



IA

INNATE ABILITY

MonaLisa Touch[®]

SMARTXIDE²

Advanced CO₂ Laser
for Vulvo-Vaginal Health

• **MonaLisa Touch[®] Procedure
for the Treatment of:**

- Genitourinary Syndrome of Menopause
 - Vaginal Dryness
 - Dyspareunia
 - Vestibulodynia
 - Itching
 - Mild Mixed Urinary Incontinence
- Postpartum Hypoestrogenism Symptoms

• **Genital Functional and Aesthetic Laser Surgery**

• **Treatment of Vaginal Laxity and
Mild Stress Urinary Incontinence
with the New RF Touch Handpiece**

DEKA
Innate Ability

All it takes
is a touch!



SmartXide²

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, M.D.

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 CO₂ lasers produce the same effects with the same safety. ”

Stefano Salvatore, M.D.

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



A Minimally Invasive Technology that Enhances Quality of Life

SmartXide² 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 CO₂ laser source, featuring proprietary **PSD[®]** (Pulse Shape Design) technology. This generates the only pulse specifically developed for treating genital mucosa: **D-Pulse** or **DEKAPulse**.

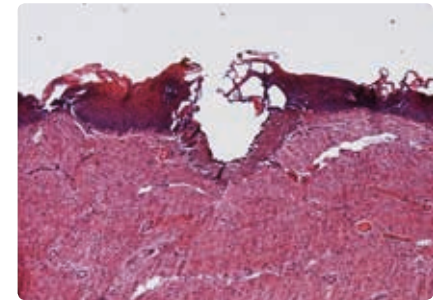
Why choose **MonaLisa Touch[®]** :

- *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 alternative methods that need to be used every day for months and that only focus on symptoms rather than address the causes.



SmartXide² PLUS

2009	DEKA was the first company to apply DOT Therapy to vulvo-vaginal 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 ² 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 few years, over 40 international publications have confirmed the great efficacy and safety of this outstanding procedure.
HiScan V²LR	DEKA's exclusive scanning system, specifically designed for V ² LR. Different probes are available for specific treatments and conditions.
RF Touch	The new single-use radiofrequency handpiece completes the DEKA offer for the vaginal health treatment, thanks to a perfect synergy between CO ₂ laser and RF in a single device!
Multimedia & Database	Integrated photos, video tutorial and protocols developed for V ² LR, Gynaecology as well as various fields of medical applications.



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.



The Only In-Depth Validated Laser Therapy for Women's Intimate Well-Being

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.

MonaLisa Touch® : Proven Total Tissue Regeneration

During menopause, fibroblasts in the vaginal mucosa slow down the production of collagen and other molecules needed for good connective tissue hydration. A detailed **histological and ultrastructural investigation** (Zerbinati et al., *Lasers Med Sci* 2014; Salvatore et al., *Menopause* 2014) has demonstrated that **MonaLisa Touch®** is absolutely safe and effective in restoring the physiological functionality of atrophic vaginal mucosa, stopping ageing, inducing true vaginal tissue restoration and returning to its pre-menopausal condition, just as it would after oestrogen hormone-replacement therapy.



effectiveness



safety



scientific recognition



speed

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. On June 2014, the first scientific peer-to-peer reviewed article on the **MonaLisa Touch®** procedure was published (Salvatore et al. *Climacteric* 2014). That first publication was followed by more than 40 scientific papers published in international journals around the world (for detailed literature references, ask for the "**MonaLisa Touch® International Scientific Community Recognition**" booklet). Many studies have been performed to confirm those initial data and to assess the long-term effects of the laser procedure on vaginal tissues (Sokol et al. *Menopause* 2017; Pieralli et al. *Arch Gynecol Obstet* 2017; Athanasiou et al. *Menopause* 2018).

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 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), Pagano et al. (*Menopause* 2016), Becorpi et al. (*Lasers Med Sci* 2018) and Gittens et al. (*J Cosmet Laser Ther* 2018) 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 CO₂ 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 sclerosis. Again, results were extremely positive and provided indisputable evidence of amelioration in symptoms such as pruritus.

Today, after thousands of CO₂ laser systems sold and hundreds of thousands of patients treated worldwide, **MonaLisa Touch®** is the only system that can boast such in-depth scientific research and such extensive casuistry.





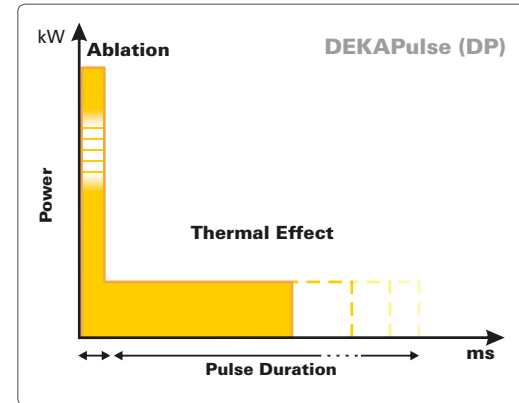
D-Pulse: the Only Laser Pulse Conceived for the Vulvo-Vaginal Mucosa

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 CO₂ 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 CO₂ 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]

Special Probes for a Special Procedure

MonaLisa Touch[®] requires the HiScan V²LR scanner system to deliver fractionated laser energy to the vaginal mucosa. A wide range of autoclavable probes are available to perform the procedure. It is now also available the single-use version of the 360° probe. Simply by changing the probe, the HiScan V²LR scanner can be easily adapted to all patients' needs.





CO₂ and RF: The Game Changing Synergy for Vulvo-Vaginal Health

RF Touch: Treatments Evolving Rapidly

The use of radiofrequency for tissue tightening is widespread in both dermatology (eg. the DOT/RF Therapy by DEKA) and in gynaecology. To be able to make the most of this radiation, it is important to understand its characteristics fully. Radiofrequency can only penetrate deeply into tissues, such as the vaginal mucosa, if these are perfectly hydrated.

The presence of water in the tissue favours the passage of the radiofrequency, producing heat in the deep connective tissue and thus stimulating tightening, toning and regeneration of new collagen. An atrophic or imperfectly hydrated mucosa is therefore not recommended for RF treatment, as it would not allow a correct passage of the RF, thwarting the therapeutic effect.

DEKA has introduced the new single-use RF Touch handpiece, with a bipolar (and therefore intrinsically safer) radio-frequency source directly connected to the laser device, providing a unique market possibility to offer a synergistic treatment for the intimate health of patients.

The sessions with ***MonaLisa Touch***[®] (which vary in number depending on the vaginal mucosal conditions) prepare the tissue, rendering it more hydrated and thus likely to respond more effectively and safely to the RF treatment.

The Missing Solution to Postpartum Intimate Problems

Many women experience postpartum sexual pain due to lactational atrophic vaginitis, following perineal trauma or for the vaginal laxity due to the delivery. These life-altering conditions can lead to both physical and psychological problems. Early, sensitive management is crucial in preventing long-term complications.

MonaLisa Touch[®], in synergy with the radiofrequency handpiece RF 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.

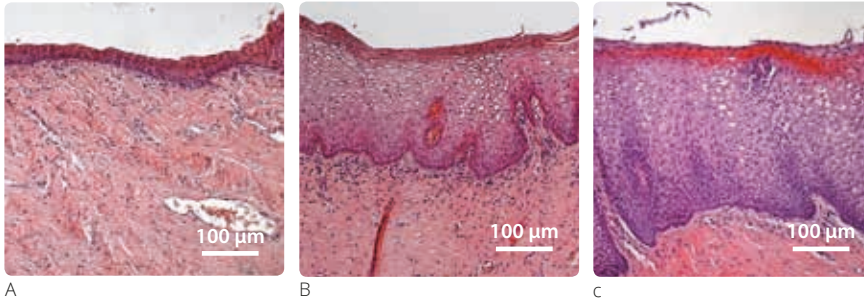
For more in-depth information on the *MonaLisa Touch*[®] procedure, please ask for the dossier "*MonaLisa Touch*[®]. The Game Changing Laser Therapy for Vulvovaginal Health" and visit the website at www.monalisatouch.com.



The new single-use radiofrequency handpiece RF Touch.



Histological & Clinical Study

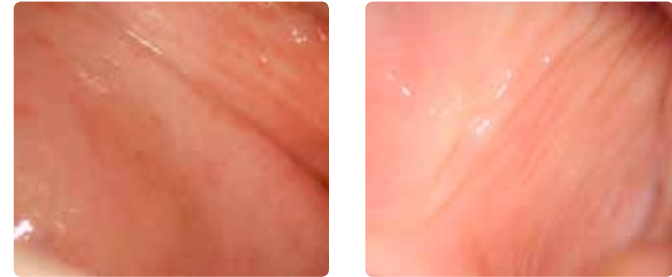


A

B

C

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].



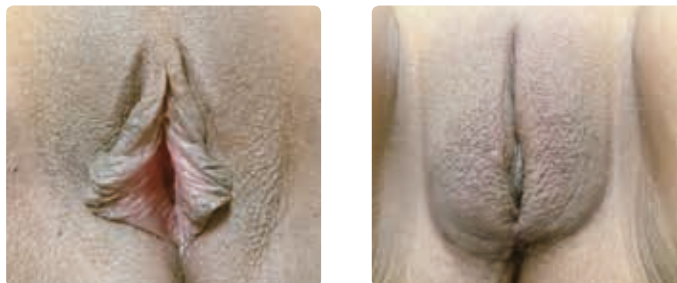
A

B

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].

Vulvo-Vaginal Aesthetic and Functional Surgery: Unmatched Technique and Performance

Reduction labiaplasty, surgical vaginal reshaping or clitoral unhooding performed with SmartXide² 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.



A

B

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

Technical Data

SmartXide² - Suggested Configurations in V²LR*

Models*	C40	C60	C80
Laser Type & Wavelength	CO ₂ RF - PSD® emitting at 10.6 µm with emission beam mode TEM ₀₀		
Emission Modes	CW - SP - DP - HP		CW - SP - DP - HP - UP
Power	CW: 0.5 - 40 W; SP: 0.1 - 12 W; DP: 0.2 - 12 W; HP: 0.1 - 4 W; UP: N/A	CW: 0.5 - 60 W; SP: 0.1 - 15 W; DP: 0.2 - 15 W; HP: 0.1 - 8 W; UP: 0.5 - 60 W	CW: 0.5 - 70 W; SP: 0.1 - 15 W; DP: 0.2 - 15 W; HP: 0.1 - 15 W; UP: 0.5 - 80 W
Emission Time & Delay	Emission Time: 0.01 - 0.9 s. Delay: 0.1 - 5 s		
Beam Delivery	7 Mirrors articulated arm with counterweight.		
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 (10.4")		
Accessories*	HiScan V ² LR Scanner System. Wide range of surgical handpieces.		
Electrical Requirements	From 100 to 120 Vac - 50/60 Hz From 220 to 230 Vac - 50 Hz - 1,600 VA		
Dimensions** and Weight	162 (H) x 59 (W) x 56 (D) cm - 95 Kg - 63.8" (H) x 23.2" (W) x 22.0" (D) - 267 lb		

HiScan V²LR Scanner System

Max Scanning Area	Square 8 x 8 mm (for single-angle and vulvar probes)
Dwell Time & DOT Spacing	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 (optional). Vulvar Probe.

RF Touch Single-Use Handpiece

Source	Radiofrequency
Maximum output voltage	70 V _{rms}
Maximum output current	1A
Working frequency	500 kHz
Power	From 1 W to 50 W, step 1 W
RF Ton time	From 25 s to 30 min, step 5 s
Treatment activation	Controlled by footswitch
Neutral electrode	Not present

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

Please refer to the SmartXide² General Catalogue for the complete list of characteristics.

** Height with folded articulated arm. *** Not available for C40 model.

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.

DEKA
Innate Ability

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SmartXIDE²

Dealer stamp



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DEKA Innate Ability

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, Japan and USA. 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.

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