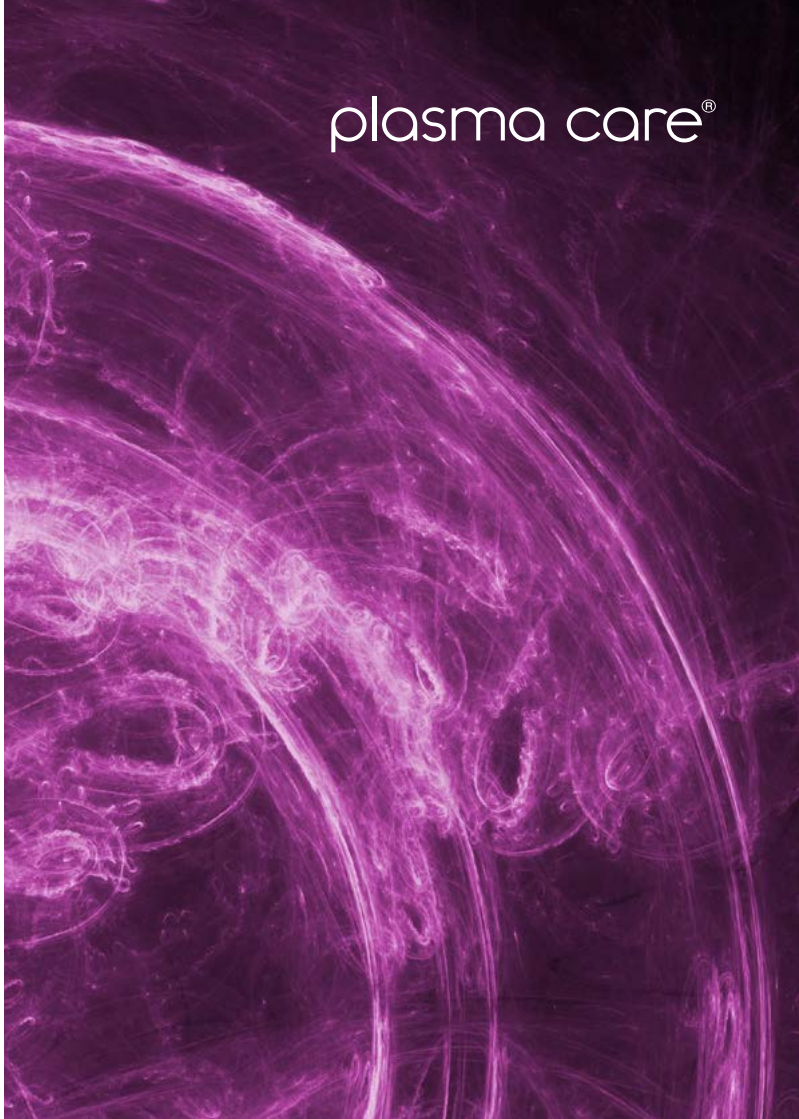
# PLASMA

Cold plasma therapy
for **wound treatment**

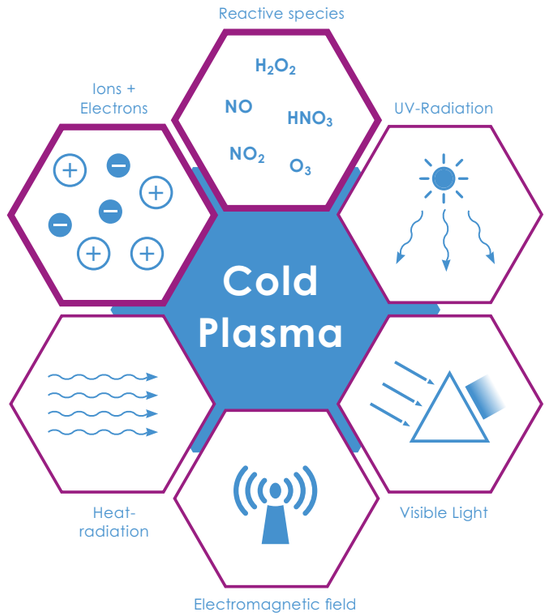


# What is cold plasma?

**Cold plasma is a partially ionised gas.** Cold plasma is generated by supplying a gas with the amount of energy required to ionise part of it so that the temperature remains below 40°C.

This process triggers a cascade of chemical reactions, which produce a so-called plasma cocktail consisting of light, heat, some ultraviolet radiation, electromagnetic fields, free electrons, ions and reactive species.

The reactive species interact with organisms, wound cells and the wound environment.




## DOUBLE ACTION FOR WOUND HEALING

**The plasma care® device is a handy, mobile medical device for the treatment of acute, infected and chronic wounds.**

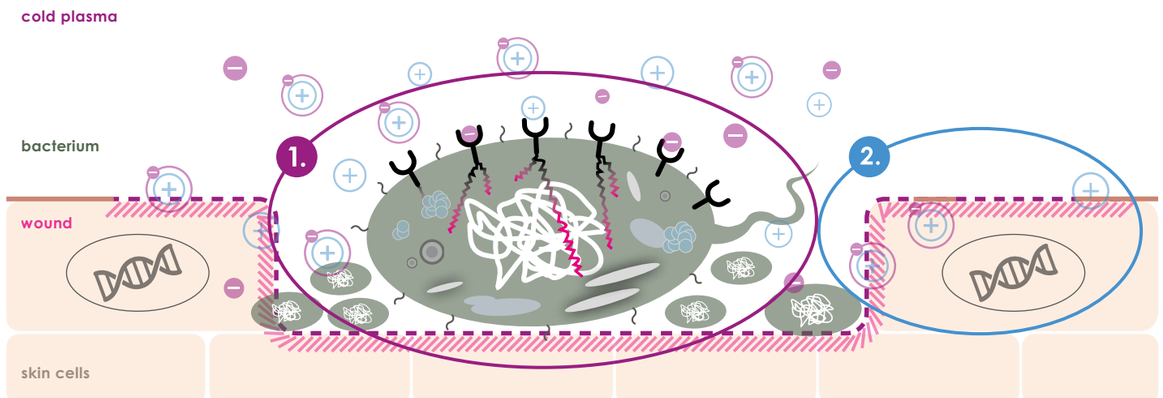
It makes use of cold atmospheric plasma (in short: cold plasma/CAP) to inactivate microorganisms including multi-resistant pathogens and to stimulate wound healing.

### 1. Inactivation of microorganisms

**CAP interacts with a microorganism**, inactivates the cells of the microorganism and prevents cell proliferation by damaging DNA

### 2. Activation of wound healing

**Cell division** of the healthy cell **is stimulated by CAP**. Subsequent processes: Release of cytokines, promotion of angiogenesis & cell metabolism.



# What can cold plasma do?

## 1. Bactericidal action | Inactivation of microorganisms

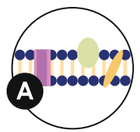
**Cold plasma interacts with the bacterial cell via interactions with the cell surface and via membrane channels where it triggers physical and chemical processes.** Proteins denature, amino acids oxidise and enzymes are inactivated, leading to the destruction of pathogens. Together with a shift in oxygen and hydrogen content, cell death ultimately occurs - the bacterium has been inactivated.

## 2. Activation of wound healing

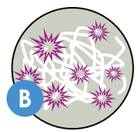
**In contrast, healthy human cells do not react negatively to cold plasma. On the contrary, cell division is stimulated in them, which additionally promotes wound healing.** Survival mechanisms are activated in healthy human cells by cold plasma. Specifically, this means the following for wounds: The release of growth factors facilitates cell growth, improves the blood flow and, together with the improved cell metabolism, promotes wound closure.

### PROCESSES IN BACTERIA

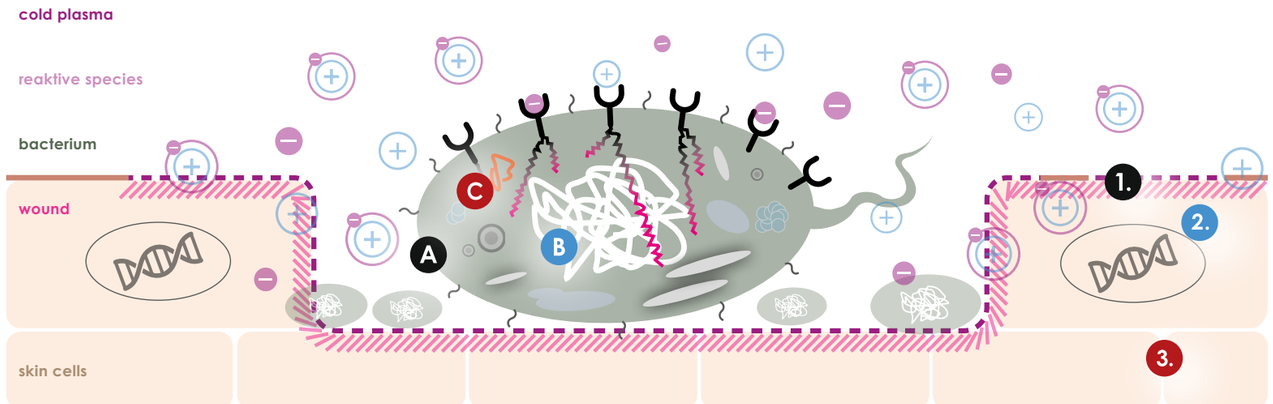
**Cell wall/cell membrane**
Decomposition of chemical compounds + opening of signalling pathways & interaction with the cell leads to the destruction of cellular components



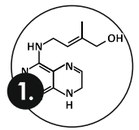

**Nucleic acids**
The destruction of DNA & RNA reduces the replication rate




**Proteins & enzymes**
Denaturing of proteins, inactivation of enzymes within the cell and oxidation of amino acids

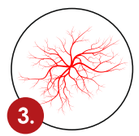




### PROCESSES IN HEALTHY HUMAN CELLS




**Release of cytokines***
promotes cell growth.
*proteins that regulate the growth and differentiation of cells


**Cell metabolism**
is stimulated, which activates the overall wound-healing process.




**Stimulation of angiogenesis***
leads to improved blood flow in the wound and the wound environment.
* formation of new vessels from pre-existing blood vessels

# For which wounds is cold plasma therapy suitable?

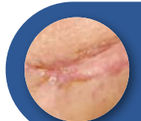
### CHRONIC WOUNDS

- Diabetic foot syndrome
- Dekubitus (bed sore)
- Ulcus cruris arteriosum (arterial leg ulcer)
- Ulcus cruris venosum (venous leg ulcer)
- Ulcus cruris mixtum (mixed leg ulcer)

### ACUTE WOUNDS

- Abrasions/cuts
- Lacerations
- Frostbite
- Burns
- Split skin removal/mesh/ artificial skin etc.
- Amputations
- Radiation injuries

### WOUNDS OF DIFFERENT ORIGIN



- Wound-healing disorders
- Tumour wounds
- Infected/deep wounds
- Sinus pilonidalis
- Akne inversa
- Pyoderma gangraenosum
- Epidermolysis bullosa
- etc.

### LINES, PROBES, LEADS ETC.

- Drivelines
- Central venous lines/ IV lines/ arterial lines
- PEG
- Stoma
- Drainage/Redon
- Puncture sites
- External fixator

**Cold plasma therapy is basically suitable for all wounds because CAP functions in a physical manner, i.e. independently of the cause of the wound.** It sets in motion the body's own processes, which support wound healing and lead to wound closure. After 2-3 treatments, an experienced wound care practitioner can already see whether the wound is responding to the cold plasma therapy.

## WHO WILL BENEFIT from cold plasma therapy with **plasma care®**?

| Physician | Patient | Wound manager/home carer | Hospital |
|---|---|---|---|
| Faster wound healing | Free of allergens and side effects | Handy device for mobile use | Prevention: Avoidance of problem wounds in at-risk patients and at-risk wounds |
| Chronic wounds: Reduction in budget costs | Pain reduction | Easy integration into the wound treatment process | Shortened length of hospital stay*, |
| Reduction in the use of dressing material | No long-term use of antibiotics or cortisone and, as a result, reduction in the risk of developing resistance | Innovative treatment option for patients | Avoidance of secondary surgical operations |
| Proactive use: Avoidance of problem wounds in at-risk patients and at-risk wounds | Breakthrough in the treatment cycle of chronic wounds | Results count: Every healed wound brings two new patients | Reduction in the use of dressing material |
| | Investment in the patient's own health | | Mesh/grafts/flap plastics heal faster - risk minimisation |
| | Closed wound: More mobility = quality of life | | Plasma medicine: State of the art of wound treatment |

**Cold plasma therapy is also effective against multi-resistant pathogens and in cases of antibiotic resistance.**

# Mode of operation of **plasma care®**

Small electric discharges in the device bring about a chain of physical and chemical reactions with the air surrounding it. These more than 600 reactions generate the plasma cocktail.
The most important components for wound care are the reactive species, which react with the environment. In order to ensure sterile treatment and avoid cross-contamination, **plasma care®** is used in combination with a sterile-packed attachment, the **plasma care®** spacer. This is a disposable product. One spacer, with which an area of up to 78 cm² can be treated, is to be used per patient treatment.

▲ Active plasma source

▲ Single-use spacer in its packaging



# User testimonials

„We use the **plasma care®** device for complementary therapy to facilitate faster wound healing and prevent infection.“

Johannes Schwaiger, Managing Director Ellipsa GmbH

„The results of the current case series confirm that cold plasma therapy is a healing-promoting addition to the guideline- and stage-appropriate wound treatment of problem wounds in specialised diabetology practices with an outpatient foot clinic.“

Dr Nikolas Scherper in „Diabetes, Stoffwechsel, und Herz“ (“Diabetes, Metabolism and Heart”) 4/2021

„Cold plasma can be used from the first day (exudation phase) until the last day (epithelialisation/scarring). The device is very easy to use as it is very handy and small.“

Rahel Wyss, Wound Expert SAfW (Swiss Association for Wound Care)

# The **plasma care®** at a glance


**Suitcase**
- **Metrics** (TxBxH): 45 x 32 x 13 cm
- **Weigt**: empty weight 990 g, with content 2,3 kg

**Charging station**
- **Metrics** (TxBxH): 11 x 9 x 8 cm
- **Power supply**: 230 V DC
- **Voltage**: 12 Volt
- **non-slip feet**

**Spacer**
- sterile **disposable**
- **Metrics** (TxBxH): 3,5 x 3,5 x 3 cm

**Device**
- **Weight**: nur 310 g
- **Metrics** (TxBxH): 16 x 5,5 x 6,5 cm
- **Battery life** sufficient for **approx. 120 treatments** on a full charge
- Illuminated **LED touch panel**

**Power cable**
- **Power supply**: 230 V DC


▲ Structure of **plasma care®**

Watch our explanatory film commissioning of the **plasma care®** *at www.terraplasma-medical.com*

# Wound treatment with **plasma care®**

## USE IN 4 STEPS

1. Use the **touch button** to switch on the device

2. Attach the **spacer** to the device

3. Place the device with the spacer **onto the wound**

4. Use the touch button to **start the treatment**

## COMPLETION OF TREATMENT

**The device stops automatically after 60 seconds.**
If necessary, the treatment can now be repeated in a grid (see following page).

Watch our explanatory film commissioning of the **plasma care®** *at www.terraplasma-medical.com*

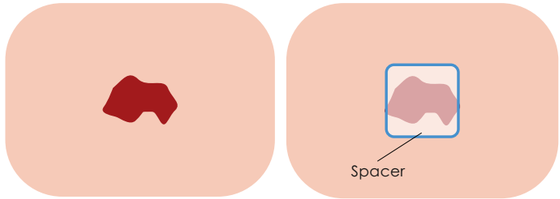


## DURATION OF TREATMENT PER WOUND AREA (12 CM²):

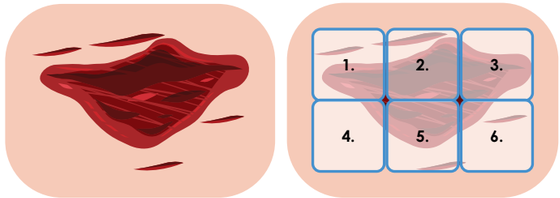
A wound area must be treated for at least 1 minute up to a maximum of 3 minutes. The duration of treatment varies with the contamination of the wound.

## TREATMENT OF LARGER WOUNDS (UP TO 73 CM²):

In the case of larger wounds the treatment can be repeated up to 5 times. To do this, simply place the device on the next part of the wound area and restart the treatment. In total 6 treatments can be performed in 10 minutes using one spacer.




▲ Small wound




▲ Large wound: Apply spacer several times

## PREPARATION OF THE WOUND:

Before the first treatment with the **plasma care®** device, the wound must be cleaned mechanically. Devitalised tissue and biofilm must be removed.

# Case studies

## Complex, chronic wounds in patients with concomitant diseases

### DIABETIC FOOT SYNDROME

**Male patient (50 years of age) 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 process::**

- 2 treatments per week for the first 3 weeks, then every 14 days (9 treatments in 12 weeks) in the course of dressing change
- Healing within 12 weeks after the start of plasma therapy

**Day 0,** Initial situation | **Day 2,** 2 CAP treatments | **Day 14,** 4 KAP treatments | **Day 42,** 7 CAP treatments | **Day 83,** 9 CAP treatments

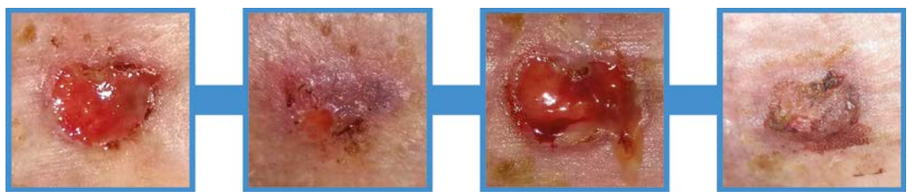


### ULCUS CRURIS

**Female patient (77 years of age), bedridden due to a spinal injury.** Recurrence of an ulcus cruris of unclear origin on the right lower leg, no oedema, vessel structure unclear. Wound healing had been stagnating for several months, purulent deposits to some extent, patient reported severe pain during mechanical wound cleaning.

**Treatment process:**

- 8 CAP treatments (1 min) in 4 weeks resulted in a significant reduction in wound size
- Progressive epithelialisation & pain reduction
- Interruption of the CAP treatment resulted in a recurrence of the ulcer, complete epithelialisation of the wound after 4 weeks of further CAP therapy (2x/week, 1 min)



Initial situation | 8 CAP treatments | Relapse after interruption of therapy | further 8 CAP treatments

# Case studies

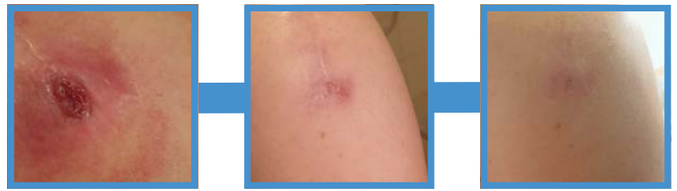
## Faster wound healing in patients without concomitant diseases

### POSTOPERATIVE WOUND HEALING DISORDER

**Female patient (28 years of age) without comorbidities**
Postoperative wound healing disorder after osteosynthesis in a displaced humeral fracture in a 28-year-old female patient. After stitch removal, a scar dehiscence of approx. 1.5 cm in diameter formed. There was a purulent secretion. Allergic reaction to the plaster.

**Treatment process:**

- treated daily for 3 min and covered with a sterile dressing
- After 1 week, significant improvements were seen, no signs of infection and no more pain; the wound secretion was clear
- After a further three days, the wound was completely closed

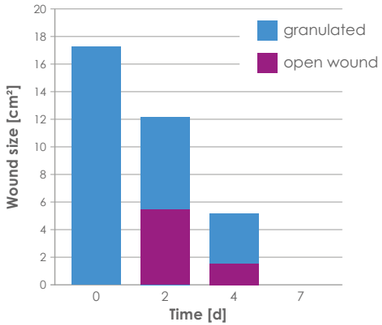


**Day 0,** Initial situation → **Day 14,** 4 CAP treatments



### MINOR WOUND

**Male patient (39 years of age) without comorbidities**
Blister acquired while skiing; because the blister was in a stress zone, it was under constant pressure also during CAP.




**Treatment process:**

- The area was treated for 1 minute on 7 days
- Day 2: Wound size reduced by 30%. 55% of the remaining wound area is 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.

Initial situation | Day 2 - 1 CAP treatment | Day 7 - 3 CAP treatments

# FAQ

**There are a lot of questions about cold plasma therapy. Here we have compiled the most common questions and their answers:**

### How long does the therapy take?

The duration of therapy depends on the type, the history and the contamination of the wound. Signs of this include a better blood flow to the wound, odour reduction, reduction in wound secretion, reduction in the wound area and less pain during the change of dressing.

### Can cold plasma also be used postoperatively?

Basically: The larger the surgical wound and the longer the operation, the greater the risk of postoperative wound healing disorders. Postoperative wounds react extremely well to cold plasma and generally heal more quickly. In the case of wound-healing disorders, cold plasma therapy ensures healthy wound healing.

### How long does one treatment take?

A wound area must be treated for at least 1 minute. Heavily contaminated wounds can be treated for up to 3 minutes per area. The duration also depends on the size of the wound. A maximum area of 70-78 cm² can be treated with one spacer. For this purpose the **plasma care®** device must be applied 6 times for one minute, i.e. the treatment takes a total time of 6 minutes.

### On which bacteria does cold plasma have an effect?

Plasma can be used against all bacteria and also MRE. A wound care therapist can already see whether the wound is responding to treatment after 2-3 treatments.

### Is the treatment painful?

Most patients do not feel the treatment itself to be painful. Wound-healing pain: There are very rare cases of patients who complain of pain after treatment. This pain is attributed to the activation of wound healing. The resumed activity of the wound is sometimes felt as pain.

### Is cold plasma hazardous to human cells?

If the wound area treatment time of 3 minutes is not exceeded, plasma does not affect healthy human cells.

### On which wounds can cold plasma be used?

Cold plasma can be used for all wounds. The treatment is not recommended, but is in principle possible, for heavily bleeding wounds and wounds from which the deposits cannot or must not be removed.

### Why is the spacer a disposable product?

The device is designed for inpatient and outpatient wound treatment, i.e. if the device is applied by different therapists to treat different patients at different times in different wards, there must be a 100% guarantee that the spacer is safe and sterile; under no circumstances must bacteria and microorganisms be carried from one patient to another. Only a disposable article can ensure this 100% guarantee.

### How do I treat cells that are difficult to access?

The **plasma care®** device should preferably be placed directly onto the wound (provided it is pain-free). In this way, a so-called “plasma chamber” with high plasma concentration can form. You can treat anatomically difficult positions (fingers/toes etc.) by “enclosing” the **plasma care®** spacer with your fingers or with the aid of compresses. Please make sure to tamponade deep pockets and fistulas in order to avoid overgranulation. If this is not possible cold plasma treatment should not be given.

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Distribution through

**VIROMED GmbH**
Flensburger Str. 18 | 25421 Pinneberg | Germany
**Tel.** +49 (0)40 429 347 077
**Mail** support@viromed.de
**Web** www.viromed.de

terraplasma MEDICAL

Manufacturer:

**terraplasma medical GmbH**
Parkring 32
85748 Garching/Munich | Germany
**Tel.** + 49 89 588 055 30
**eFax** + 49 89 588 055 99

**Let's stay in contact**

**LinkedIn** terraplasma-medical
**Mail** info@terraplasma-medical.com
**Web** www.terraplasma-medical.com

**Jens Kirsch** | CEO
**PD Dr. rer. nat. habil. med. Julia Zimmermann** | CMO
**Prof. Dr. Dr. h.c. Gregor Morfill** | Scientific advisory board

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