

# Instructions for Use

CPT®cube / CPT®patch / HV cable

E100.113 / A100.T43 / Z100.104



This device may only be used by trained medical specialists!

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# 1. General information

These instructions for use contain important information about the medical device and how it should be used. The use of technical medical equipment always poses a certain risk for patients, staff and the environment despite all design-related measures. Therefore, safety also depends on staff training and the correct operation of the device. The safety information in this document helps to protect you and your patients from injury and prevent damage to the device.

- » All persons who work with, prepare, operate, clean, or dispose of Coldplasmatech products must read, understand and apply the instructions for use.

## 1.1 Explanation of symbols

Symbols used in these instructions for use



Immediate danger that can lead to fatal, serious or irreversible injuries.




























Dangerous situation that could lead to minor injuries or damage.



Information to help better understand the device and how it should be used correctly.

## Symbols used in product labelling

	Comply with the instructions for use		CE conformity marking
	Warning: electrical voltage		Warning: non-ionising radiation
	Warning: electrical voltage		POAG connection
	Connection socket for HV cable		Type B applied part
	Operation of the CPT®cube with AC voltage		Waste electrical and electronic equipment must not be disposed of in household waste
	Name and address of manufacturer		Production date
	Serial number		Expiry date, do not use the product after this date
	Production lot / batch number		Article number (reference number)
	Medical device		Machine-readable UDI (Device Identifier)
	Do not reuse! (Disposable product)		Do not use if the package is damaged!
	CPT®patch is sterilised using ethylene oxide		Single sterile barrier system
	Temperature limits for storage and transport		Keep dry; protect from moisture!
	Do not resterilise		

## 2. Mode of action



### Improper use

- Only use the CPT®cube, the HV cable and the CPT®patch for the intended purpose stated in these instructions for use.
- The medical devices are only intended for use in professional healthcare facilities.

The CPT®patch is a sterile, active wound dressing for single use and is only designed for use with the CPT®cube and the HV cable. The CPT®patch has an atraumatic adhesive frame for simple application above the wound area that is to be treated. 'Physical plasma' is created in the shape of a glow skin between the wound and the underside of the CPT®patch during the treatment process.

Due to the plasma, the air within the defined volume between the CPT®patch and the wound surface is turned into an energised state. This also involves the generation of alternating electric fields, light in the UV and infrared range, the formation of ions and a slight increase in temperature. The clinical benefit arises from the combination of these physical effect mechanisms. This results in an antimicrobial / antimycotic effect of the physical plasma as well as stimulation of the body's own cells and tissue which, in combination, helps the wound to heal.

### 2.1 Purpose / indication

The purpose of the CPT®patch / CPT®cube / HV cable treatment system is to generate a flat, cold atmospheric pressure plasma to help the wound or any local infected tissue defects to heal. Indications include both natural and artificial tissue defects. The treatment system can be used on male and female patients over the age of 18.

## 2.2 Contraindications

Due to insufficient data and lack of clinical studies:

- Application in the direct facial area (eyes, nose, mouth)
- Pregnant or nursing patients
- Children and infants
- Tumours in the treatment area, risk of cell transfer

Precautions In the following cases, increased caution is required, and the indication for use should be determined by the physician at their own discretion after careful consideration of the risk-benefit ratio:

- Application on or close to patients with active implants or under physiological monitoring

## 2.3 Side effects

There are no known side effects if used as intended.


## 2.4 Important features

Maintenance of an AC voltage signal with an amplitude of 6.9 to 7.1 kV, a frequency of 6 to 7 kHz, and a pulse/pause ratio of 1:9 over a period of 2 minutes.




### 3. Description of the device

#### 3.1 CPT<sup>®</sup>cube



Dangerous electrical voltage. Do not insert any objects into the HV socket (except for the HV plug of the HV cable).



The connection of a potential equalisation cable is mandatory in Group 1 and 2 rooms.

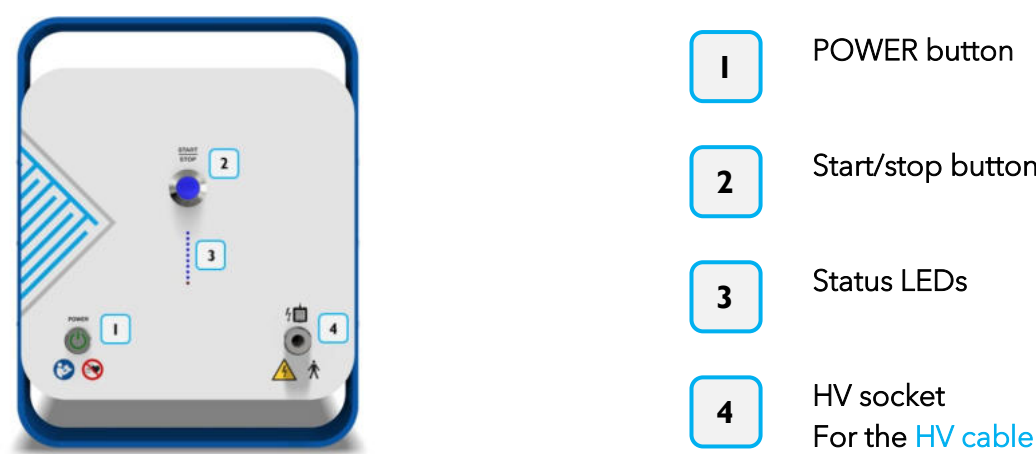


Fig. 1: Front view of the CPT<sup>®</sup>cube with operating controls

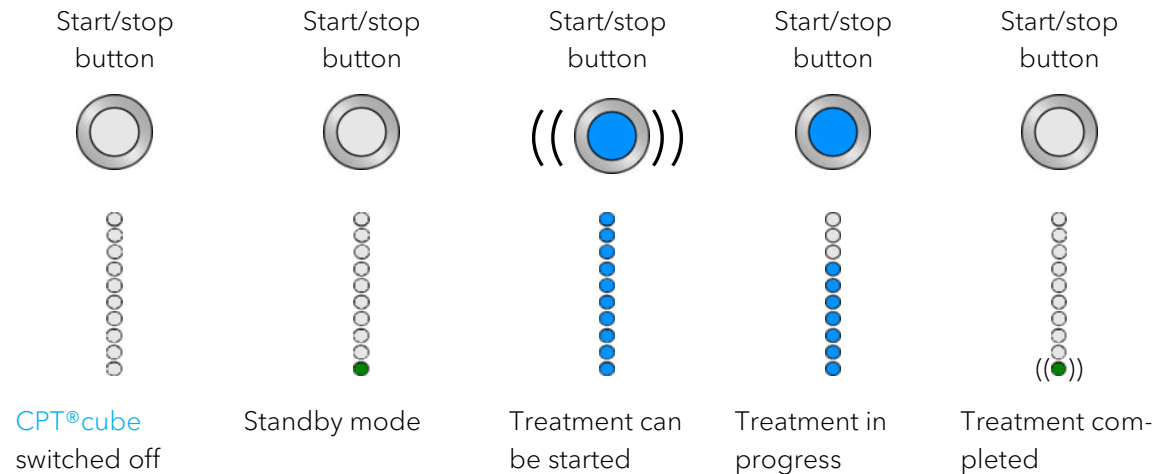


Fig. 2: Display of the status LEDs in normal operating modes.

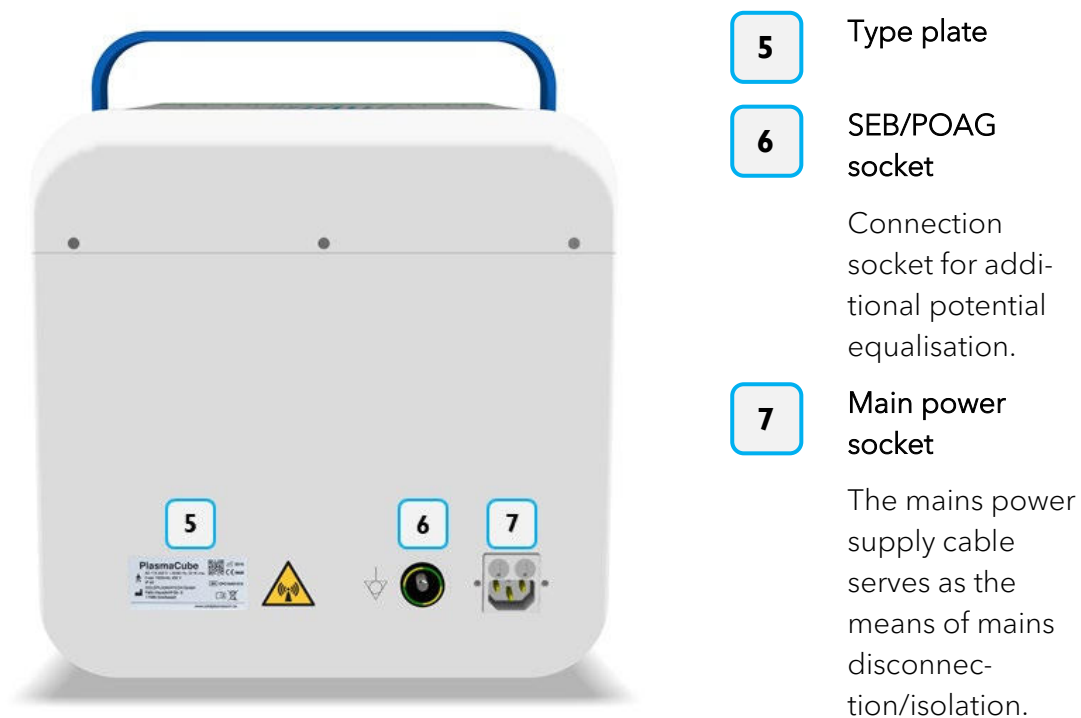


Fig. 3: Rear view of the CPT®cube

### 3.2 CPT®patch



The CPT®patch is a Type B applied part.



#### Disposable product

Only use each CPT®patch once.

The CPT®patch is a sterile active wound dressing. The CPT®patch and the adhesive frame are for single use only. Reusing them poses the risk of transferring pathogens from one patient to another or between different areas of skin. Neither the CPT®patch nor the adhesive frame are suitable for reuse. Uncontrolled material damage can occur unnoticed if they are used several times. There is a risk of electrical shock.

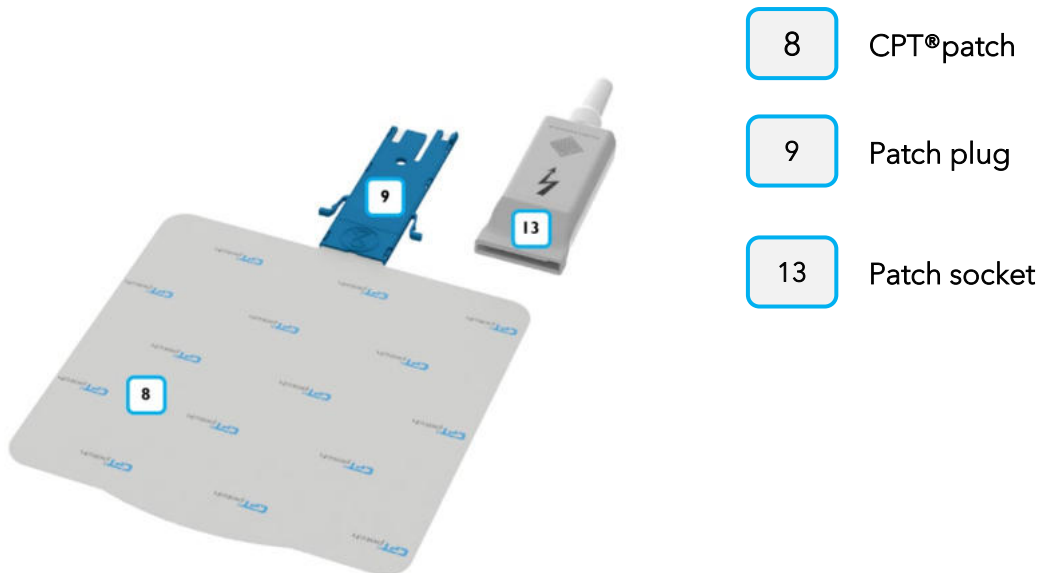


Fig. 4: Side of the CPT®patch facing away from the patient.

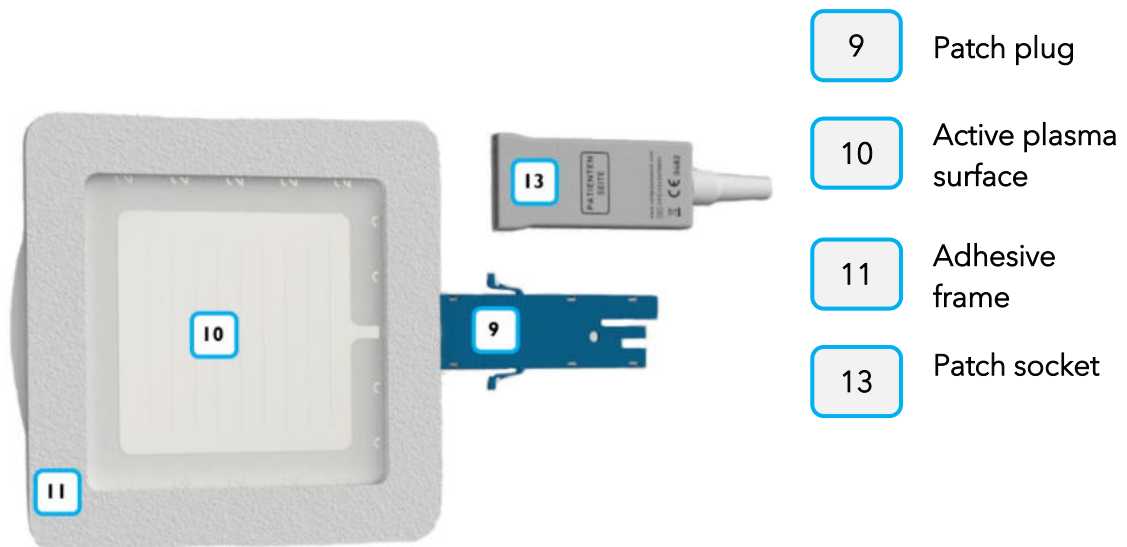


Fig. 5: Side of the CPT®patch facing the patient.

### 3.3 Adhesive frame



Fig. 6: Adhesive frame to affix the CPT®patch over the wound.

Both sides of the adhesive border are covered with an atraumatic silicone adhesive. The transparent liners serve to protect the adhesive and must be removed before affixing on the body or on the CPT®patch.

### 3.4 High-voltage cable (HV cable)

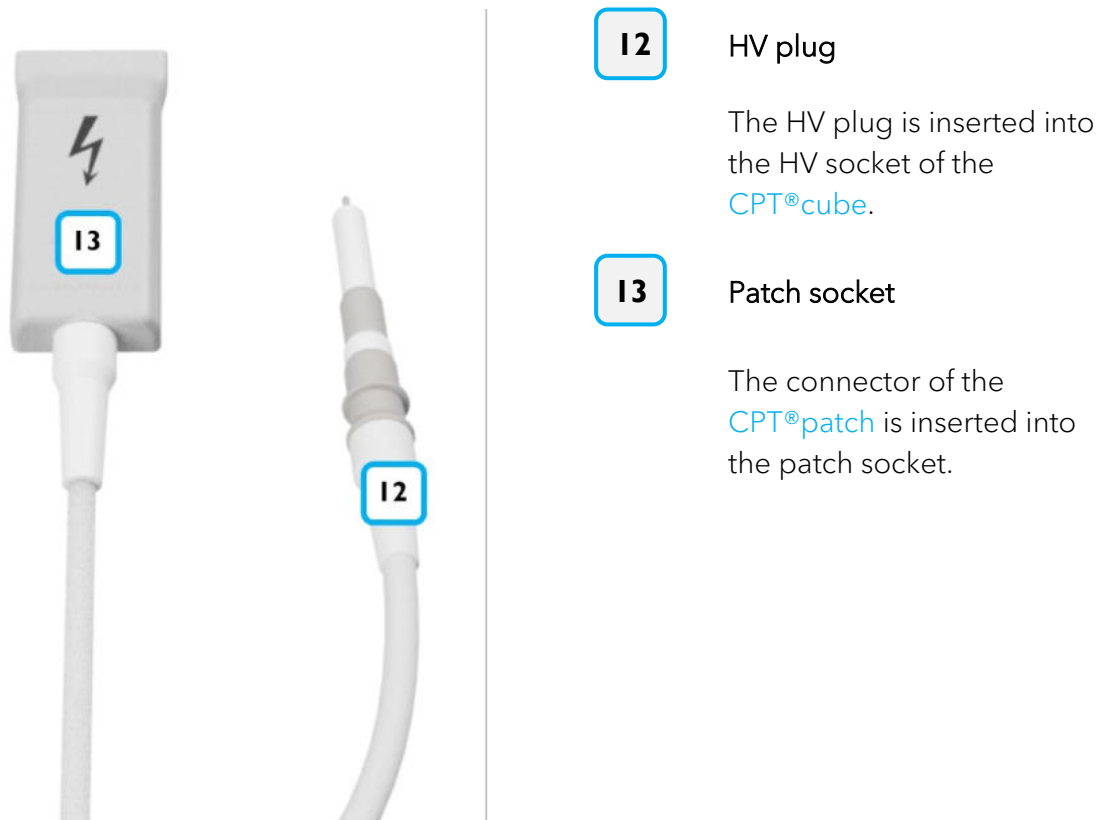


Fig. 7: HV cable with HV plug and patch socket.

## 4. Installation



### Initial installation by Coldplasmatech GmbH

The device may only be installed for the first time by a technician who has been trained and authorised by the manufacturer. During installation, the technician completes a log which is given to both the manufacturer and the customer.



### Risk of electric shock due to incorrect or defective mains connection

- Ensure that the device is connected to the mains voltage specified on the type plate.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Only use the supplied mains power supply cable for connection to the mains supply; check the mains power supply cable regularly for damage.
- Do not use extension cables, multi-socket outlets, adapters or other accessories that are **not** approved by the manufacturer for use in combination with the CPT®cube/CPT®patch.



### Installation location

- Ensure that the CPT®cube is always placed on a level, sturdy surface, and that it cannot fall down when the CPT®patch is used.
- All switches and sockets must be freely accessible; the mains plug must be disconnectable at any time.

Please proceed as follows to install the CPT®cube:

- (1) Open the outer packaging and remove the CPT®cube.
  - » Keep the outer packaging and filling material in case there is a complaint in the future or if the CPT®cube is relocated.
- (2) Installation of the CPT®cube
- (3) If the CPT®cube has been transported or stored outside the specified conditions, it must not be put into operation. Contact the manufacturer about inspecting the device. If it was stored or transported below +10 °C or above +40 °C, leave the CPT®cube out for 3 hours at room temperature to acclimatise!

- (4) If equipotential bonding is required for the connection of the electrical devices, connect the CPT<sup>®</sup>cube using the SEB/POAG socket on the rear side of the device with the in-house equipotential bonding.
- (5) Connection of the CPT<sup>®</sup>cube to the power supply mains using the supplied mains power cable.
- (6) Switch on the CPT<sup>®</sup>cube by pressing the POWER switch. The device starts an initialisation (blue status LEDs light up in succession) and then goes automatically into standby mode (lowest status LED lights up green).

Once you have carefully carried out steps (1) - (6), as described in these instructions for use, and no error message is shown on the status LED, the CPT<sup>®</sup>cube is **ready for operation**

## 5. Treatment process



### Only trained specialists

Ensure that only trained medical specialists (doctors or healthcare professionals) perform the treatment! Ensure that the CPT®cube is in **operational condition**.



### Ignitable/flammable gases and fluids

The CPT®cube creates an electrical gas discharge on the CPT®patch and is therefore an ignition source.

Please take special precautions when using the CPT®cube and CPT®patch in areas where there is a higher risk of fire and explosion (e.g. when using anaesthetic gases, pure oxygen, nitrous oxide).

Observing the following instructions is beneficial for treatment with cold plasma:

- Before treatment, the biofilm in the wound should be removed if necessary, or debridement should be performed
- In any case, the cause of the wound should be clarified and accompanied by appropriate therapies or medication
- Topical drug therapies should ideally take place after the respective treatment with cold plasma
- Appropriate wound hygiene should also be maintained by the patient outside of consultation hours
- There should be an interval of 24 h between treatments

### 5.1 Patient preparation

- (1) Clean the wound bed. Any barriers in the form of expanded biofilms and/or residues of ointments, salves or creams can diminish the effect of the treatment.
- (2) To guarantee that the adhesive frame adheres well, ensure that the area around the wound is dry, clean and free of oils and grease.
- (3) If the wound area to be treated exceeds a size of 10x10 cm, it must be prepared in such a way that a sealed treatment space is created with the CPT®patch and the adhesive frame does not stick directly onto the wound, see Section 5.4.



## 5.2 Treatment preparation



### Triggering the self-test

The self-test is only triggered by plugging the **HV cable** into the HV socket. If the **HV cable** is already plugged in (for example, due to a previous treatment), it will not be triggered and treatment cannot be started. In this case, unplug the **HV cable** and plug it in again to initiate the self-test.



### Checking for damage

Check the **CPT®patch**, the **CPT®cube** and the **HV cable** for damage before each treatment. Do not use damaged devices (risk of electric shock).



### Tampering or manipulation prohibited

Any tampering or manipulation of the **CPT®patch** (e.g. cutting, bending) or the **HV cable** is prohibited. There is a risk of electrical shock!



### Only use from undamaged packaging, check date

If the packaging of the **CPT®patch** is damaged, or if the sterile packaging has been opened by mistake, the product must not be used. Only apply **CPT®patches** within the period in which they can be safely used (see label).

- (4) Ensure that the **CPT®cube** / **HV cable** is in an **operational condition**.
- (5) Take a sterile bag with a **CPT®patch** from an outer packaging. Open the sterile pouch at the indicated place.
- (6) First, remove the adhesive frame from the sterile pouch.
- (7) Remove the first protective film from the adhesive frame.
- (9) Adhere the adhesive frame around the wound with the side from which you have just peeled off the protective film. Ensure that the adhesive frame keeps its square shape as far as possible and that the wound is in the middle of the adhesive frame.
- (10) Now pull off the second protective film from the adhesive frame.
- (11) Place the **CPT®patch** with the patient side (recognisable by the silver electrodes) onto the adhesive frame and press the **CPT®patch** firmly onto the adhesive frame. Ensure that the **CPT®patch** completely covers the adhesive frame.

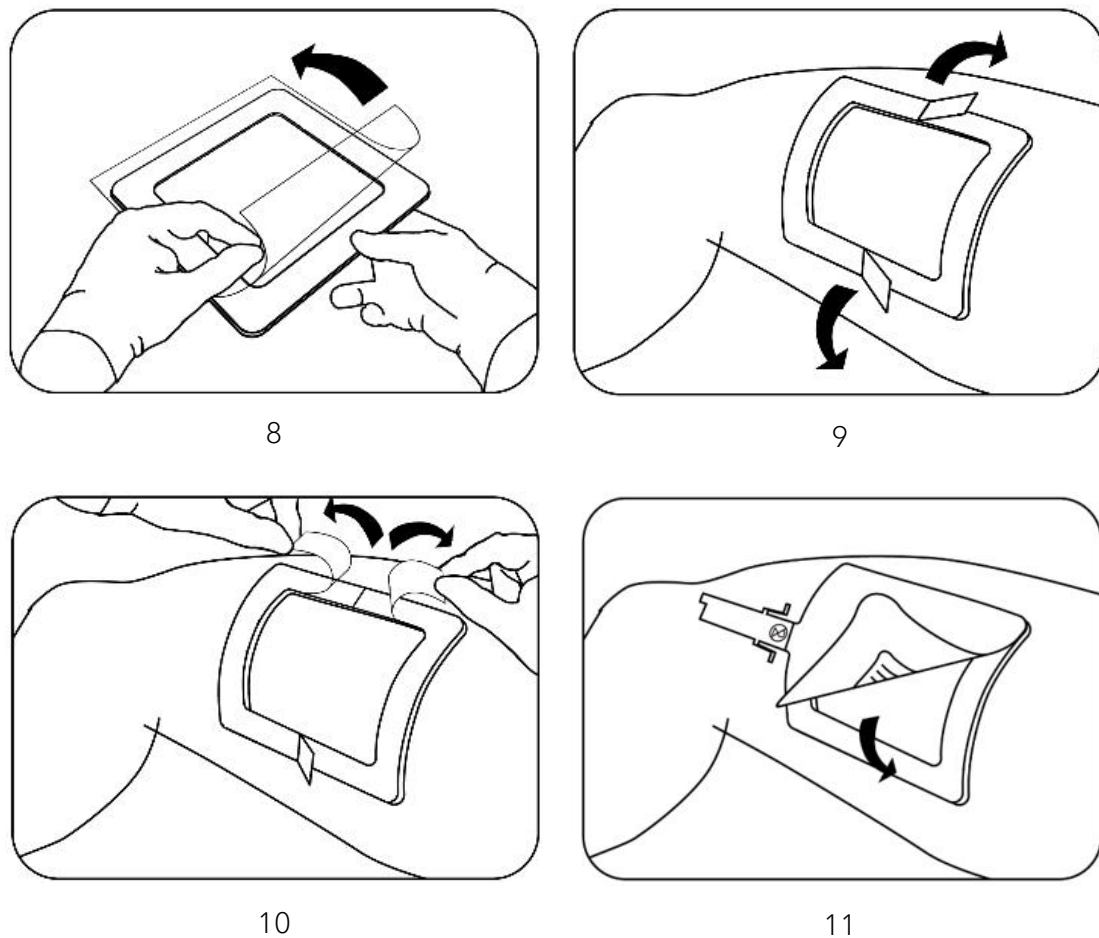
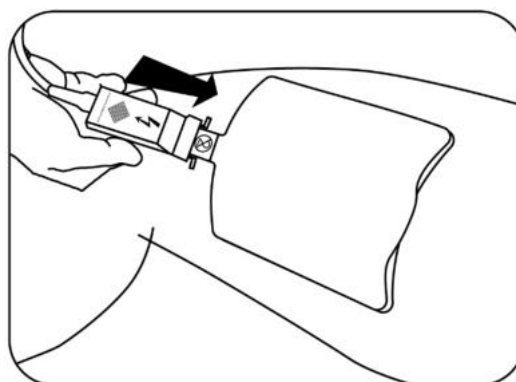


Fig. 8: Positioning the adhesive frame and the CPT® patch over the wound.

- (12) If necessary, remove the HV cable from the packaging, and remove the cable ties and the pink safety cap.
- (13) Then insert the HV plug of the HV cable into the HV socket of the CPT®cube. A self-test is performed. If all status LEDs light up blue, the self-test has been completed successfully and the CPT®cube is completely operational. The flashing start/stop button indicates that the CPT®cube is ready to operate.



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Fig. 9: Connecting the CPT® patch with the CPT® patch socket.

- (14) Insert the CPT®patch connection into the CPT®patch socket. A clicking sound indicates that the CPT®patch has locked firmly into place.

### 5.3 Treatment process



**Do not apply any pressure on the CPT®patch**

During the treatment, no pressure may be put on the CPT®patch.

If the electrodes of the CPT®patch and the patient's skin come too close, the safety systems of the CPT®cube stop the treatment to prevent excessive patient leakage current



**Only use in vented rooms**

Only treat patients in well-ventilated rooms.

If several treatments are administered in quick succession, adequate ventilation is advised.

The following points should be observed during treatment:

- Too small a distance between the wound and the CPT®patch can lead to automatic termination of the treatment and an error message (4th LED from above flashes blue) on the device.
  - If the CPT®patch is not completely attached to the adhesive frame, gas can escape continuously during the treatment. This may affect the success of the treatment and cause discomfort (unpleasant odour).
  - During treatment, the patient may experience sensations (e.g. tingling).
- (15) Start the treatment by pressing the start/stop button on the CPT®cube for 1 s. As soon as the treatment starts, you will hear a noise in the CPT®cube and the start/stop button stays continuously lit up in blue. The status LEDs turn off from top to bottom according to the progress of the treatment. If necessary, the treatment can be stopped by pressing the Start / Stop button or the POWER button again or by unplugging the HV cable from the CPT®cube. After two minutes, the treatment ends automatically. Once the treatment has been completed successfully, the lowest status LED flashes green.
- (16) Then remove the HV plug of the HV cable from the HV socket of the CPT®cube. The lowest status LED lights up green again.
- (17) Then disconnect the CPT®patch from the HV cable.

- (18) Remove the CPT®patch and the adhesive frame carefully from the wound and dispose of both as described in Section 6.
- (19) Then carry out the normal wound preparation and dressing steps.
- (20) Switch off the CPT®cube.

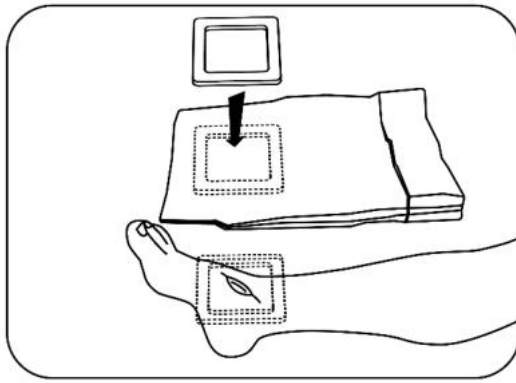
## 5.4 Application for wounds larger than 10 x 10 cm

If the adhesive frame cannot be adhered because the wound is e.g. larger than 10x10 cm or is located in a complicated area, the treatment space must be created in another way. For this purpose, use a sterile bag / a sterile drape with a plasma-stable surface made of PE, PP, PET, PA, PU, such as Hartmann Foliodrape® Protect Stockinette. The intended purpose of the product must be compatible with the application of the CPT®patch.

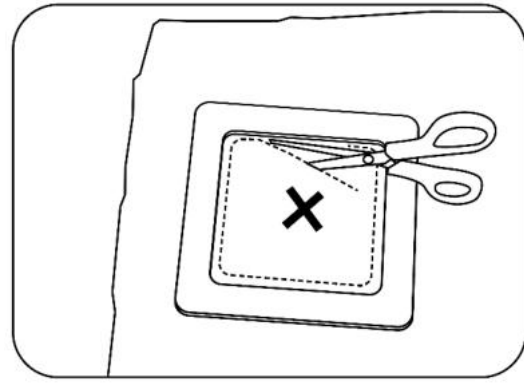
Prepare the treatment as follows:

1. Unpack the drape and place it next to the area to be treated. Mark on the drape where the wound will be located after application. The adhesive frame can be used as a template for this.
2. Peel off the liner from one side of the adhesive frame and stick the frame onto the outside of the drape. Use the marking from step 1 for positioning.
3. Cut as large a hole as possible in the area enclosed by the adhesive frame.
4. Apply the drape to the patient
5. Seal the drape with a rubber band or tape it down with adhesive strips. Ensure a tight seal, as escaping plasma reduces effectiveness.
6. Peel off the liner from the second side of the adhesive frame and stick the CPT®patch onto the frame

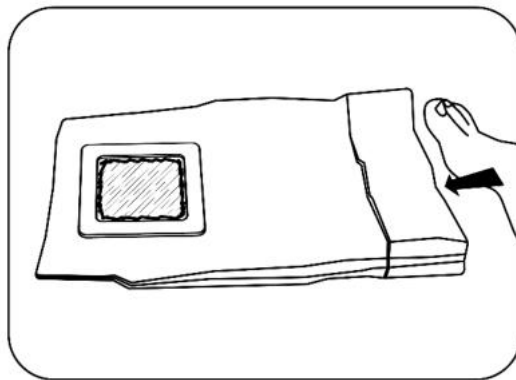
Start the CPT®cube and connect it to the CPT®patch as described in Section 5.2 (12) and following and start the treatment.



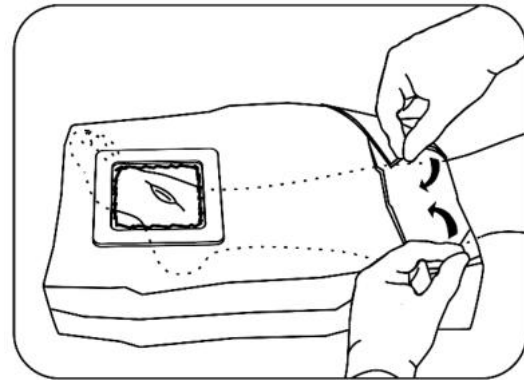
Step 1-2



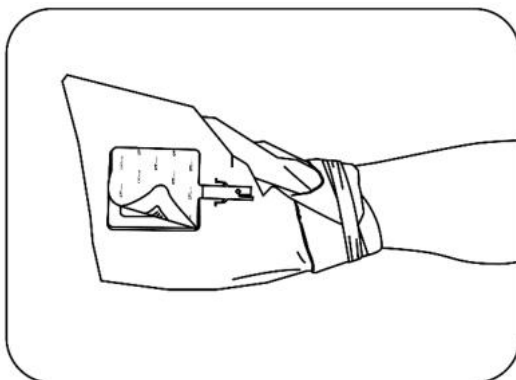
Step 3



Step 4



Step 5



Step 6

## 5.5 Application with negative pressure therapy

For some wounds, negative pressure therapy is used in addition to conventional and cold plasma treatment. If this is the case, you can carry out the plasma treatment during the VAC dressing change before applying the new absorber.

## 5.6 Cleaning



### Penetrating fluids

The CPT®cube and the socket of the HV cable are not protected against the penetration of liquids.

Do not pour liquid cleaning agents or disinfectants directly onto the devices.

Both the CPT®cube and the HV cable can be cleaned with moist wipes if necessary. Pre-impregnated, low-alcohol ( $\leq 30\%$  alcohol content) disinfectant wipes with good material compatibility are recommended. Use a soft brush if necessary to clean transitions and grooves of the HV cable. If necessary, dry the CPT®cube and the HV cable with a clean disposable cloth after cleaning.

The following disinfectants have been tested for use with the CPT®cube:

- Baccilol 30 Tissues
- Baccilol 30 Foam
- Schülke mikrozyd universal wipes premium maxi, low alcohol based
- Neoform Classic
- Terraline PPA

## 6. Transport, storage, disposal

### 6.1 Transport, storage

The CPT<sup>®</sup>cube is supplied in an outer packaging. This offers protection against environmental influences during transportation. We recommend keeping the original packaging in case the device needs to be returned to the manufacturer or transported or stored in-house.

Do not store the CPT<sup>®</sup>cube below 0 °C or above 50 °C. Ensure a dry storage environment, as moisture in the CPT<sup>®</sup>cube can lead to damage to electronic components.

### 6.2 Disposal



**CPT<sup>®</sup>patch is not packaging waste (recycling bin)**

The CPT<sup>®</sup>patch is not recyclable and must not be disposed of in packaging waste (recycling bin).

When disposing, observe the applicable laws for the disposal of infectious waste if necessary.



**Used CPT<sup>®</sup>cubes may not be disposed of in the regular waste bin (household waste).**

If this device needs to be disposed of, please send it to the manufacturer for professional disposal.

## 7. In case of a fault, malfunction or power failure



### Service, maintenance, and repairs only by the manufacturer

- Any tampering with the CPT®cube, the CPT®patch or the HV cable by the user is prohibited! There is a risk of electric shock if the housing of the CPT®cube is opened.
- In case of a malfunction, please first refer to the instructions in Section 7.2 Error messages. If this does not remedy the problem, please contact the manufacturer directly.

### 7.1 Maintenance of the CPT®cube



#### Lack of maintenance

The manufacturer needs to perform regular maintenance to ensure that the device functions correctly.

A faulty device or a device that has not been serviced may not be used!

To maintain the device properties and to ensure proper device function, maintenance of the CPT®cube and the HV cable must be carried out every 2 years. This includes a recurrent test of the important features and basic safety, as well as a test of portable electrical equipment, and is carried out exclusively by a technician authorised by the manufacturer. The date for the next maintenance can be found in the accompanying documents; please contact the manufacturer for an appointment. Apart from the maintenance of the CPT®cube and the HV cable by the manufacturer every 2 years, the user does not need to perform any further maintenance.

### 7.2 Error messages



#### Exceeding the treatment time

If you restart the treatment, remember that you must not exceed a treatment time of 2 min.

In the event of an error, the status LEDs below the start/stop button indicate the type of error by means of various colour and flashing combinations. Error messages can be acknowledged by unplugging and re-plugging the HV cable into the HV socket of the CPT®cube and/or by restarting the CPT®cube via the POWER button.



1	●	<b>Cause:</b>	●	<b>Cause:</b>
2	●	The CPT®patch is faulty.	●	The patient leakage current is too
3	●		●	high.
4	●	<b>How to deal with this error:</b>	●	<b>How to deal with this error:</b>
5	●	Please take a new CPT®patch.	●	Ensure sufficient distance be-
6	●		●	tween the CPT®patch and the pa-
7	●		●	tient's skin and restart the treat-
8	●		●	ment.
9	●		●	
10	●		●	

Additional safety functions have been integrated into the CPT®cube to guarantee the safety of the patient and the user at all times. If an error not described in more detail here cannot be acknowledged by unplugging and re-plugging the HV cable into the CPT®cube or by restarting the CPT®cube, please contact the manufacturer.

### 7.3 Steps to take in case of malfunction

If the CPT®cube does not behave as expected, you can stop the treatment at any time by unplugging the HV cable or pressing the start/stop button. Unplugging the mains power cable or pressing the POWER button disconnects the CPT®cube from the mains. If a suspected serious incident has occurred in relation to this product, this must be reported to the manufacturer and the competent authority in the country of your establishment.

## 8. Technical data

Table 1: Technical data

<b>Security requirements</b>	
Protection against electrical shock	Class I
Applied part type	B
Mains fuse	T315mA H250 V
<b>CPT®cube</b>	
Mains voltage	230 V AC
Power frequency	50 Hz
Maximum power consumption	100 VA
Operating mode	Continuous operation
Dimensions L x W x H	375 mm x 315 mm x 395 mm
Weight	13 kg
<b>CPT®patch</b>	
Dimensions L x W x H	244 mm x 150 mm x 3 mm (without adhesive frame, with clip)
Weight	30 g
<b>HV cable</b>	
Length	2 m
<b>Plasma</b>	
Sine-wave voltage	6.5 KHz
Pulse frequency	5 Hz
UV emission UV-A (315-380 nm)	95%
UV emission UV-B (280-315 nm)	5%
UV emission UV-C (100-280 nm)	0%
Ozone concentration	Below the limit
Nitrogen oxide concentration	Below the limit
<b>Transport and storage conditions</b>	
The CPT®cube must be stored and transported between 0 - 50 °C. The CPT®cube must be protected from wet conditions.	
<b>Operating conditions</b>	
Ambient temperature	+15 °C to +30 °C
Relative humidity	30% to 75% rH, non-condensing
Air pressure	800 hPa to 1,060 hPa
<b>Acclimatisation</b>	
If the device is stored or transported at temperatures below +10 °C and over +40 °C, the device requires about 3 hours at room temperature to acclimatise.	

\* All specified values are subject to a certain tolerance due to manufacturing reasons.

## 8.1 Delivery scope

Designation	Quantity	Article number
CPT <sup>®</sup> cube	1	E 100.113
HV cable	1	Z 100.104
Mains power cable	1	Z 100.102
Instructions for Use	1 (this document)	U 100.110

## 8.2 Consumables and spare parts



### Use of non-original accessories

There is a risk of electrical shock if accessories other than the original CPT<sup>®</sup>patch and HV cable are connected. Therefore, use only original accessories.

The CPT<sup>®</sup>cube provides high voltage for generating plasma on the CPT<sup>®</sup>patch. The system is designed so that the high voltage can be fed safely to the CPT<sup>®</sup>patch. Please use only the following CPT<sup>®</sup>patch with adhesive frame: Art. No. A 100.T43, A 100.T42.

## 9. Information on electromagnetic compatibility (EMC)

With regard to EMC, electrical medical devices are subject to special precautions and need to be installed and then commissioned according to the EMC information stated here.



The emission-specific properties of this device mean that it can be used in industrial environments and in hospitals (CISPR 11, Class A). This device may not provide adequate protection against radio (communication) services if used in residential spaces/rooms (which usually requires Class B pursuant to CISPR 11).



Portable HF communication devices (radio devices, including their accessories such as antennas or antenna cables) may not be used closer than 30 cm (12 inches) to the [CPT®cube/CPT®patch](#). Non-compliance with this can lead to a reduction in the device performance.



Avoid using this device directly next to other devices or stacked onto other devices because this may cause it to operate incorrectly.

**Electromagnetic emissions**

The device is designed for operation in the electromagnetic environment stated below. The user of the device should ensure that it is used in this kind of environment.

Measurement	Result	Description
HF emissions pursuant to CISPR 11	Group I	It is highly unlikely that the CPT®cube or the CPT®patch will interfere with adjacent devices. Nevertheless, there should be a safety clearance of at least 30 cm to other devices.
HF emissions pursuant to CISPR 11	Class A	The CPT®cube and CPT®patch may only be operated in industrial sectors and in professional healthcare environments.
Voltage fluctuations and flicker according to IEC 61000-3-3	Met	The CPT®cube and CPT®patch may only be operated in industrial sectors and in professional healthcare environments.
Harmonics according to IEC 61000-3-2	Class A	The CPT®cube and CPT®patch may only be operated in industrial sectors and in professional healthcare environments.

**Electromagnetic immunity**

Immunity test	Test level	Result	Impact
Electrostatic discharges (ESD) according to IEC 61000-4-2	2 kV, 4 kV, 8 kV, 15 kV on buttons, cables and CPT®patch; 2 kV, 4 kV, 6 kV, 8 kV on the housing	Met, interruption of the plasma operation is accepted.	Floors should be made of wood or concrete or be covered with ceramic tiles. If floor is covered with non-conductive synthetic material, the relative humidity should be at least 30%.
Electrical fast transient disturbances/bursts according to IEC 61000-4-4	0.5 kV, 1 kV, 2 kV	Met, interruption of the plasma operation is accepted.	The quality of the supply voltage should correspond to that of a typical hospital environment.
Surge voltages according to IEC 61000-4-5	0.5 kV, 1 kV, 2 kV	Met	The quality of the supply voltage should correspond to that of a typical hospital environment.
Power frequency magnetic fields according to IEC 61000-4-8	30 A/m, 50 Hz, 60 Hz	Met	Power frequency magnetic fields should correspond to the values that are typical in hospital environments.

Voltage dips, short interruptions and voltage fluctuations according to IEC 61000-4-11	100%, 10 ms 100%, 20 ms 60%, 200 ms 30%, 500 ms 100%, 5 s	Met, interruption of the plasma operation is accepted.	The quality of the supply voltage should correspond to that of a typical hospital environment. If the user of the device wants the function to continue even though the power supply is interrupted, the device must be connected to an uninterrupted power supply or a battery.
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### Electromagnetic immunity

When portable and mobile HF communication equipment is used, the recommended safety distance from the device (including the cables) may not be exceeded. The safety distance is calculated using various equations depending on the transmission frequency of the portable and mobile HF communication equipment:

- 1)  $d = 1.2 * P^{1/2}$
- 2)  $d = 1.2 * P^{1/2}$
- 3)  $d = 2.3 * P^{1/2}$

'P' stands for the rated output of the transmitter in watts (W) according to the information provided by the manufacturer of the transmitter. 'd' stands for the recommended safety distance in metres (m).

Theoretically, the field strength of stationary transmitters, e.g. base stations of mobile phones and land mobile services, amateur stations, AM and FM radio and TV stations, cannot be precisely determined in advance. We recommend examining the site to determine the electromagnetic environment caused by stationary HF transmitters. If the field strength determined at the site of the device exceeds the test level stated below, the device needs to be observed when in normal mode at every application location. If unusual performance features are noticed, it may be necessary to take additional action, e.g. reorientation or relocation of the device.

Immunity test	Test level	Result	Impact
Conducted disturbances induced by high-frequency fields according to IEC 61000-4-6	150 kHz to 80 MHz, 6 V	Met	Equation 1
High-frequency EM fields according to IEC 61000-4-3	80 to 800 MHz	Met, interruption of the plasma operation is accepted.	Equation 2
High-frequency EM fields according to IEC 61000-4-3	800 MHz to 2.7 GHz	Met	Equation 3

## 10. Manufacturer

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## 11. Disclaimer

The CPT<sup>®</sup>cube, the CPT<sup>®</sup>patches and the HV cable may only be used under the specified conditions and for the intended purposes, and must be maintained as stated in these instructions for use. The manufacturer is not liable for any damage caused by incorrect or improper use of the CPT<sup>®</sup>cube, the CPT<sup>®</sup>patch and the HV cable.



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