V²LR (Vulvo Vaginal Laser Reshaping)

SmartXide Touch

SMARTXIDE TOUCH

The New Era of Vaginal Rejuvenation

Advanced CO_2 Laser System.

- Genitourinary Syndrome of Menopause
- Vaginal Laxity
- Stress Urinary Incontinence
- Vulvar Lichen Sclerosus
- Vestibulodynia
- Postpartum Perineal Trauma
- Genital Functional and Cosmetic Laser Surgery

All it takes is a touch

MonaLisa Touch®

DEKA
The Code of Excellence

SmartXide Touch

MONALISA TOUCH®: THE REVOLUTIONARY NON-SURGICAL APPROACH TO GYNAECOLOGICAL HEALTH

MonaLisa Touch® is the best-known and most widespread laser procedure designed to treat vulvovaginal conditions. Issues related to gynaecological health are commonly seen in millions of postmenopausal women, breast cancer survivors and hysterectomized women. ***MonaLisa Touch***® provides a unique solution for all women experiencing post-menopausal symptoms, without any of the adverse side effects caused by drug-based therapies.

*"I feel that the **MonaLisa Touch**® procedure is a game changing technology. It is truly remarkable that such a simple minimally invasive office procedure can be so effective in treating a variety of skin conditions of the vagina and vulva. The success we have seen with this therapy has far exceeded our expectations, with almost all women noting significant improvement or even a complete cure of their condition."*

Mickey Karram, MD
Director of Fellowship Program on Female Pelvic Medicine & Reconstructive Surgery,
The Christ Hospital, Cincinnati - OH (USA)

*"**MonaLisa Touch**® is certainly the procedure that has the best evidence in medical literature, showing how safe and how good it is. Other lasers still have to produce that evidence and each single laser is completely different from the other, so we cannot actually say that all CO_2 lasers produce the same effects with the same safety."*

Stefano Salvatore, MD
Head of the Urogynaecology Department,
San Raffaele Hospital and Vita Salute University, Milan - Italy

*"I found that **MonaLisa Touch**® has a beneficial effect on the vaginal microenvironment in women with symptoms of GSM. This laser therapy restores the vaginal equilibrium to a healthier status, as would normally be expected if estrogen levels were sufficient. The more acidic pH of vaginal fluid, achieved after **SmartXide Touch** therapy, could protect postmenopausal women from vaginal infections, inflammation and possibly from UTIs."*

Stavros Athanasiou, MD, MRCOG
Associate Professor of Urogynaecology
Urogynaecology Unit, 1st Dept. of Obstetrics and Gynaecology, "Alexandra" Hospital
National and Kapodistrian University of Athens, Athens - Greece

*"My studies demonstrated that the uniquely delivered DEKA CO_2 laser is capable of treating lichen sclerosus effectively. **MonaLisa Touch**® procedure represents a significant divergence from steroid- and corticosteroid-bulwark dependence and their expected serious side effects."*

Michael S. Baggish, MD, FACS, FACOG
St. Helena Hospital, St. Helena - CA (USA)
Dept. of Obstetrics and Gynecology, University of California, San Francisco - CA (USA)

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 the ***MonaLisa Touch***® procedure and cosmetic/functional female genital surgery. To perform these innovative procedures, DEKA has designed a new radiofrequency CO_2 laser, featuring proprietary **PSD**® (Pulse Shape Design) technology. This generates the only pulse specifically developed for treating genital mucosa: **D-Pulse** or **DEKAPulse**.

Why choose ***MonaLisa Touch***®:

- *Effective.* The sole procedure demonstrated by clinical, histological and ultrastructural studies published in the international peer-reviewed literature.
- *Simple.* In-office non-surgical procedure, 5-minute treatments; the ergonomic scanner and probes make it easy to perform.
- *Safe.* Virtually side effect-free. Minimally invasive. Thousands of women successfully treated since 2009.
- *Painless*. Requiring no anaesthesia inside the vagina. Very short downtime.
- *Immediate*. Symptom relief after just 1 treatment, even greater improvement after treatments 2 and 3.
- *Non-hormonal therapy*. Suitable for patients who cannot, or prefer not to receive oestrogen therapy.
- *Cheaper* than alternatives involving tablets or creams that need to be taken/applied every day for months and that only focus on symptoms rather than address the causes.

PLUS

2009	DEKA was the first company to apply DOT Therapy to vulvovaginal treatments.
2012	In conjunction with Italian centres of excellence, DEKA presented amazing clinical and histological results achieved with the revolutionary ***MonaLisa Touch***® treatment.
PSD® Technology	The exclusive Pulse Shape Design technology assures maximum pulse shape flexibility: S-Pulse, D-Pulse, H-Pulse, U-Pulse and CW mode make SmartXide Touch the most effective and versatile laser system.
D-Pulse	The exclusive pulse shape specifically developed for treating vaginal mucosa.
Peer-reviewed studies	Clinical assessments of ***MonaLisa Touch***® have been published worldwide in the peer-reviewed literature. In just two and a half years, over 20 international publications have confirmed the great efficacy and safety of this outstanding procedure.
HiScan V²LR	DEKA's exclusive scanning system, specifically designed for V²LR. Different probes are available for specific treatments and conditions.
Multimedia & Database	Integrated photos, video tutorial and protocols developed for V²LR, Gynaecology as well as various fields of medical applications.

SmartXide Touch

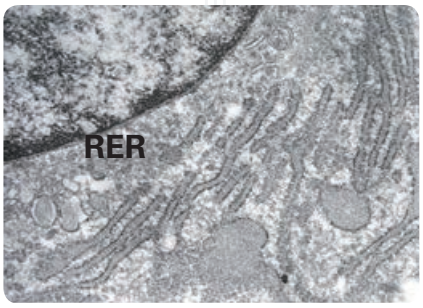
CHANGES THAT CAN AFFECT QUALITY OF LIFE

The full-angle probe emits 360° laser energy with one application. There are faster and less invasive treatments for more severe atrophies.

Menopause, whether natural or induced, determines a range of changes caused by lower levels of circulating oestrogen in a woman's body. **Genitourinary syndrome of menopause** (GSM), previously known as vulvovaginal atrophy (VVA), affects quality of life and sexual function in up to 50% of postmenopausal women.

GSM is characterized by atrophy of vaginal and vulvar tissues. Common manifestations include reduced lubrication and symptoms of itching, burning, dryness, irritation, dysuria and dyspareunia. The vagina is less nourished and increasingly prone to trauma, tearing, bleeding and pain as the mucosa thins and becomes more fragile. The prevalence of urogenital infection may also rise as vaginal secretions become more alkaline, altering the character of the vaginal flora.

The most recent consensus statement includes GSM as a cause of vulvar pain (**vulvodynia**). Finally, vulvar lichen sclerosus also commonly affects postmenopausal women.

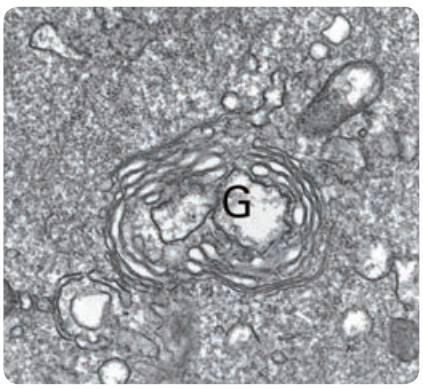


Electron microscope image inside a vaginal mucosa fibroblast after ***MonaLisa Touch***® treatment. The Rough Endoplasmic Reticulum (***RER***) is well-developed, with many ribosomes attached to the membranes of flattened cisternae. Some of these cisternae develop vesicles with filamentous structures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

MONALISA TOUCH®: THE ONLY IN-DEPTH VALIDATED LASER THERAPY FOR WOMEN'S INTIMATE WELL-BEING

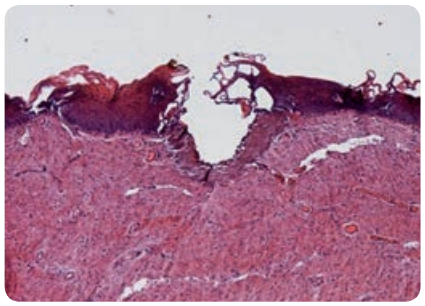
During menopause, fibroblasts in the vaginal mucosa slow down and can no longer produce enough collagen and other molecules to maintain the extracellular matrix structure, needed for good connective tissue hydration. ***MonaLisa Touch***®, using DEKA's unique CO_2 lasers, is the only procedure proven to be absolutely safe and effective in restoring atrophic vaginal mucosa, stopping ageing and inducing true vaginal rejuvenation. A detailed **histological and ultrastructural investigation** (*Zerbinati et al., Lasers Med Sci 2014; Salvatore et al., Menopause 2014*) has demonstrated all these 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, boosting thickness of connective tissue and epithelium. The result is improved nourishment, tonicity, elasticity and firmness, similar to when the patient was younger. Restabilizing the natural turnover of epithelial cells restores the natural conditions in which lactobacilli flourish; pH returns to lower levels, reactivating the acid barrier to pathogens. The regenerated mucosa can thus restore the physiological functionality it had lost over the years, returning to its pre-menopausal condition, just as it would after oestrogen hormone-replacement therapy.

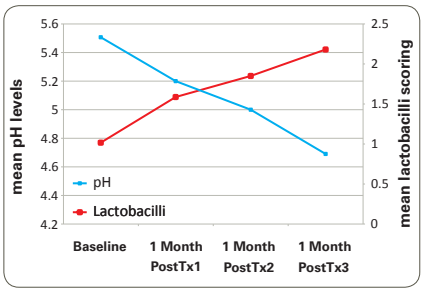


Electron microscope image inside a vaginal mucosa fibroblast after ***MonaLisa Touch***® treatment. The Golgi apparatus (***G***) is particularly well-developed. We can observe vesicles containing components forming a ground matrix.

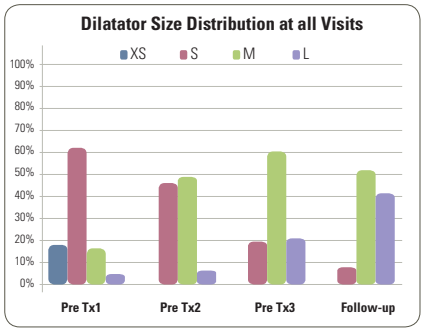
MONALISA TOUCH®: PROVEN TOTAL TISSUE REGENERATION



H&E vaginal mucosa histological image. The D-Pulse produces a superficial vaporization on the epithelium forming a layer of denatured collagen. Below this layer, laser stimulation produces a controlled temperature gradient which activates HSP47, a protein specific for synthesising new collagen fibroblasts.



Decrease in the mean vaginal pH levels and increase in the growth of lactobacilli at baseline and after subsequent treatments (*Athanasiou et al., Climacteric 2016*).



Distribution of dilator size data shown as percentages of women able to accept an XS, S, M, or L vaginal dilator at each of four time points: before treatments 1, 2, and 3 as well as 3-month follow up (*Sokol et al., Menopause 2016*). At 1-year time point 73.3% of women were comfortable with a dilatator size larger than that one accepted at 3-month follow up; 21% were comfortable with the same dilatator size (*Sokol et al., Menopause 2017*).

Since its introduction, ***MonaLisa Touch®*** has given a new boost to the development of genital mucosa treatments. The international peer-reviewed literature confirmed that it is feasible, safe, and effective for the treatment of **GSM symptoms**, improving patient's sexual health and quality of life. Perino et al. (*Eur Rev Med Pharmacol Sci 2016)* and Gonzalez et al. *(Int Urogynecol J 2017)* underline the efficacy of this new approach not only on VVA but also for related **stress urinary incontinence** management. Stimulation of vaginal tissues using the D-Pulse CO_2 laser restores urinary continence, with a dramatic improvement in quality of life, at both physical and psychological level.

Women suffering from **hormone-dependent cancers** are affected by therapy-induced menopause symptoms, such as VVA. Pieralli et al. (*Arch Gynecol Obstet 2016*) and Pagano et al. (*Menopause 2016*) focused their attention on these patients, in whom hormone-replacement therapy is strongly contraindicated. Their results show that ***MonaLisa Touch®*** is safe, well-tolerated and effective.

Murrina et al. (*J Sex Med 2016*) evaluated the effectiveness and safety of the DEKA CO_2 laser for the vulvar vestibule in the management of patients presenting idiopathic vulvar pain (**vestibulodynia**). They reported a statistically significant improvement in more than 67% of patients.

Dr M.S. Baggish (*J Gynecol Surg 2016*) investigated ***MonaLisa Touch®*** for the treatment of vulvar **lichen sclerosus**. Again, results were extremely positive and provided indisputable evidence of amelioration in symptoms such as pruritus.

The Missing Solution to Postpartum Sexual Problems

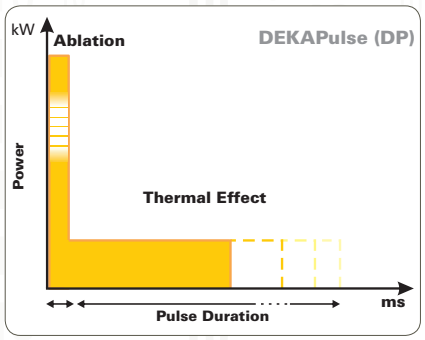
Many women experience postpartum sexual pain due to lactational atrophic vaginitis or following perineal trauma. These life-altering conditions can lead to both physical and psychological problems. Early, sensitive management is crucial in preventing long-term complications. ***MonaLisa Touch®*** helps solve these situations delicately and safely. The treatment acts gently, improving the functionality of the treated area and restoring proper trophic balance to the mucous membranes.

Non-Surgical Tightening for Vaginal Laxity

Stretching of the vagina and introitus can occur from vaginal delivery or may be part of the natural ageing process. Vaginal laxity is a bothersome condition that may impact sexual function. ***MonaLisa Touch®*** acts on the vaginal mucosa, improving its elasticity (*Sokol et al., Menopause 2016; Sokol et al., Menopause 2017*) and pelvic floor support (*van Raatle et al., IUGA Meeting 2016*). The **SmartXideTouch** laser acts directly on the mucosal walls, tightening, reshaping, toning and stimulating tissue and regenerating collagen.

SmartXide Touch

D-PULSE: THE ONLY LASER SPECIFICALLY CONCEIVED FOR THE VULVOVAGINAL MUCOSA



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

Vaginal mucosa and skin differ significantly in epithelium structure. The outer skin layer has plenty of keratin and little water, while mucosal epithelium is nonkeratinized, containing water and glycogen. Due to their different levels of hydration, the CO_2 laser (highly absorbed by water) has different effects on skin and on mucosa. It follows that in order to stimulate these two tissues in depth, two different barriers have to be overcome. Therefore, a laser conceived for skin rejuvenation does not have the same efficacy on mucosa. This led DEKA to develop a special pulse shape, known as the **D-Pulse** or **DEKA-Pulse**, designed specifically for the vaginal mucosa.

The **D-Pulse** consists of:

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

The result is the right CO_2 laser penetration beyond the epithelium, and into the connective tissue, activating mucosa regeneration without any risk to surrounding tissues and organs. This is the only way to achieve the structural improvements needed to restore nourishment and full functionality to the supporting structures of the vaginal walls.

Only the combined use of **D-Pulse** and fractional DOT Therapy guarantees durable results like no other!

Vaginal appearance immediately after treatment with ***MonaLisa Touch***®. Observe the mucosa without any reddening or bleeding. *[Filippini et al., Photomed Laser Surg 2017]*

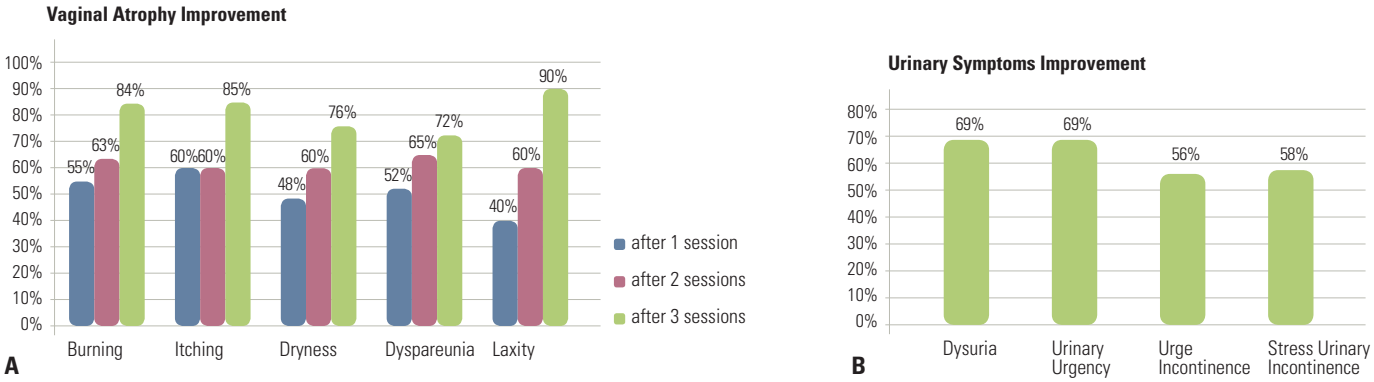
VULVOVAGINAL COSMETIC AND FUNCTIONAL SURGERY: UNMATCHED TECHNIQUE AND PERFORMANCE

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

Simply by changing the probe, the Hi-Scan V²LR scanner can be easily adapted to all patients' needs.

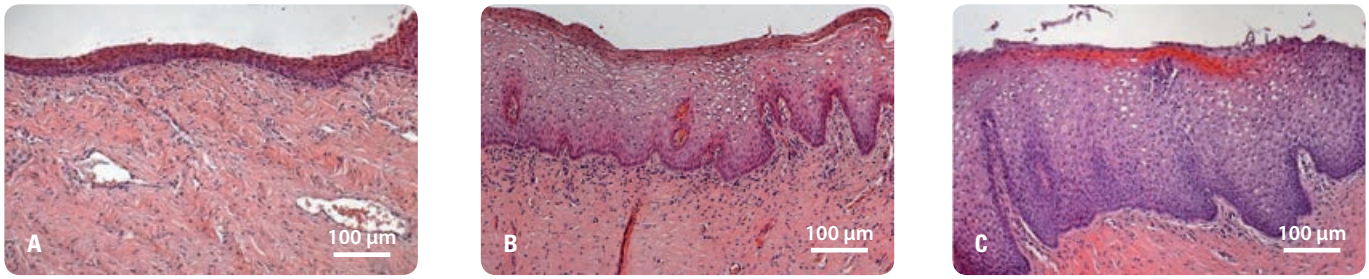
MONALISA TOUCH®: SPECIAL PROBES FOR A SPECIAL PROCEDURE

MonaLisa Touch® requires the Hi-Scan V²LR scanner system to deliver fractionated laser energy to the vaginal mucosa. A wide range of autoclavable probes are available to perform the procedure, depending on the patient's specific needs.



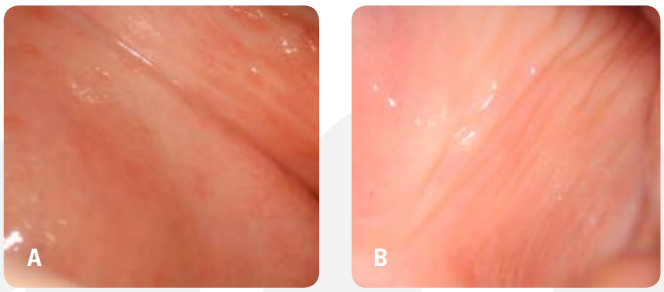
The graphs show the improvement (%) in the main symptoms of vaginal atrophy (**A**) and urinary incontinence (**B**) after 3 ***MonaLisa Touch***® sessions. The study was carried out at the San Raffaele Hospital Department of Gynaecology on patients with GSM symptoms. *[Courtesy of S. Salvatore, M.D.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

MONALISA TOUCH®: HISTOLOGICAL STUDY

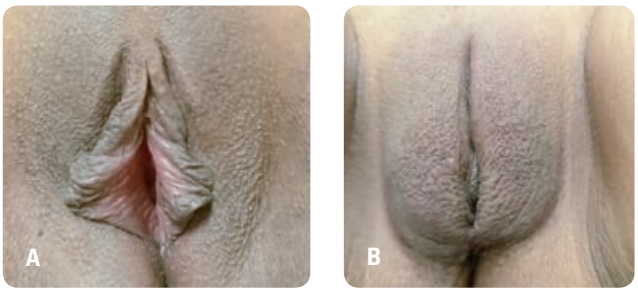


Histological preparation of vaginal mucosa section stained with haematoxylin and eosin (H&E). (**A**): Basal condition. The morphology indicates an advanced stage vaginal atrophy with the epithelium formed by few cell layers and no papillae. (**B**) & (**C**): The same patient one month after the 1st 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]*

For detailed literature references, please ask for the "*MonaLisa Touch® International Scientific Community Recognition*" booklet.

For more in-depth information on the ***MonaLisa Touch***® procedure, please ask for the dossier "*MonaLisa Touch®. The Game Changing Laser Therapy for Vulvovaginal Health*" and visit the website at www.monalisatouch.com.

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 0.1 to 5 s
Beam Delivery	7 Mirrors articulated arm.
Aiming Beam	Laser diode @ 635 nm - 4 mW - Adjustable intensity from 1% to 100%. 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

CAUTION

Visible and invisible laser radiation.
Avoid eye or skin exposure to direct or scattered radiation.
Class 4 laser product.

This brochure is not intended for the market of USA.

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Stress Urinary Incontinence - Vulvar Lichen Sclerosus
Vestibulodynia - Postpartum Perineal Trauma
Genital Functional and Cosmetic Laser Surgery

CE 0123

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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 is in accordance with the ISO 9001 and ISO 13485 standards.