plasma care®

INSTRUCTION FOR USE

www.terraplasma-medical.com

CE 0197

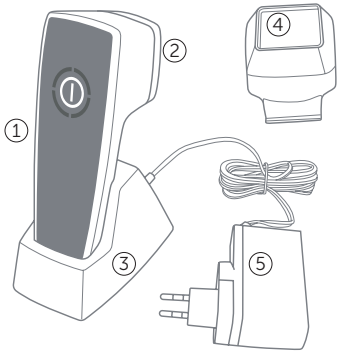
Content

Before using the plasma care, read the instructions for use carefully and completely. Damage can be avoided by following the instructions for use. The warnings and precautions must be observed, as disregard may result in serious injury or even life threatening situations. Keep these instructions for use in a safe place.

1. Product description

The plasma care is a medical device for cold plasma therapy and is used in combination with a spacer designed for the desired application.
The following illustration shows plasma care with its components.

① plasma care device
② Plasma source unit (PSU)
③ Docking station
④ Training spacer
⑤ Power supply

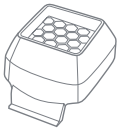


1.1 Intended Purpose

The plasma care is a medical device that must be used together with a spacer, whereby user group and indications depend on the spacer type.
The plasma care generates cold, atmospheric plasma from the surrounding air and inactivates microorganisms. It is battery-operated and can be used in both professional and domestic environments.

2. Compatibilities

These instructions for use are only complete when read in conjunction with the respective instructions for the spacer and its detailed intended purpose.
The following table provides a more detailed description of the various spacers:

	**wound spacer** Treatment of wounds and injured skin sterile No. of Sessions: **1** | Duration Session: **10 min** No. of Units: **6** | Duration Unit: **1 min**
	**derma spacer** Treatment of intact skin non-sterile No. of Sessions: **1** | Duration Session: **45 min** No. of Units: **10** | Duration Unit: **2 min**
	**podo spacer** Treatment of nails non-sterile No. of Sessions: **6** | Duration Session: **60 min** No. of Units: **4** | Duration Unit: **5 min**

3. Warnings and Precautions

Risks due to contamination / infection

Only use a spacer for one patient. Otherwise cross contamination may occur. The spacer must not be reprocessed.

Ensure that the plasma does not come in direct contact with nitrile and latex protective gloves. These can be damaged by prolonged exposure.

Clean and disinfect the plasma care device and the plama source unit after each patient treatment with an agent approved by the manufacturer to avoid cross contamination.

The (colored) training spacer is not intended for medical treatment.

Dispose of a spacer safely in accordance with applicable regulations, as described in the spacer's instructions for use.

Cleaning and disinfection of the plasma care device must only be carried out without a spacer attached.

Use spacers strictly in accordance with the instructions for use to ensure the correct application of sterile and non-sterile spacers.

Risks of electric shock

Only use the original power supply unit supplied by the manufacturer. The use of other power supply units is not permitted.

Check the plasma care for mechanical damage before each treatment. Undetected damage can lead to injuries.

Avoid spray disinfection, as electronic components may be damaged. Cleaning or disinfection in an immersion bath is prohibited.

If the plasma source is damaged it must be replaced.
The repairs may not be carried out independently or by third parties.

Do not make any changes to the plasma care.
Especially do not open the plasma care as there is a danger of high voltage.

Do not use sharp objects when cleaning the plasma source. This can damage it, which can lead to faulty plasma generation and danger from high voltage. Carry out cleaning as described and pay particular attention to the use of a lint-free cloth.

Always allow the device and plasma source to dry thoroughly before putting them back into operation, as the device may be damaged by high voltage.

Risks which lead to health impairments or serious injuries

Never place a spacer in a position that overlaps the nostrils, mouth, or eyes. If plasma is applied in the immediate vicinity of these areas, care must be taken to ensure that there is no air gap between the skin surface and the spacer. The species generated by the plasma can irritate the respiratory tract and eyes.

Treatment with the plasma care produces low concentrations of ozone. When used as intended, the legal limits are not exceeded, but the "olfactory limit" may be exceeded.
The ozone is sufficiently diluted by the ambient air. When used in small rooms and/or with several devices and/or for longer treatment times, ensure adequate ventilation (e.g. by opening windows or doors).
Individual sensitivity to ozone varies greatly. When using the plasma care in the presence of people with chronic respiratory illnesses as well as infants and small children, particular care must be taken to ensure adequate ventilation due to their particular sensitivity.

Treatment with the plasma care generates very low-intensity UV radiation. Avoid treatments on the eyes.

Risks due to fire/explosion

The use of disinfectants can cause flammable vapors, which can be ignited when the appliance is switched on. Therefore, only switch on a completely dry appliance.

Risk of reduced performance characteristics

Use of the plasma care immediately adjacent to other devices or stacked with other devices should be avoided as this could result in incorrect operation.
If use in the manner described is nevertheless necessary, the plasma care and the other devices should be observed to ensure that they are working properly.

Only use the plasma care with the manufacturer's original components and accessories. The use of other accessories, in particular power supply units other than those specified or provided by the manufacturer, may result in increased electromagnetic emissions or reduced electromagnetic immunity of the device and lead to incorrect operation.

Contamination of the plasma source must be avoided. After each use, check whether there are any residues of body fluids on the back of the plasma source or on the front of the device. If there is still dirt residue on the plasma source after cleaning, it must be replaced with a new one.

Only clean and disinfect the product with agents approved by the manufacturer to avoid damaging the material

The generation of cold atmospheric plasma within the predefined treatment time by the plasma care is determined as an essential performance. In the presence of electromagnetic disturbances the essential performance may be interrupted and can be reactivated.

Other electronic devices, especially high frequency (HF) devices such as mobile phones can impact electronic medical devices. The use of plasma care in direct vicinity of such devices can therefore lead to an increased emission of or a strongly reduced immunity of the plasma care against disturbances.
Portable HF communication devices such as radio transceiver or mobile phones (including accessories such as aerial cable and complementary antenna) must not be used within a distance less than 30 cm to the plasma care. Inobservance may lead to a performance decrease of the plasma care.

Further safety instructions

Always use the plasma care with a plasma care spacer. It is not possible to use the plasma care without a spacer.

Before treatment with plasma care, you must remove all dressings and bandages and clean the area to be treated. Otherwise, the plasma treatment may not be effective.

Solutions, creams or other products containing active ingredients must not be used immediately before treatment with the plasma care.

Only use plasma care under the specified environmental conditions. Excessive heat/cold or humidity can impair the function of the device or destroy it. If the plasma care has been transported or stored outside the specified environmental conditions, wait until the device has adjusted to the conditions before using it.

The plasma care is sensitive to liquids. If liquid enters the device, especially when used in an upward position, this may result in malfunctions or damage to the device.

4. Medical Application

The aim of plasma care is to treat wounds, skin and nail diseases caused by bacteria, fungi or viruses, or to alleviate the symptoms of such conditions. Reactive plasma species reduce the burden of bacteria, fungi and viruses.

The medical application of a spacer varies depending on the model. Information on indications, contraindications, and other application-specific details can be found in the instructions for use of the respective spacer.

Use spacers strictly in accordance with the instructions for use to ensure the correct application of sterile and non-sterile spacers.

5. Operation of the Device

5.1 Charging

Um das plasma care zu laden, stellen Sie die Ladestation auf eine ebene Fläche und stecken das Netzteil an.
Eine blaue LED zeigt die Bereitschaft der Ladestation an. Stellen Sie das Gerät in die Ladestation, um den induktiven Ladevorgang zu starten.

In der Ladestation zeigt das plasma care während des Ladevorgangs die gelbe Batterieanzeige. Ist das Gerät vollständig geladen, wird die Batterieanzeige durchgehend grün angezeigt.

The plasma care can be placed in the charging station at any time (over night). There is no risk of overcharging the battery.

After removing the device from the station, the green indicator may remain active for a few minutes.

The device must be fully charged before initial use.

Meaning of the battery display color

Green:	The plasma care is sufficiently charged.
Yellow:	At least 1 full therapy session possible.
Red:	Treatment is still possible; a full therapy session cannot be guaranteed.
Pulsating red:	Plasma treatment no longer possible.

If a therapy session is started in red battery status, it may be interrupted due to a low charge status. This will invalidate the current session on the spacer.

5.2 Preparation of the Therapy

Before you use a spacer for the therapy, you can try out plasma care with the (colored) training spacer supplied.

This special training spacer can be used for practice/demonstration for 24 practice sessions, whereby one practice session allows 6 plasma units of 1 minute each within a timeframe of 10 minutes.

The (colored) training spacer is not intended for medical treatment.

Prepare the desired spacer for your application. Observe the specific instructions in the spacer's user manual.

Now switch on the plasma care.
To do this, place your thumb on the touch button for 2–3 seconds.

The device is switched on as soon as the touch button lights up white.
Remove your thumb from the button, otherwise the device will switch off again.

In accordance with the instructions in the spacer manual, the spacer must now be connected to the plasma care device. Make sure that the tab is facing forward and that the spacer clicks into place.

The device immediately starts the initialization phase as soon as the spacer is fixed.
During this phase, the LED ring flashes blue and the characteristic noise can be heard.

After about 15–45 seconds, initialization is complete and the LED ring lights up solid blue.
The device has now successfully tested the quality of the plasma and is ready for therapy.

5.3 Performing the Therapy

Each spacer contains a predetermined number of therapy sessions. A certain number of therapy units can be performed per session within a predetermined session duration.

The detailed instructions for using the therapy must be found in the instructions for use for the respective spacer. These vary depending on the application.

A continuously glowing blue LED ring indicates that a therapy session can be started.

Start the therapy by briefly touching the button.

As soon as you hear a clear beep, remove your thumb from the button. The therapy is now running. Each segment of the LED ring flashes sequentially for a quarter of the therapy time.

When the therapy session is complete, this is indicated by a blue LED ring that lights up continuously and the absence of sound. You can now perform further therapy sessions.

5.4 Completion of the Therapy

Once the session time has elapsed or all therapy units have been completed, the spacers session is over. This is indicated by the LED ring flashing red.

To remove the spacer, press down on the tab with your thumb. Please do not use force or pull on the spacer.

Dispose of the contaminated spacer according to the regulation if all sessions are expired.
Multi-session spacers can be used again.

The device can now be switched off by holding the button for 2–3 seconds. The light of the LED ring and the button switches off.

6. Cleaning | Disinfection | Care

Clean and disinfect device and plasma source unit after each patient treatment with an agent approved by the manufacturer to avoid cross contamination.

To clean the plasma care device and the plasma source, the plasma source must first be removed. To do this, grasp the plasma source and turn it gently to the left.

Do not apply any force when turning off the plasma source, otherwise the device may be damaged.

The device and plasma source can be cleaned and disinfected using lint-free disinfectant wipes approved for device disinfection.
The manufacturer has demonstrated the basic suitability of the product for effective cleaning and disinfection with the following products:
Bacillol®AF Tissues and Bacillol® Wipes.

If an alternative product is used, the product specifications must be equivalent and the respective manufacturer's instructions for disinfection (e.g. exposure time) must be considered.

6.1 Cleaning Device

To clean, thoroughly remove coarse dirt residues and deposits by using a slightly wet cloth and carefully wiping the surface. After cleaning, visually check whether the appliance is clean. Only a clean appliance can be properly disinfected. A visibly dirty appliance must no longer be used.

6.2 Disinfection of the Device

The plasma care device (without plasma source) must be disinfected using wipe disinfection. Wipe all surfaces for at least 30 seconds and leave to act according to the instructions of the wipe manufacturer (at least 5 minutes).

6.3 Cleaning & Disinfection of the Plasma Source

Carefully dab the plasma source on the front with a lint-free disinfectant wipe. The front must not be wiped, otherwise lint may remain on the electrode.

Carefully wipe the back of the plasma source.

6.4 Drying & Assembly

Allow the plasma care device and the plasma source to dry sufficiently.

As soon as the hand-held device and the plasma source have dried, they can be reassembled.
To do this, carefully attach the plasma source and turn it to the right.

Do not apply any force when turning on the plasma source, otherwise the appliance may be damaged. As soon as the plasma source is easily engaged, the appliance can be used again.

The use of disinfectants can cause inflammatory vapors to develop, which can be ignited when the device is switched on. Therefore, only switch on a completely dry device.

Always allow the device and plasma source to dry thoroughly before putting them back into operation, as the device may be damaged by high voltage.

7. Problem Solving

If these troubleshooting tips do not result in a functional device, please contact customer service.

Removing the spacer and switching off the device will NOT interrupt or invalidate the therapy session and can therefore be used at any time as a troubleshooting measure.

If a different spacer is inserted during a therapy session than the one with which the session was started, the current session is ended. This also applies to training spacers.

A contaminated plasma source no longer produces the intended plasma. This is indicated by a constantly red LED ring segment on the plasma care device. The plasma source must be cleaned sufficiently or replaced with a new one.

Red pulsating/flashing LED ring:
This indicates an invalid spacer. The spacer has already been used or is invalid.

Troubleshooting:
1. Switch the device off an on again
2. Remove the spacer and replace it.
3. Use a different spacer.

A constantly illuminated red segment BOTTOM RIGHT indicates a malfunction of the high-voltage source.

A constantly illuminated red segment BOTTOM LEFT indicates a malfunction of the plasma source.

Troubleshooting:
1. Switch the device off and on again.
2. Switch the device off, remove and replace the plasma source and switch the device back on.
3. Check whether the plasma source is damp or dirty and clean it according to the instructions if necessary.

Initialization of the device takes longer than 15 seconds.
If the first check of the plasma source fails, the device repeats the initialization two more times. If all three attempts fail, the device displays the red LED ring. Follow the instructions from the previous case.

The touch button does not respond and the charging indicator is inactive in the charging station. The plasma care may be completely discharged. Place the device in the charging station. If the device still does not respond, please contact terraplasma medical customer service.

8. Feedback | Regulatory Compliance

Complaints, problems and safety concerns should be reported to the manufacturer or its distribution partner. In accordance with Regulation (EU) 2017/745 (MDR) on medical devices, serious incidents related to the product must be reported to both the manufacturer and the competent authority of the Member State in which the user is located.

The plasma care meets all relevant requirements of Regulation (EU) 2017/745 (MDR) and the necessary standards. It also complies with the regulatory requirements for interference emission and immunity (EMC) for operation in medical and domestic environments.

The tables at the end of this manual show compliance with the relevant standards for interference emission and immunity. There are no deviations.

9. Support| Maintenance | Disposal

9.1 Maintenance

In addition to cleaning and care, as described in chapter 6 no further maintenance work is required for the plasma care. There are no prescribed or recommended electronic safety checks or recurring tests to be carried out by the manufacturer. If desired, the plasma care can be returned to the manufacturer for maintenance purposes. Inform the manufacturer in writing before each return, stating the serial number of the plasma care and request a return authorization number (RMA number).

Please clean and disinfect the plasma care before each return and use original packaging for shipment.

9.2 Transportation

To transport the plasma care with its components, it is recommended to use the transport case provided with the medical device at any time. The product is sensitive to mechanical stress and must be transported carefully.

9.3 Spare Parts

plasma care	PC100001
plasma care handheld device	PC110001
plasma source unit	PZ240002
docking station	PZ210001
power supply unit ACM24US12	PZ220002
transport case	PZ230009
plasma care training spacer	VB312003

9.4 Disposables

wound spacer	VB319002
derma spacer	VB319007
podo spacer	VB319009

9.4 Expected Service-Life | Waste Disposal

The expected service life of the plasma care device is 10 years from the date of first use.

The plasma care must be disposed of separately as electrical and electronic equipment. The applicable country-specific disposal regulations and laws must be observed.

10. Symbols

	**Warning**: Failure to do so may result in serious personal injury or damage to property.
	**Note** on operation, maintenance or repair that is important but not associated with danger.
CE0197	CE marking with ID of the notified body

	Read the instructions for use	IP	Protection class (dust & liquid)
	CE-Mark with ID of notified body		Temperature
	Dangerous Voltage		Relative Humidity
	Manufacturers Address		Air Pressure
	Manufacturing Date		Store Dry
SN	Serial-Number		Protect from direct light
LOT	LOT-Number		Application Part Type BF
REF	Article-Reference		Do not use if damaged
MD	Medical Device		Use until

11. Storage and transportation conditions

Trade name	plasma care
REF	PC100001
Plasma technology	Surface-Micro-Discharge (SMD)
Weight plasma care device	320g
Dimensions plasma care device	L16 x W5,5 x H6 cm
Power supply unit	100-240V AC, 50-60Hz, max 24W (XP-Power ACM24US12)
Battery	LiFePO4, 6,4V, 2000mAh
IP class	IP22 (device), IP21 (power supply unit & docking station)
Operating conditions plasma care	+10 °C – +35 °C; 25% – 70% RH; 800 hPa – 1060 hPa
Storage & transport operations of plasma care	+5 °C – +45 °C; 15% – 90% RH; 700 hPa – 1060 hPa

12. Emission & Immunity Tests

Phenomenon	Limit / Compliance Level	Electromagnetic environment - guidance
Conducted and radiated emission	CISPR 11, Group 1, Class B	Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic current emissions (IEC 61000-3-2)	Class A	Device is suitable for direct connection to the public low-voltage power supply network.
Voltage fluctuations and flickering	—	
Radiated RF EM filed (IEC 61000-4-3)	80-2700 MHz; 1kHz AM 80 %; 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part ofthe device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance

Radiated RF EM filed (IEC 61000-4-3)	80-2700 MHz; 1kHz AM 80 %; 10 V/m	d = 1.2√P for 80 MHz to 800 MHz d = 2.3√P for 800 MHz to 2,7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Proximity fields form RF wireless communications equipment (IEC 61000-4-3)	385 MHz; Pulse Modulation: 18 Hz; 27 V/m 450 MHz, FM + 5 Hz deviation: 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m; 5240, 5500, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance 30 cm.

Phenomenon	Limit / Compliance Level	Electromagnetic environment - guidance
Proximity fields form RF wireless communications equipment (IEC 61000-4-3)	385 MHz; Pulse Modulation: 18 Hz; 27 V/m 450 MHz, FM + 5 Hz deviation: 1 kHz sine; 28 V/m 710, 745, 780 MHz; Pulse Modulation: 217 Hz; 9 V/m 810, 870, 930 MHz; Pulse Modulation: 18 Hz; 28 V/m 1720, 1845, 1970 MHz; Pulse Modulation: 217 Hz; 28 V/m 2450 MHz; Pulse Modulation: 217 Hz; 28 V/m; 5240, 5500, 5785 MHz; Pulse Modulation: 217 Hz; 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance 30 cm.
Electrical fast transients / bursts (IEC 61000-4-4)	Power lines: 2 kV; 100 kHz repetition frequency	Mains power quality should be that of a typical environment.
Surges (IEC 61000-4-5)	L-N: 1kV at 0°,90°,180°,270°	Mains power quality should be that of a typical environment.

Conducted disturbances inducted by RF fields (IEC 61000-4-6)	0.15-80 MHz; 1kHz AM 80 %; 3 Vrms, 6 Vrms in ISM and amateur radio band	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ for 150 kHz to 80MHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Rated power frequency magnetic fields (IEC 61000-4-8)	30 A/m, 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Phenomenon	Limit / Compliance Level	Electromagnetic envron-ment - guidance
Voltage dips / Voltage interruptions (IEC 61000-4-11)	0 % UT for 0.5 cycle at 0°,45°,90°,135°,180°, 225°,270°,315° 0 % UT for 1 cycle at 0° 70 % UT for 25/30 cycles at 0° 0 % UT for 250/300 cycles 0°	Mains power quality should be that of a typical environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterrupti-ble power supply or battery.
Proximity magnetic fields (IEC 61000-4-39)	30 kHz; 8 A/m; CW 134 kHz; 65 A/m; 50 % PM with 2,1 kHz 13,56 MHz; 7,5 A/m; 50 % PM with 50 kHz	RFID, WPT and similar equipment should be used no closer to any part of the device, including cables, than the recommended separation distance 15 cm.

Transmission- and receiving frequencies of the plasma care	
Receiving frequency	13,56 MHz
Preffered frequency	13,56 MHz
Receiver bandwidth	14 kHz
Transmission frequency	13,56 MHz
Transmitter bandwidth	14 kHz
Modulation of frequency	Amplitude modulation (ASK)
Effective radiated power	200 mW

Characteristics of the plasma care wireless charging module	
Input Voltage	4,75 – 13 V
Output Voltage	15W
Frequenzy	110 – 148 KHz
Min Load	0,1A
Max Load	1,25A
Peak Load	1,5A
Storage High Temp	16h at 60 °C
Storage Low Temp	16h at -20 °C
Operation High Temp	8h at 40 °C
Operation Low Temp	8h at -20 °C

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