V²LR (Vulvo Vaginal Laser Reshaping)

SmartXide Touch

SMARTXIDE TOUCH

The New Era of Vaginal Rejuvenation

Advanced CO_2 Laser System.

- Atrophic Vaginitis
- Vaginal Laxity
- Stress Urinary Incontinence
- Postpartum Perineal Trauma
- Genital Functional and Cosmetic Laser Surgery

All it takes is a touch

MonaLisa Touch®

DEKA
The Code of Excellence

SmartXide Touch

THE REVOLUTIONARY NEW APPROACH TO WOMEN INTIMATE PARTS

Many disorders related with women's intimate area are often overlooked and ignored because they are perceived as an inevitable consequence of a natural physiological process that occur as a result of childbirth or menopause, for which little or nothing can be done. It is thought that these disorders may have an important impact both physical discomfort (pain, burning, incontinence), and psychological, causing an adverse effect on the relationship with the partner and quality of life in general.

SmartXide Touch is the new CO_2 laser system specifically designed for V^2LR (Vulvo-Vaginal Laser Reshaping) and ***MonaLisa Touch***®, the breakthrough procedure developed by DEKA known worldwide for treating age-related and postpartum vulvovaginal troubles. A unique solution for women without the adverse side effects of drug therapies.

*"We consider **SmartXide Touch** a versatile and irreplaceable instrument for vaginal mucosa regeneration and outpatient genital surgery. I have found the system to be particularly effective, consistently ensuring excellent results and maximum comfort for my patients. With the **MonaLisa Touch**® we have experienced amazing improvements on atrophic mucosa as early as a month after a single treatment with immediately noticeable results."*

Stefano Salvatore, M.D.
Head of the Urogynaecology department,
San Raffaele Hospital and Vita Salute, Milan - Italy

"Histological studies conducted on women suffering from genitourinary syndrome of menopause, have shown that the ***MonaLisa Touch***® treatment with ***SmartXide Touch*** restores the mucosa to a pre-menopausal condition, as it would occur after an oestrogen hormone replacement therapy. This particular laser system stimulates epithelial surface and connective tissue through a physical medium rather than using drugs, basically making the vaginal mucosa younger."

Prof. Alberto Calligaro
Professor of Histology and Embryology,
University of Pavia - Italy

"Postpartum perineal pain following a vaginal delivery (both spontaneous and instrumental), or related to the episiotomy is a disabling condition of women after giving birth, especially when lasting over time. For symptom relief we have successfully used the ***MonaLisa Touch***® method which acts gently on vaginal tissues to restore its correct functionality. First created to solve problems related to vaginal atrophy in post-menopause, ***MonaLisa Touch***® is proving also to be extremely useful and effective in other situations."

Maurizio Filippini, M.D.
Gynaecological Endoscopy Functional Unit
of the Republic of San Marino State Hospital - San Marino

SMARTXIDE TOUCH FOR V²LR: A MINIMALLY INVASIVE TECHNOLOGY THAT ENHANCES QUALITY OF LIFE

SmartXide Touch, with V²LR configuration, offers the latest breakthrough laser treatment for vulvo-vaginal problems (***MonaLisa Touch***®) and cosmetic/functional female genital surgery. These safe and minimally invasive procedures present a new alternative to:

- pharmacological therapy for post-menopause or postpartum atrophy of genital mucosa;
- surgical treatment of vaginal laxity;
- pharmacological analgesic therapy for dyspareunia due to postpartum perineal trauma;
- annoying or invasive treatments for urinary incontinence;
- traditional plastic surgery for correction of vulvo-vaginal morphological alterations due to hereditary factors, pregnancy or natural ageing.

To perform these innovative procedures, DEKA has designed a new radiofrequency CO_2 laser, with the exclusive **PSD**® (Pulse Shape Design) technology that generates pulses specifically developed for V²LR applications: **D-Pulse** or **DEKAPulse**.

PLUS

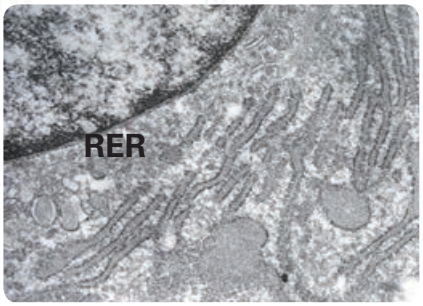
2009	DEKA is the first company to introduce the V²LR procedure, applying DOT Therapy to vulvo-vaginal treatments.
2012	DEKA, in collaboration with important Italian centres of excellence, presents amazing clinical and histological results achieved with the revolutionary *MonaLisa Touch*® vaginal treatment.
PSD® Technology	The exclusive Pulse Shape Design technology assures the maximum pulse shape flexibility: S-Pulse, D-Pulse, H-Pulse, U-Pulse and CW mode greatly expands the surgical capabilities of the SmartXide Touch making it the most effective and versatile laser system.
D-Pulse	The exclusive pulse shape specifically developed for treating vaginal mucosa.
HiScan V²LR	DEKA's exclusive scanning system, specifically designed for V²LR. Different probes (intra-vaginal 360° and single-angle probes; vulvar probe) are available for specific treatments and conditions.
Multimedia & Databese	Integrated photos, video tutorial and protocols developed for V²LR, Gynaecology as well as various fields of medical applications (Dermatology, Cosmetic Surgery and Dentistry).

SmartXide Touch

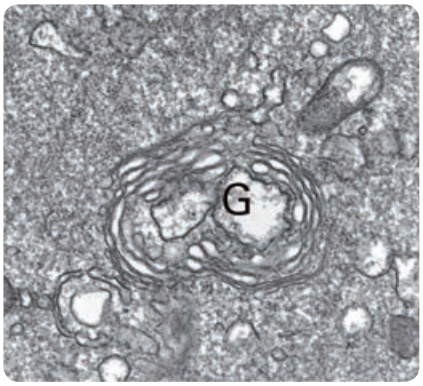
VAGINAL ATROPHY: CHANGES THAT AFFECT THE QUALITY OF LIFE

	sexual maturity	pregnancy	post menopause
Oestrogens	++	+++	-
Epithelium of mucosa			
Glycogen	+	++	-
pH	3,5 - 5	3 - 4,5	6 - 8
Microorganisms population	lactobacilli		mixed

Vaginal environment at different ages and physiological conditions.



Electron microscope image inside a fibroblast of the vaginal mucosa after a ***MonaLisa Touch***® treatment. The Rough Endoplasmic Reticulum (***RER***) can be seen, well-developed with many ribosomes that are attached to the membranes of flattened cisternae. Some of these cisternae develop vesicles in the terminal part, in which filamentous structures can be observed.



Electron microscope image inside of a fibroblast in the vaginal mucosa after a ***MonaLisa Touch***® treatment. The Golgi apparatus (***G***) is particularly well developed. We can observe vesicles which contain the components that will form the ground matrix.

Menopause, whether natural or induced, determines a range of changes, involving virtually all organs and systems of a woman's body. The end of oestrogen production by the ovaries is linked to the onset of disorders resulting from the uro-genital atrophy such as dryness, dyspareunia, vaginal irritation with itching and burning, vaginal laxity, and stress urinary incontinence. Studies show that symptoms caused by the atrophic vaginitis are present in 50% of post-menopausal women, determining adverse effects on their overall well-being and, in many cases, their sexual life.

During menopause, the fibroblasts sited in the vaginal mucosa, reduce their own activity and cannot produce the proper amount of collagen and molecules required to maintain an adequate ground matrix structure that is necessary to preserve a correct connective tissue hydration. The mucosa becomes dry, less nourished and therefore fragile and prone to infection due to the higher pH, setting up the environment to colonization of pathogenic microorganisms.

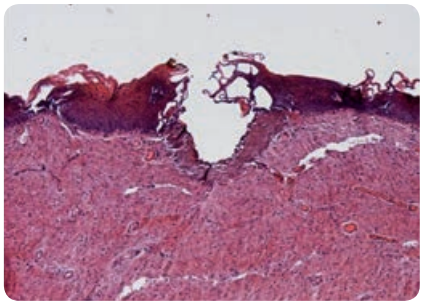
PREVENTION AND CURE WITH *MONALISA TOUCH*®: ANOTHER STEP FORWARD WOMEN'S WELL-BEING

MonaLisa Touch® is the application of unique DEKA CO_2 lasers on the vaginal walls by using specifically designed probes. To render this procedure absolutely safe and fast **SmartXide Touch** is equipped with an exclusive pulse, called **D-Pulse** or **DEKA-Pulse**, together with a fractional emission mode that have been proven to be effective in restoring the atrophic vaginal mucosa by stopping ageing and inducing a true rejuvenation. A detailed histological investigation carried out by the University of Pavia has demonstrated these ultrastructural aspects in-depth. The laser acts directly on the mucosa by stimulating the metabolic activation of the fibroblasts and the biosynthesis of collagen. The vagina rolls back the years regaining extramatricial components and water, thickness of the connective tissue and epithelium, thus recovering trophism, tonicity, elasticity and firmness as when it was younger. Restabilizing the natural turnover of the epithelial cells the natural conditions for nourishment of lactobacilli is restored; pH goes back to lower levels, reactivating the acid barrier to pathogens. In this way the regenerated mucosa restores its physiological functionality that it had lost over the years.

Not only cure but prevention! Thanks to the treatment ***MonaLisa Touch***® it is possible to slow down the aging process, while preserving the functionality of the vaginal mucosa. A simple and safe way for all women who want to regain the intimate part of their femininity.

MONALISA TOUCH®: TOTAL TISSUE REGENERATION

The full-angle probe emitting the laser energy in a 360 angle in one time. Faster and less invasive treatments are now possible even for the more severe atrophies.



Vaginal mucosal histological preparations stained with haematoxylin and eosin (H&E). The effect produced by a D-Pulse on the epithelium is a superficial vaporization and the formation of a band of denatured collagen. Below this area, laser stimulation produces a controlled temperature gradient which induces the activation of a specific Heat Shock Protein (HSP47) capable of promoting the synthesis of new collagen fibroblasts.

The simple and intuitive **SmartXide Touch** interface allows quick access to all functions. Its large LCD Touch Screen makes it easy to select the operating parameters.

Since the introduction of fractional CO_2 laser technology, DEKA V²LR procedure has given a new boost to the development of genital mucosa treatments.

The Missing Solution to Postpartum Intimate Problems

Postpartum sexuality is an important aspect of women's health. Many women commonly experience postpartum sexual problems such as dyspareunia due to lactational atrophic vaginitis or following perineal trauma. Consequently, painful sexual intercourse is the most common sexual problem for puerperae and represents both a physical and psychological problem for many women and their partners. In these situations, an early and sensitive management is crucial in preventing long-term problems. Today, thanks to the capabilities of ***MonaLisa Touch***® to stimulate tissue regeneration, it is now possible to resolve these situations delicately and safely. The treatment acts gently by stimulating collagen production, improving the functionality of the treated area and restoring the proper trophic balance of the mucous membranes.

Non-Surgical Tightening for Vaginal Laxity

Stretching of the vagina and introitus can occur from vaginal delivery or to be part of natural ageing process. Vaginal laxity may be a bothersome condition to patients that may impact on "happiness and sexual function". Thanks to the effective action of the D-Pulse, ***MonaLisa Touch***® improves and replaces also the most common techniques for treating vaginal relaxation due to a loss of tone of vaginal mucosa. When inserted in the vagina by using the special probe of the HiScan V²LR scanning system, the laser acts directly on the mucosa of the walls, tightening, reshaping, toning and stimulating tissue and regenerating collagen.

Stress Urinary Incontinence

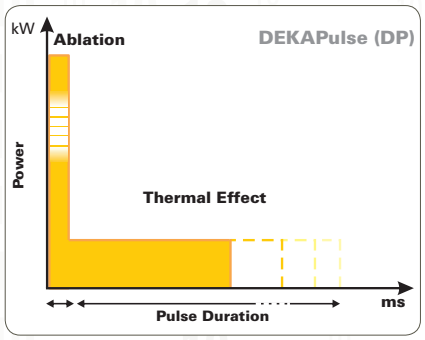
Recent studies show that ***MonaLisa Touch***® is largely effective in treating one of the most embarrassing symptoms that seriously affect many women after childbirth or in menopause: **mild urinary incontinence**. The beneficial stimulation of vaginal tissues, due to the DEKA-pulse CO_2 laser emission, re-establish the proper functionality of urogenital involved structures. This allows restoration of correct urinary continence, with a dramatic positive improvement in the quality of life, both physically and psychologically.

VULVO-VAGINAL V²LR COSMETIC AND FUNCTIONAL SURGERY: UNMATCHED TECHNIQUE AND PERFORMANCE

Reduction labiaplasty, vaginal reshaping or clitoral unhooding performed with **SmartXide Touch** offers better results and safer procedures than a scalpel. In fact, laser coagulates, minimizes scarring and swelling, reduces the patient's post-op discomfort, and increases the firmness and elasticity of the mucosa while stimulating collagen production.

SmartXide Touch

D-PULSE: THE PERFECT PULSE FOR V²LR. UNIQUE, SAFE, MINIMALLY INVASIVE, PAINLESS AND EFFECTIVE



D-Pulse: the pulse specifically developed by DEKA for ***MonaLisa Touch***® and V²LR.

DEKA developed **SmartXide Touch**, capable of supplying energy with the dedicated pulse shape called **D-Pulse** or **DEKA-Pulse** that takes into account the peculiarities of vaginal mucosa.

The **D-Pulse** consists of:

- an initial part with constant and high peak power for rapid and painless superficial removal of the epithelial component of atrophic mucosa characterized by low water content;
- a second variable part, with lower peak power and longer emission times, that allows the laser energy to penetrate in the mucosa and stimulate it properly in-depth.

The result is the structural improvements needed to restore the trophism and full functionality of the supporting structures of the vaginal walls.

With ***MonaLisa Touch***® the combined use of **D-Pulse** and DEKA fractional DOT Therapy guarantees durable results and unrivalled advantages:

Safe. With DOT Therapy the laser energy is distributed in small spots (called DOTs) of 200 microns separated from each other by healthy tissue. This is important to achieve the right mechanisms of regeneration without side effects.

Minimally Invasive. **D-Pulse** allows the right CO_2 laser penetration in the connective tissue. The penetration is beyond the epithelium for activation of the regeneration, without any risk to all the surrounding tissues and organs.

Painless. The ***MonaLisa Touch***® procedure is absolutely painless inside the vagina (no anaesthesia) and well tolerated on vulva. The treatment takes only a few minutes of application to get an important and deep stimulation.

Unique. ***MonaLisa Touch***® is a DEKA trademark. The first and only laser procedure to be used for reducing vaginal atrophy and laxity.

Effective. ***MonaLisa Touch***® is the sole treatment demonstrated not only with clinical results, but also by histological and ultrastructural detailed studies.

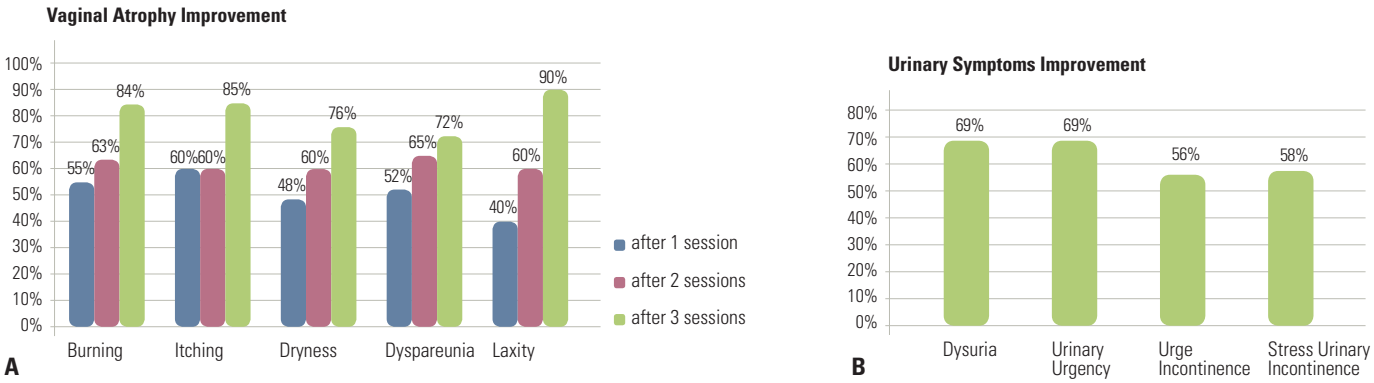
Vulva appearance immediately after ***MonaLisa Touch***® treatment. Observe the DOTs on the mucosa without any reddening or bleeding. *[Courtesy of M. Filippini, M.D. and M. Farinelli, M.D. San Marino State Hospital, San Marino]*

The full range of available probes for HiScan V²LR. Simply changing the probe, the scanner can be easily adapted to all patient's needs.

MONALISA TOUCH®: SPECIAL PROBES FOR A SPECIAL PROCEDURE

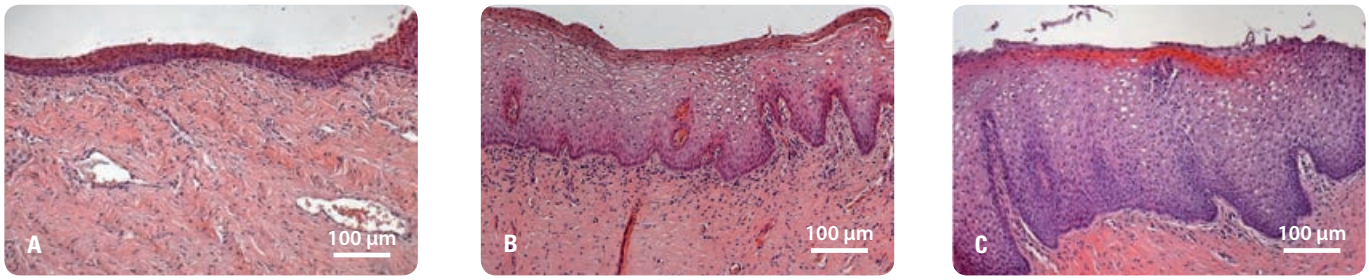
MonaLisa Touch® requires a special scanner system to deliver the fractioned laser energy on the vaginal mucosa. A wide range of autoclavable probes is available to perform the procedure depending on the specific patient needs:

- full-angle probe, useful even for the most atrophic vaginas. The CO_2 laser DOTs are distributed in a 360° angle frame thanks to the exclusive pyramidal mirror assembly;
- single-angle probes for urinary incontinence. In choosing from among different shapes and sections make it suitable for treatment of various introitus of vaginas;
- vulvar probe for DOT Therapy of external genitalia.



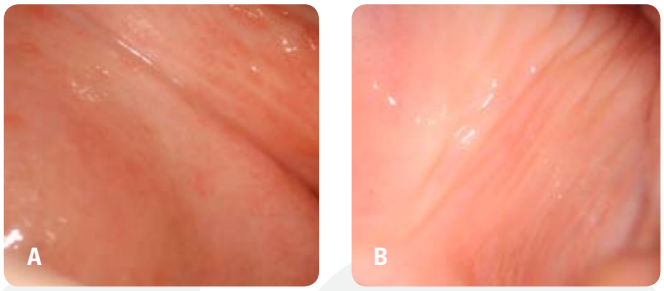
The graphs show the improvement (%) for the main symptoms of vaginal atrophy (**A**) and urinary incontinence (**B**) after 3 ***MonaLisa Touch***® sessions. The study was carried out at the Department of Gynaecology of the San Raffaele Hospital on patients with symptoms of uro-genital atrophy. *[Courtesy of S. Salvatore, M.D. - IRCCS San Raffaele Hospital. Milan, Italy]*

MONALISA TOUCH®: HISTOLOGICAL STUDY

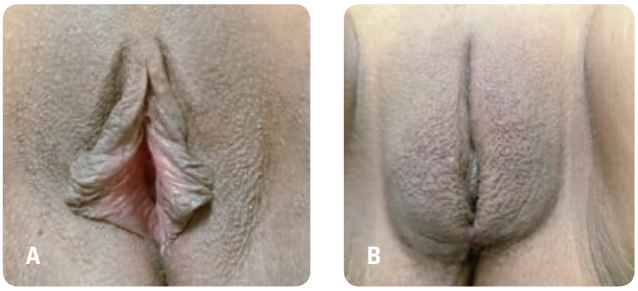


Histological preparation of vaginal mucosa section stained with haematoxylin and eosin (H&E). (**A**): Basal condition. The morphology indicates an advanced stage vaginal atrophy with the epithelium formed by few cell layers and no papillae. (**B**) & (**C**): The same patient one month after the 1st session (**B**) and after the 2nd session (**C**) with ***MonaLisa Touch***® treatment. The much thicker epithelium and the larger diameter of epithelial cells rich in glycogen, demonstrate the restored metabolic trophism and dynamics of the whole epithelium. *[Courtesy of Prof. A. Calligaro. University of Pavia, Italy]*

CLINICAL CASES



Colposcopic images of vaginal mucosa: (**A**) atrophic thin epithelium with petechiae, lack of vaginal rugae and muco; (**B**) the same patient 30 days after 1 ***MonaLisa Touch***® treatment. The mucosa aspect is typical of a premenopausal healthy epithelium with natural pink colour, no petechiae, evidence of vaginal rugae and mucous lubrication. *[Courtesy of MG. Fallani M.D.; A. Pieralli M.D.; Prof. S. Guaschino, M.D.; Prof. C. Penna, M.D. Careggi University Hospital. Florence, Italy]*



Left labia minora hypertrophy. (**A**) Asymmetrical condition before laser labioplasty. (**B**) Picture showing post-op 10 days after the surgery. *[Courtesy of P. González Isaza, M.D. - Pereira, Colombia]*

Scientific Bibliography Selection

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3. **Is vaginal fractional CO_2 laser treatment effective in improving overactive bladder symptoms in post-menopausal patients? Preliminary results.** A. Perino et al. Eur Rev Med Pharmacol Sci 2016 Jun; 20(12):2491-7.
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8. **A 12-week treatment with fractional CO_2 laser for vulvovaginal atrophy: a pilot study.** S. Salvatore et al. Climacteric Aug 2014; Vol. 17, No. 4:363-369. Epub 2014 Jun 5.

TECHNICAL DATA

Smartxide Touch - Suggested Configurations in V²LR	
Laser Type	CO_2 RF - PSD®
Wavelength	10.6 µm
Emission Beam	TEM_{00}
Emission Modes	CW - SP - DP - HP - UP
CW Power	From 0.5 to 60 W
SP Power	From 0.1 to 15 W
DP Power	From 0.2 to 15 W
HP Power	From 0.1 to 8 W
UP Power	From 0.5 to 60 W
Emission Time	From 0.01 to 0.9 s
Delay Emission Time	From 0.3 to 5 s
Beam Delivery	7 Mirrors articulated arm.
Aiming Beam	Laser diode @ 635 nm - 4 mW - Adjustable intensity from 2% to 100%. Aiming light OFF or Diode Off While Lasing (DOWL).
Internal Database	About 150 factory stored protocols, upgradable by USB. Possibility of storing unlimited number of custom user's protocols.
Control Panel	Wide LCD Colour Touch Screen (8.4")
Accessories*	HiScan V²LR Scanner System. Wide range of surgical handpieces.
Electrical Requirements	From 100 to 230 Vac (automatic selection). 1,200 VA - 50/60 Hz.
Dimensions and Weight**	118 (H) x 42 (W) x 54 (D) cm - 62 kg.

HiScan V²LR Scanner System	
Max Scanning Area	Square 8 x 8 mm (for single-angle and vulvar probes)
Dwell Time	From 100 to 2,000 µs
DOT Spacing	From 0 to 2,000 µm
SmartStack Level	From 1 to 5
Scanning Methods	Normal, Interlaced, SmartTrack.
Emission Modes	SP - DP - HP
Accessories	Vaginal Probes: 360° full-angle, 90° single-angle "closed" (optional), 90° single-angle "open" (optional). Vulvar Probe.

* In this catalogue only the technical features of the V²LR (Vulvo-Vaginal Laser Reshaping) applications are listed.
** Height with folded articulated arm

This brochure is not intended for the market of USA.

Atrophic Vaginitis - Vaginal Laxity - Stress Urinary Incontinence - Postpartum Perineal Trauma Genital Functional and Cosmetic Laser Surgery

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SmartXIDE Touch

Dealer stamp

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DEKA The Code of Excellence

A spin-off of the El.En. Group, DEKA is a world-class leader in the design and manufacture of lasers and light sources for applications in the medical field. DEKA markets its devices in more than 80 countries throughout an extensive network of international distributors as well as direct offices in Italy, France, Germany, Japan and USA. Excellence is the hallmark of DEKA's experience and recognition garnered in the sphere of R&D in over thirty years of activity. Quality, innovation and technological excellence place DEKA and its products in a unique and distinguished position in the global arena. DEKA manufactures laser devices in compliance with the specifications of Directive 93/42/EEC and its quality assurance system, certified by , is in accordance with the ISO 9001 and ISO 13485 standards.