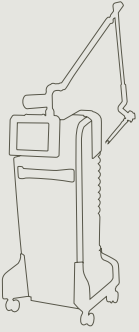


SURGERY - WOUND HEALING

SmartXide²



SMARTXIDE²

A New Light in Wound Healing Management

**Innovative CO₂ Laser Treatment*
for Debridement and Tissue
Regeneration Enhancement**

- Diabetic foot ulcers
- Venous leg ulcers
- Pressure ulcers
- Wound dehiscence

*Patent Pending



The Code of Excellence



DEKA REVOLUTION FOR ADVANCED WOUND HEALING AND CARE

Chronic wound care has become a top-priority issue for health systems worldwide. The expenditure for wound management has been rising in last years and will experience further growth, due to progressive ageing of population. It is estimated that about 7 million patients are affected by chronic wounds in U.S.A. alone, where US\$25 billion dollars are spent annually.

The continuous DEKA's innovation research has revolutionized the field of chronic wounds management thanks to **SmartXide²** surgical CO₂ laser. **SmartXide²** offers a great adjunctive treatment approach in wound therapy, particularly in difficult-to-heal cutaneous wounds, allowing clinicians to achieve unexpected results in wound closures as never before.

*"I've been using the DEKA CO₂ laser to treat skin ulcers and wounds for several years, and I regard myself as a pioneer in this field. Chronic wounds have an enormous impact on public health and a devastating one on patients' daily lives. The problem cuts across many medical disciplines. In fact, patients who come to my surgery present wounds with various etiology (vascular, pressure, traumatic, surgical, iatrogenic, etc.) that fail to respond to usual treatments, even protracted after years, or potentially difficult to heal due to the position, comorbidity or depth. Therefore, they require advanced and innovative treatments. The **SmartXide²** laser creates conditions for correct tissue reparation through ulcer debridement and needling. Patients are very satisfied, as the results are noticeable after just a few sessions, with a considerable reduction in pain both during and after the treatment".*

Carlo Mirabella, M.D.

*Department of Cellular Therapy and Transfusion Medicine
Careggi University Hospital, Florence - Italy*

*"I started using the laser for my toughest cases of chronic diabetic foot ulcers, which were usually infected and non-responsive to treatment. The **SmartXide²** system has proved really useful both for preparing the wound bed and for deep decontamination, facilitating the tissue-healing process with often surprising results. Indeed, in many cases I have found significantly quicker healing times as well as a better cosmetic outcome. The **EndoScan** scanning system enables me to perform extremely accurate, uniform treatment, for careful vaporization of fibrin in the ulcer bed even in complex situations that I would be unable to handle adequately with a scalpel. This instrument has not yet fully expressed its potential. New studies we are drawing up on exposed-bone lesions give us cause for great optimism for the near future, showing that **SmartXide²** may become the turning point for the treatment of diabetic foot".*

Matteo Monami, M.D.

*Diabetic Foot Unit Director - Diabetology Department
Careggi University Hospital, Florence - Italy*



H Version

SmartXide²



DEKA TECHNOLOGIES: BEYOND PROGRESS WITH SMARTXIDE² FOR WOUND HEALING

The role of lasers in medicine continues to evolve, as an increasing number of indications arise spanning in the medical treatment of chronic wounds.

The technological evolution and ongoing scientific research in DEKA laboratories have pushed the **SmartXide²** design beyond current boundaries, with a decisive impact on wound care management.

When employing laser therapy in chronic wounds, it is crucial to induce a 'cold injury' in the wound bed, using a pulsed CO₂ laser with high peak power and extremely short pulse duration. In this way the thermal damage on tissue is minimized while the haemostatic effect on blood vessels is effective. The development of innovative RF CO₂ laser source with the exclusive **PSD[®]** (*Pulse Shape Design*) technology allowed DEKA to create a CO₂ laser system with high emission versatility and capable of generating pulses, especially designed for surgical applications (U-pulses).

With the miniaturized **EndoScan** scanning system laser debridement is controlled electronically, improving precision ablation and reducing the risk of healthy tissue damage.

By proper selection of laser technical parameters (such as power, pulse shape, frequency and scanning features), physicians can induce different effects on tissues, ranging from precise cut and/or ablation to deep and effective tissue regeneration enhancement.



PLUS

PSD[®] Technology

The first RF CO₂ laser system with the exclusive Pulse Shape Design Technology (patent pending). It enables the maximum flexibility of the pulse shape: S-pulse, D-pulse, H-pulse, U-pulse and the CW mode, greatly expand the surgical capabilities of the SmartXide² making it an effective, versatile and powerful system.

EndoScan

The only scanning system on the market with single-mirror technology that allows extreme miniaturization. Scan On/Off and centring controlled by microswitch on scanner body.

Power

High peak power (more than 200 W) for better results.

Database

Integrated protocols designed for wound care management.

Multimedia Features

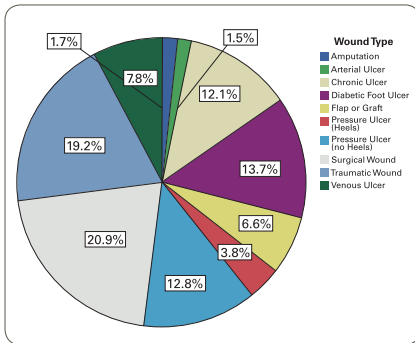
Integrated photos and video tutorial.



EndoScan ultra miniaturized scanning system and its available scanning figures. EndoScan, patented and exclusive to DEKA, allows a very precise control of tissue layers vaporization and, together with UP-pulse, minimizes thermal damage to healthy tissue.



A NEW GAME-CHANGING TREATMENT WITH SMARTXIDE² LASER



The percent distribution of wound and ulcer types in U.S.A. (Caroline E. Fife et. al. *Wound Care Outcomes and Associated Cost Among Patients Treated in US Outpatient Wound Centers: Data From the US Wound Registry. WOUNDS 2012; 24(1): 10–17.*



DEKA software interface: user-friendly right from the start

Chronic wounds are a significant issue not only in wound care facilities, but also for general practitioners and specialists across a wide range of disciplines. These wounds can result from a combination of factors including neuropathy, vascular insufficiency and impaired wound healing. In addition to a significant health care cost, ulcerations have a devastating impact on patient’s daily life such as extensive pain, sleep impairment, restricted mobility and work capacity.

Diabetic foot ulcers and *chronic venous ulcers* are considered to be among the most difficult chronic wounds to treat as they typically do not respond well to standard wound closure approaches having an associated risk in minor or major amputations.

CO₂ DEKA laser technology is strategic for effective and efficient wound healing management, providing a therapeutic chance to extremely non-responsive wounds so far.

SmartXide² RF CO₂ laser can play a key role in “wound bed preparation”, being effective in most phases of TIME¹ framework. It allows a very accurate, delicate and safe removal of fibrin and necrotic tissue from the wound bed (“T” phase). CO₂ laser debridement, performed with the specifically implemented ultra-miniaturized scanning system **EndoScan** and the **U-pulse** shape emission, provides an excellent and perfectly controlled ablation of target tissues. The ability of DEKA CO₂ laser debridement to reduce infection in wounds (“I” phase) was confirmed in a recent forthcoming randomized controlled trial. The contactless operation, combined with the high temperature reached by the laser ablated tissue, leads to an effective microbial destruction. Moreover, results from clinical cases suggest that the progress of the epithelial margins towards a physiological healing (“E” phase) is promoted by **SmartXide²** laser. Thanks to a special beam delivery device, the treatment can be performed on all kind of wound tissues, at a controlled penetration depth. As outcome, the post-debridement ulcers appearance is remarkably improved in comparison to the results that routinely occurred using a scalpel.

Compared to traditional surgical procedure with scalpel, laser debridement is associated with significantly reduced procedural discomfort due to many components, including “contactless” surgery without any pressure on exposed tissues. The reduction in pain allowed physicians to perform a more meticulous wound bed preparation.

1: TIME is the acronym for “Tissue non-viable or deficient; Infection or Inflammation; Moisture imbalance; Epidermal margin – non advancing or undermined”.



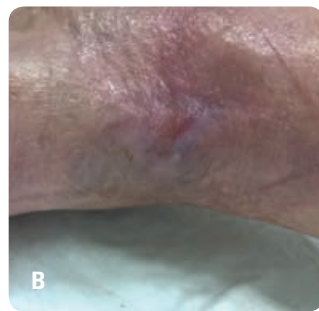
DEKA: ALWAYS LOOKING AHEAD TO THE FUTURE

The impressive clinical results achieved in recent years has led to several still ongoing research projects, aiming to gain a better understanding of the laser-tissue mechanisms of action in wound-healing and other sectors. An initial randomized clinical study, to be published soon, concludes that treatment with the SmartXide² CO₂ laser, compared with traditional surgical debridement, can significantly reduce bacterial load in the ulcer bed. Further studies are being performed to examine the effect of this laser, which appears to induce a significant response in the tissues in terms of inflammation, growth factors expression, collagen regeneration, immune-modulation and neo-angiogenesis.

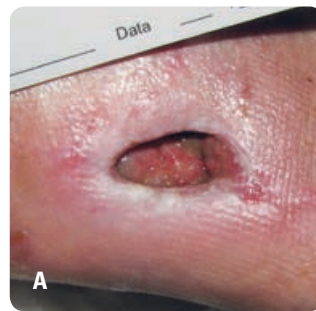
Finally, at the 5th WUWHS World Congress held in Florence in September 2016, preliminary results were presented on diabetic foot ulcers with exposed bone treated with a new laser technique (patent pending). The treatment of foot ulcers with exposed bone is challenging, due to the risk of infection and of difficulties in granulation tissue development, a necessary part of the healing process. Significant bone surface exposure is usually considered an indication for amputation. All patients in this preliminary trial had been placed on a surgical waiting list for minor or major amputations. Despite several months of standard wound care (debridement surgery and advanced medication) and prolonged antibiotic therapy, the wounds showed no significant improvement. The SmartXide² laser beam was used to produce discontinuities in the periosteum, so as to expose blood, containing multipotent stem cells capable of initiating the healing process. Most patients showed noticeable improvement after a few weeks, with the presence of granulation tissue and a reduction in wound area. This pilot experience is the first report of applying this technique. The efficacy of a therapeutic procedure should be tested in a randomized trial with a control group. However, it is simple to imagine the great makings of a so innovative procedure for all patients with diabetic foot ulcers.



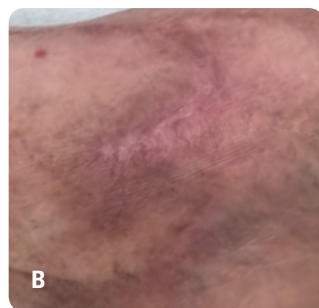
CLINICAL CASES



Surgical dehiscence. The patient underwent suturing of the right Achilles tendon. A part of the Achilles tendon (infected and necrotic) had to be cleaned and removed due to the onset of an infection post-op. **(A)**: The wound as it appeared prior to initiating treatment with the SmartXide² CO₂ laser. **(B)**: Wound completely re-epithelialized after 4 months and a half of treatment. A total of 14 weekly laser sessions have been carried out. *[Courtesy of: C. Mirabella, M.D. – Florence, Italy].*



Surgical dehiscence. The patient underwent percutaneous osteotomy surgery for a bursitis on the 5th metatarsal. **(A)**: The lesion as it appeared before CO₂ laser treatment. **(B)**: Follow-up 2 months after discharge, with fully re-epithelialized lesion. Eight laser sessions were performed over the 2 months of treatment. *[Courtesy of: C. Mirabella, M.D. – Florence, Italy].*



Lesion on the front of the left ankle, caused by poor superficial circulation on the rotation flap. Relapse which was suspected to be of a traumatic nature. **(A)**: The lesion as it appeared after an initial phase of wound dressings and sessions with the SmartXide² CO₂ laser used to debride the ulcer and stimulate the edges (small holes can be seen on the edge of the wound, made with the laser, in order to enhance epithelialization). Compared to initial conditions, the ulcer was far more superficial. **(B)**: Wound follow-up 3 months and half after the end of the second course of treatment. The laser sessions were performed every 7-15 days. Patient was discharged after 7 months when the lesion was fully re-epithelialized. *[Courtesy of: C. Mirabella, M.D. – Florence, Italy].*



Patient with type 2 diabetes mellitus, diabetic retinopathy, diabetic neuropathy. Ulcers resulting from surgical dehiscence due to a serious infection after amputation of the second toe on the left foot with a fistula to midfoot. The lesion initially presented an infection of the dermal tissues reaching the underlying bone surfaces with a perilesional oedema and leakage of abundant pus-like material. **(A)**: The lesion as it appeared before the SmartXide² CO₂ laser treatment. **(B)**: Follow-up 3 weeks after the last treatment with the CO₂ laser. Lesion completely re-epithelialized. *[Courtesy of: M. Monami, M.D. – Florence, Italy].*

TECHNICAL DATA

SmartXide² - Suggested Configurations in Wound Healing

Models*	C60 and C60H	C80 and C80H
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	From 0.5 to 70 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	From 0.1 to 15 W
UP Power	From 0.5 to 60 W	From 0.5 to 80 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 with counterweight.	
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 and accessible over USB. Possibility of storing unlimited number of custom user's protocols.	
Control Panel	Wide LCD Colour Touch Screen (10.4").	
Accessories*	EndoScan Scanner System. Wide range of surgical handpieces.	
Electrical Requirements	From 100 to 120 Vac - 50/60 Hz From 220 to 230 Vac - 50 Hz - 1,600VA	
Dimensions** and Weight	162 (H) x 59 (W) x 56 (D) cm. - 95 kg for C60 and C80 192 (H) x 59 (W) x 56 (D) cm. - 100 kg for C60H and C80H	

EndoScan Scanner System

Max Scanning Size	From 4 mm @ 4" EFL to 6 mm @ 7" EFL
Dwell Time	From 100 to 1,000 µs (Circle) – 350 µs (Clover)
Scanning Shapes	Cut Mode (Point), Circle, Clover.
Emission Modes	CW - UP

* In this catalogue only the technical features of the Wound Healing applications are listed.

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

** 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.

Diabetic Foot Ulcers - Venous Leg Ulcers
Pressure Ulcers - Wound Dehiscence



The Code of Excellence

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SmartXIDE²

CE
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Dealer stamp



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DEKA The Code of Excellence

A spin-off of the Ei.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.