XCELLARIS PRO
by Dermaroller GmbH

TWIST

MICRONEEDLING-SYSTEM

INSTRUCTION MANUAL

CE
0482

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1 GENERAL NOTES

1.1 Brief description of the device

The XCELLARISPRO TWIST is a microneedling treatment system. It consists of a handpiece and a control unit.

The system is complemented by sterile needling modules as consumables.
The motorised handpiece creates a stroke on a single use needling module so that its needles can penetrate the patient's skin. The stroke frequency can be adjusted using the control unit.

Optionally, the handpiece can be switched on and off using a foot switch.

1.2 Instruction manual

This instruction manual describes the safe and intended use of the device and serves to prevent hazards. It must be read in full and observed by all who install, use, maintain, service and inspect this device before commissioning / use.

This instruction manual is part of the device and must be available to the user at all times. If the device is passed on to a third party, this manual must be handed over with the device.

To ensure safe operation of the device, please also note the following:

- The instruction manual for the associated needling modules.
- Safety data sheets on disinfectants and cleaning agents.
- Legal regulations on workplace safety and microneedling.

1.3 Presentation of warning notices in this instruction manual

General safety sign, indicates a danger that can lead to injury or death if the danger is not avoided
or
indicates possible risks that may lead to damage to the environment, property or equipment if the hazard is not avoided

Indicates a hazard due to live electrical equiment

Danger of injury from sharp object

1.4 Limitation of liability

This device may only be operated by authorised, qualified personnel and only for the purposes specified in this instruction manual! Details can be found in chapter 2.2 “Indications” and chapter 2.3 “User group”.

The use of the device and the associated risks are taught in a training course.
The user is obliged to observe the principles of cleanliness and hygiene and to work only with sterile or disinfected working materials. This explicitly includes the single use of sterile needling modules. For more information, see chapter 2.5 “Important hygiene and safety instructions”.
The contraindications must be observed without exception. Please consider chapter 2.7 “Contraindications and adverse reactions”.
Inform patients about possible risks before each use.
Use of the device is only permitted in combination with the associated original needling modules from Dermaroller GmbH.

The manufacturer accepts no liability for any commissioning or use of the device that deviates from this instruction manual and the consequences thereof!

1.5 Changes to the device and technical progress

This device must not be modified in any way by the user! Any modification to the device involves a risk of injury or even death, e.g. due to an electric shock.

The manufacturer reserves the right to make changes in line with technical progress.

2 IMPORTANT USE AND SAFETY INFORMATION

2.1 Purpose

The purpose of the “XCELLARISPRO TWIST and XCP Needling Module” system is the

minimally invasive perforation of the epidermis / dermis (microneedling)

Microneedling treatment minimally invasively punctures the epidermis and, with longer needles also the dermis, without leaving open wounds on the skin. This allows epithelial function to be restored within a very short time, resulting in a very short regeneration phase. Among other effects, the micropunctures cause an increased collagen production of the skin. The mechanism of action is called “Percutaneous Collagen Induction” (PCI) or "Collagen Induction Therapy” (CIT).

2.2 Indications

Medical Indication:
Treatment of disease- and injury-related skin changes, especially atrophic and hypotrophic scars (e.g. acne scars) as well as mature hypertrophic scars on the entire body; treatment of striae distensae.

Non-medical indication:
Stimulation of collagen production with the aim of reducing the signs of ageing / wrinkles and general skin tightening on the face, neck, décolleté or body.

2.3 User and recommended needle length

Medical indication:
Use in the context of a medical indication is reserved for qualified medical professionals. Depending on the type and severity of the scar and the area of skin to be treated, the user selects the needle length up to a maximum of 1.5 or 2.5 mm (depending on the needling module). To minimise adverse reactions, always set the shortest possible needle length on the handpiece of the XCELLARISPRO TWIST microneedling device to achieve even redness or superficial pinpoint bleeding.

Non-medical indication:
In the context of a non-medical indication, non-medical professional users such as trained professionals may also use the medical device. For this group of users, we recommend staying below a needle length of 1.5 mm, always selecting the needle length on the handpiece of the XCELLARISPRO TWIST microneedling device so that the treated skin area is evenly and slightly reddened, but there is no bleeding.
For information on how to safely set the needle length, see item 4.2.3.


Please check your national regulations before using the device.

2.4 Applicability

Skin types
Treatment with the XCELLARISPRO TWIST is suitable for all skin types according to Fitzpatrick (I-VI) and all scar depths (I-IV).

Age
The present clinical study results were obtained predominantly with adults. Therefore, the age recommendation for the treatment is “18 years and over”. However, there is no evidence that treatment in adolescents poses an increased risk to safety.

Burn Scars
For the treatment of burn scars in children with the “Dermaroller MC”, the manual microneedling medical device from Dermaroller GmbH, there is conclusive clinical data that proves the safety of the application even under 18 years of age.

Body parts on which the XCELLARISPRO TWIST can be used:
In principle, the XCELLARISPRO TWIST can be used on almost all skin areas. Exceptions are described under “2.7 Contraindications”.

2.5 Intended environment of use

Parameters	Intended environmental conditions	Remarks
Places of use	• Clinic / operating theatre and other treatment rooms • Medical practice, healing practice • Other rooms with cleanliness and hygiene regulations suitable for use	Burn scar treatments take place in operating theatres.
Hygienic conditions	• Closed windows • No air locks required • Surface and equipment disinfection • Appropriate staff behaviour and clothing • Disposable gloves	Operating theatres: Operation rooms with appropiate ventilation system. Sterilised clothing incl. face mask.
Viewing conditions	• Ambient brightness min. 300 lux, work area min. 750 lux • Visual distance 30 cm to 100 cm • Viewing angle: normal to ± 30	
Physical environmental conditions (temperature, humidity, pressure, sound, vibration)	• Room temperature 10 - 35 °C, • Humidity 30 - 75%, no condensation • Air pressure 500 -1080 hPa • Background sound level: <70 dB(A) in the range from 100 Hz to 8 kHz • No or low vibrations at the location The XCELLARISPRO TWIST is not intended for use in an oxygen-rich environment.	Electrical safety for SG/HS up to 75% LF given. (Integrity of sterile-pouches for needling modules is given at 30 - 60%.)

2.6 Safety instructions and precautions for use

- Microneedling must be performed under low-germ conditions and in hygienically suitable treatment rooms with sufficient lighting.
- The device must be used and maintained in accordance with this instruction manual.
- The XCELLARISPRO TWIST medical device may only be used with the associated authorised accessories (e.g. adapter, foot switch) and consumables (needling modules): Non-observance may endanger the user or the patient. This device and accessories must not be modified without the permission of the manufacturer.
- Check the control unit, handpiece and accessories for damage before each use! If damage is suspected, never repair the device yourself; only an authorised specialist dealer may carry out repairs. Workshops are named by the manufacturer on request.
- The usability study of the device was conducted using a basis of 4 treatments of 20 minutes each (at the highest operating frequency of 150 [Hz]) per user and day.
- To avoid the risk of electric shock, this device must only be operated on a supply mains with a protective earth conductor.
- Pulling out the mains plug disconnects the device from the mains supply. Therefore, place the device that the mains plug is easily accessible at all times. The mains switch must also always be easily accessible.
- Only switch on the control unit when you are holding the motor hand piece securely in your hand or when it is in the handpiece rest.
- **Only** change the needling module when the handpiece is switched off.

Switch off the device immediately if the needling module triggers or the motor jams.

Attention: The handpiece could become hotter than 43 °C if the device is operated for a very long period of time at high ambient temperatures and high stroke frequency.

The housing must never be opened by the user. Also, do not remove any covers from the control unit, handpiece or foot switch - there is a risk of electric shock as some unit components are powered.

Please never touch the plug and the patient at the same time!

Never touch the tips of the needling modules while the handpiece is running - danger of injury!

The needling modules must be replaced with special care immediately after use - there is a danger of injury!

All needles of the needling module must be fully retracted into the module when removed.

Restriction of function due to electromagnetic faults

Mobile communication devices (mobile phones, WiFi routers, etc.) can impair the correct functioning of the device by emitting electromagnetic radiation.

Attention: To avoid the RISK of electric shock, this device must only be connected to a SUPPLY MAINS with a protective earth conductor.

- Do not use mobile / portable communication equipment near the device. Therefore, always position the device in the recommended protective distances to potential sources of interference. Please observe chapter 10.5, “Recommended protective distances to portable and mobile HF communication equipment”.
- Also advise patients of the possibility of such faults.

2.7 Important hygiene instructions

Microneedling treatment can transmit infectious diseases if the required hygiene standards are not maintained. Improper handling may result in injury to the user or patient. Therefore, the following hygiene instructions must be observed.

- The treatment must be carried out under low-germ conditions and in hygienically suitable treatment rooms with sufficient lighting.

- For safety reasons, disposable impermeable nitrile or latex gloves must be worn during treatment. Disinfect the gloves with 70 % isopropanol before and regularly during the treatment. To reduce the risk of infection for patients and practitioners, wear disposable mouth/nose protection (according to EN 14683 type II) and protective goggles (according to DIN EN 116).

- As an additional hygiene measure, disposable sleeves for the handpiece, connecting cable and a transparent cover for the control unit can be used.

- Before and after each use: Clean the device according to the instructions. Prevent liquid from entering the control unit. If liquid enters, electronic components could be destroyed. Disconnect the mains plug before cleaning the device.
  Please refer to chapter 5 “EQUIPMENT MAINTENANCE, CLEANING AND DISINFECTION”.

- Contamination of the interior of the handpiece by backflowing liquids is excluded by the design of the needling module. Should external contamination occur, operation must be interrupted immediately and suitable cleaning / disinfection carried out.

- When inserting the needling modules into the handpiece, make sure you do not touch the front area (needling or module tip). Also during application make sure that consumables do not accidentally come into contact with contaminated objects, e.g. clothing. Contaminated needling modules must be replaced immediately.

- Please also refer to the instruction manual of the corresponding XCELLARISPRO needling modules.

Attention: An injury with a contaminated needle can result in the transmission of dangerous diseases. In the unlikely event that such an injury occurs, a doctor should be consulted immediately.

- Touching the freshly punctured skin should generally be avoided.

2.8 Contraindications and adverse reactions

The contraindications and adverse reactions listed below are described in the clinical literature for microneedling treatments.
If the user has any doubt about the safety of the patients, for example due to concomitant diseases, the treatment must be discontinued.
Please note that all serious incidents occurring in connection with the product must be reported to the manufacturer and the responsible authority of the country in which the treatment was performed (see section 7.3).

2.8.1 Contraindications

Microneedling treatment is **strictly** contraindicated in the following cases:

Treatment of mucous membrane or eyes

Treatment of areas with skin cancer

Patients with keloids or a history of keloids

Microneedling treatment is contraindicated in the following cases:

- Active herpes simplex, skin infections, raised moles, warts, photokeratoses (except the targeted treatment of photokeratoses using photodynamic therapy),
- Increased bleeding tendency or wound healing disorders, e.g. due to uncontrolled diabetes mellitus,
- Anti-coagulant therapy, chemotherapy, radiotherapy, high doses of cortisone,
- Planning a pregnancy, pregnant and breastfeeding women,
- Children and adolescents (Present clinical study results were obtained predominantly with adults. Therefore, the age recommendation for the treatment is “18 years and over”. However, there is no evidence that treatment in adolescents poses an increased risk to safety.

In case of doubt, ALWAYS consult a doctor BEFORE any aesthetic treatment.

- The device is only intended to be used with therapeutic products approved by the competent Authority.

2.8.2 Adverse reactions

Compared to other methods of scar treatment, e.g. laser light, adverse reactions to microneedling are rare and usually mild.

Known transient side effects of the application

- Pain, redness, swelling of the treated skin areas
- Micro haemorrhages (“blood dew”) for minutes

Undesired adverse reactions

- Infections after insufficient skin disinfection
- Inflammatory reaction (due to pyrogens)
- Transient pigmentary disorders
- Scarring with inclination to keloid formation
- Granuloma formation after introduction of substances during microneedling treatment

Basically, freshly treated skin areas should be protected from UV and sun exposure for at least 8 days, e.g. by applying sunscreen factor 50.

In case of doubt, always consult a physician.

3 SCOPE OF DELIVERY, ACCESSORIES, SPARE PARTS, CONSUMABLES

3.1 Scope of delivery

Control unit, power cable with power supply unit (country-specific power cables on request), handpiece with connection cable belonging to the control unit, foot switch with connection cable, instructions for use, test report of the safety-related product inspection.

The sterile needling modules (consumables) are not included. They can be ordered through an official distributor. The needling module is a separate medical device and it is intended to be in contact with the patient´s skin (applied part).

3.2 ACCESSORIES, SPARE PARTS, CONSUMABLES

Art. No.	Description	Piece / unit
VK-2000.002.01	XCELLARISPRO TWIST control unit (incl. EU power supply cable GSM90A48-P1M or GSM60A48-P1J)	1
VK-2000.003.01	XCELLARISPRO handpiece (application part type B - belonging to the control unit)	1
VK-2000.004.01	Foot switch	1
VK-2000.005.01	UK power cable (optional)	1
VK-2000.006.01	USA power cable (optional)	1
VK-2000.007.01	AUS power cable (optional)	1
Consumables		
NM-615-XCP	Needling module 1.5 mm (applied part)	5
NM-625-XCP	Needling module 2.5 mm (applied part)	5

Only use the supplied cables for all connections.

4 COMMISSIONING, OPERATION AND DECOMMISSIONING

4.1 Control unit

- XCELLARISPRO TWIST

Front view with operating and control elements

Rear view

Bottom view

4.1.1 Commissioning

- Before using the device for the first time, carry out a visual inspection to detect any damage that may have occurred during transport. Please keep the packaging during the service life of the device. The device may only be transported or stored in the original packaging or equivalent.
- The device must adapt to room temperature before use, otherwise the resulting condensation may damage the electronics. Only use the device indoors at room temperatures of 10°C - 35°C. If there is a temperature difference of 10 ° C, wait at least three hours before starting the device.
- Always place the device on a firm, level surface (tabletop unit).

- The connection sockets for the power cable and handpiece are on the back of the device and must always be accessible.
- The device may only be operated with an original XCELLARISPRO power cable. The mains voltage must match the primary voltage indicated on the devices label!
- The device becomes ready for operation by connecting it to the connected power cable. When the device is connected to the power, a light on the power supply unit appears.

Never touch the plug and the patient at the same time!

4.1.2 Setting up and preparing the device

1. Place the device on a firm surface so that the ventilation slots are not covered.
2. If you want to use the foot switch, insert the plug of the foot switch into the right socket.
3. Connect the jack of the thin cable from the power supply to the lower socket of the control unit. Connect the device to the mains voltage socket with the end plug. Once the device is connected to the power, a light on the power supply unit appears.
4. Before connecting the handpiece to the control unit, check that the turning knob on the display is in the OFF position.
   Attach the connecting cable of the handpiece to the left bush of the TWIST control unit and plug it in (see picture above).
5. Position the device in such a way that the operating elements are easy to reach and the cable to the handpiece can be guided easily in the work area.
6. The patient is to be treated in a resting position, sitting or lying down.


Patient

7. The main switch is integrated into the turning knob on the front of the device. Rotate this knob to the right or left to switch the device on and off. Only switch on the control unit when you are holding the motor handpiece securely in your hand.

Safe operation is not guaranteed:

if the device or accessories show visible damage,

if the device is not working properly,

after prolonged storage under unsuitable storage conditions,

in the event of transport damage following improper transport.

In these cases, the device should always be handed over to the authorised distributor for inspection and it will be afterwards forwarded to a specialised service center or to the manufacturer.

4.2 Handpiece and needling module

4.2.1 General information about the handpiece

The handpiece is the application part (type B) in which the patient-contact needling modules (sterile consumables) are inserted for microneedling. It is connected to the control unit via a cable. See **item 4.1.2.** for connecting the handpiece.

Before connecting the handpiece to the control unit, check that the turning knob on the display is in the OFF position.

You can then insert a new sterile needling module on the handpiece. See the following items 4.2.2 and 4.2.3.

4.2.2 General information about the needling module (consumables)

The needling modules are intended for single use. They are individually packed and supplied in sterile condition. Keep the modules in their original packaging until use. Do not remove the needling module from the sterile packaging until immediately before use.

- Before using the needling module, be sure to read chapter 2.7 “Important hygiene instructions” and the needling module instruction manual.
- The marking (label) of the needling modules contains lot number, date of manufacture and expiry date. The lot number is used to uniquely identify the manufacturing lot and must be noted in the patient record. This number must be communicated to the manufacturer in the event of a complaint.
- Only original needling modules of the type “NM-6xx-XCP” from Dermaroller GmbH (e.g. NM-625-XCP) may be used in conjunction with the XCELLARISPRO handpiece.

ATTENTION! The handpiece must be switched off and set to “0.0” before the needling module is assembled/disassembled.
For technical reasons, the needles can be pushed out in individual cases when the needling module is installed in the handpiece and there is a danger of injury.

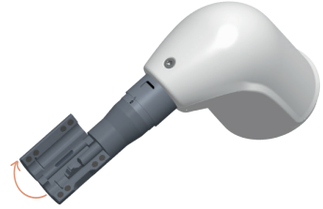
Always keep the needling module tip down and away from the body.

4.2.3 Assembly of the needling module on the handpiece

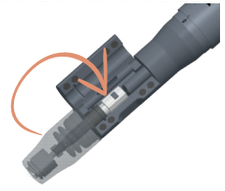
1. Do not remove the needling module from its packaging until immediately before use. Ensure that the sterile bag is not damaged or torn.

   NEVER use a needling module whose sterile pouch is damaged or the expiry date has been exceeded.

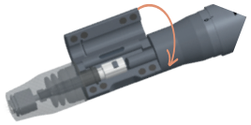
2. The handpiece must be switched off and set to “0.0” before the needle module is fitted. Hold the handpiece on the pipe above the flap with one hand and open it with the thumb of the other hand. Be sure the end of the axle points upwards (see picture below).



3. Insert the needling module so that it hooks onto the axle.



4. Now press the flap shut until it is completely closed. It is held by strong magnets. Check the needling module to ensure that it is firmly seated.



4.2.4 Adjusting the insertion depth

⚠	Adjustment of the insertion depth must be made on the switched-off handpiece.

The insertion depth is set on the rotatable scaled part of the handpiece. The scale on the handpiece shows the set needle length.

1. Hold the handpiece with one hand on the long shaft body and rotate the front handpiece area with the other hand.

2. Rotate clockwise to increase the insertion depth. With each full turn, the needle length increases by 1 mm. By rotating anti-clockwise, you reduce the depth of insertion. The value in the window indicates the whole millimetres.

Example: 0 mm
No needle protrusion

Example: 2,0 mm
Needle protrusion

3. The value on the revolving scale indicates the digit after the decimal point.

Example: 0 mm
No needle protrusion

Example: 1,25 mm
Needle protrusion

Example: 2, 5 mm
Needle protrusion

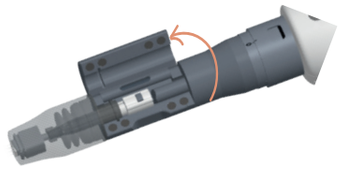
4. The optimal needle protrusion differs with respect to the indication, the area of skin to be treated and other factors. For example, a needle length of 1.5 mm is recommended for the treatment of acne scars.

4.2.5 Removing the needling module from the handpiece

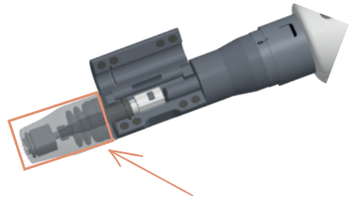
⚠	Switch off the handpiece before removing the needling module.
⚠	**ATTENTION! Danger of injury.** The handpiece must be switched off and set to “0.0” before the needling module is assembled/disassembled. For technical reasons, the needles can be pushed out in individual cases when the needling module is installed in the handpiece and there is a danger of injury.
⚠	**ATTENTION!** An injury with a contaminated needle can result in the transmission of (dangerous) diseases. In the unlikely event that such an injury occurs, a physician should be consulted immediately.

Safe disposal instructions can be found in the instruction manual of the needle module and in Chapter 4.2.6 of the present manual.

1. Hold the handpiece so that the needling module points slightly downwards. For removal, the flap of the handpiece is opened upwards again.



2. Carefully remove the needling module from the handpiece. Please make sure that the inside of the handpiece does not come into contact with the gloves you are using. When removing the needling module, touch it only in the area marked below. This avoids possible contaminations.



3. Make sure that any liquid residues do not run into the handpiece by holding it appropriately. Therefore, the drive end must always point downwards (see figure above).

4.2.6 Disposal of the needling module

⚠	Do not dispose of used needling modules in household waste under any circumstances (risk of infection from the needles), but only as potentially infectious hospital waste in suitable special containers (Safety Box).

- **Check the local disposal regulations.**

4.3 Operation of the XCELLARISPRO TWIST

The sequence of operating steps is described below. The individual steps are then discussed in detail. Be sure to read the complete instructionsbefore you start any treatment.

⚠	Follow the hygiene instructions in chapter 2.6 “Important hygiene instructions”
⚠	The information on contraindications (chapter 2.7) and further warning notices must be observed!
⚠	When selecting the parameters needle length and stitch frequency, the individual skin characteristics and the treatment goal for the patient must be taken into account.
⚠	Is the puncturing frequency too high or the needle length too long, injury to the patient may occur.
⚠	Without moving the handpiece on the skin, the high-frequency needling may cause skin damage. Therefore, this should be avoided at all costs.

1. Attach a needling module to the handpiece (chapter 4.2.3 “Assembly of the needling module on the handpiece”). Make sure that the needling module is inserted firmly according to the instructions.

2. Take the handpiece in your hand and use the adjustment ring to set the desired needle length. The whole millimetre values are displayed via the small window, smaller steps via the line scale (item 4.2.4.).

3. To start, move the turning knob on the control unit to the right.

4. Set the desired puncturing frequency by turning the control knob.

5. Start with a frequency of 50 - 100 Hz and then adjust the puncturing frequency depending on the skin texture and working speed.

6. Carefully place the handpiece on the skin, applying light pressure. Start guiding the handpiece on the skin immediately in small, circular movements.

Without moving the handpiece, the high-frequency needling may cause skin damage. This should be always avoided.

7. After completing the treatment, switch the device off by turning the control knob back to “OFF”.

8. After finishing or for a pause during the treatment, place the handpiece on the holder of the control unit.

9. Optional operation: You can also optionally operate the device using a foot switch available as an accessory. The handpiece is switched on and off by stepping on the foot switch.

10. Disconnect the device from the mains overnight or if you will not be using it for a long time.

4.3.1 Safety instructions for operating the handpiece

The handpiece, especially the motor inside it, is a mechanical precision work that must not be contaminated. Please make sure that no liquid enters into the handpiece.

During use and cleaning, make sure that the needling module tip points at least slightly downwards to prevent liquid from entering the motor.

Damage caused by the penetration of substances into the motor will not be accepted by the manufacturer as grounds for complaint. Furthermore, make sure that the cable on the handpiece is not subjected to tension or kinked.

4.4 Decommissioning

Take the device out of operation by disconnecting the power supply cable from the device.
The device may only be transported or stored in the original packaging or equivalent packaging.

5 EQUIPMENT MAINTANCE, CLEANING AND DESINFECTION

As long as the device is still connected to the mains, the components must not be taken apart. There is a risk of damaging the electronic components.

ALWAYS disconnect the device from the mains by pulling the plug (power supply unit) before you start cleaning.

DO NOT attempt to clean the needling modules. The needling modules are ONLY intended for single use. Do not use the needling modules more than once.

Protect the handpiece from damage by placing it in the holder of the control unit after use.

5.1 Care instructions

Disconnect the device from the mains before starting any cleaning or maintenance work!

Control unit

- Clean and disinfect the outer surfaces of the control unit, power supply and handpiece holder with a mild disinfectant (e.g. 70% isopropanol) and a lint-free soft cloth before any use or treatment. The recommended disinfectants are listed in section 5.5.1 “Recommended disinfectants for daily use”.
- Do not spray the disinfectant directly into any of the equipments. Use a lint-free cloth to swipe and disinfect the surfaces to prevent unwanted moisture from entering the electrical parts of the device.
- The disinfectant wipe should be damp, but not dripping wet. Excess moisture should be removed before using the cloth on electrical devices.
- After disinfecting, the surfaces must be completely air-dried before the device is switched on. No moisture should be visible on the surfaces before it is switched on.

Handpiece

- After treatment, open the module lock and check the interior for moisture or liquids that may have entered.
- Spray the disinfectant on the opening and the complete handpiece, the cable and the bracket on the control unit with the disinfectant until the surfaces are wet. Leave it to work in the open handpiece according to the manufacturers instructions and then wipe off any liquid residue with a clean cloth. Make sure the drive end points downwards to prevent liquid from entering the motor.
- Do not use the handpiece until there is no more moisture in it and the disinfectant has evaporated completely.
- Regular cleaning and disinfecting during the specified service life of the device does not affect the functionality of the device, provided that the specifications in this instruction manual are observed.

5.1.1 Recommended disinfectants for daily use

Manufacturer	Product	Active time
Antiseptica	Big Spray "new"	1 - 5 min
Bode Chemie	Bacillol AF	30s - 1 min
Schülke & Mayr	Mikrocide AF Liquid	1 - 2 min
-	Isopropanol 70%	1 - 5 min

The handpiece and the control unit must never be immersed in disinfectant, otherwise the parts inside may be damaged. Such damage is not covered by the manufacturer's warranty.

NEVER clean the handpiece, the control unit, the foot switch or the power supply unit with an autoclave or in an ultrasonic bath.

5.1.2 Material resistance of the handpiece

Resistant: to mild acids (e.g. boric acid, acetic acid ≤ 10%, citric acid ≤ 10 %), aliphatic hydrocarbons (e.g. pentane, hexane), ethanol and most inorganic salts and their aqueous solutions (e.g. sodium chloride, calcium chloride, magnesium sulphate).

Not resistant: to strong acids (e.g. hydrochloric acid ≥ 20 %, sulphuric acid ≥ 15 %), oxidising acids (e.g. peracetic acid), alkalis (e.g. caustic soda, ammonia; all substances with a pH value >7), aromatic/halogenated hydrocarbons (e.g. phenol, chloroform) as well as acetone and petrol.

6 MAINTENANCE AND SERVICING

6.1 Safety inspection

- The device has passed the safety test after its manufacture. The safety inspection protocol is included in the scope of delivery.
- Technical information on inspections and repairs (IEC 62353):
  Testing interval : 24 months
  Protection class: I
  Application part: Type B
  The protective conductor is connected to the inner 4 screws of the rear panel.

  Necessary functional checks: Injection speed, voltage system, tightness
- Before each use, ensure that the deadline specified on the inspection sticker attached to the device is not exceeded. DO NOT use the device if the date on the safety inspection sticker has expired and arrange a new inspection if necessary.

6.2 Maintenance

What?	How often?	By whom?
Inspection / maintenance of the system parts and renewed safety inspection (see 6.1)	every 24 month	Manufacturer (first test), qualified / authorised workshop (periodic safety inspection)

After initial commissioning, the device must be subjected to a periodic safety check every **24 months**.
Hand over the control unit and handpiece with all accessories (incl. foot switch, if applicable) in the original packaging to an authorised workshop for this purpose.

7 FUNCTIONAL FAILURE, REPAIRS, COMPLAINTS, DISPOSAL

7.1 Functional failure / repairs

- If the device malfunctions, first disconnect all components such as the foot switch and handpiece from the device.
- Check all connections and reconnect them. The device should then work again.
- If the malfunction cannot be remedied, take the device to your authorized distributor who will forward it to the manufacturer or a service center.

Under no circumstances should you attempt to carry out repairs yourself.

- If the device can no longer be operated safely, it must be taken out of service and safeguarded against accidental or unauthorised use.

7.2 Complaints

Complaints are to be made exclusively to the manufacturer. For this purpose, the specialist dealer can be used as an intermediary.

7.3 Reporting obligations

Operating companies, distributors and traders who have knowledge of incidents in accordance with EU Regulation 2017/745 (MDR) must report them.

The method of reporting is defined in the EU Regulation 2017/745 (MDR).

Outside Europe, the relevant regulations of the respective country apply.

7.4 Disposal of the device

Europe: According to the German Waste Electrical and Electronic Equipment Act (ElektroG), which implements Directive 2012/19/EU ("WEEE Directive") in Germany, all manufacturers are obliged to take back old devices exclusively for commercial use that are to be disposed of free of charge and to dispose of them properly.

As the manufacturer of the XCELLARISPRO TWIST, we are registered with the Waste Electrical and Electronic Equipment or “WEEE” Register (WEEE Reg. No. 18153250).

If you wish to dispose of your XCELLARISPRO TWIST device or electrical accessories, please contact us. The device must not be disposed of with household waste or at public collection points for electrical waste. Outside Europe: At the end of the product lifetime, dispose of the product in accordance with applicable regulations for waste electronic equipment. If necessary, ask your distributor or the competent authorities about the applicable regulations.

System type	XCELLARISPRO TWIST
Total weight	825g
Weight of the handpiece incl. cable	260g
Width x Height x Depth	B 114 x H 86 x D 183 mm
Input voltage	100 V - 240 V~, 50/60 Hz
Power consumption	0,07A (100V) - 0,03A(240V)
Fuse in the control unit REF VK-2000.002.01	250V - 1,25 A, LOW, 5x20 (only change at specialist workshop)
Control unit REF VK-2000.002.01 Protection class	II
Control unit REF VK-2000.002.01 and handpiece REF VK-2000.003-01 Protection class	IP21
Power supply unit GSM90A48-P1M Protection class	I
Handpiece REF VK-2000.003-01 Application part	Type B
Medical device classification	Class IIa
Needle stroke operating frequency	50 to 150 Hz ± 10 %
Operating mode	Continuous operation

9 OPERATING, TRANSPORT AND STORAGE CONDITIONS

Operating conditions	
Ambient temperature	+10 °C to +35 °C
Relative humidity	30 % to 75 %
Transport and storage conditions	
Avoid moisture and direct sunlight/heat	
Ambient temperature	+10 °C to +35 °C
Relative humidity	30 % to 75 %

10 MANUFACTURERS DECLARATION

10.1 Guarantee / Warranty

You have purchased a high-quality brand product. The device is covered by the **statutory warranty of 2 years** from the date of purchase for device faults that are due to material defects or processing defects. No liability is accepted for consequential damage. No warranty is given for damage caused by improper handling or non-compliance with our instruction manual.

A supply of spare parts is guaranteed for a period of 3 years from the date of purchase.

10.2 Note on Electromagnetic Compatibility

Medical, electrical devices are subject to special precautions with regard to Electromagnetic Compatibility (EMC). This device is to be used exclusively for the purposes described in this manual and is to be installed and commissioned in compliance with the instructions for EMC. Portable and mobile RF communication devices such as mobile phones can affect medical electrical devices.

DIN EN 60601-1-2 / IEC 60601-1-2 was implemented with the aim of ensuring EMC requirements and preventing unsafe equipment conditions. This standard defines levels of electromagnetic disturbances for medical devices. The XCELLARISPRO TWIST microneedling devices are compliant with the above standard, for both immunity and radiance.

The manufacturer guarantees conformity with EMC requirements only when original accessories and spare parts are used. The use of other accessories may result in increased emission of electromagnetic faults or reduced resistance to electromagnetic faults.

10.3 Manufacturer's declaration on electromagnetic emission

The device is only intended for operation with original accessories in an electromagnetic environment as specified below. The user of the device should ensure that it is operated in such an environment.

Interference emission measurements	**Compliance**	**Electromagnetic Environment Guide**
HF emission according to CISPR 11	Group 1	The device uses HF energy only for its internal function. Therefore, its HF emission is very low and it is unlikely to interfere with neighbouring electronic devices.
HF emission according to CISPR 11	Class B	The device is for use in professional environments as described in item 2.5.
Harmonics according to IEC 61000-3-2	Class A	
Voltage fluctuations / flicker according to IEC 61000-3-3	Meets the standard	

10.4 Manufacturer's declaration on electromagnetic immunity

The device is intended for operation in the electromagnetic environment specified below. The user of the device should ensure that it is operated in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 8 kV Contact discharge ± 2, 4, 8, 15 kV Air discharge	Complies	Floors should be ceramic tiled. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Fast transient electrical disturbances / bursts according to IEC 61000-4-4:	± 2kV for mains lines ± 1 kV for input and output lines 100 kHz repetition frequency	Complies	The quality of the supply voltage should correspond to that of a typical business or hospital environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidelines
Surges according to IEC 61000-4-5:	± 1 kV Push-pull voltage ± 2 kV Common mode voltage	Complies	The quality of the supply voltage should correspond to that of a typical business or hospital environment
Voltage dips, short-time interruptions and fluctuations of the supply voltage according to IEC 61000-4-11:	0 % UT; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0 % UT; 1 period and 70 % UT; 25/30 periods Single-phase: at 0 degrees 0 % UT, 250 periods	Complies	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the device requires continued operation even when power interruptions occur, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Magnetic field at the supply frequency (50/60 Hz) according to IEC 61000-4-8:	30 A/m	Complies	Magnetic fields at the mains frequency should correspond to typical values found in business and hospital environments.

* Note: UT is the mains AC voltage before the application of the test levels

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - Guidelines
			Portable and mobile radios should not be used at a distance from the device, including lines, less than the recommended separation distance calculated using the equation applicable to the transmit frequency. Recommended safety distance:
Conducted RF disturbances according to IEC 61000-4-6	3 Vrms 150 kHz - 80 MHz outside ISM and amateur radio bands	Complies	When operating portable or mobile RF communication devices (transmitters), a safety distance should be maintained from all parts of the device, including cables, which varies depending on the Transmission frequency calculated from one of the following equations. $d= 0.35x\sqrt{P}$
Conducted RF disturbances according to IEC 61000-4-6	6 Vrms 150 kHz - 80 MHz in ISM and ama-teur radio bands	Complies	$d= 0.35x\sqrt{P}$
Radiated RF disturbances according to IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz	Complies	See table below (test specifications for the immunity of ENCLOSURES to high-frequency wireless communication equipment) **WARNING:** PORTABLE RF communications devices (radios) (including their ACCESSORIES such as antenna cables and external antennas) should not be used within 30 cm (or 12 inches) of the [ME DEVICE or ME SYSTEM] parts and wiring designated by the

			MANUFACTURER. Failure to comply may result in a reduction in the performance characteristics of the device.”.

NOTE 1 At 80 MHz and 800 MHz, the higher value applies.

NOTE 2 These guidelines may not apply in all situations. The propagation of electromagnetic waves is influenced by absorption and reflection from buildings, objects and people.

a) The field strength of stationary transmitters, such as base stations of radio telephones and land mobile services, amateur stations, AM and FM radio and television transmitters, cannot theoretically be predicted accurately. To determine the electromagnetic environment as a result of stationary HF transmitters, an inves-tigation of the site is recommended. If the determined field strength at the location of the device exceeds the compliance level specified above, the device shall be observed for normal operation at each application loca-tion. If unusual performance characteristics are observed, it may be necessary to take additional measures, such as reorienting or relocating the device.

b) Above the frequency range from 150 kHz to 80 MHz, the field strength should be less than 3 V/m.

Test specifications for the immunity of ENCLOSURES to high-frequency wireless communication equipment

Test frequency MHz	Frequency band MHz	Radio service	Modulation	Maximum Output W	Distance m	IMMUNITY TEST LEVELL V/m
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 to 470	GMRS 460, FRS 460	Pulse modulation 217 Hz	2	0,3	28
710 745 780	704 to 787	LTE Band 13, 17	Pulse modulation 18 Hz	0,2	0,3	9
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b 217 Hz	2	0,3	9
1720 1845 1970	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
2450	2400 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9

10.5 Recommended safety distances to portable and mobile HF communication equipment

The device is intended for operation in an electromagnetic environment in which HF disturbances are controlled. The user of the device can help to avoid electromagnetic faults by maintaining the minimum distance between portable and mobile HF telecommunication devices (transmitters) and the device - depending on the output power of the communication device, as specified below.

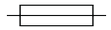
Nominal transmitter power [W]	Safety distance depending on the transmission frequency [m]		
	150 kHz to 80 MHz in the ISM bands	80 MHz to 800 MHz	800 MHz to 2,7 GHz
0,01	0,04	0,04	0,07
0,1	0,13	0,11	0,22
1	0,4	0,35	0,7
10	1,3	1,1	2,2
100	4,0	3,5	7,0

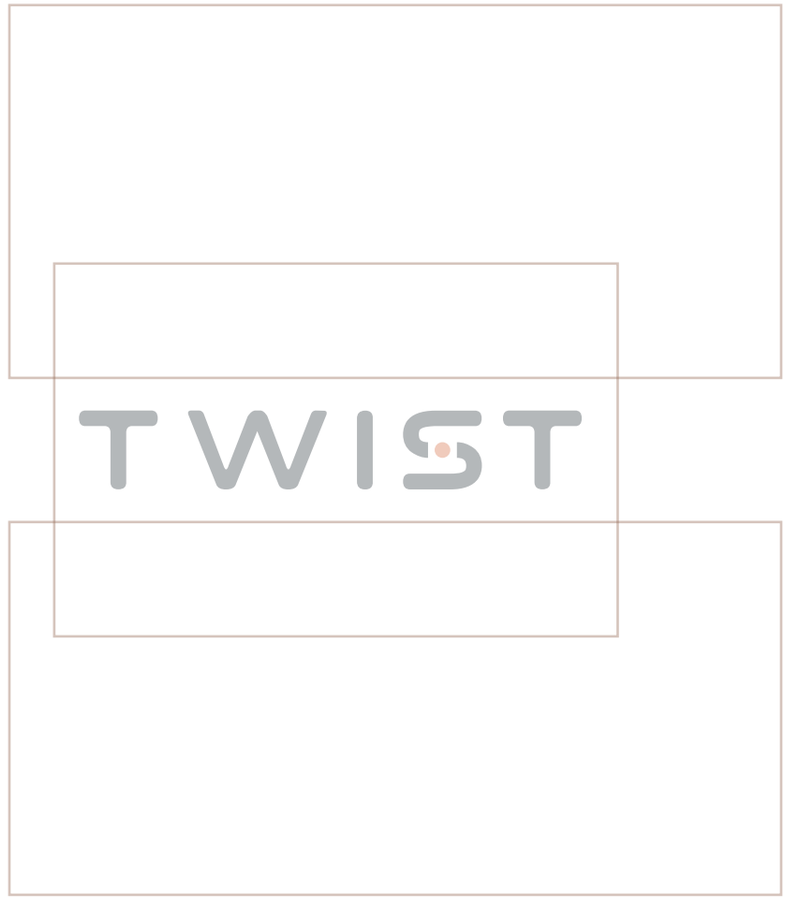
For transmitters whose maximum power rating is not given in the above table, the recommended safety distance “d” in metres (m) can be determined using the equation associated with each column, where “P” is the maximum power rating of the transmitter in watts (W) as specified by the transmitter manufacturer.

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not be applicable in all cases. The propagation of electromagnetic quantities is influenced by absorptions and reflections of buildings, objects and people.

10.6 List of symbols on the product incl. accessories / packaging

SymbolS	Description
IP21	IP protection class (contact protection, dust, water)
	Protection class II
	Application part type B
	DC connection - inner pin positive
CE 0482	The device fulfils the European requirements for medical devices
	“Observe instruction manual!”
	“Name and address of the manufacturer”
	“Date of manufacture”
REF	“Catalogue number”
SN	“Serial number”
	“Attention!” / General safety sign
	Danger due to live components
	Danger of injury from pointed object
	“Store in a dry place”
	“Fragile”
	Temperature limit (upper and lower temperature limit)
	Humidity: permitted range
	“Product must not be disposed of in household waste!”
	Safety inspection sticker
	Alternating current
	Direct current
	Fuse
	Foot switch socket
	For indoor use only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