## plasma care®

# Cold plasma therapy in wound treatment and dermatology

Mode of action | application | case studies | research results



## The effects of plasma care® in one minute

#### Physical mode of action





No known side effects

No resistance of bacteria to cold plasma

#### Accelerated wound healing



Promotion of wound healing



Inactivation of bacteria, fungi and viruses



Normalization of pH value



#### Mobile device



Handy and battery powered



Without addition of carrier gas



Safe and easy to use, can be delegated

#### Wide range of indications



Chronic and acute wounds



Inflammatory skin

diseases



Nail and foot fungus

#### Expert opinions on plasma care®



#### Dr. Nikolaus Scheper, Diabetologist, Germany

"I have been using plasma care<sup>®</sup> in our diabetology practice for over a year to treat diabetic foot syndrome (DFS) and other problematic wounds. I am convinced that cold plasma should definitely be part of standard care for DFS in the future."



#### Rahel Wyss, Wound expert, Switzerland

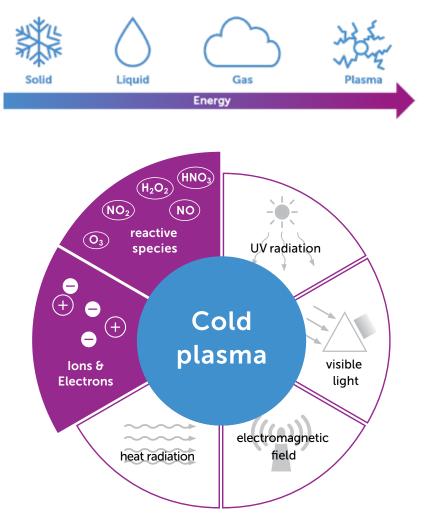
"Cold plasma therapy can be used from the first day (exudation phase) to the last day (epithelialization/scar formation). It is very easy to use as the plasma care<sup>®</sup> is very handy and small."

## **Cold atmospheric plasma - the "miracle substance" from physics conquers medicine**

When ice or water are heated - i.e. energy is supplied to them - they change their state of aggregation: ice melts and water boils.

When energy is supplied to gas, plasma is formed. Therefore, plasma is the fourth fundamental state of matter, in which a gas is completely or partially ionized.

Cold atmospheric plasma (CAP) is the term used when the temperature increases only slightly during the formation of the plasma and the atmospheric pressure prevailing on earth is sufficient to produce it<sup>1</sup>. The term "non-invasive physical plasma" (NIPP) has also become established for use in science.



Components of cold atmospheric plasma

The gas mixture in the air can also be converted into plasma through the supply of energy. This plasma has properties that can be used in medicine to treat patients.<sup>2, 3</sup>

Physically, CAP consists of free electrons, radicals, ions and reactive species that are generated from the air. The electric field generated when plasma care<sup>®</sup> is used is minimal. Implanted and external pacemakers or defibrillators are therefore not a contraindication. The UV radiation generated is also minimal and well below the permitted limit.

lons & electrons	N <sup>+</sup> , N2 <sup>+</sup> , N3 <sup>+</sup> , N4 <sup>+</sup> , O <sup>+</sup> , O2 <sup>+</sup> , NO <sup>+</sup> , NO2 <sup>+</sup> , H <sup>+</sup> , H2 <sup>+</sup> , H3 <sup>+</sup> , OH <sup>+</sup> , H2O <sup>+</sup> , H3O <sup>+</sup> , e <sup>-</sup> , O <sup>-</sup> , O2 <sup>-</sup> , O3 <sup>-</sup> , O4 <sup>-</sup> , NO <sup>-</sup> , N2O <sup>-</sup> , NO2 <sup>-</sup> , NO3 <sup>-</sup> , H <sup>-</sup> , OH	
Reactive species	excited N2, excited O, H, N, O, excited O2, O3, NO, N2O, NO2, N2O3, N2O4, N2O5, H2, OH, HO2, H2O2, HNO, HNO2, HNO3	
UV radiation	Max. 0,00198 J/m <sup>2</sup> in 3 minutes (limit = $30 \text{ J/m}^2$ per day)	
Visible light	purple glow	
Heat radiation	$\Delta T$ = approx. 1 °C/minute, always $\leq$ 40 °C	





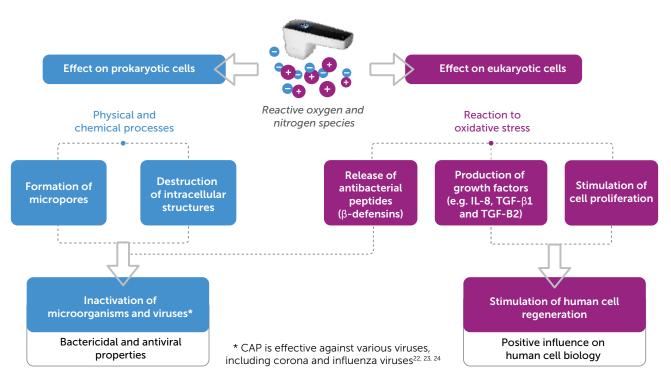
Plasma source with mesh electrode and activated plasma source.

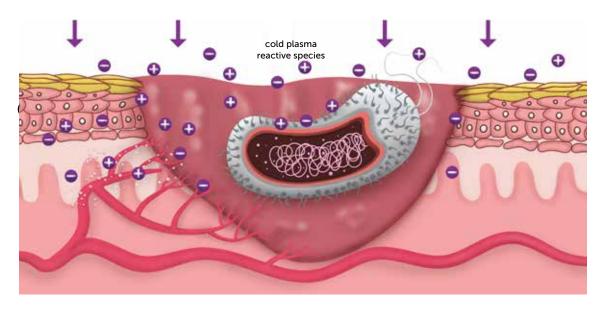
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The use of cold atmospheric plasma has been established in medicine for over 10 years and has proven to be extremely successful.<sup>4,5,6,7,8,9</sup> The effective inactivation of bacteria and the stimulation of intracellular processes in human (eukaryotic) cells have been well researched.<sup>10,11,12,13</sup>

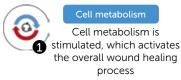
The reactive species in the plasma have an effect on the cell membrane. The effects vary greatly depending on the type of cell. In bacteria (prokaryotic cells), long-lived reactive species of the CAP destroy macromolecules and the DNA inside the cell. This physical mode of action is also used to inactivate bacteria that have developed antibiotic resistance.<sup>14,15,16,17,18</sup>

In eukaryotic cells, cold atmospheric plasma triggers intracellular mechanisms through oxidative stress that have a very positive effect on wound healing. Although fungi are eukaryotic cells as well, they are inactivated by oxidative stress when CAP is applied. The antiviral effect of the reactive oxygen species produced by cold atmospheric plasma has also been demonstrated.<sup>19</sup>





#### Intracellular processes



#### Effect on bacterial cells



Cell wall/cell membrane Breaking of chemical

compounds and opening of signalling pathways as well as interaction with cells leads to the destruction of cellular components



#### Stimulation of angiogenesis\*

leads to better blood circulation in the wound and the surrounding area.

\*vessel formation from existing blood vessels



Destruction of DNA and RNA reduces the replication rate



#### Release of cytokines\*

promotes cell growth

\*Proteins that regulate cell growth and differentiation



#### Proteins and enzymes

Denaturation of proteins, inactivation of enzymes within the cell and oxidation of amino acids

Human cells are protected against inactivation by the cold plasma owing to their cell nucleus and cellular repair mechanisms. It has also been observed in vitro that the oxidative stress caused by cold plasma stimulates the biological survival mechanisms of cells. A new study also shows that treatment with cold plasma regulates the pH value in the wound and thus favors wound healing.<sup>20</sup>

# Optimal plasma design from research – the technology

The plasma care<sup>®</sup> and plasma derma care<sup>®</sup> devices use an indirect plasma source based on patented surface micro-discharge technology (SMD).

With this surface micro-discharge, no current flows through the patient's skin. The skin and the wound surface only come into contact with the therapeutically effective plasma components.

Therefore, plasma care<sup>®</sup> is suitable for use on patients with pacemakers and defibrillators.

#### Homogeneous plasma quality without carrier gas

The reactive species formed in the plasma care<sup>®</sup> spacer are generated directly from the air without a carrier gas. In order to guarantee for a most homogeneous and repeatable plasma quality possible, two parameters are constant with plasma care<sup>®</sup>:

- 1. The spacer precisely defines the volume in which the plasma generates reactive species.
- 2. The treatment time is set and the device stops automatically. The area covered by the spacer is thus treated homogeneously within the treatment time.

The device is suitable for use on patients with pacemakers or defibrillators.

## plasma care<sup>®</sup> – mobile, safe and easy to use

plasma care<sup>®</sup> is a mobile medical device for the treatment of wounds and inflammatory skin diseases using cold, atmospheric plasma.

It is light, handy and battery-operated - approx. 100 treatments are possible with a fully charged battery. It is charged inductively in a charging station. This means that plasma care<sup>®</sup> can be used in clinical or private practice setting, as well as by outpatient care services and wound specialists.



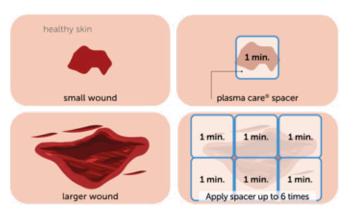
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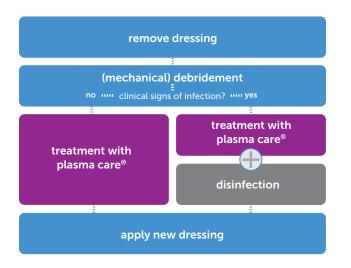
## plasma care® – easy integration into wound treatment

#### Handling the plasma care® spacer

plasma care<sup>®</sup> is available with a sterile packed spacer for wound treatment. This enables a treatment area of 13 cm<sup>2</sup>. If larger areas need to be treated, a spacer can be applied up to 6 times during one therapy session.

plasma care<sup>®</sup> spacers are individually sterile packed to ensure the sterile wound treatment of all patients and to avoid cross-contamination. The spacer is placed lightly on the wound without causing any additional pain through pressure.





#### Wound care procedure

Therapy with CAP does not replace conventional wound care. The wound bed must be mechanically debrided to allow the cold plasma to work optimally. We recommend integrating treatment with plasma care<sup>®</sup> into standard wound care after cleaning the wound bed.

In the case of heavily contaminated wounds, an antiseptic can also be used to achieve a long-term antibacterial effect.

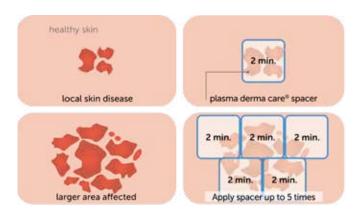
Of course, any treatment of underlying diseases should always be an integral part of guideline-compliant wound care.

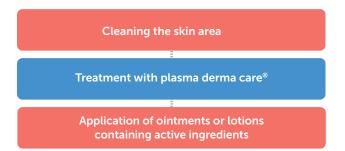
### plasma derma care® - for the treatment of skin diseases

#### Skin treatment procedure

For the treatment of inflammatory skin conditions, we offer plasma derma care<sup>®</sup> with a non-sterile, but softly padded plasma derma care<sup>®</sup> spacer.

As skin conditions often occur on curved areas of skin such as the cheeks and chin, the plasma derma care<sup>®</sup> spacer is padded with soft foam. It therefore lies comfortably on the skin and optimally seals off the plasma space.





#### Procedure of the skin treatment

For the treatment of inflammatory skin diseases, we recommend cleaning the area to be treated.

If ointments containing active ingredients (e.g. cortisone) are used, only apply them after the plasma treatment.

Plasma therapy is in line with guidelines for the treatment of wounds: S2k guideline"Rational therapeutic use of cold physical plasma" by the Association of the Scientific Medical Societies in Germany (AWMF)

Cold plasma therapy is part of specialist dermatology training in Germany.

## Indication areas in wound care

	Indication	Clinical aspects
Chronic wounds	<ul> <li>ulcers of any genesis (e.g. arterial, venous, diabetic, neuropathic)</li> <li>decubitus ulcers</li> <li>pyoderma gangrenosum</li> </ul>	<ul> <li>critical colonisation or infektion with bacteria</li> <li>prevention of bacterial load (prophylactic)</li> </ul>
Acute, open wounds	<ul> <li>burns</li> <li>frostbite</li> <li>abrasions, cuts &amp; puncture wounds</li> <li>contusions</li> <li>lacerations</li> <li>bite wounds</li> <li>amputations</li> <li>gunshot wounds</li> </ul> Entry points: <ul> <li>catheter, port, stoma driveline entry</li> <li>points PEG/SPK</li> </ul> External fixator Postoperative wound healing disorder: <ul> <li>infected or infection-prone surgical wounds</li> <li>surgical wounds healing by secondary intention</li> <li>split-thickness skin grafts (STSG) (donor site and graft)</li> </ul>	<ul> <li>wound healing disorder</li> <li>wound areas difficult to clean (e.g. groin, pubic, anus area)</li> <li>large wounds</li> <li>long surgical sutures/suture tension/ suture dehiscence</li> <li>long surgeries</li> <li>wound areas at stromgly stressed extremities</li> </ul>

## **Dermatological fields of application**

Indication	Cause	Clinical aspects
<ul> <li>Shingles</li> <li>Ringworm</li> <li>Thrush</li> <li>Perioral dermatitis</li> <li>Acne</li> <li>Psoriasis</li> <li>Atopic eczema</li> <li>Rosacea</li> <li>Nail fungus</li> <li>Athlete's foot</li> </ul>	<ul> <li>inflammatory</li> <li>autoimmune</li> <li>bacterial</li> <li>viral</li> <li>acute</li> <li>vasculitic</li> </ul>	<ul> <li>Inactivation of herpes viruses favours healing</li> <li>Avoidance of bacterial superinfections</li> <li>CAP kills fungi and spores. This makes it an effective therapy for skin mycoses</li> <li>Diseases such as psoriasis and atopic eczema are not cured by CAP. However, CAP can significantly alleviate inflammation and itching</li> </ul>

Ongoing research and experimental application of CAP in clinics and research facilities will permanently expand the areas of application.

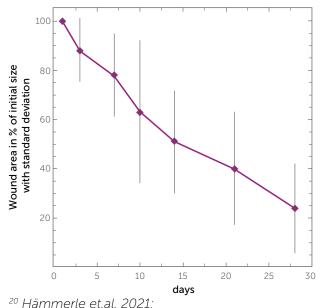
# Promoting wound healing with plasma care<sup>®</sup> - results of a pilot study

In a pilot study<sup>20</sup>, 10 patients with chronic wounds were treated with plasma care<sup>®</sup> in addition to standard-of-care treatment. The reduction in wound size and the pH value within the wound were measured.

#### Treatment plan:

- Week 1: 3 treatments
- Week 2 and 3: 2 treatments
- Week 4 and 5: 1 treatment

#### Average reduction of wound area in 28 days



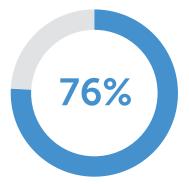
### Results of the pilot study:

All wounds showed a significant reduction in wound area within the five weeks.

Three patients showed clinical signs of infection at the start of treatment, but these had healed by day 14 at the latest.

The amount of exudate decreased in all patients. The proportion of stable granulation tissue increased significantly during the study period.

## Significant reduction in pain after just 3 treatments.



Average reduction in wound area of 76% in 28 days after just seven treatments.

#### The role of pH in wound healing:

- An alkaline pH range favours the growth of ٠ bacteria and biofilm.
- An alkaline pH value restricts the function of ٠ fibroblasts, which are responsible for wound closure.
- At alkaline pH values, hemoglobin releases less oxygen (Bohr effect). As a result, the cells in the wound are less well supplied with oxygen.

Treatment with CAP lowers the pH value in the wound and thus additionally favors wound healing.

13

11

9

7

5

3

1

0

injury

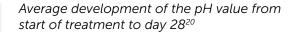
inflammation

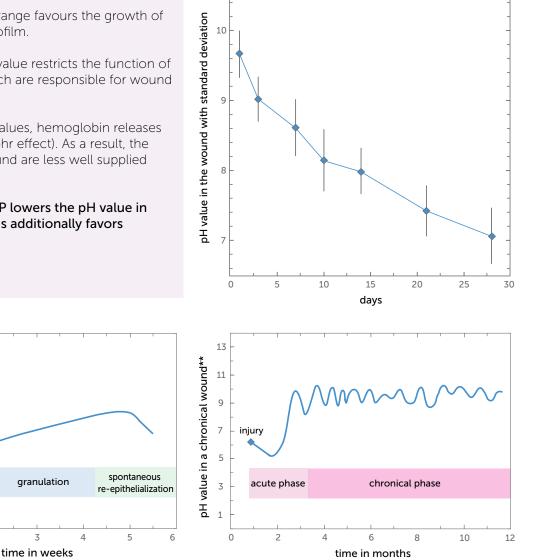
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2

3

pH value in an acute wound\*\*





\*\* Illustrations according to Dargaville et.al. 2012. Sensors and imaging for wound healing: A review<sup>23</sup>

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## Case studies – Complex, chronic wounds of various origins

#### Diabetic foot syndrome

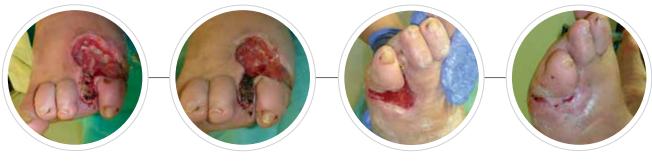
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Patient (50 years) with diabetic foot syndrome.

Infected ulcers above the metatarsal bones (left) and necrotic 4th toe. Amputation due to deterioration of the wound situation. Wound infection with partially resistant corynebacteria, enterococci and staphylococci.

#### Treatment procedure:

- 2 CAP treatments per week in the first 3 weeks, followed by 1 CAP treatment every 14 days
- 9 treatments in 12 weeks as part of the dressing change
- healing within 12 weeks of starting
   plasma therapy



Day 0 initial situation

Day 2 2 CAP treatments

Day 14 4 CAP treatments

Day 83 9 CAP treatments

#### **Treatment success**

Amputation of the 5th toe could be averted. Complete wound closure on day 105.

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#### **Ulcus cruris**

Patient (77 years old), bedridden due to a spinal injury.

Recurrence of a leg ulcer of unknown origin on the right lower leg, no edema, vascular status unclear.

Wound healing had stagnated for several months, partly purulent coatings, patient reported severe pain during mechanical wound cleansing.

#### Treatment procedure:

- 8 CAP treatments (1 min) in 4 weeks lead to a significant reduction in wound size
- Progressive epithelialisation & pain reduction
- Interruption of CAP treatment leads to recurrence of ulcer; complete epithelialization of the wound after 4 weeks of renewed CAP therapy (2 x week, 1 min)



#### **Treatment success**

Patient is pain-free. Complete wound closure after 14 weeks.

## Postoperative wound healing disorder

Patient (77 years),

Secondary healing wound (split-thickness skin graft and flap plasty) after trauma (contusion in a car accident).

Wound healing disorder with known chronic venous insufficiency and cardiac insufficiency.

Infection with Enterobacter aerogenes, additional tendency to edema formation in the lower legs.

#### Treatment procedure:

- 2 CAP treatments per week (1 min each)
- Switch to moist wound care to soften the incrustations and necroses
- Mechanical cleaning
- After 18 treatments in 11 weeks, wound completely epithelialized except for one superficial skin opening (wound size: 0.22 x 0.17 cm)



Week 0 initial situation

Week 1 3 CAP treatments

Week 2 5 CAP treatments

Week 9 12 CAP treatments

Week 11 14 CAP treatments

#### Treatment success

Complete wound closure two weeks after the last plasma treatment.



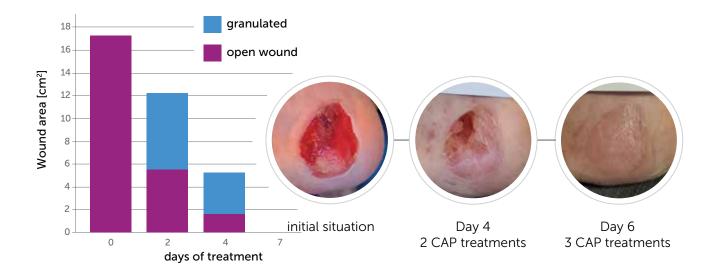
#### Simple wound on the heel

Patient (39 years old), without comorbidities

Blister while skiing. The bladder was permanently exposed to mechanical stress as the patient continued to ski throughout the entire treatment period.

#### Treatment procedure:

- 3 CAP treatments in 7 days
- Day 2: Wound size reduced by 30%. The remaining wound area is 55% granulated
- Day 4 (2 CAP treatments): 70% of the original wound healed, 71% of the remaining wound granulated
- 3 CAP treatments (7 days after first documentation): wound completely healed



#### **Treatment success**

Complete wound closure after one week. Patient could continue to put weight on the heel.

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## **Case studies from dermatology -CAP for inflammatory skin diseases**

#### Psoriasis on the ankle joint

20

Patient (52 years old) with type 2 psoriasis, which occurs intermittently and is very itchy. The disease has been present for approx. 6 months.

**Previous treatment:** Application of a cortisone ointment only led to a short-term improvement.

#### Treatment procedure:

- 4 CAP treatments in 7 days
- Additional skin care: 10% urea cream and salicylic acid plasters



#### Treatment success:

The patient feels more comfortable, no pain, hardly any itching and no more tightness in the ankle.

## Postoperative adjunctive therapy after aesthetic facelift

Patient (66 years old) in good general health presented for liposuction and skin tightening.

Correction with typical pre- and retroauricular scar.

#### Treatment procedure:

- Start CAP treatment three days after the operation
- Treatment of all surgical sutures for one minute each
- 7 CAP treatments in 22 days



#### Treatment success:

There were no signs of inflammation, infection, epidermolysis or dehiscence. The wound healed quickly and without irritation.

#### Acne vulgaris

Patient (17 years old), without comorbidities

Pronounced acne, especially on the cheeks and forehead. Papules cause an unpleasant feeling of tension.

#### Treatment procedure:

- 6 CAP treatments in 3 weeks
- Peeling, professional cleansing, plasma treatment and tonic



Week 0 initial situation

Week 2 4 CAP treatments Week 3 6 CAP treatments

#### **Treatment success**

Inflammation and redness are significantly reduced. The feeling of tension has disappeared.

#### Rosacea

Patient (44 years), without underlying diseases

Rosacea on both cheeks for several years.

#### Treatment procedure:

- 3 CAP treatments in two weeks
- The patient's make-up was removed only with cosmetic wipes without product
- The affected areas were each treated treated with CAP for 2 minutes



Initial situation

Day 4 1 CAP treatment Day 9 2 CAP treatments

#### Treatment success:

After just three treatments, the pustules were almost healed and the redness was visibly reduced.

# Clinical and observational studies with plasma care<sup>®</sup>

Hygcen (2020) Skin disinfection test according to VAH Method 13 on natural skin flora and supplemented with E. coli

Scheper et al. (2021) Cold plasma therapy with the handheld device plasma care® improves the tendency to heal in problem wounds - 10 case studies from diabetological practice

Yuta Terabe et al. (2021) Using cold plasma to treat chronic foot ulcer infection

Yuta Terabe et al. (2021) Treating hard-to-heal skin and nail onychomycosis of diabetic foot with plasma therapy

Brüning et al. (2021) Using cold atmospheric plasma to treat hard to heal wounds. A case study with 10 Patients (with 19 wounds) treated in a dermatological outpatient clinic Hämmerle et al.2021; Positive effects of cold atmospheric plasma on pH in wounds: a pilot study

Dejonckheere et al. 2022. Non-Invasive Physical Plasma for Preventing Radiation Dermatitis in Breast Cancer: A First-In-Human Feasibility Stud

Deitmerg et al. 2022; Wundbehandlung mit Kaltplasma. <u>https://www.bibliomed-pflege.de/sp/</u> <u>artikel/47048-wundbehandlung-mit-kaltplasma</u>

Dejonckheere et al. 2024. Non-invasive physical plasma for preventing radiation dermatitis in breast cancer: Results from an intrapatient-randomised double-blind placebo-controlled trial

Current studies and clinical data can also be found on our website



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<sup>4</sup> Isbary, G. et al. First Prospective Randomized Controlled Trial to Decrease Bacterial Load Using Cold Atmospheric Argon Plasma on Chronic Wounds in Patients. Br. J. Dermatol. 2010, 163 (1), 78–82. <u>https://doi.org/10.1111/j.1365-2133.2010.09744.x</u>.

<sup>5</sup> Isbary, G. et al. Successful and Safe Use of 2 Min Cold Atmospheric Argon Plasma in Chronic Wounds: Results of a Randomized Controlled Trial. Br. J. Dermatol. 2012, 167 (2), 404–410. https://doi.org/10.1111/j.1365-2133.2012.10923.x. <sup>6</sup> Isbary, G. et al. Cold Atmospheric Argon Plasma Treatment May Accelerate Wound Healing in Chronic Wounds: Results of an Open Retrospective Randomized Controlled Study in Vivo. Clin. Plasma Med. 2013, 1 (2), 25–30. <u>https://doi.org/10.1016/j.</u> <u>cpme.2013.06.001</u>.

<sup>7</sup> Heinlin, J. et al. Randomized Placebo- Controlled Human Pilot Study of Cold Atmospheric Argon Plasma on Skin Graft Donor Sites. Wound Repair Regen. Off. Publ. Wound Heal. Soc. Eur. Tissue Repair Soc. 2013, 21 (6), 800–807. <u>https://doi.org/10.1111/</u> <u>wrr.12078</u>.

<sup>8</sup> Stratmann, B. et al. Effect of Cold Atmospheric Plasma Therapy vs Standard Therapy Placebo on Wound Healing in Patients With Diabetic Foot Ulcers: A Randomized Clinical Trial. JAMA Netw. Open 2020, 3 (7), e2010411. <u>https://doi. org/10.1001/jamanetworkopen.2020.10411</u>.

<sup>9</sup> Jensen, J.-O. et al. The Repetitive Application of Cold Atmospheric Plasma (CAP) Improves Microcirculation Parameters in Chronic Wounds. Microvasc. Res. 2021, 138, 104220. <u>https://doi.org/10.1016/j.mvr.2021.104220</u>. <sup>10</sup> Arndt, S. et al. Effects of Cold Atmospheric Plasma (CAP) on ß-Defensins, Inflammatory Cytokines, and Apoptosis-Related Molecules in Keratinocytes in Vitro and in Vivo. PloS One 2015, 10 (3), e0120041. <u>https://doi.org/10.1371/journal.</u> <u>pone.0120041</u>.

<sup>11</sup> Arndt, S. et al. Cold Atmospheric Plasma (CAP) Activates Angiogenesis-Related Molecules in Skin Keratinocytes, Fibroblasts and Endothelial Cells and Improves Wound Angiogenesis in an Autocrine and Paracrine Mode. J. Dermatol. Sci. 2018, 89 (2), 181– 190. <u>https://doi.org/10.1016/j.jdermsci.2017.11.008</u>.

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<sup>20</sup> Hämmerle et al. Journal of Wound Care. 2023, 32, 9, 530-536.

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<sup>23</sup> Dargaville, T. et al. (2012). Sensors and Imaging for Wound Healing: A review. Biosensors & bioelectronics. 41. 10.1016/j.bios.2012.09.029.



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