size 4 mm Adjustable 62.5 cm²

T-Runner

Er:YAG Adapter for PS03 and R11 Intraoral treatments

LA adapter

Customize your Possibilities

	Hair removal	Veins	Wrinkles	Skin rejuvenation	Benign lesion	Onychomycosis	Vascular lesions	Skin resurfacing	Fractional skin resurfacing	TightSculpting
SP Dynamis	•	•	•	•	•	•	•	•	•	•
SP Spectro	•*	•	•	•	•	•	•	•	•	•*
XS Dynamis			•	•	•			•	•	
XP Spectro	•*	•	•	•		•	•			
XP Dynamis	•	•	•	•		•	•			

^{*} Treatment may take longer due to lower power output

	Scars	Active acne	Pigmented lesior	Warts	Gynecology	Snoring	Lypolysis, Hyperhidrosis	EVLA
SP Dynamis	•	•	•	•	•	•	•	•
SP Spectro	•	•	•	•	•	•	•	•
XS Dynamis	•		•	•	•	•		
XP Spectro		•		•			•	•
XP Dynamis		•		•			•	•

Model	SP Dynamis /	SP Spectro	XS Dynamis	XP Dynamis / XP Spectro		
Laser type	Er:YAG	Nd:YAG	Er:YAG	Nd:YAG		
Wavelength	2940 nm	1064 nm	2940 nm	1064 nm		
Power	20 W	80 W / 35 W	20 W	80 W / 35 W		
Energy	3 J	50 J	3J	50 J		
Scanner	S–Runner F–Runner T–Runner	S–11 L-Runner	S–Runner F–Runner T–Runner	S–11 L-Runner		
Modalities	MSP, SP, LP, VLP, XLP, SMOOTH, TURBO	FRAC3®, VERSA, PIANO, QCW	MSP, SP, LP, VLP, XLP, SMOOTH, TURBO	FRAC3®, VERSA, PIANO, QCW		



World Class Training







- led by leading international laser experts
- live demos and hands-on
- explore all areas of medical lasers
- a great experience-sharing opportunity

To get the most out of your Dynamis Pro system, our practitioner workshops, coorganized with the Laser and Health Academy, provide hands-on demonstrations of our lasers from international clinical experts. Fotona also works closely with other leading educational authorities in the field of medical lasers to offer additional high-level training opportunities to help you on your path to becoming a top laser specialist.



www.laserandhealth.com

The Laser and Health Academy

The Laser and Health Academy (LA&HA®) is a not-for-profit organization dedicated to the promotion of research, education and publishing in the field of laser medicine.

Research: LA&HA® collaborates with industry, medical professionals and universities on projects aimed at the development and improvement of laser applications.

Education: LA&HA® serves as a platform for continuous education, with a focus on practical instruction and the demonstration of laser techniques and procedures, delivered through a variety of workshops and seminars by experienced lecturers.

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Fotona's 50 years of experience has inspired some of the world's most advanced multi-application aesthetic laser technologies. At the heart of Fotona's medical lasers are high-performance, solid-state crystal laser sources that generate the industry's proven and effective treatment wavelengths. These 'golden-standard' wavelengths are well suited for handling an exceptionally wide range of aesthetic and clinical procedures. Fotona's proprietary handpieces, innovative operating modes and advanced beam-profile technologies further enhance these medical wavelengths to ensure maximum performance and efficacy.



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

