

USER GUIDE

dermagold100[®]

MTS Spark Wave[®] Therapy





MTS Medical UG, a committed leader in the advancement of electrohydraulic ESWT technology, specialises in the research, development and manufacturing of highly advanced Spark Wave Therapy systems. Our premium shock wave therapy systems, designed and equipped with MTS' own advanced Spark Wave Technology, are successfully used worldwide in the healthcare fields of orthopaedics, traumatology, wound care, aesthetics and urology.

Hospitals, clinics and practicing physicians from around world have realized, and prefer, the superiority of MTS Spark Wave Therapy systems. They know that MTS therapy systems guarantee the most effective shock waves for pain-free, high quality treatment as well as outstanding healing results in fewer treatment sessions. And, most importantly, patients realize the benefits as well.

Since 1998 MTS has collaborated with internationally renowned universities and research institutions and has become recognized as a pioneer in the field of non-invasive tissue healing and regeneration. It is the vision of MTS to improve the quality of life through advanced healing methods that drives us and will continue to guide us in the future.

Every premium MTS therapy system features our signature Spark Wave Technology. Additionally, MTS supports all customers with our dedicated and well-trained Technical Service and After Sales Support departments.

Witness. The Spark of Life.

CONTENT

1. INTRODUCTION

// page 6

- 1.1 Background and History
- 1.2 What Are Spark Waves®?
- 1.3 Biological and Therapeutic Effects of Spark Waves®
- 1.4 Side Effects of Spark Wave® Therapy?

2. GENERAL TREATMENT INFORMATION

// page 10

- 2.1 Spark Wave® Therapy Parameters
- 2.2 Treatment Procedure
- 2.3 Approved Indications of the dermagold100® - OW100 / 100S
- 2.4 Individual Spark Wave® Applicators

3. TREATMENT PROCEDURE

// page 12

- 3.1 No Local Anaesthetics
- 3.2 Preparation of the Treatment Site
- 3.3 After Therapy
- 3.4 Monitoring and Follow-Up

4. TREATMENT PROTOCOLS

// page 13

- 4.1 Cellulite
- 4.2 Scarring, Stretch Marks
- 4.3 Lymphoedema

5. MEDICAL INFORMATION

// page 14

- 5.1 Cellulite
- 5.2 Scarring, Stretch Marks
- 5.3 Lymphoedema

6. SUMMARY

// page 17

- 6.1 Treatment with dermagold100® Stimulates Healing Processes at the Cellular Level
- 6.2 Benefits of dermagold100® at a Glance

7. BIBLIOGRAPHY

// page 18

- 7.1 Recommended Literature
- 7.2 MTS Spark Wave® References

1. INTRODUCTION

1.1 BACKGROUND INFORMATION AND HISTORY

This manual supports the user of the dermagold100 - OW100 / OW100S with practical instructions and important information when using extracorporeal Spark Wave Therapy in medical practice.

Shock wave therapy is a multidisciplinary application that has been successfully used for decades in orthopaedics, physiotherapy, sports medicine, urology, dermatology and veterinary medicine.

Its main benefits are rapid pain relief, restoration of mobility as well as improved tissue regeneration and wound healing. It is a non-invasive, practically side effect- and painless therapy, ideal for accelerating the healing of various indications that cause acute or chronic conditions.

The recommendations and information given here are evidence-based, state of the art and in accordance with world renowned expert committees.

The term „shock wave therapy“ is historically derived from extracorporeal shock wave lithotripsy (ESWL), which was first used clinically in 1980 for the non-invasive disintegration of kidney stones.

Since the early 1990s, these acoustic waves have been used under the term extracorporeal shock wave therapy for the treatment of chronic pain and bone healing disorders. The spectrum of indications to be treated is still expanding. In the meantime, treatment of numerous orthopaedic conditions, chronic wounds, aesthetic applications and several urogenital indications including erectile dysfunction are acknowledged worldwide. Furthermore, cardiac and neural applications are being performed and investigated experimentally.

About the ISMST – The International Society of Medical Shockwave Treatment

The International Society for Medical Shockwave Treatment (ISMST) is the most important society for shock wave applications with good cooperation of all national societies in many countries. The society promotes research and development of shock wave therapy worldwide. Annual congresses, certification courses and recommendations of the ISMST experts represent important guidelines for shock wave therapy. The ISMST recommendations and guidelines are available at

<https://www.shockwavetherapy.org/home/>

The spread of shock wave therapy and the ISMST continued enormously. With further indications of the successful therapy the spectrum of users and scientists enlarged from the trauma surgery and orthopaedics to the sports medicine, rehabilitation medicine, rheumatology, dermatology, plastic surgery, cardiology and veterinarian medicine.



ISMST Consensus Statement on ESWT Indications and Contraindications – Status July 2020:

INDICATIONS

1. Approved standard indications

- 1.1. Chronic Tendinopathies
 - 1.1.1. Calcifying tendinopathy of the shoulder
 - 1.1.2. Lateral epicondylopathy of the elbow (tennis elbow)
 - 1.1.3. Greater trochanter pain syndrome
 - 1.1.4. Patellar tendinopathy
 - 1.1.5. Achilles tendinopathy
 - 1.1.6. Plantar fasciitis, with or without heel spur
- 1.2. Bone Pathologies
 - 1.2.1. Delayed bone healing
 - 1.2.2. Bone Non-Union (pseudarthroses)
 - 1.2.3. Stress fracture
 - 1.2.4. Avascular bone necrosis without articular derangement
 - 1.2.5. Osteochondritis Dissecans (OCD) without articular derangement
- 1.3. Skin Pathologies
 - 1.3.1. Delayed or non-healing wounds
 - 1.3.2. Skin ulcers
 - 1.3.3. Non-circumferential burn wounds

2. Common empirically-tested clinical uses

- 2.1. Tendinopathies
 - 2.1.1. Rotator cuff tendinopathy without calcification
 - 2.1.2. Medial epicondylopathy of the elbow
 - 2.1.3. Adductor tendinopathy syndrome
 - 2.1.4. Pes-Anserinus tendinopathy syndrome
 - 2.1.5. Peroneal tendinopathy
 - 2.1.6. Foot and ankle tendinopathies
- 2.2. Bone Pathologies
 - 2.2.1. Bone marrow edema
 - 2.2.2. Osgood Schlatter disease: Apophysitis of the anterior tibial tubercle
 - 2.2.3. Tibial stress syndrome (shin splint)
- 2.3. Muscle Pathologies
 - 2.3.1. Myofascial Syndrome
 - 2.3.2. Muscle sprain without discontinuity
- 2.4. Skin Pathologies
 - 2.4.1. Cellulite
- 2.5. Skin calcinosis
- 2.6. Periodontal disease

- 2.7. Jawbone pathologies
- 2.8. Complex Regional Pain Syndrome (CRPS)
- 2.9. Osteoporosis

3. Exceptional indications – expert indications

- 3.1. Musculoskeletal pathologies
 - 3.1.1. Osteoarthritis
 - 3.1.2. Dupuytren disease
 - 3.1.3. Plantar fibromatosis (Ledderhose disease)
 - 3.1.4. De Quervain disease
 - 3.1.5. Trigger finger
- 3.2. Neurological pathologies
 - 3.2.1. Spasticity
 - 3.2.2. Polyneuropathy
 - 3.2.3. Carpal Tunnel Syndrome
- 3.3. Urologic pathologies
 - 3.3.1. Pelvic chronic pain syndrome (abacterial prostatitis)
 - 3.3.2. Erectile dysfunction
 - 3.3.3. Peyronie disease
- 3.4. Others
 - 3.4.1. Lymphedema

4. Experimental Indications

- 4.1. Heart Muscle Ischemia
- 4.2. Peripheral nerve lesions
- 4.3. Pathologies of the spinal cord and brain

CONTRAINDICATIONS

1. Focused waves with low energy

- 1.1. Malignant tumor in the treatment area (not as underlying disease)
- 1.2. Fetus in the treatment area

2. High energy focused waves

- 2.1. Lung tissue in the treatment area
- 2.2. Malignant tumor in the treatment area (not as underlying disease)
- 2.3. Epiphyseal plate in the treatment area
- 2.4. Brain or Spine in the treatment area
- 2.5. Severe coagulopathy
- 2.6. Fetus in the treatment area

Source: <https://www.shockwavetherapy.org/about-eswt/indications/>

1.2 WHAT ARE SPARK WAVES®?

Spark Waves are high-energy acoustic waves that behave much like other sound waves except that they have much greater pressure and energy. The energy of a shock wave is released as pressure on the environment. This pressure wave builds up extremely quickly and consists of a very high positive and a minor negative part (Fig. 1.1.). The technology that generates the shock wave has a considerable influence on the energy distribution. Spark Wave Technology uses traditional electrohydraulic generation principles and ensures optimum energy composition and distribution; the pressure amplitude is mainly positive with only minimal negative tensile wave energy and provides regenerative energy not only in the focal area, but in the entire acoustic field extending from the spark source (Fig. 1.2.).

The original principle used in medicine is that in which the shock waves are generated by a spark plug, the electrohydraulic principle.

As with sound waves, Spark Waves can travel great distances with ease as long as the acoustic impedance stays the same. However, when the acoustic impedance changes, energy is released and the greater the change in impedance the greater the release of energy. There is a much higher release of energy at a soft tissue / bone interface than at a muscle / fascia interface (Fig. 1.3.).

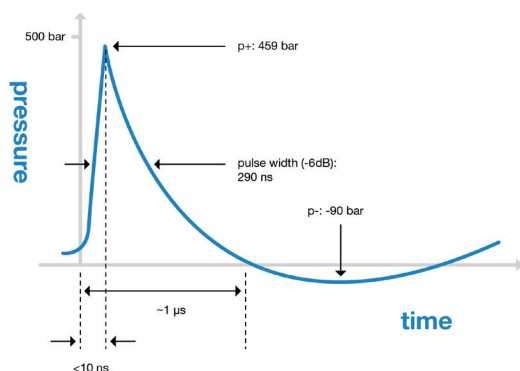


Fig. 1.1. Schematic Pressure Profile of a Focused Shock Wave. Characteristic properties: Extremely fast rise of the curve, very high pressure, low negative wave compared to very high peak pressure.

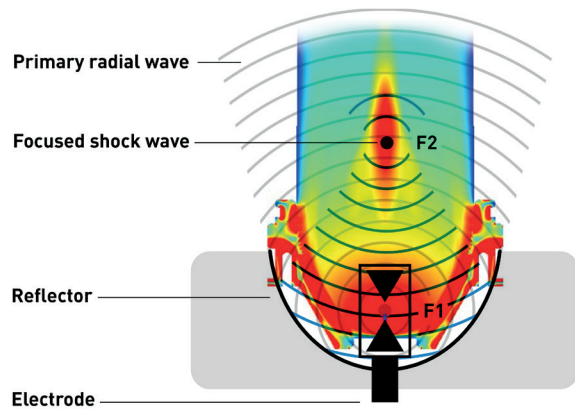


Fig. 1.2. Electrohydraulic Shock Wave Generation. An electrode is placed in the first focal point of a water-filled semi-ellipsoid reflector and high voltage is applied to the tips of the electrode. Thereby, an electric spark is generated between these tips and a spherical shock wave is released by the rapid vaporization of the water between the tips. The shock wave spreads out from the applicator leading to a low intensity radial primary wave, followed by a focused shockwave with focus F2 which occurs due to the reflection of the spherical wave at the reflector. The colours display imaging by a DICOM (Digital Imaging and Communications in Medicine) MATLAB (matrix laboratory) simulation of the acoustic field with Spark Wave Technology. Red corresponds to the area with the maximum energy.

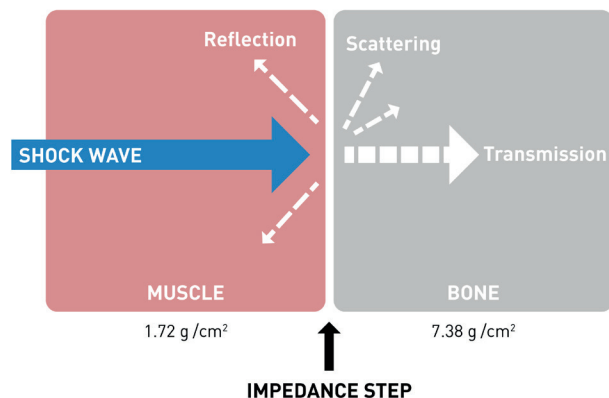


Fig. 1.3. Acoustic Impedance. As with other waves, the energy is released at interfaces, at those places where the waves from one medium meet another medium. These phenomena occur at the interfaces, which are also known from classical wave theory: Transmission (transverse waves, longitudinal wave), (partial) reflection, diffraction and / or deflection, scattering, wave velocity x density of the medium = acoustic impedance, pressure / tension wave, shear forces.

1.3 BIOLOGICAL AND THERAPEUTIC EFFECTS OF SPARK WAVES®

In regenerative medicine, the physical energy of Spark Waves is applied to all kinds of tissues at a desired depth and with an adjustable energy flux density (EFD), depending on the respective indication and pathophysiology. With its unique wide focus size, Spark Wave Technology delivers the highest possible amount of total biologically effective energy to the target area. This physical energy produces mechanical stimulation which is recognized by mechanoreceptors of the cell and transduced into various cellular responses: The expression and release of regeneration-associated molecules, like growth factors and other signaling molecules (chemokines and cytokines), is activated (Fig. 1.4.). All these factors trigger intracellular signalling cascades which are implicated in processes including metabolic activation, proliferation, migration and recruitment of mesenchymal and haematopoietic progenitor cells, which finally lead to improved angiogenesis, neovascularisation, tissue remodelling and regeneration (Fig. 1.5.).

Additionally, the anti-inflammatory as well as the antibacterial effect of Spark Waves, in combination with various other biological regeneration processes,

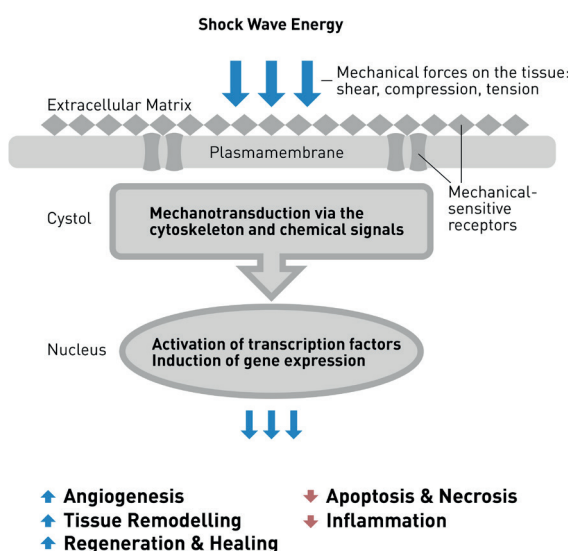


Fig. 1.4. Mechanotransduction Mechanism - Phases of Spark Wave Therapy. **1. Physical Phase:** Shock waves generate a positive pressure to generate absorption, reflection, scattering and transmission. **2. Chemical Phase:** The mechanical stimulus leads to biochemical reaction, biomolecules are released and cell signaling pathways are activated. **3. Biological Phase:** Modulation of angiogenesis, alteration of inflammatory response, bone and soft tissue healing.

support the natural self-healing of the diseased tissue. The efficacy of Spark Wave Therapy has been thoroughly proven in clinical studies and state of the art research has demonstrated its curative effects on dermatological indications.

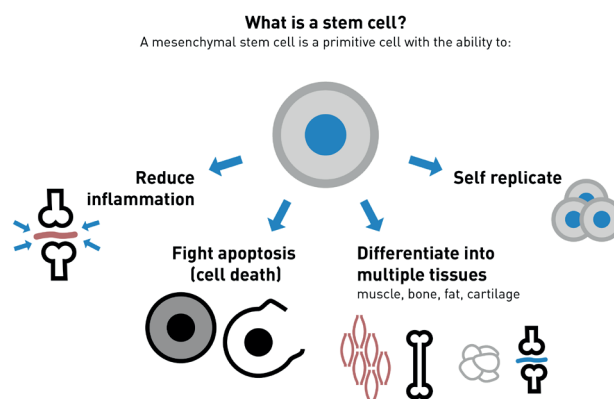


Fig. 1.5. Biological Function and Regenerative Potential of Stem Cells. Spark Wave Therapy has a highly beneficial effect on most every kind of tissue. Spark Waves promote sustainable regeneration of blood vessels and skin as well as of musculoskeletal and nervous tissues, which has been widely proven by comprehensive research and numerous clinical trials.

1.4 SIDE EFFECTS OF SPARK WAVE® THERAPY?

No serious side effects have been reported by clinicians even when using highest energy settings; however, the following minor and transient side effects have been observed in very rare cases:

- Transient moderate increase in pain
- Redness and swelling
- Hematoma and petechial haemorrhage
- Headaches and fainting during extracorporeal shock wave treatments
- Short-term hypaesthesia
- Nausea during therapy
- Tingling during therapy

2. GENERAL TREATMENT INFORMATION

2.1 SPARK WAVE® THERAPY PARAMETERS

The Spark Waves generated by the applicator are transmitted through the skin into the tissue by using coupling gel. The penetration depth of the energy focus is preset on the device by the membrane pressure and can, if required, be manually increased in real time during the treatment by increasing the pressure of the applicator on the skin surface.

The number of shocks and their energy is proportional to the size of the treatment site: the larger the area - the greater the number of shocks required. Specific information on recommended treatment parameters for individual indications can be found under Section 4 Treatment Protocols.

Aesthetic disorders require about 3 to 6 Spark Wave treatments. Many conditions respond very well and require only a few sessions, while others require more. The total number of treatments is case specific, no general predictions can be made. As long as the chronic condition continues to respond to the treatment, Spark Wave Therapy should be continued.

The healing and remodelling of tissue are processes that take months, so the full therapeutic effect of Spark Wave Therapy naturally starts a few weeks after the treatment.

2.2 TREATMENT PROCEDURE

During therapy, the Spark Waves should be directed into the affected tissue region and adjacent areas with maximum therapeutic energy. During the entire treatment, it is important to ensure good coupling between the applicator and the skin. The applicator is then moved slowly in a circular motion on the skin. This ensures an even distribution of energy throughout the treatment area and at the same time a firm contact without air entering between the membrane and the skin. When treating large areas, it may be necessary to reposition the membrane at different points. The applicator should always be moved smoothly and can be angled up to 20 degrees from the vertical when it is moved across the treatment site.

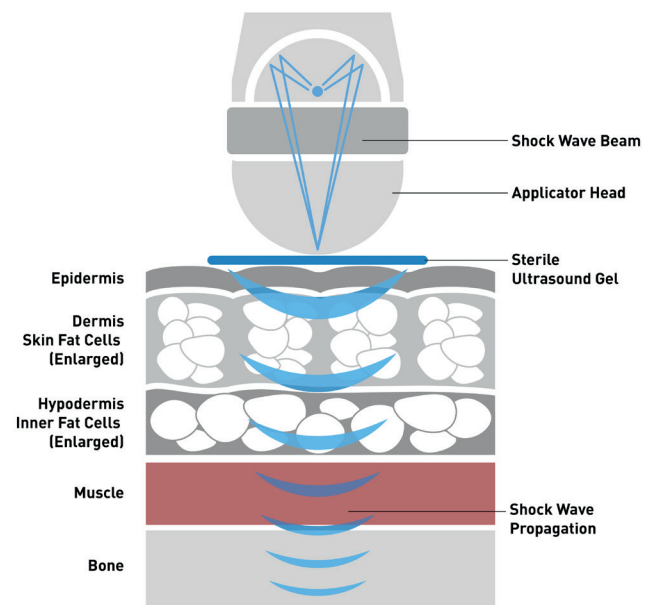


Fig. 2.1. Schematic Representation of Cellulite Treatment with Spark Wave Therapy.

2.3 APPROVED INDICATIONS OF THE DERMA^{GOLD}100®

derma^{gold}100 utilizes a specially designed applicator to treat a specific set of dermatologic indications.

Unfocused applicator OP155

Perfectly suited for

Wound care:

- Post traumatic lesions
- Post-operative healing disorders
- Diabetic foot ulcers
- Burns

Aesthetics:

- Cellulite
- Scarring / stretch marks
- Lymphoedema

2.4 INDIVIDUAL SPARK WAVE® APPLICATORS

All MTS applicators feature MTS's highly sophisticated SmartTrove® technology, which provides consistent Spark Wave performance quality.

The OW100 / OW100S Series utilizes three specially designed applicators, each to treat a specific set of indications.

Applicators are easily interchangeable with the device and offer the user an economical and practice-oriented treatment.

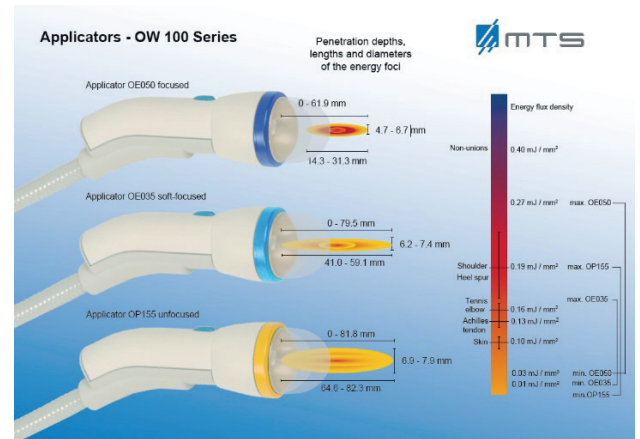


Fig. 2.2. Individual OW100 / OW100S Applicators, Focus Sizes, Penetration Depths and Application Areas. The applicator OE050 / OE050S and the OE035 / OE035S are perfectly suited for musculoskeletal applications. The OP155 / OP155S applicator is especially effective for dermatological and urogenital indications.

3. TREATMENT PROCEDURE

3.1 NO LOCAL ANAESTHETICS

Spark Wave Therapy for aesthetic indications may be uncomfortable in some cases. Nevertheless, pain anaesthesia is usually not necessary for the treatment, as patients tolerate the therapy very well. If necessary (e. g. in a highly sensitive patient), the energy level and frequency for the initial pulses can be reduced and then gradually increased.

Please note that local infiltration of anaesthetics into the treatment area may decrease the response rate of the therapy.

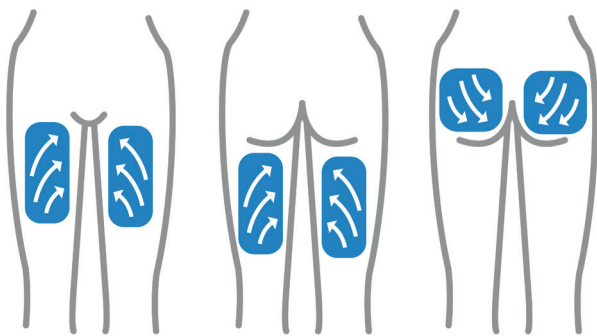


Fig. 3.1. Schematic Representation of Treatment Directions in the Direction of Lymph Flow for Cellulite Spark Wave Therapy.

3.2 PREPARATION OF THE TREATMENT SITE

- Shave the hair if necessary to avoid air bubbles in the coupling area around the treatment site.
- Measure the treatment site and calculate the number of pulses (see chapter 4 Treatment Protocols Table 4.1. & 4.2.).
- Apply sterile ultrasound gel to the treatment site.
- Apply generous amounts of ultrasound gel to the treatment site. The gel can be re-applied as required to ensure good membrane / skin coupling.
- Perform the treatment according to the recommended protocol (see chapter 4 Treatment Protocols Table 4.1. & 4.2.).
- Also follow the instructions and information in the user manual.
- MTS also recommends reviewing the latest Digest (Deutschsprachige internationale Gesellschaft für Extrakorporale Stoßwellentherapie) guidelines, as well as up-to-date expert literature for the treatment of dermatologic indications with shock wave therapy.

3.3 AFTER THERAPY

Treatment according to current standards and as indicated by the treating physician is applied.

No special instructions regarding shock wave therapy are necessary for the patient.

3.4 MONITORING AND FOLLOW-UP

Regular monitoring of skin appearance should be arranged after the sessions. The treatment data should be recorded precisely.

If there is no improvement in the condition, alternative therapies should be considered.

4. TREATMENT PROTOCOLS

Indication	Energy Range [mJ / mm ²]	Frequency [Hz]	Impulses / Session	Number of Sessions	Treatment Interval
4.1 Cellulite	0.08 - 0.13	2 - 4	~1500/ treatment site	~3 - 6	1 - 2 weeks
4.2 Scarring / Stretch marks	0.08 - 0.13	2 - 4	350 + 20/cm ²	~3 - 6	1 - 2 weeks
4.3 Lymphoedema	0.08 - 0.13	2 - 4	350 + 20/cm ²	~3 - 6	1 - 2 weeks

Table 4.1. Recommended Treatment Parameters for Aesthetic / Dermatological Indications.

Recommended applicator: OP155 / OP155S

Note: The number of shock waves results from the total surface of the affected area. The surface is calculated from the total length x total width of the affected area. (The wound periphery should also be treated: edge of the wound plus 1 cm).

WOUND SIZE, WIDTH (CM)																	
0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15		
1	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	size in cm²	
	370	390	410	430	450	470	490	510	530	550	570	590	610	630	650	number of pulses	
2	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	size in cm²	
	390	430	470	510	550	590	630	670	710	750	790	830	870	910	950	number of pulses	
3	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	size in cm²	
	410	470	530	590	650	710	770	830	890	950	1010	1070	1130	1190	1250	number of pulses	
4	4	8	12	16	20	24	28	32	36	40	44	48	52	56	60	size in cm²	
	430	510	590	670	750	830	910	990	1070	1150	1230	1310	1390	1470	1550	number of pulses	
5	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	size in cm²	
	450	550	650	750	850	950	1050	1150	1250	1350	1450	1550	1650	1750	1850	number of pulses	
6	6	12	18	24	30	36	42	48	54	60	66	72	78	84	90	size in cm²	
	470	590	710	830	950	1070	1190	1310	1430	1550	1670	1790	1910	2030	2150	number of pulses	
7	7	14	21	28	35	42	49	56	63	70	77	84	91	98	105	size in cm²	
	490	630	770	910	1050	1190	1330	1470	1610	1750	1890	2030	2170	2310	2450	number of pulses	
8	8	16	24	32	40	48	56	64	72	80	88	96	104	112	120	size in cm²	
	510	670	830	990	1150	1310	1470	1630	1790	1950	2110	2270	2430	2590	2750	number of pulses	
9	9	18	27	36	45	54	63	72	81	90	99	108	117	126	135	size in cm²	
	530	710	890	1070	1250	1430	1610	1790	1970	2150	2330	2510	2690	2870	3050	number of pulses	
10	10	20	30	40	50	60	70	80	90	100	110	120	130	140	150	size in cm²	
	550	750	950	1150	1350	1550	1750	1950	2150	2350	2550	2750	2950	3150	3350	number of pulses	
11	11	22	33	44	55	66	77	88	99	110	121	132	143	154	165	size in cm²	
	570	790	1010	1230	1450	1670	1890	2110	2330	2550	2770	2990	3210	3430	3650	number of pulses	
12	12	24	36	48	60	72	84	95	108	120	132	144	156	168	180	size in cm²	
	590	830	1070	1310	1550	1790	2030	2270	2510	2750	2990	3230	3470	3710	3950	number of pulses	

Table 4.2. Calculation of Wound Size and Number of Pulses. The number of pulses depends on the size of the treatment site. The recommended standard is 350 pulses plus an additional 20 pulses per square centimeter of treatment area. To calculate the number of pulses required, the treatment area is given in square centimeters, multiplied by 20 and added 350.

5. MEDICAL INFORMATION

5.1 CELLULITE

Cellulite is a multifactorial condition that is present in 80-90 % of post-pubertal women, commonly found on the posterolateral thighs, buttocks, and abdomen. It is described by an orange peel appearance of the skin surface and classified into four grades. Despite its high prevalence, it remains a major concern for women.

Factors for cellulite include, among others, connective tissue architecture, estrogen action, microvascular alterations, and certain genetic and hormonal cha-

racteristics. Inadequate nutrition and poor lifestyle tend to worsen the appearance of cellulite. Body fat, stress, fatty, sugary and salty food, inactivity, alcohol and smoking favour cellulite.

Treatment of cellulite can be conservative and pharmacological or surgical (e. g. subcision). Conservative treatments must be carried out before surgical procedures are performed. Spark Wave Therapy is an efficient and safe method of first choice.

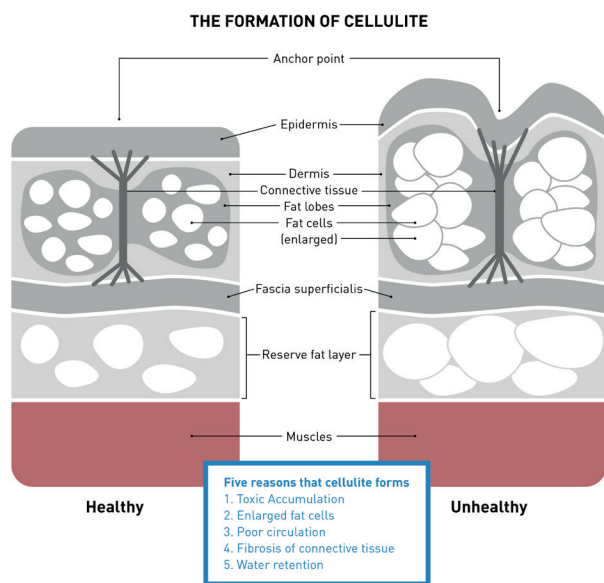


Fig. 5.1. The Formation of Cellulite. The mechanism of Spark Wave therapy for cellulite is to improve local blood circulation via neovascularisation. Furthermore, it increases the cell proliferation of collagen and elastin fibres, which improves the elasticity of the skin and the revitalisation of the dermis. SWT has a positive effect on lymphoedema / lipedema by promoting lymph transport (lymphatic drainage), which is a pathway often associated with cellulite. In vitro tests have further shown that SWT increases cell permeability, which may stimulate the exchange of fat cells and activate phospholipases through the beta-receptors on the fat cells' membrane.

5.2 SCARRING / STRETCH MARKS

Stretch marks (striae distensae) are narrow scars at the skin that occur when there is a sudden stretch of the skin due to obesity, puberty, pregnancy, steroid medication and a quick weight gain. Familiar genetic predisposition may also play a role. They form at the thighs, abdomen, breasts, hips, lower back and upper arms when the dermis is overstretched and tears.

Sometimes stretch marks cause burning and itching and in rare cases, healing disorders can lead to swelling and inflammation of the affected skin. Dependent on their etiology, striae are divided into striae atrophica, striae distensae (rubrae, albae) and striae gravidarum.

A scar is fibrous tissue that leaves after wound healing due to injury, sores or burns. Abnormal scarring remains a burdensome functional and aesthetic consequence for affected patients. Pathological scars may develop, which are divided into atrophic and hypertrophic scars, the latter being further divided into simple hypertrophic and keloid scars and may cause

pain or pruritus. Retracting scars are characterized by collagen fibers in a cord-like disposition exerting significant traction on surrounding healthy tissue and may cause significant functional deficit and pain. Local and systemic factors contribute and promote pathologic scarring.

Treatment of scars can be conservative and pharmacological or surgical (e. g. scar revision). Conservative treatments must be carried out before surgical procedures are performed. Spark Wave Therapy is an efficient and safe method of first choice.

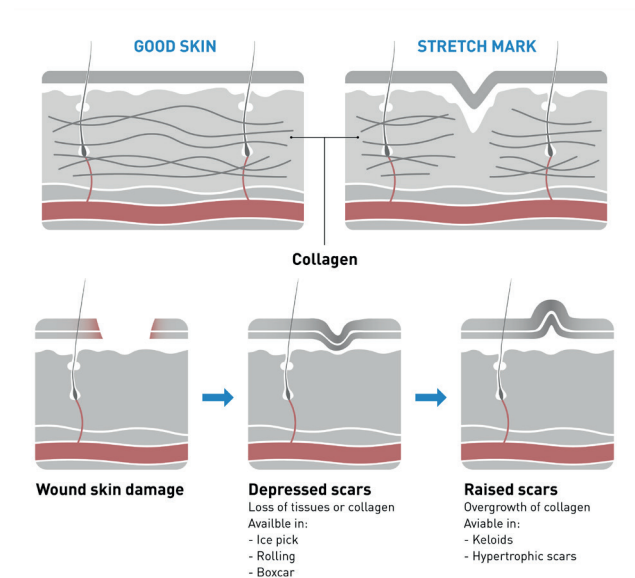


Fig. 5.2. Schematic Representation of Different Scar Types. Scars form when the dermis is damaged. Skin cells form new collagen fibers to repair the injury, resulting in a scar. The new scar tissue has a different texture and quality than the surrounding tissue. Scars form after a wound has completely healed. Most scars are flat and pale. In cases where the body produces too much collagen, the scars can be lifted. Elevated scars are called hypertrophic scars or keloid scars. Some scars can have a sunken or pitted appearance. This kind of scarring occurs when underlying structures supporting the skin (for example, fat or muscle) are lost. The right cell population equilibrium (fibroblasts, myofibroblasts, keratinocytes) and a properly balanced expression of all factors involved (growth factors and cytokines, e. g. TGF- β , PDGF, fibronectin, hyaluronic acid, biglycan, collagen...) are essential for normal skin healing. Spark Wave Therapy rebalances activation, proliferation, synthesis and differentiation of cells and the connective tissue.

5.3 LYMPHOEDEMA

Lymph is a clear fluid that derives from body tissue. Its function is 1. to transport absorbed fats and proteins from the small intestine, 2. to remove bacteria, viruses, toxins and certain proteins from the tissue, and 3. to introduce white blood cells, especially lymphocytes, into the bloodstream to help fight infections and other diseases. Lymphoedema is a pathological condition that either results from loss of function or occurs after structural damage to the lymphatic circulation.

The primary congenital lymphoedema is based on malformations of the lymphatic system. The acquired form can result secondarily from malignancies, trauma, surgery, infection, anti-inflammation or radiation therapy. Symptoms mainly include swelling in arms, legs or other parts of the body, feeling of heaviness and tension or tingling, hypersensitivity of limbs, reduced flexibility and range of motion, skin infections (cellulitis).

Treatment of lymphoedema can be conservative and pharmacological or surgical (e. g. lymphatic reconstruction, lymph node transplantation, liposuction, resection). Conservative treatments must be carried out before surgical procedures are performed. Spark Wave Therapy is an efficient and safe method of first choice.

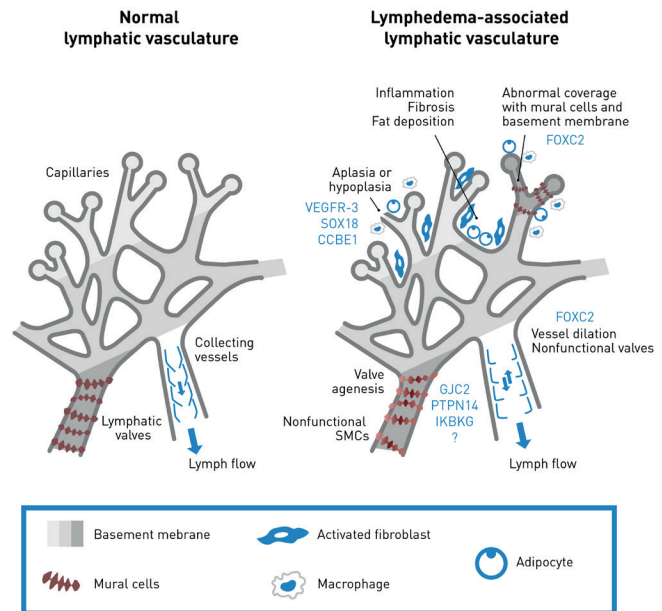


Fig. 5.3. Development of Lymphoedema by Insufficiency of the Lymphatic Vasculature. The therapeutic action of Spark Wave therapy for lymphoedema is increased cell permeability and stimulated lymphangiogenesis through increased proliferation of lymphatic endothelial cells. It also improves lymphatic drainage and microcirculation.

6. SUMMARY

6.1 TREATMENT WITH DERMAGOLD100® STIMULATES HEALING PROCESSES AT THE CELLULAR LEVEL

- Activating endogenous growth factors (e. g. BDNF, BMP, FGF-2, IGF-1, NO, PCNA, PLGF, TGF- β , VEGFs)
- Inducing stem cell proliferation and migration
- Stimulating neovascularisation and angiogenesis
- Enhancing blood circulation and cell metabolism
- Reducing cell apoptosis and tissue necrosis
- Acting anti-inflammatory and antibacterial
- Stimulating the catabolism and the natural anabolic growth function of tissues (blood and lymphatic vessels, skin, connective tissue, bones, cartilage, tendons, joints, smooth and striated muscles, nerves ...)
- Promoting tissue remodelling and regeneration

6.2 BENEFITS OF DERMAGOLD100® AT A GLANCE

- Safe and effective therapy system for regenerative medicine
- Promotes wound healing
- Effectively improves the appearance of cellulite, stretch marks and scars
- Non-invasive, tissue-conserving, painless and highly efficient method to enhance dermal tissue remodelling and regeneration
- Strengthens and rebuilds connective tissue which visibly improves the skin's elasticity and resistance
- Activates the metabolism and proliferation of progenitor cells
- Improves blood flow, lymph circulation and tissue perfusion
- Regenerative and anabolic action
- Anti-inflammatory and antibacterial effect
- Analgesic power
- User-friendly and patient-convenient
- Premium MTS Spark Wave® Technology

7. BIBLIOGRAPHY

7.1 RECOMMENDED LITERATURE

Angehrn, F., Kuhn, C., Son nabend, O., & Voss, A. (2008). Extracorporeal shock waves as curative therapy for varicose veins? *Clinical Interventions in Aging*, 3(1), 175–182.

Angehrn, F., Kuhn, C., & Voss, A. (2007). Can cellulite be treated with low-energy extracorporeal shock wave therapy? *Clinical Interventions in Aging*.

Bae, H., & Kim, H. J. (2013). Clinical outcomes of extracorporeal shock wave therapy in patients with secondary lymphedema: A pilot study. *Annals of Rehabilitation Medicine*, 37(2), 229–234. <https://doi.org/10.5535/arm.2013.37.2.229>

Chen, R. F., Chang, C. H., Wang, C. T., Yang, M. Y., Wang, C. J., & Kuo, Y. R. (2019). Modulation of vascular endothelial growth factor and mitogen-activated protein kinase-related pathway involved in extracorporeal shockwave therapy accelerate diabetic wound healing. *Wound Repair and Regeneration*. <https://doi.org/10.1111/wrr.12686>

Chen, R. F., Yang, M. Y., Wang, C. J., Wang, C. T., & Kuo, Y. R. (2020). Proteomic analysis of peri-wounding tissue expressions in extracorporeal shock wave enhanced diabetic wound healing in a streptozotocin-induced diabetes model. *International Journal of Molecular Sciences*. <https://doi.org/10.3390/ijms21155445>

de Lima Morais TM, Meyer PF, de Vasconcellos LS, E Silva JC, E Andrade IF, de Farias VAF, da Silva IC, Araújo RMFG, da Silva RMV, Pacheco EF, S. C. (2018). Effects of the extracorporeal shock wave therapy on the skin: an experimental study. *Lasers Med Sci*, [Epub ahead of print]. <https://doi.org/10.1007/s10103-018-2612-8>

Fischer, S., Mueller, W., Schulte, M., Kiefer, J., Hirche, C., Heimer, S., ... Reichenberger, M. A. (2015). Multiple extracorporeal shock wave therapy degrades capsular fibrosis after insertion of silicone implants. *Ultrasound in Medicine and Biology*, 41(3), 781–789. <https://doi.org/10.1016/j.ultrasmedbio.2014.10.018>

Heine, N., Prantl, L., & Eisenmann-Klein, M. (2013). Extracorporeal shock wave treatment of capsular fibrosis after mammary augmentation—Preliminary results. *Journal of Cosmetic and Laser Therapy*. <https://doi.org/10.3109/14764172.2012.738915>

Kim, S.-Y., Bae, H., & Ji, H. M. (2015). Computed Tomography as an Objective Measurement Tool for Secondary Lymphedema Treated With Extracorporeal Shock Wave Therapy. *Annals of Rehabilitation Medicine*, 39(3), 488. <https://doi.org/10.5535/arm.2015.39.3.488>

Knobloch, K., & Kraemer, R. (2015). Extracorporeal shock wave therapy (ESWT) for the treatment of cellulite - A current metaanalysis. *International Journal of Surgery*. <https://doi.org/10.1016/j.ijsu.2015.07.644>

Kubo, M., Li, T. S., Kamota, T., Ohshima, M., Shirasawa, B., & Hamano, K. (2010). Extracorporeal shock wave therapy ameliorates secondary lymphedema by promoting lymphangiogenesis. *Journal of Vascular Surgery*, 52(2), 429–434. <https://doi.org/10.1016/j.jvs.2010.03.017>

Kuhn, C., Angehrn, F., Son nabend, O., & Voss, A. (2008). Impact of extracorporeal shock waves on the human skin with cellulite: A case study of an unique instance. *Clinical Interventions in Aging*. <https://doi.org/10.2147/cia.s2334>

Mahmoud El-Shazly, Wafaa Hussien Borhan, Wael Naeem Thabet, A. H. (2016). Response of Post-Mastectomy Lymphedema to Extracorporeal Shockwave Therapy. *Journal of Surgery*, 4(3–1), 14–20. <https://doi.org/10.11648/j.js.s.2016040301.13>

Modena, D. A. O., da Silva, C. N., Grecco, C., Guidi, R. M., Moreira, R. G., Coelho, A. A., ... de Souza, J. R. (2017). Extracorporeal shockwave: mechanisms of action and physiological aspects for cellulite, body shaping, and localized fat—Systematic review. *Journal of Cosmetic and Laser Therapy*. <https://doi.org/10.1080/14764172.2017.1334928>

Serizawa, F., Ito, K., Matsubara, M., Sato, A., Shimokawa, H., & Satomi, S. (2011). Extracorporeal shock wave therapy induces therapeutic lymphangiogenesis in a rat model of secondary lymphoedema. *European Journal of Vascular and Endovascular Surgery : The Official Journal of the European Society for Vascular Surgery*, 42(2), 254–260. <https://doi.org/10.1016/j.ejvs.2011.02.029>

Wang, C. J., Ko, J. Y., Chou, W. Y., Cheng, J. H., & Kuo, Y. R. (2018). Extracorporeal shockwave therapy for treatment of keloid scars. *Wound Repair and Regeneration*. <https://doi.org/10.1111/wrr.12610>

7.2 MTS SPARK WAVE® REFERENCES

Antonic V, Hartmann B, Münch S, Belfekroun C, Niedobitek G, et al. (2015). Extracorporeal Shockwaves (ESW) Promote Proliferation and Differentiation of Keratinocytes In vitro-Histology and Immunohistochemistry. *J Bioengineer & Biomedical Sci* 5:161. <https://doi.org/10.4172/2155-9538>

Belloli, L., Cugno, M., D'Agostino, M. C., Ughi, N., Tedeschi, A., Respizzi, S., & Marasini, B. (2013). Shock wave therapy for systemic sclerosis. *Rheumatology International*. <https://doi.org/10.1007/s00296-011-2277-0>

Davis, T. A., Stojadinovic, A., Anam, K., Amare, M., Naik, S., Peoples, G. E., ... Elster, E. A. (2009). Extracorporeal shock wave therapy suppresses the early proinflammatory immune response to a severe cutaneous burn injury. *Int Wound J*, 6(1), 11–21. <https://doi.org/10.1111/j.1742-481X.2008.00540.x>

Delgado-Márquez, A. M., Carmona, M., Vanaclocha, F., & Postigo, C. (2015). Effectiveness of extracorporeal shock wave lithotripsy to treat dystrophic calcinosis cutis ulcers. *Actas Dermo-Sifilograficas*. <https://doi.org/10.1016/j.adengl.2014.12.004>

Mittermayr, R., Antonic, V., Hartinger, J., Kaufmann, H., Redl, H., Téot, L., ... Schaden, W. (2012). Extracorporeal shock wave therapy (ESWT) for wound healing: Technology, mechanisms, and clinical efficacy. *Wound Repair and Regeneration*. <https://doi.org/10.1111/j.1524-475X.2012.00796.x>

Ottomann, C., Hartmann, B., Tyler, J., Maier, H., Thiele, R., Schaden, W., & Stojadinovic, A. (2010). Prospective randomized trial of accelerated re-epithelization of skin graft donor sites using extracorporeal shock wave therapy. *Journal of the American College of Surgeons*. <https://doi.org/10.1016/j.jamcollsurg.2010.05.012>

Ottomann, C., Stojadinovic, A., Lavin, P. T., Gannon, F. H., Heggeness, M. H., Thiele, R., ... Hartmann, B. (2012). Prospective Randomized Phase II Trial of Accelerated Reepithelialization of Superficial Second-Degree Burn Wounds Using Extracorporeal Shock Wave Therapy. *Annals of Surgery*, 255(1), 23–29. <https://doi.org/10.1097/SLA.0b013e318227b3c0>

Ottomann et al. (2009). Accelerated reepithelisation of a IIb ° scald through extracorporeal shock wave therapy. Reepithelisierung, Beschleunigte Fallvorstellung, Stoßwellentherapie, 3, 1–4.

Rohringer, S., Holnthoner, W., Hackl, M., Weihs, A. M., Rünzler, D., Skalicky, S., ... Redl, H. (2014). Molecular and cellular effects of in vitro shockwave treatment on lymphatic endothelial cells. PLoS ONE, 9(12).
<https://doi.org/10.1371/journal.pone.0114806>

Saggini, R., Saggini, A., Spagnoli, A. M., Dodaj, I., Cigna, E., Maruccia, M., ... Scuderi, N. (2015). Extracorporeal shock wave therapy: An emerging treatment modality for retracting scars of the hands. Ultrasound in Medicine and Biology, 42(1), 185–195.
<https://doi.org/10.1016/j.ultrasmedbio.2015.07.028>



Aesthetics



dermagold100®





MTS Medical UG (limited liability)
Rev. 03-03-21
www.mts-medical.com