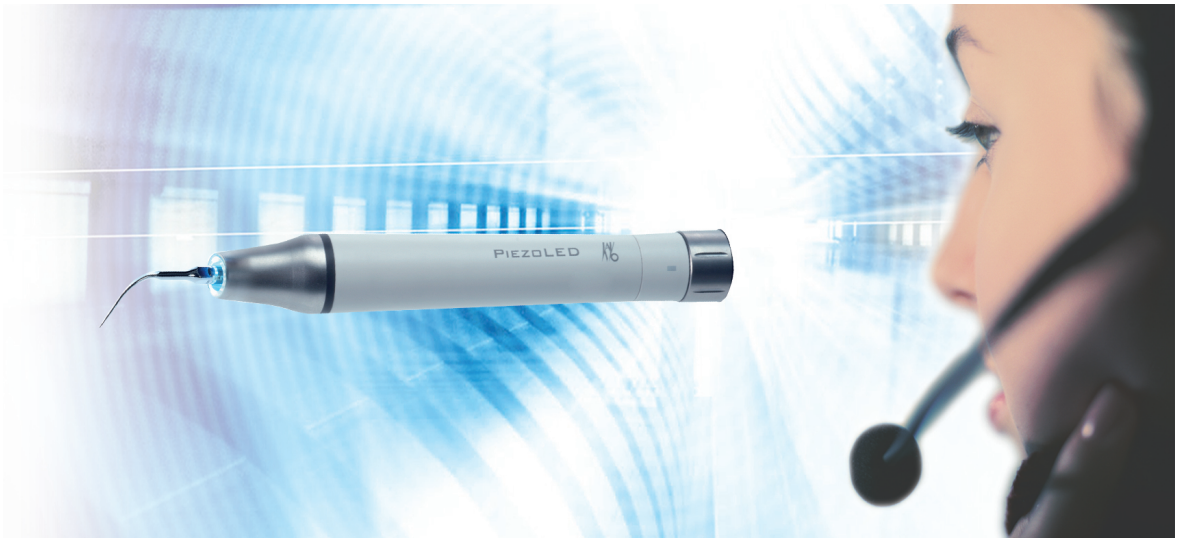
Instructions for use

KaVo PiezoLED Ultraschall Scaler



Always be on the safe side.

KaVo. Dental Excellence.

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CE 0124

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1 User instructions

1.1 User guide

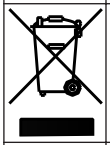
Requirement
Read these instructions prior to first use to avoid misuse and prevent damage.

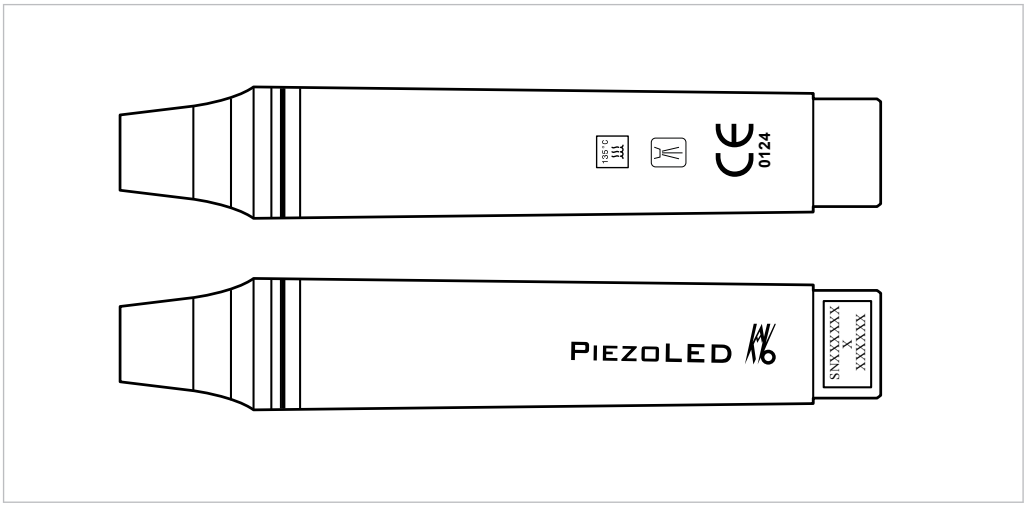
1.1.1 Abbreviations

Abbre-viation	Explanation
IfU	Instructions for use
CI	Care instructions
AI	Assembly instructions
TI	Technician's instructions
SC	Safety checks
IEC	International Electrotechnical Commission
RI	Repair instructions
RK	Retrofitting kit
AS	Assembly set
EP	Enclosed parts
EMC	Electromagnetic compatibility
PI	Processing instructions

1.1.2 Symbols

	Refer to the chapter on Safety/Warning symbol
	Important information for users and service technicians
▶	Action request

REF	Material number
CE 0124	CE mark according to Medical Devices Directive EC 93/42
	Disposal instructions, intended use
135 °C	Can be steam-sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
	Thermodisinfectable



1.1.3 Target group

This document is for dentists and dental office staff.

1.2 Service

KaVo Customer Service:
+49 (0) 7351 56-1000
Service.Einrichtungen@kavo.com
Please refer to the serial number of the product in all inquiries!
For further information, please visit: www.kavo.com

2 Safety

2.1 Description of safety instructions

2.1.1 Warning symbol

	Warning symbol

2.1.2 Structure

⚠ DANGER

The introduction describes the type and source of the hazard.

This section describes potential consequences of non-compliance.

- The optional step includes necessary measures for hazard prevention.

2.1.3 Description of hazard levels

Safety instructions distinguishing between three hazard levels are used in this document to prevent personal and property damage.

⚠ CAUTION

CAUTION

indicates a hazardous situation that can cause damage to property or mild to moderate injuries.

⚠ WARNING

WARNING

indicates a hazardous situation that can lead to serious or fatal injury.

⚠ DANGER

DANGER

indicates a maximal hazard due to a situation that can directly cause death or fatal injury.

2.2 Proper use

The user must ensure that the unit works properly and is in satisfactory condition before each use.

Purpose:

This KaVo product is designed for use in dentistry only and may only be used by trained medical personnel. Any other type of use is not permitted.
"Proper use" includes compliance with all instructions for use and the inspection and maintenance intervals.
The overarching guidelines and/or national laws, national regulations and the rules of technology applicable to medical devices for start-up and use of the KaVo product for the intended purpose must be applied and followed.
The ultrasound handpiece is designed for dental applications using KaVo PIEZO Scaler Tips in the following areas:

Piezo Scaler Tips (Scaling):
- Removal of calculus and concretions (supragingival and subgingival)
- Removal of deposited pigments

Piezo Paro Tips (periodontic therapy):
- Scaling and root smoothing
- Subgingival concretions

Piezo Endo Tips and files (endodontics):
- Preparation and cleaning of root canals
- Retrograde preparation of root canals

Piezo Prep Tips (preparation):
- Cavity preparation

Piezo Cem Tips:
- Cementation of restorations

Contraindication

The ultrasonic vibrations of PIEZOsoft products might interfere with pacemakers and defibrillators. KaVo does not recommend treatment of patients who have pacemakers or defibrillators.

Proper use:

KaVo accepts liability for the safety, reliability, and performance of components supplied by KaVo, provided:
- installation, instructions, expansions, adjustments, changes or repairs were carried out by technicians trained by KaVo or third parties authorised by KaVo, or by the personnel of authorised distributors.
- the unit was operated in accordance with the instructions for use, care and installation.
- the IT components supplied by the operator meet the technical requirements in these instruction for use for hardware and software, and they are installed and set up according to the descriptions of these components.
- in the case of repairs, the requirements of IEC 62353 (DIN VDE 0751-1) "Repeat tests and tests before start-up of electrical items of medical equipment and systems - general regulations" are met in full.

Users have a duty to:
- Only use equipment that is operating correctly
- to protect himself, the patient and third parties from danger.
- to avoid contamination from the product

The applicable national legal regulations must be observed during the use of the device, in particular the following:
- Applicable regulations governing the connection and start-up of medical devices.
- Current occupational safety regulations.
- Current accident prevention regulations.

Regular performance of maintenance and safety checks is essential for the permanent assurance of the operating and functional safety of the KaVo product and for the prevention of damage and hazards.
Testing and maintenance intervals: Maintenance must be performed once a year, the safety check (STK) at intervals of 2 years. Shorter intervals for the safety check may be specified by the tester if necessary.

The following persons are authorised to repair and service the KaVo product:
- Technicians of KaVo branch offices after appropriate product training.
- Specifically KaVo-trained technicians of KaVo franchised dealers.

In Germany, operators, equipment managers and users are obliged to operate their equipment in accordance with the MPG regulations.
The services encompass all the test tasks required in accordance with § 6 of the medical devices operator ordinance (Medizinprodukte-Betreiberverordnung, MPBetreibV).

Note
Do not use PIEZO Ultrasonic scalers and tips with products from other companies!

2.3 Safety instructions

⚠ WARNING

Hazard to the care provider and patient.
In case of damage, irregular noise during operation, excessive vibration, atypical heating or when the tip cannot be firmly held.
- ▸ Stop working and contact service support.

⚠ CAUTION

Risk of burn injury due to oscillating PIEZOscaler tip.
During the use of the PIEZOscaler tip, contact to non-cooled parts can lead to burn injuries.
- ▸ Make sure that the oscillating PIEZOscaler tip does not contact soft tissues, e.g. by placing it on the lip while using it.

⚠ CAUTION

Sharp-edged tips.
Injury hazard.
- ▸ Leave the enclosed torque wrench on the PIEZOsoft dental handpiece when it is not being used!

⚠ CAUTION

Risks from electromagnetic fields.
Electromagnetic fields might interfere with the functions of implanted systems (such as pacemakers).
- ▸ Ask patients if they have a cardiac pacemaker or other system implanted before you start the treatment!

⚠ CAUTION

Risk of confusing tips from different manufacturers.

- Please note the labelling on the tips.
- Please note the characteristic feature of KaVo tips, i.e. the low-positioned thread.

① KaVo tip ② Non-KaVo tip

⚠ CAUTION

Product damage and personal injury due to tips from other manufacturers.

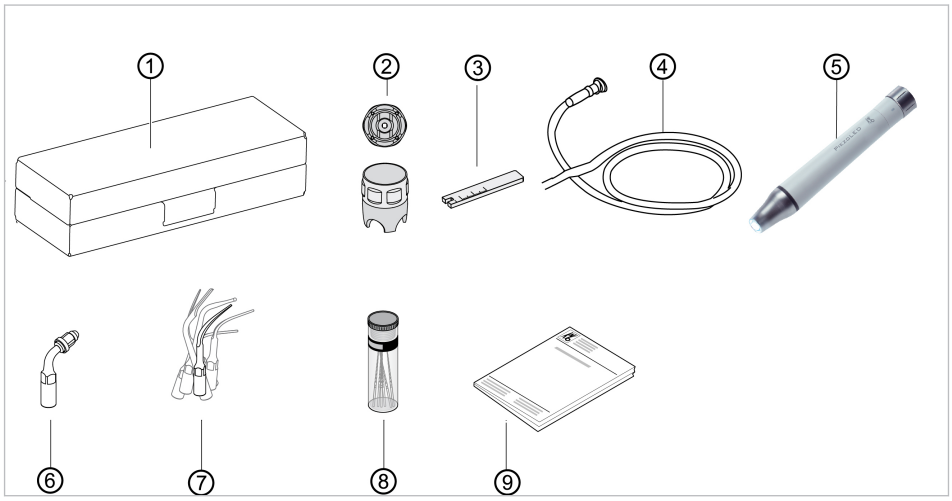
The use of tips from other companies can lead to injuries to users and patients as well as to the destruction of the product.

- Only use KaVo PIEZO tips.

3 Product description

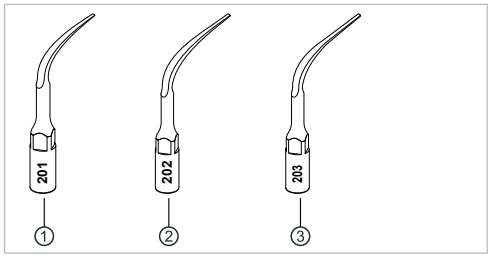
3.1 Product

3.1.1 Ingredients



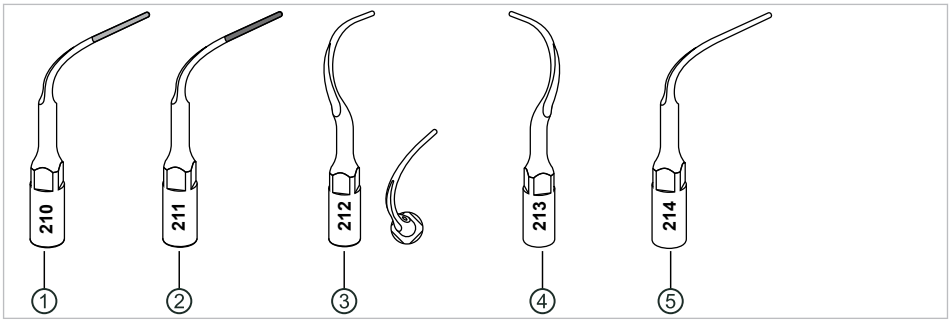
① Steri-Box ¼ DIN (general description for boxes of 5 and 6 each)
② Torque wrench
③ Wrench for file holder
④ PIEZO Scaler hose R1300
⑤ PiezoLED handpiece
⑥ Piezo Endo Tip 222 file holder
⑦ Tips (general description)
⑧ File container (5 units)
⑨ Instructions for use

3.1.2 PIEZO Scaler Tips



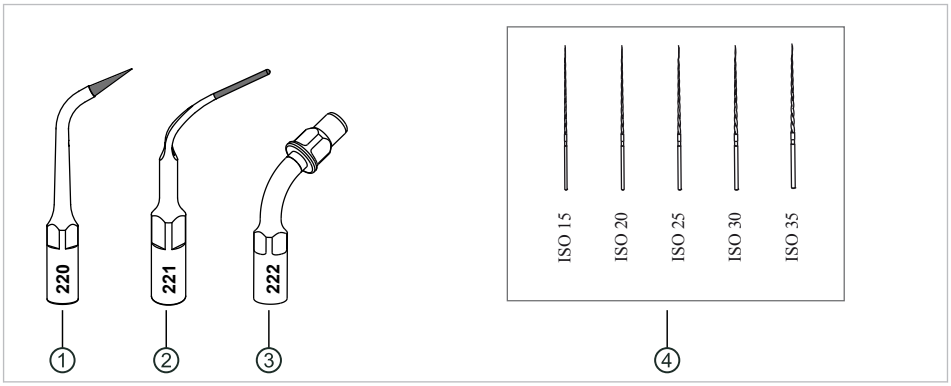
① Piezo Scaler Tip 201
② Piezo Scaler Tip 202
③ Piezo Scaler Tip 203

3.1.3 PIEZO Paro Tips



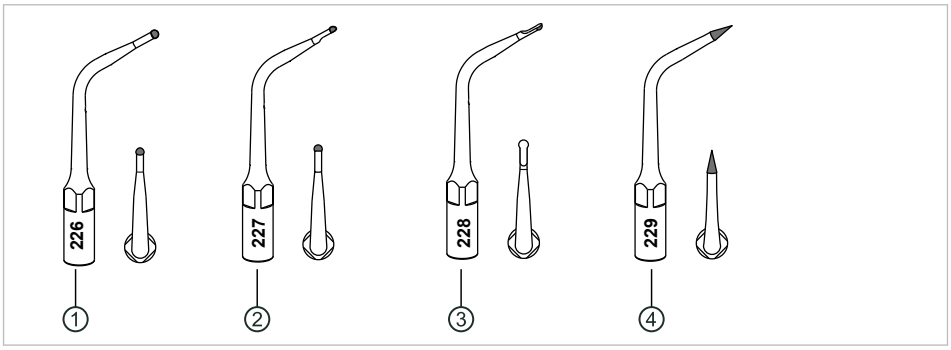
① Piezo Paro Tip 210
② Piezo Paro Tip 211
③ Piezo Paro Tip 212
④ Piezo Paro Tip 213
⑤ Piezo Paro Tip 214

3.1.4 PIEZO Endo Tips



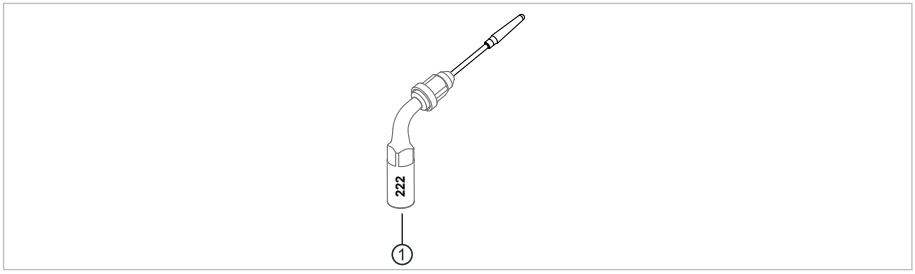
① Piezo Endo Tip 220
② Piezo Endo Tip 221
③ Piezo Endo Tip 222
④ Piezo Endo Tip files (ISO 15 to ISO 35)

3.1.5 PIEZO Prep Tips



① Piezo Prep Tip 226
② Piezo Prep Tip 227
③ Piezo Prep Tip 228
④ Piezo Prep Tip 229

3.1.6 PIEZO Implant Tips Set



① Piezo Endo Tip 222 with Piezo Implant Tip

3.2 Technical Data

Classification 93 / 42 EEC	Class IIa
Classification EN 60601-1	Application part type BF
Installation category DIN EN 60664	CAT II

Electrical system

Supply voltage	33 V DC
Power consumption	20 VA
Ultrasound specifications	max. output power: 8 Watt, frequency range: 24-32 kHz
ON-time	With fluid: continuous operation, with / without fluid: working cycle, 10 % for max. 10 min.

Operating conditions

Temperature	+10 °C to +40 °C (+50 °F to +104 °F)
rel. humidity	30 % to 75 %
Height	3,000 m
Air pressure	700 to 1,060 hPa (10 psi to 15 psi)
Degree of soiling	P2

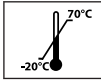
3.3 Transport and storage conditions

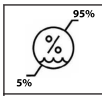
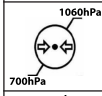
⚠ CAUTION

It is hazardous to start up the medical device after it has been stored strongly refrigerated.

This can cause the medical device to malfunction.

- Prior to start-up, very cold products must be heated to a temperature of 20°C to 25°C (68°F to 77°F).

	Temperature: -20°C to +55°C (-4°F to +131°F)

	Relative humidity: 10% RH to 95% RH absence of condensation
	Air pressure: 500 hPa to 1060 hPa (7 psi to 15 psi)
	Protect from moisture

4 First use

⚠ WARNING

Hazard from non-sterile products.

Infection hazard for care provider and patient.

- Before first use and after each use, prepare and sterilise the medical device and accessories accordingly.

⚠ WARNING

Disposal of the product in the appropriate manner.

Prior to disposal, the product and accessories must be appropriately prepared or sterilised if this is necessary.

4.1 Reduce germ count in aerosols

The use of oscillating dental tips and the requisite rinsing fluid causes the production of an aerosol spray mist.

KaVo recommends to reduce the germ count by using oxygenal in the treatment unit.

This reduces the germ count in the spray mist.

The bacterial level in the fluid-containing tubes is reduced.

4.2 Attaching the tips

⚠ CAUTION

Cleaning the connecting pieces with compressed air.

Irreparable damage to the system.

- Never apply compressed air directly to sites of contact and orifices.

⚠ CAUTION

Incorrect position of the tip.

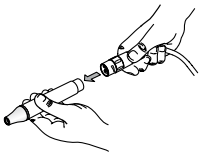
Not an appropriate spray pattern of the rinsing fluid.

- Position tip correctly.
- Check for noises when you start up the tip. Noises could indicate that the tip is not clamped tightly enough in the tip holder.

- In order to ensure perfect electronic connection, the individual components must be dry.

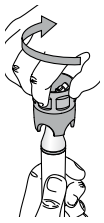
Note

It is imperative to use only the enclosed torque wrench for attachment of the tips on the handpiece with the appropriate torque. The enclosed torque wrench is a combination of a torque wrench and an individual file holder. It ensures installation in accordance with the pertinent specifications, orderly storage of the tips, and provides protection against injury or contamination.



- Mount the handpiece on the coupling.

- Screw-on the tips.



- Tighten the tips with the torque wrench by another quarter of a turn.

⇨ This ensures that the appropriate torque is applied.

4.3 Attaching the file holder

⚠ CAUTION

Incorrect attachment of the screws.

Failure to treat the sensitive tips gently.

- Use only the enclosed wrench for attaching the file holder on the handpiece.
- Use only the enclosed wrench for attaching the tips and files in the chuck.
- Tighten union nut screwed sleeve only if files or tips have been placed in the chuck.
- Do not tighten the screws excessively.

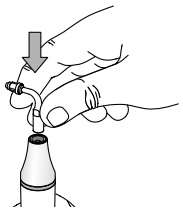
⚠ CAUTION

Incorrect position of the file or tip.

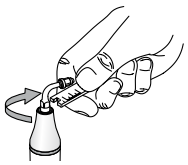
Not an appropriate spray pattern of the rinsing fluid. Fracture of the files, scratching along the walls of the root canal, and inadvertent enlargement of the apical foramen.

- Position file or tip correctly.
- Check for noises when you start using the file or tip. Noises may indicate that the file or the tip is not clamped tightly enough in the file holder.

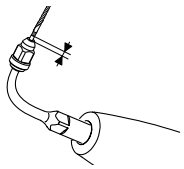
Position the file



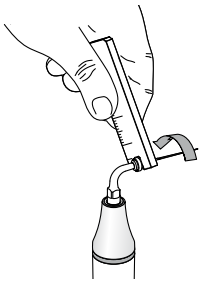
- Screw the file holder on the handpiece.



- Attach the file holder to the handpiece with the torque wrench.



- Slide the file into the file holder until the mark is reached.



- Gently tighten the union nut screwed sleeve with the torque wrench.

5 Operation

⚠ CAUTION

Working with non-sterile handpieces.

Non-sterile handpieces and tips can elicit bacterial or viral infections.

- Sterilise all handpieces and tips prior to each use.

See also:

6 Rehabilitation method in accordance with ISO 17664, Page 32

⚠ CAUTION

Working with dry PIEZO Tips.

The working tip of the instruments heats up very quickly during dry work.

- Ensure that there is sufficient rinsing fluid at all times.
- Work with dry tips only if this option is expressly stated.

⚠ CAUTION

Damage to restorations and dental prostheses.

- Use tips with metal or ceramic restorations and dental prostheses only if this option is expressly stated.

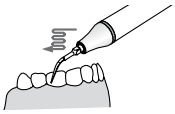
Piezo Tips vibrate in a controlled back-and-forth motion. If the power settings of the device are identical, a longer and thinner tip produces less clinical output.

Notes regarding the working procedure

Note

The insertion depth of the PIEZO Tip must be at a distance of 1 mm from the colour marker.

- Always keep the tip tangential to the tooth surface during treatment.
  Never touch the tip frontally against the enamel.
  Point the instrument tip against the tooth surface only if this option is expressly stated.



- Perform brush-like motions with little lateral pressure with the handpiece.

- For more gentle treatments, select a longer tip.
  For treatments with higher clinical output, select a shorter tip.

Notes regarding the use of diamond-coated tips

The diamond-coated tips are highly efficient.

- Use the tips with sufficient fluid at all times.

⇨ This prevents damage to hard and soft tissues.
⇨ Rapid wear of the tips is also prevented.

If very strong pressure is applied to the instrument tip, the ultrasonic vibrations are less than optimal.

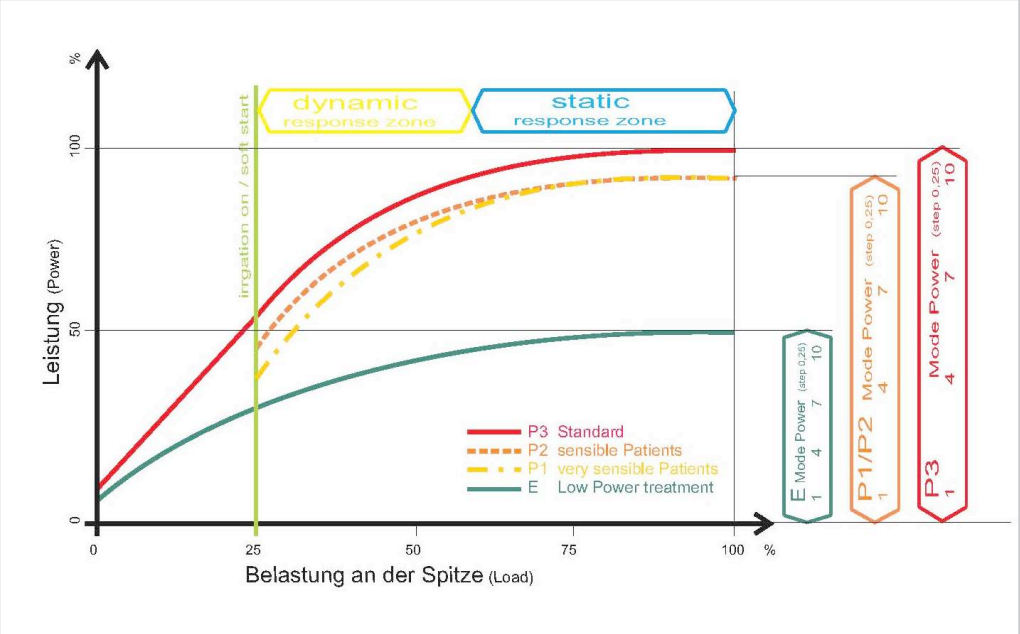
- Apply only gentle pressure to the tip.

⇨ This ensures optimal performance and protection of the tissue.
⇨ The wear and tear on the tip is minimal.

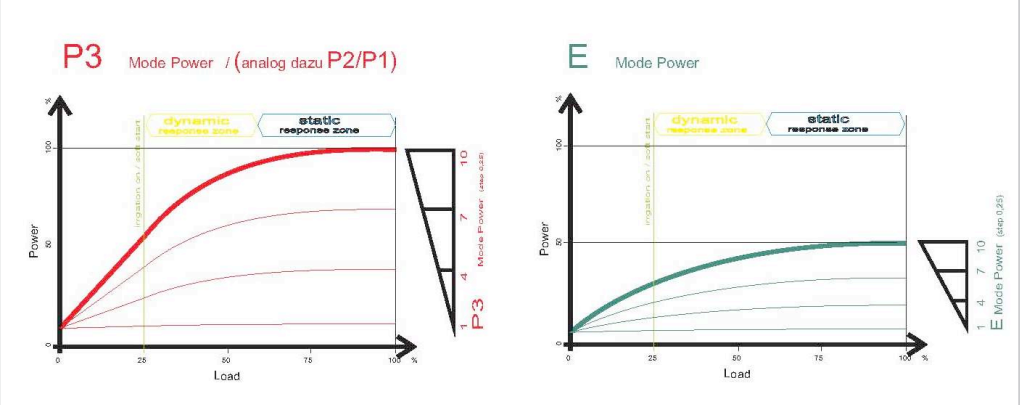
A worn coating reduces the efficiency of the tip significantly.

- Before use, check visually if the diamond-coating is in good shape.
- Use the handpiece while using a mouth protector at all times.
- Always check for correct position of the mouth protector.

5.1 Operating mode P3 / P2 / P1 / E



Power output as a function of operating mode and tip load



Power output as a function of device pre-setting (foot control) and tip load (shown using modes P3 and E as examples)

Note
If you stay in the range of dynamic response, the treatment is ensured to be gentle. The output is adjusted according to load.

5.2 General operating settings on the device

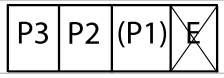
- Select the mode on the device
- Control the output by means of the foot control or display
- Pre-select spray water by means of the foot control or display
- Adjust spray water by means of adjustment ring on the handpiece

The device-specific operation of individual devices is described in the Instructions for Use of the respective device.

5.3 Tip-related information

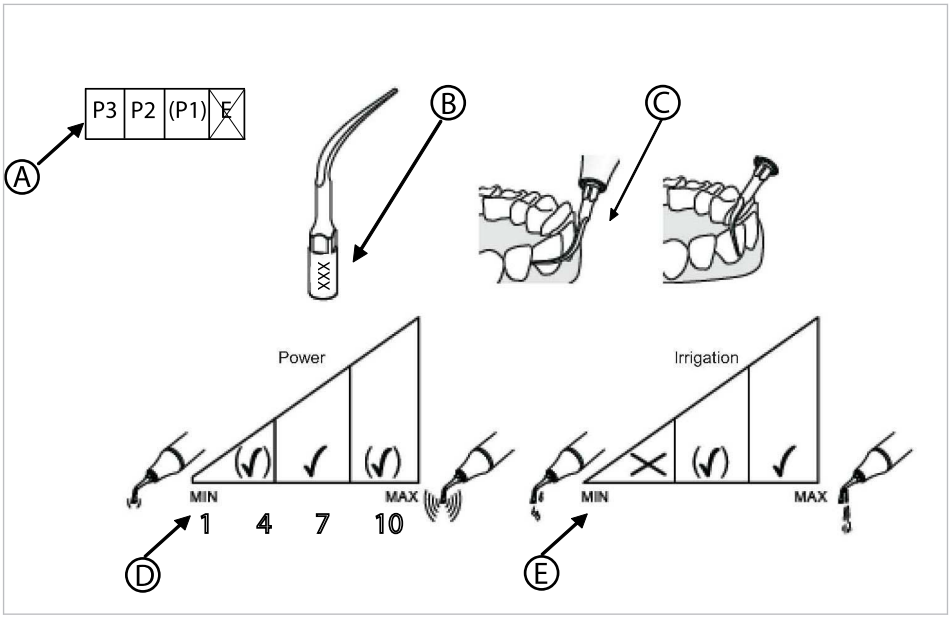
- Information concerning permissible modes
- Information concerning permissible output
- Information concerning permissible spray water volume

Explanations concerning the operating mode:



Symbol	Explanation
	: permissible
( )	: possible
	: non-permissible

Example:



Operating mode

Product identification

Indication

Permissible power setting

Permissible spray water volume

5.4 Scaling tips

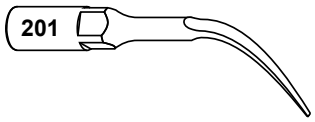
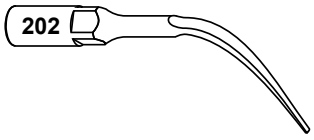
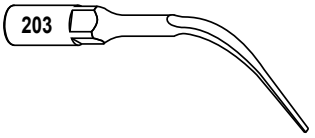
⚠ CAUTION

Instrument tip heats up too rapidly.

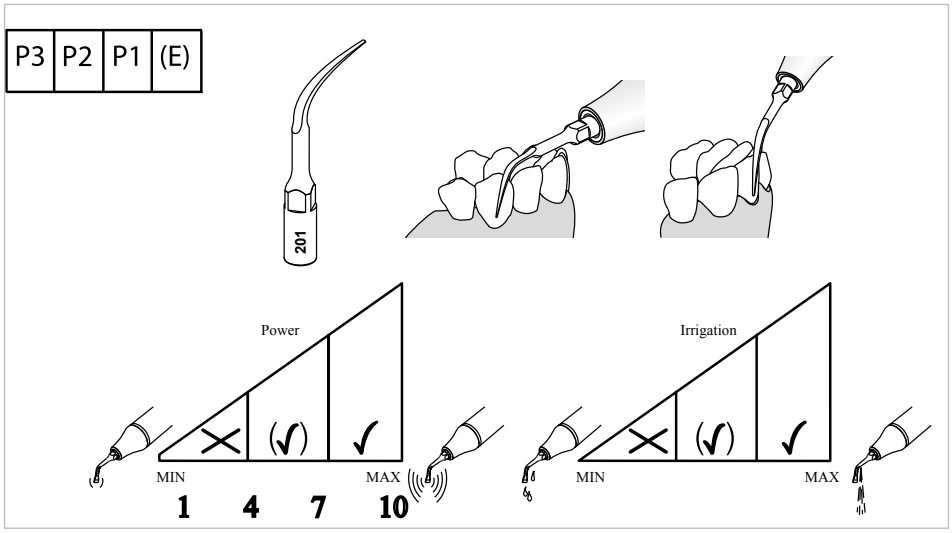
Tooth is cooled insufficiently.

- ▸ Distance from tip with spray mist aspiration.
- ▸ Cooling power must be ensured.

5.4.1 Select tip

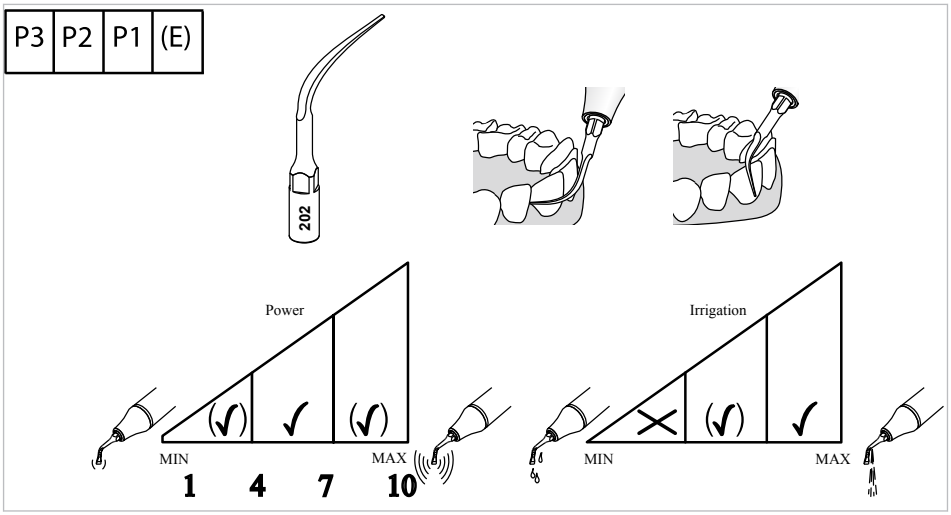
	Piezo Scaler Tip 201	Universally-applicable scaling tip for the removal of supragingival calculus in all quadrants.
	Piezo Scaler Tip 202	Perio tip for the removal of supra- and subgingival concretions in all quadrants, in particular in the interdental spaces and sulcus.
	Piezo Scaler Tip 203	Delicate Perio tip for the removal of subgingival depositions on root surfaces and for rinsing pockets with antimicrobial solutions. Also suitable for periodontal recall treatments.

5.4.2 Using the PIEZO Scaler Tip 201



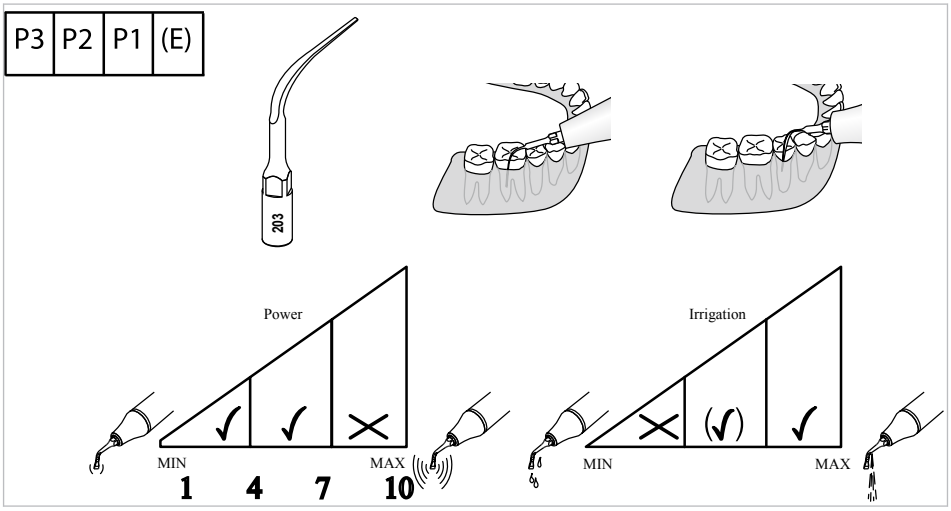
Power	High, for hard concretions.
	Medium, as a standard.
	Low, for pain-sensitive patients and recall treatments.
Flow rate	High to medium.

5.4.3 Using the PIEZO Scaler Tip 202



Power	High, for hard concretions and first treatments.
	Medium, for pain-sensitive patients.
Flow rate	High to medium.

5.4.4 Using the PIEZO Scaler Tip 203



Power	High, for hard concretions.
	Medium, as a standard.
	Low, for pain-sensitive patients or recall treatments.
Flow rate	High to medium.

5.5 Paro tips

⚠ CAUTION

Instrument tip heats up too rapidly.

Tooth is cooled insufficiently.

- Keep a distance from tip with spray mist aspiration.
- Cooling power must be ensured.

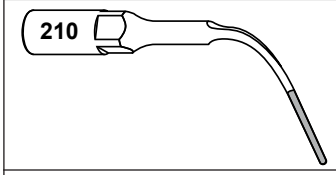
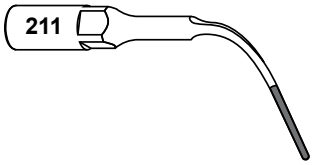
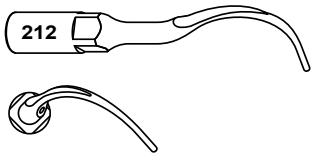
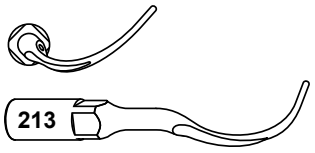
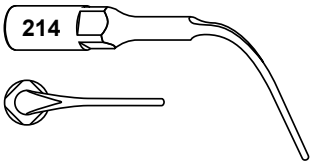
⚠ CAUTION

Injury of the surface of the tooth.

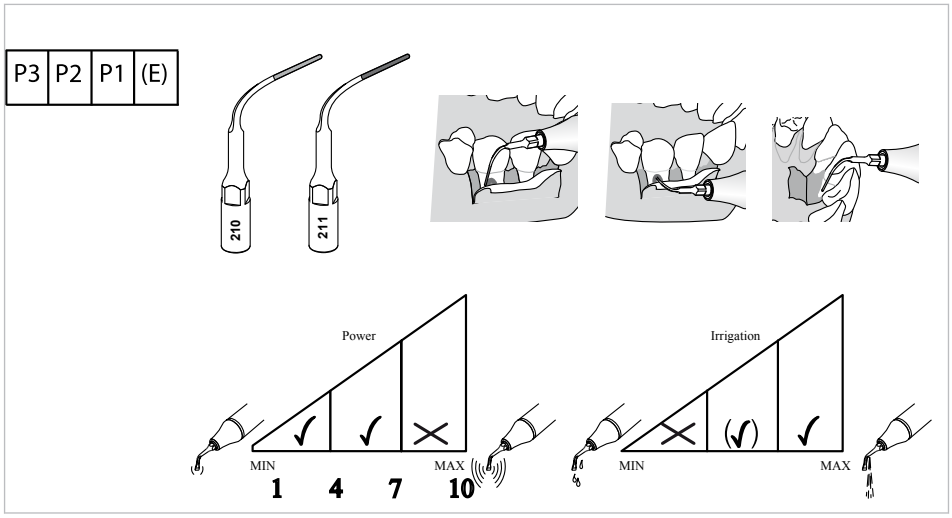
- Never point the instrument tip directly at the tooth surface.
- Never touch the tip frontally against the enamel.

All lateral surfaces (including front and back) of the curved PiezoLED tips can be used for treatment.

5.5.1 Select tip

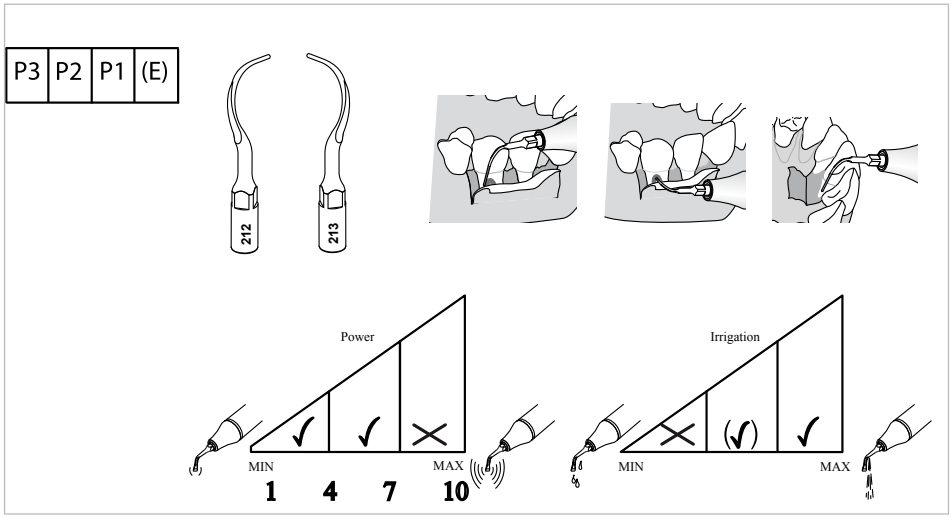
	Piezo Paro Tip 210	Diamond-coated tip with 15 µm-grain for surface polishing after cleaning and shaping.
	Piezo Paro Tip 211	Diamond-coated tip with 70 µm-grain for thorough root cleaning under direct view (flap procedure) and smoothing of restoration overhang and extension of furcation roofs.
	Piezo Paro Tip 212 curved left	For periodontal debridement, particularly well-suited for approximal surfaces and root furcations that are difficult to access.
	Piezo Paro Tip 213 curved right	
	Piezo Paro Tip 214	For rinsing and disinfection of periodontal gingival pockets.

5.5.2 Using the PIEZO Paro Tip 210 and PIEZO Paro Tip 211



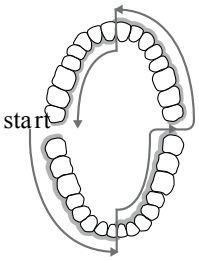
Power	Low to medium.
Flow rate	High to medium.

5.5.3 Using the PIEZO Paro Tip 212 and PIEZO Paro Tip 213



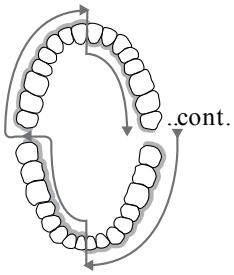
Power	No more than medium, even with hard concretions.
	Low, as a standard.
Flow rate	High to medium.

Only a single change of tips is required for treatment of the entire dentition.



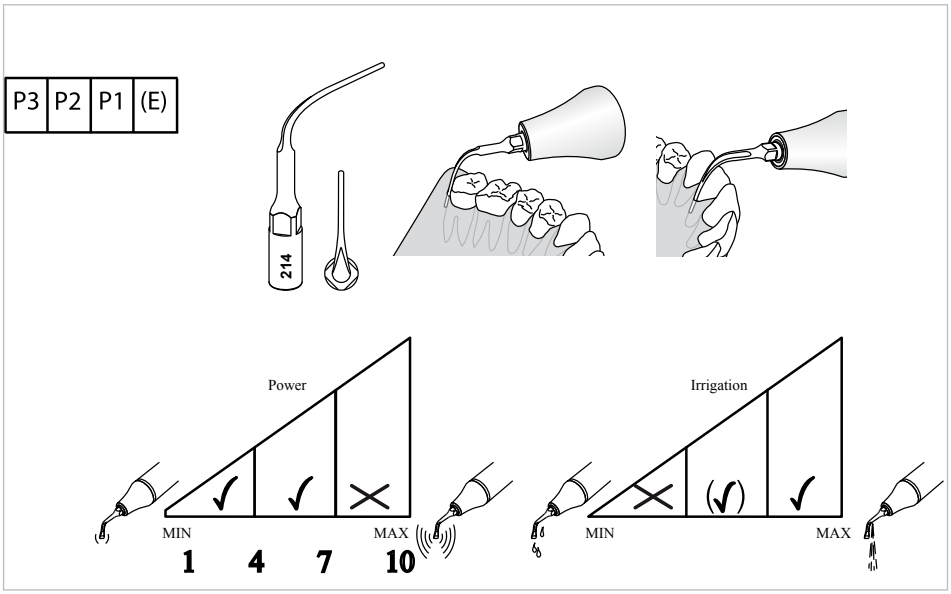
- Guide the Piezo Paro Tip 212 (curved left) in the direction of the arrow. Work only with low lateral pressure.

- Change tips.



- Guide the Piezo Paro Tip 213 (curved right) in the direction of the arrow. Work only with low lateral pressure.

5.5.4 Using the PIEZO Paro Tip 214

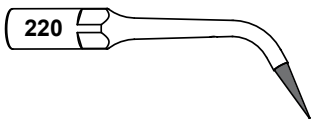
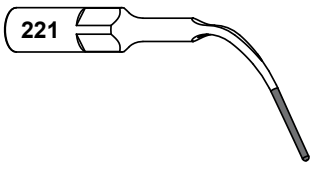


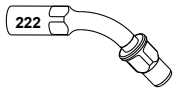
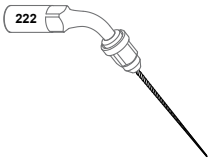
Power	No more than medium, even with hard concretions.
	Low, as a standard.
Flow rate	High to medium.

5.6 Endo tips

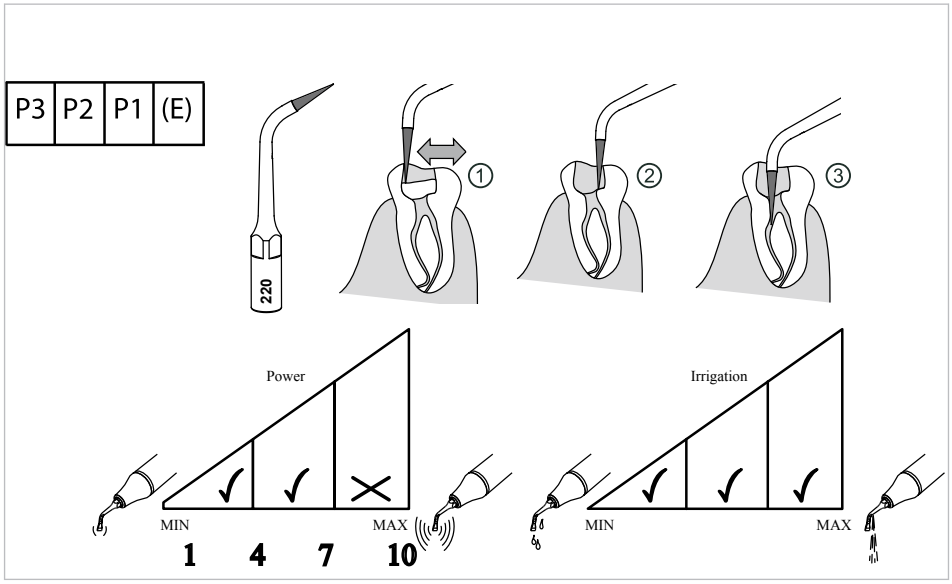
5.6.1 Select tip

The tips are well-suited for work on the pulp cavity, work on coronal root parts and effective revision treatment of root canals, e.g. for removal of fractured instrument tips or files or removal of filling materials.

	Piezo Endo Tip 220	Cone-shaped and diamond-coated tip for the detection of root canals and the removal of calcifications in the coronal third of the root canal system.
	Piezo Endo Tip 221	Slender diamond-coated tip for the removal of steps and other obstructions and for the formation of a straight access to a fractured part of a tip in the root canal.

	Piezo Endo Tip 222	File holder for Piezo Endo Tip and Piezo Implant Tip Set. **Also refer to:** Scaling tips
	Piezo Endo Tip files	Stainless steel files for the preparation, cleaning, and disinfection of the root canal system for use with a file holder. Use Endo mode only.

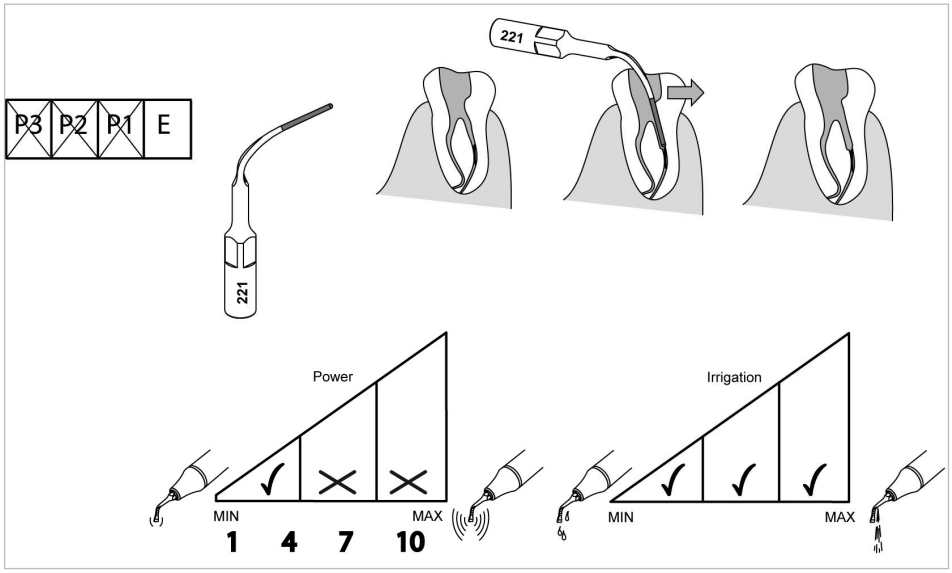
5.6.2 Using the PIEZO Endo Tip 220



Power	Low to medium.
Flow rate	Low to high.

- Remove calcifications without applying pressure to the tip.

5.6.3 Using the PIEZO Endo Tip 221



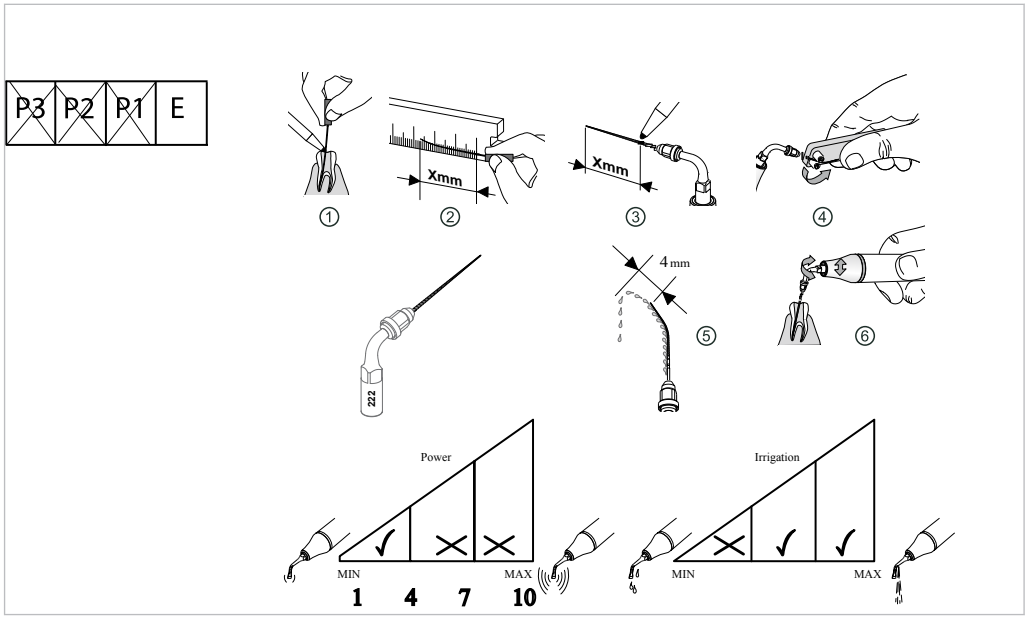
Power	Low.
Flow rate	Low to high.

⚠ CAUTION

Hazard if the fractured part of the tip is pushed further into the root canal.

- Avoid contacting the fractured part of the tip.
- Do not apply pressure in axial direction on the tip.

5.6.4 Using PiezoLED Endo files with file holder



Power	Low, max. 30 %.
Flow rate	Medium to high.

Work with Endo files

- Measure the length of the root canal ①.
- Mark the length of the root canal, e.g. with water-resistant felt-tip pen, on the file ②.
- Mark Endo file ③.
- Bend file to shape ④.
- Keep tip upright, activate rinsing and ultrasonic function, and ensure that the liquid jet projects 4 mm beyond the tip of the file ⑤.
- Activate the file for 4 seconds. Ensure that the file is never activated for more than 10 seconds ⑥.

⚠ CAUTION

Fracturing of the file

- Activate file in the presence of rinsing fluid or outside of the root canal only.
- Produce a guiding canal using a manual file.
- Frequently check the file for symptoms of fatigue and replace the file as early as possible on a prophylactic basis.

Produce a guiding canal using a manual file

⚠ CAUTION

Swallowing or inhalation of a loosened or fractured fragment.

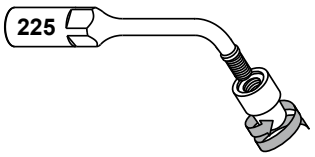
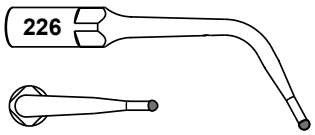
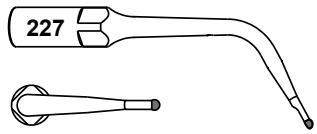
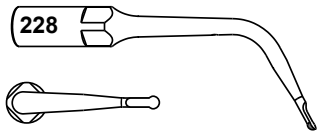
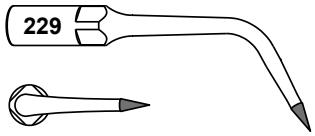
Place a rubber dam.

If a rubber dam cannot be placed, ensure that the patient does not swallow any parts.

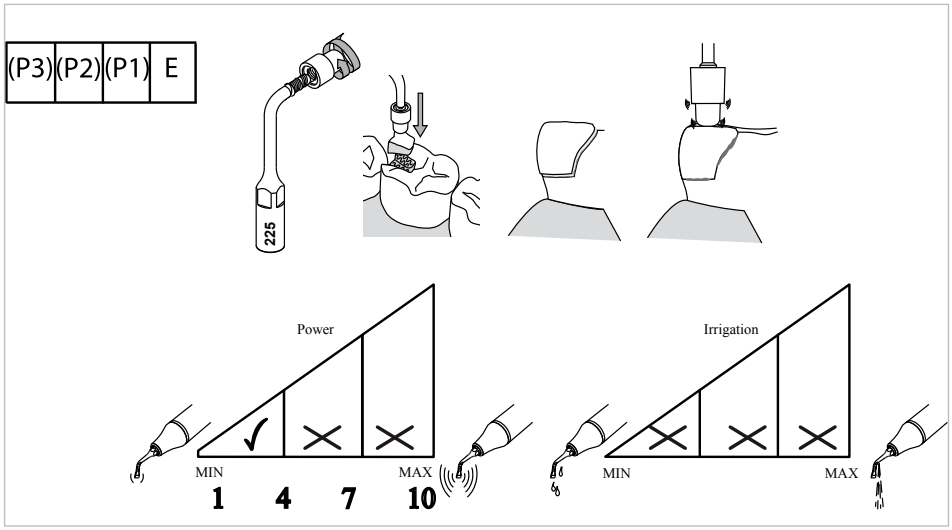
- If required, adapt a manual file of size ISO 15 to the shape of the root canal.
- File inside the root canal proceeding with slow, circling up-and-down motions using the "stepback" procedure.
- Produce a guiding canal.
- Retract the file slowly and careful apply only gentle pressure.

5.7 Preparation tips

5.7.1 Select tip

	Piezo Cem Tip 225	For cementing ceramic inloays, onlays, and veneers with highly thixotropic, dual-curing composite cements.
	Piezo Prep Tip 226	Diamond-coated tip for exposure of small occlusal and buccal defects.
	Piezo Prep Tip 227	Diamond-coated tip for slanting and finishing mesial margins of cavities.
	Piezo Prep Tip 228	Diamond-coated tip for slanting and finishing distal margins of cavities.
	Piezo Prep Tip 229	Diamond-coated tip for cleaning and enlarging fissures prior to sealing.

5.7.2 Using the PIEZO Cem Tip 225



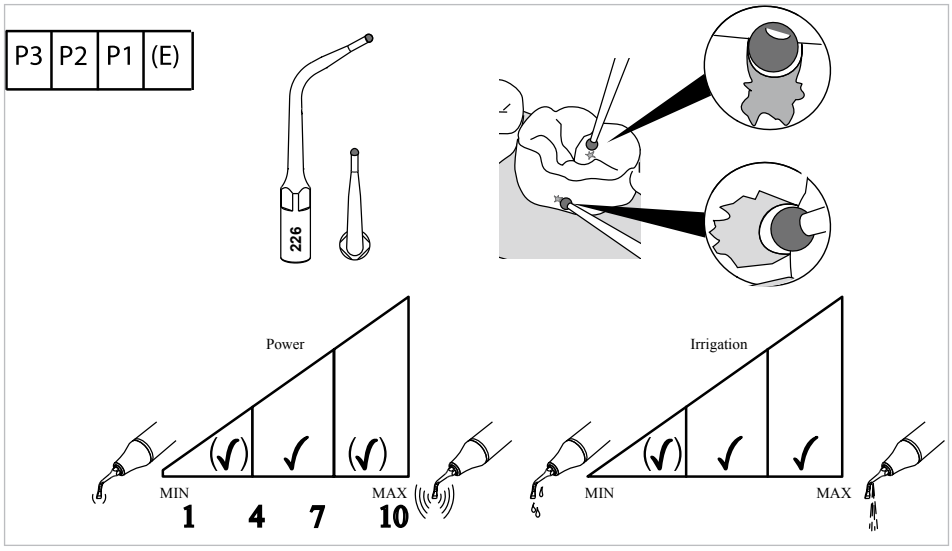
⚠ CAUTION

Instrument tips heat up rapidly.

- Always activate tips for a short period of time only.
- Do not exceed a maximal activation period of 1 minute in a maximal period of use of 10 minutes.

In contrast to other Piezo Tips, the Piezo Cem Tip 225 is used without rinsing fluid. The ultrasonic vibrations of the tips are transferred via the inlay or onlay to the fixation composite. The composite has thixotropic properties. It becomes liquefied briefly when exposed to ultrasonic and is distributed evenly over the cavity.

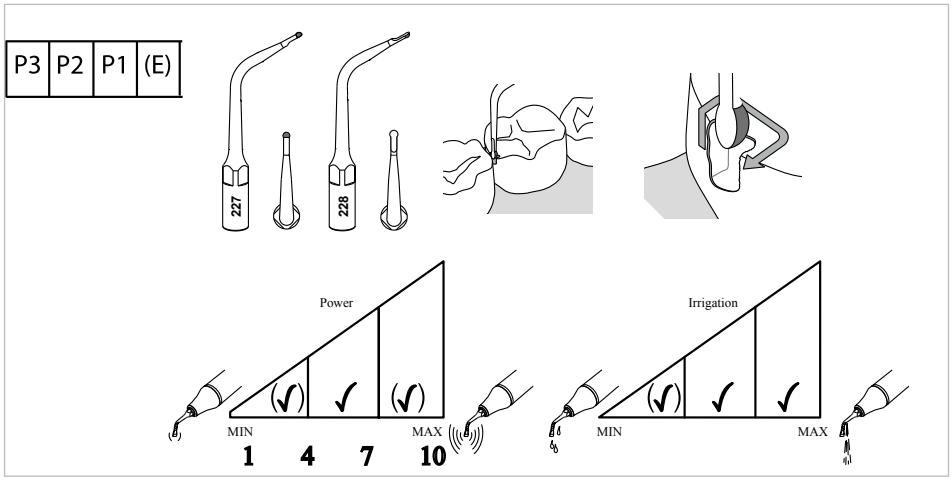
5.7.3 Using the PIEZO Cem Tip 226



Power	Medium, as a standard.
	High or low, according to need.
Flow rate	Medium to high.

- Place the tip at the defect and then guide it into the defect with gentle pressure.

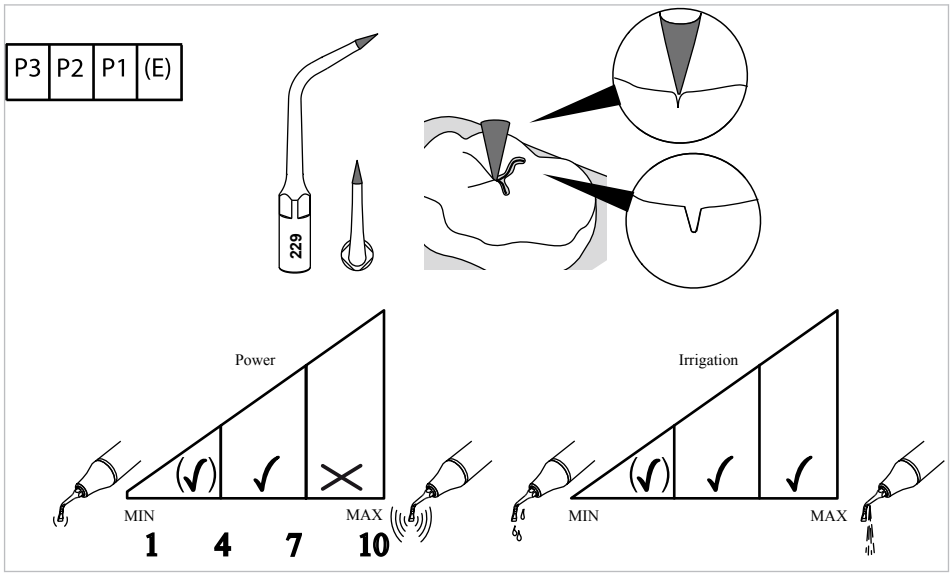
5.7.4 Using the PIEZO Prep Tip 227 and PIEZO Prep Tip 228



Power	Medium, as a standard.
	High or low, according to need.
Flow rate	Medium to high.

- Place the tip at the margin of the cavity and then guide slowly over the margin of the cavity applying gentle pressure.

5.7.5 Using the PIEZO Prep Tip 229

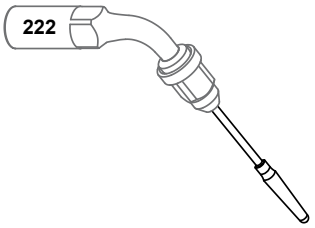


Power	Medium to low.
Flow rate	Medium to high.

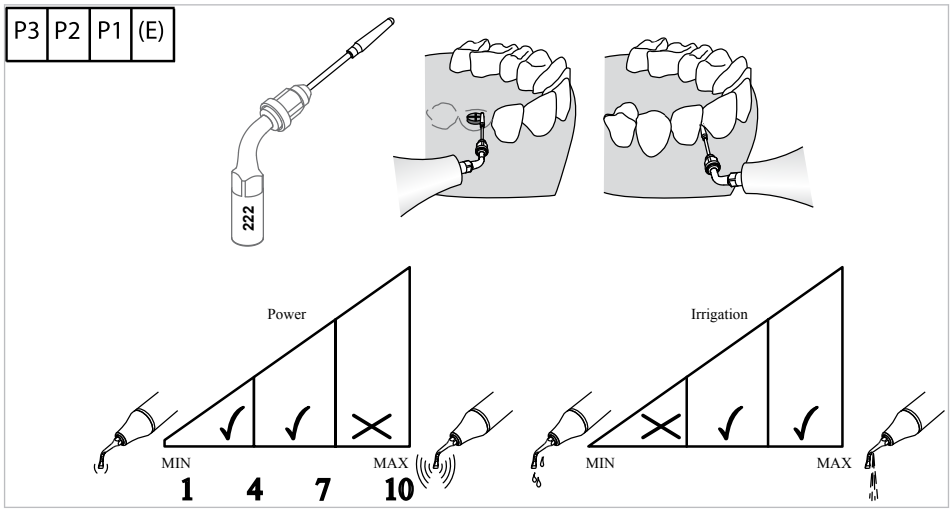
- Place the tip at the fissure and then guide it through the fissure with gentle pressure.

5.8 Implant Set

5.8.1 Select tip

	Piezo Implant Tip Set	For removing plaque and calculus from implant surfaces and restorations made of metal or ceramics. For cleaning the surfaces of dental prostheses. Must be used in conjunction with Piezo Endo Tip 222. **Also refer to:** Endodontics tips

5.8.2 Using the PIEZO Implant Tip Set 222



Power	Low or medium with hard concretions.
Flow rate	High to medium.

⚠ CAUTION

Swallowing or inhalation of a loosened or fractured fragment.

- Ensure that the plastic coating of the tip is not worn or damaged.

⚠ CAUTION

Fracturing of tips at maximal power.

- Use the approved power levels only.

6 Rehabilitation method in accordance with ISO 17664

⚠ CAUTION

Rehabilitation and re-use of expired products.

- Use disposable products a single time only.
- Replace reusable products complying with the usage cycles specified by the manufacturer.

⚠ CAUTION

Sterilisation carried out inadequately.

Infection hazard.

- Sterilise only after cleaning and disinfection are complete.
- Ensure that the disinfection solution does not foam.
- Ensure to use only freshly prepared solutions.
- Ensure to use adequately validated instruments and product-specific procedures for cleaning/disinfection and sterilisation only.
- Ensure compliance with the valid parameters in each cycle.
- Ensure compliance with the concentration and exposure times specified by the manufacturer of the cleaning and disinfection agents

⚠ CAUTION

Damage due to improper cleaning and disinfection.

Using improper servicing cleaning and disinfection agents can restrict the function or damage the unit.

- Clean external surfaces only!
- Only use a soft cloth and mild cleaning solution!
- Do not use solvents or aggressive chemicals!

⚠ CAUTION

Damage from liquid inside the device.

If the cleansers and disinfectants are improperly handled, liquid in the interior of the unit can cause malfunctions or destruction.

- Make sure that no liquid cleanser or disinfectant enters the device.
- Do not place the medical device in disinfectant baths.

Note

Improper service and care can cause premature wear and malfunctioning.
KaVo only guarantees that its products will function properly when disinfectants are used that are listed by KaVo since they were tested for proper use on KaVo products.

Note

Ensure compliance with the local legal regulations and the hygiene provisions of the hospital or clinic. Moreover, ensure compliance with the additional requirements regarding the inactivation of prions.

KaVo recommends setting up the instruments as soon as they are used.
The aim of the rehabilitation of reusable instruments is to reduce the overall germ count and attain sterility of the product. This is the only way to exclude the risk of infection upon reuse of these products.
The recommended sterilisation with steam must be carried out. Prior to any sterilisation, all parts of the assembly need to be cleaned.

Service life

The products have been developed with a large number of thermal disinfection and/or sterilisation cycles in mind. The materials used for manufacture have been selected accordingly. However, the thermal and chemical stress during each preparation for re-use cause the products to age.
If the number of sterilisation cycles is limited, this will be clearly stated in the product-specific instructions.
The use of ultrasound baths and strong cleaning and disinfection liquids (alkaline pH value > 9 or acidic pH value < 5) might reduce the service life of the products. Under these circumstances, the manufacturer accepts no liability.
The products must not be exposed to temperatures above 138 °C.

6.1 Preparations at the site of use

⚠ WARNING

Hazard from nonsterile products.

There is a risk of infection from contaminated medical devices.

- ▸ Take suitable personal protective measures.

- ▸ Remove all residual cement, composite or blood without delay.
- ▸ The medical device must be dry when transported for reconditioning. (Do not place it in a solution or the like).
- ▸ Recondition the medical device as soon as possible after treatment.

6.2 Preparation after an operation

Any treatment after an operation must be carried out without delay, no later than maximally 30 minutes after completion of the operation. For more information, if required, please refer to the respective product-specific Instructions for Use.

Rinse-off outer surfaces

Remove all contamination from the outer surface using a soft brush or soft cloth.

- ▪ Distilled, deionised water
- ▸ Rinse contamination off the surface of the product.

6.3 Cleaning

⚠ CAUTION

Malfunctions from cleaning in the ultrasonic unit.

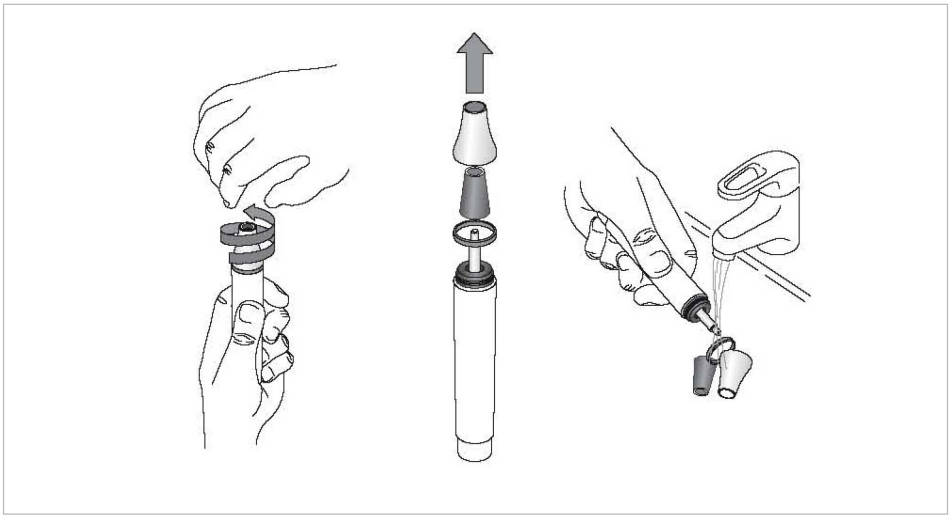
Defects in the product.

- ▸ Only clean manually or in a thermodisinfector.

The subsequent cleaning/disinfection must be started within 2 hours.

6.3.1 Cleaning of handpieces

Manual cleaning - external



- Unscrew sealing cap and fibre optic conductor.
- Gently clean the individual parts under running water using a soft brush or a soft cloth.
- Attach disposable syringe (at least 50 ml) to the nozzle of the product.
- Rinse all product lumens (e.g. rinsing and suction connections) at least five times in the flow direction. Do not rinse against the flow direction.
- Rinse the external housing of the handpiece thoroughly.

Manual cleaning - internal

- Distilled, deionised water
- (aqua purificata as specified in Pharm. Eur. or USP)
  - with microbial count < 10 cfu/ml or sterilised
  - with sufficiently low endotoxin and particle concentration
- Attach disposable syringe to the back nozzle.
- Rinse in the normal flow direction, do not rinse against the flow direction.
- If an aldehyde-free cleaning and disinfection solution is used, subsequently rinse at least thrice with distilled or deionised water.

Automated external cleaning

KaVo recommends thermodisinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g. Miele G 7781/G 7881 – Validation was carried out with Programme "VARIO-TD", cleaning agent "neodisher® mediclean", neutralisation agent "neodisher® Z" and rinsing agent "neodisher® mielclear" and only applies to the material compatibility with KaVo products).

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).

- In order to prevent negative effects on the medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then grease it immediately with servicing agents from the KaVo care system.

Automated internal cleaning

Possible only with devices providing the option or function of intensive germ reduction.

- Leave the handpiece on the device and carry out the intensive germ reduction (see Instructions for Use of the respective treatment unit).

6.3.2 Cleaning of tips, endo files, file holders, endo wrenches, torque wrenches

Note

For exposure times and concentrations of disinfection agents, please refer to the instructions of the manufacturers.

- Place the products in the disinfection solution at least for as long as specified by the manufacturer of the disinfection agent.
- Remove all contamination from the outer surface by careful brushing using a soft brush or soft cloth.
- Rinse the inside of products thoroughly at least five times using fresh distilled or deionised water (at least 50 ml).
- If the final rinse is not clear or if the product continues to contain visible contamination, the cleaning process must be repeated.

6.4 Disinfection

⚠ CAUTION

Malfunctioning from using a disinfectant bath or chlorine-containing disinfectant.

Defects in the product.

- Disinfect manually only!

6.4.1 Disinfection of handpieces

Note

For times and concentrations, please refer to the instructions of the manufacturers of the cleaning/disinfection agent.

Manual disinfection - external

KaVo recommends the following products based on material compatibility. The microbiological efficacy must be ensured by the disinfectant manufacturer.

- Mikrozid AF made by Schülke & Mayr (liquid or cloths)
- FD 322 made by Dürr
- Incidin (cloths or liquid) made by EcoLab

- Attach disposable syringe (at least 50 ml) to the nozzle of the product.

- Rinse all product lumens (e.g. rinsing and suction connections) at least five times in the flow direction.
  Do not rinse against the flow direction.
- If the final rinse is not clear or if the product continues to contain visible contamination, the cleaning process must be repeated.
- Clean the surface with alcohol-based disinfection cloths.
- Dry the products with filtered compressed air (max. 3 bar).
- If required, dry again at a clean place.
- Package products immediately after drying (see section on Packaging and Sterilisation).

Machine disinfection - external and internal

KaVo recommends thermodisinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g. Miele G 7781/G 7881 – Validation was carried out with Programme "VARIO-TD", cleaning agent "neodisher® mediclean", neutralisation agent "neodisher® Z" and rinsing agent "neodisher® mielclear" and only applies to the material compatibility with KaVo products).

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).
- In order to prevent negative effects on the medical device, make sure that the interior and the exterior of the medical device are dry after completion of the cycle, and then grease it immediately with servicing agents from the KaVo care system.

6.4.2 Disinfection of tips, endo files, file holders, endo wrenches, torque wrenches

- Place the products in the cleaning solution at least for as long as specified by the manufacturer of the cleaning/disinfection agent.
- Remove all contamination from the outer surface by careful brushing using a soft brush or soft cloth.
- Rinse the inside of products thoroughly at least five times using fresh distilled or deionised water (at least 50 ml).
- If the final rinse is not clear or if the product continues to contain visible contamination, the cleaning process must be repeated.

Note
Optionally, a thermodisinfector can be used for automated disinfection.

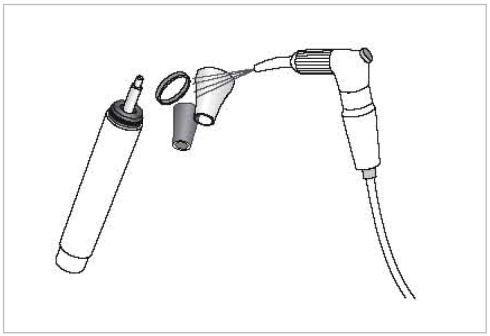
KaVo recommends thermodisinfectors in accordance with EN ISO 15883-1, which are operated with alkaline cleaning agents with a pH value of max. 10 (e.g. Miele G 7781/G 7881 – Validation was carried out with Programme "VARIO-TD", cleaning agent "neodisher® mediclean", neutralisation agent "neodisher® Z" and rinsing agent "neodisher® mielclear" and only applies to the material compatibility with KaVo products).

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).

6.5 Drying

6.5.1 Drying of handpieces

Manual drying



- Blow off the outside and inside with compressed air until water drops are no longer visible.

Automatic Drying

The drying procedure is normally part of the cleaning program of the thermodisinfector.

- Follow the instructions for use of the thermodisinfector.

6.5.2 Drying of tips, endo files, file holders, endo wrenches, torque wrenches

- Dry the products with filtered compressed air (max. 3 bar).
- If required, dry again at a clean place.
- Package products immediately after drying (see section on Packaging and Sterilisation).

6.6 Maintenance

⚠ CAUTION

Check handpiece and hose for visible damage prior to use.

They need to be replaced if any damage is evident.

⚠ CAUTION

Check tips for visible damage and wear and tear prior to use.

If the damage or wear and tear exceeds the tolerance, dispose of the tip and use a new tip.

⚠ CAUTION

Use of third-party components.

Inury to dentist or patient.

- Use original components only.

Note

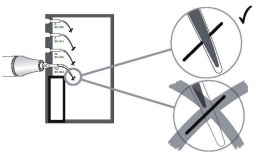
Handpiece and tube must be checked for visible damage prior to use. Handpiece and tube need to be replaced if there is any evidence of damage.

Check the PIEZO Tips

Note

Ultrasonic tips are subject to wear and tear and become shorter during use. Worn tips are less effective and might reduce the patient comfort.

For prophylactic reasons, it is recommended not to use the components beyond the specified expiry date.



- Check scaler tips regularly using the PiezoLED tip card.
- Replace tips with worn diamond coating.
- Check O-rings of handpieces regularly for damage.

6.7 Packaging

Note

The sterilisation bag must be large enough for the handpiece so that the bag is not stretched.
The quality and use of the sterilisation packaging must satisfy applicable standards and be suitable for the sterilisation procedure!

- Individually seal the medical device in the sterilised item packaging.

6.8 Sterilisation

6.8.1 Sterilisation of handpieces

Sterilisation in a steam steriliser (Autoclave) EN 13060/ISO 17665-1

⚠ CAUTION

Premature wear and malfunctions from improper servicing and care.
Reduced product life.

- Before each sterilisation cycle, service the medical device with KaVo care products.

⚠ CAUTION

Contact corrosion due to moisture.

Damage to product.

- Immediately remove the product from the steam steriliser after the sterilisation cycle!

Note

Handpieces must be sterilised before each use. Non-sterile handpieces and tips can cause bacterial or viral infections.

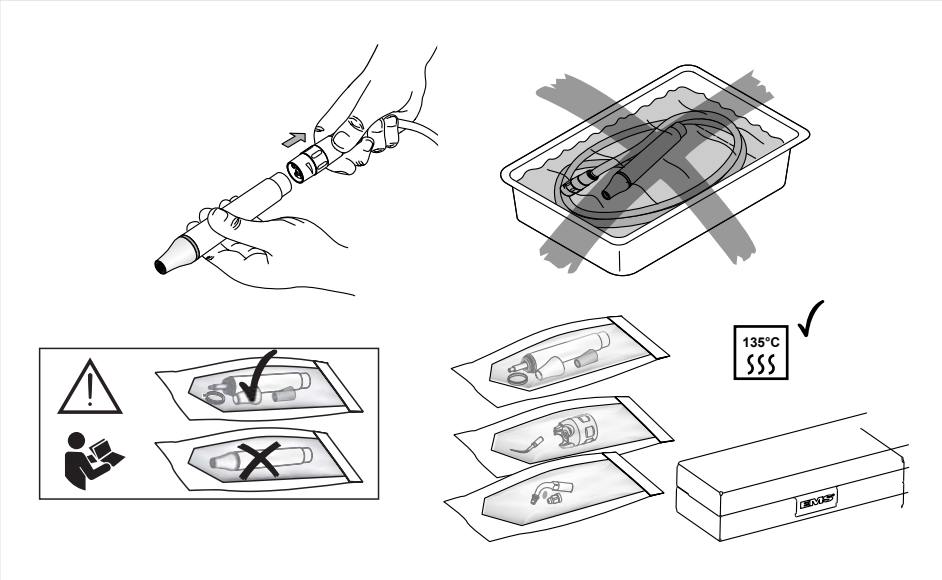
Note

Please comply with the current local regulations governing the re-use and disposal of equipment.

135 °C

The medical device is resistant to temperatures of up to 138 °C (280.4 °F).

- Place the cleaned and disinfected handpieces separately in sterilisation packages and weld them to be sealed, e.g. KaVo STERIclave bags **Mat. no. 0.411.9912**).



KaVo recommends, e.g.
- STERIclave B 2200/ 2200P from KaVo
Citomat / K series from Getinge
Autoclave with a triple pre-vacuum for at least 4 minutes at 134 °C ± 1 °C
(273.2 °F ± 33.8 °F)
For range of applications, refer to the manufacturer's Instructions for Use.

Only for handpieces with fibre optic conductor sleeve

- If the fibre optic conductor sleeve**Mat. no. 1.007.4021** looses its brightness due to sterilisation, replace the fibre optic conductor sleeve.

The light source in the handpiece cannot be replaced.

6.8.2 Sterilisation of tips, endo files, file holders, endo wrenches, torque wrenches

Note

The maximal number of sterilisation cycles must not be exceeded.

Note

The use of hot-air sterilisation and radio-sterilisation is not permissible (causes destruction of the products). KaVo shall not be held responsible if non-permissible procedures such as ethylene oxide, formaldehyde, and low temperature plasma sterilisation are used.

Note

Only cleaned and disinfected products may be sterilised.

Note

Please comply with the current local regulations governing the re-use and disposal of equipment.

- ▸ Place the cleaned and disinfected tips, endo files, file holders, endo wrenches and torque wrenches separately in sterilisation packages (e.g. KaVo STERIclave bags **Mat. no. 0.411.9912**) and weld them to be sealed or sterilise them in a sterilisation cassette (e.g. KaVo sterilisation cassette **Mat. no. 0.411.9101**).

Sterilisation container requirements:

- EN 868 and ISO 11607
- Resistant up to 138 °C with appropriate permeability for steam
- Regular servicing

The requirements also apply to double disposable sterilisation packages.

Permissible sterilisation apparatus:

- Sterilisation apparatus with validated cycle parameters
- Sterilisation apparatus with non-validated cycle parameter which comply with DIN EN ISO 14161:2000

Permissible procedures:

Procedures	Time /Temperature
Fractionated pre-vacuum	3 to 20 minutes at 132 °C/ 134 °C
Steam sterilisation apparatus (AAMI TIR no. 12, DIN EN ISO 14161, DIN EN ISO 17665) (DQ, IQ, OQ and PQ)	138 °C

6.9 Storage

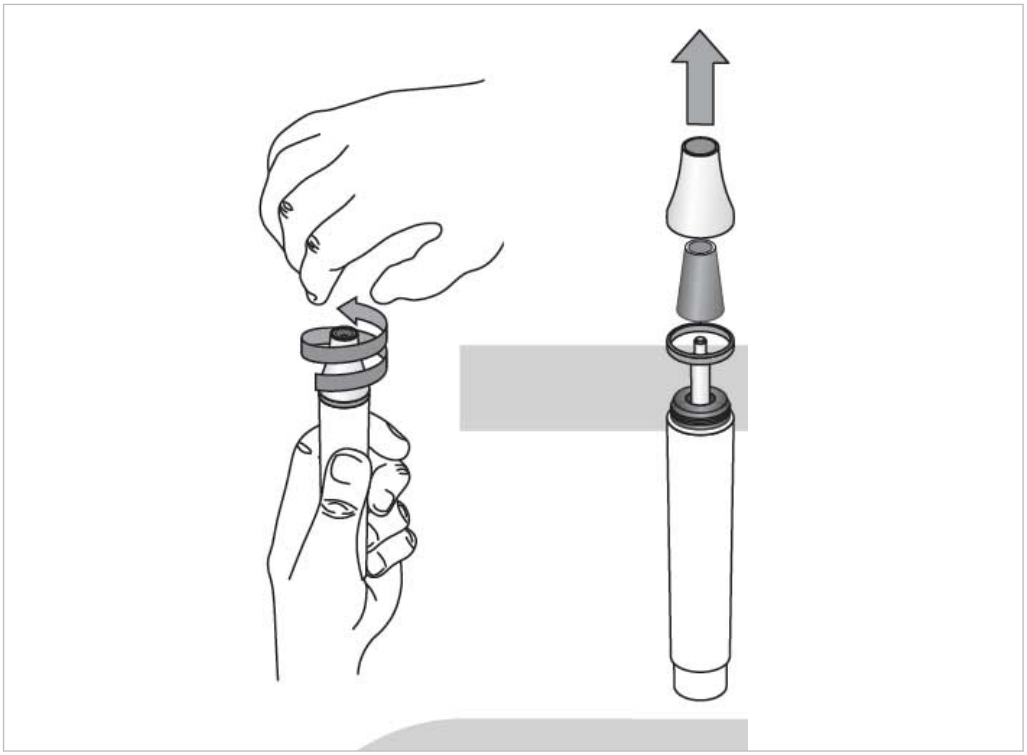
- ▸ Reprocessed products should be stored protected from dust with minimum exposure to germs in a dry, dark and cool space.
- ▸ Comply with the expiry date of the sterilised items.

7 Troubleshooting

Malfunction	Cause	Remedy
No rinsing or flow rate too low.	Tip or handpiece obstructed. Incorrect setting on setting ring on handpiece.	▸ Check device for obstructions and carefully remove any obstruction with compressed air. ▸ Use a different handpiece in order to check if the handpiece is obstructed. ▸ If the obstruction cannot be removed, ship the handpiece to a KaVo authorised repair centre. ▸ Comply with the instructions in the Instructions for Use of the device. ▸ Check the spray volume setting on the handpiece and correct it, if required.
No spray water or flow rate too low.	Spray water is not selected on the device.	▸ Correct spray water selection on the device.
No ultrasonic vibrations.	Device error.	▸ Comply with the instructions in the Instructions for Use of the device.
Decreasing or insufficient ultrasonic output.	Tip is clamped incorrectly or worn. The handpiece no longer works correctly.	▸ Comply with the instructions in the Instructions for Use of the device. ▸ Check if the tip is clamped correctly and retighten with the torque wrench, if required. ▸ Check the tip for wear and replace it, if required. ▸ Check the handpiece with a different tip. ▸ Ship the handpiece and the tip to a KaVo authorised repair centre.

Malfunction	Cause	Remedy
Fracturing of a file or tip, possibly inside the cavity or in the root canal.		▸ Ensure that all fragments are removed. ▸ Compare the total length of the fragments to a new file or a new tip to verify that all fragments have been removed. ▸ Attempt to rinse out the fractured file or instrument tips in root canals using maximal liquid supply of a file (no ultrasound). ▸ Comply with the instructions for the use of the Piezo Endo Tip 221 which was developed especially for this purpose.
Diamond-coated tips no longer work efficiently.	The tip is damaged or worn.	▸ Visually inspect the diamond-coating and replace the tip, if applicable.

7.1 Replacing defective parts

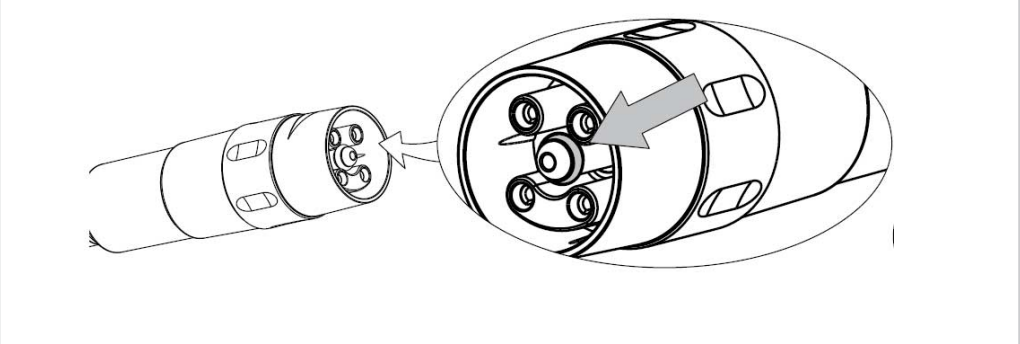


- Unscrew the sleeve and fibre optic conductor sleeve.
- Take off flat gasket
- Replace defective parts.

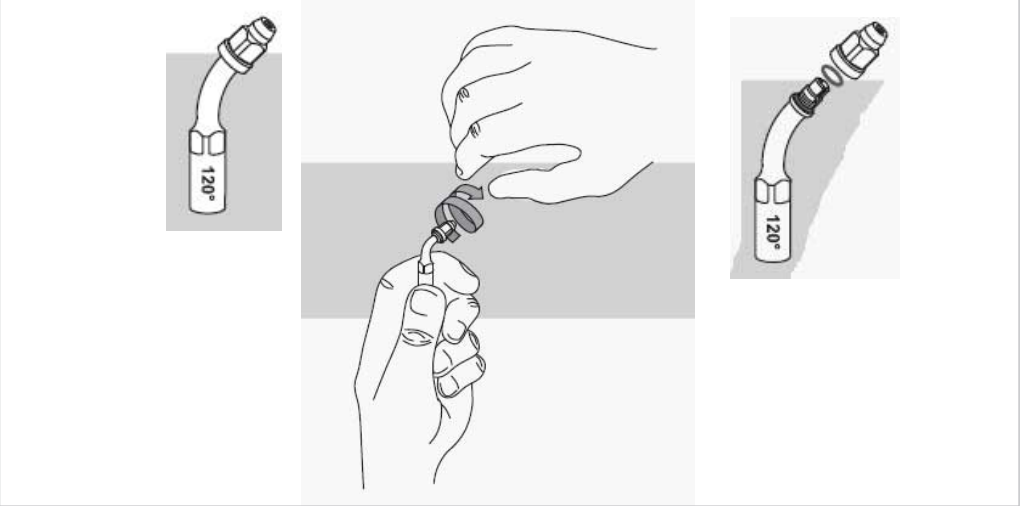
- Follow the reverse sequence for assembly.

Note

The guide light (if present) might loose its brightness due to sterilisation which might reduce the total light intensity of the handpiece. In this case, please replace the optic fibre conductor sleeve. The light source in the handpiece cannot be replaced.



- Take-off the O-ring
- Replace defective O-ring.



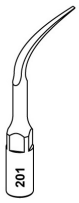
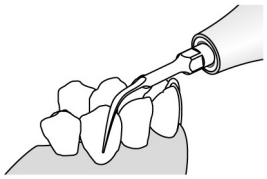
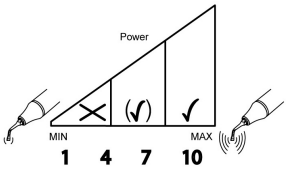
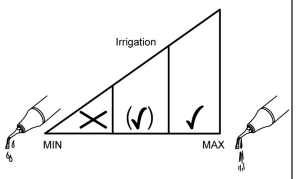
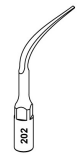
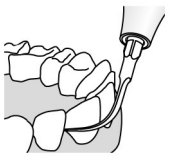
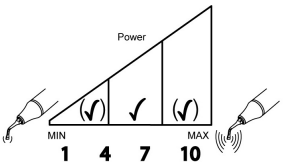
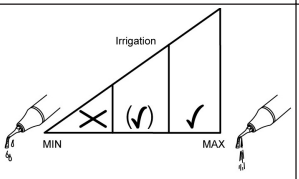
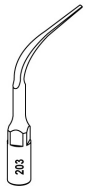
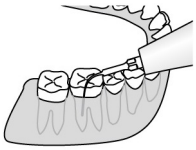
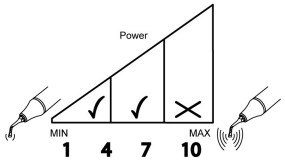
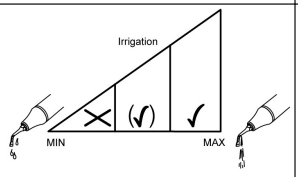
- Unscre the nut carefully.
- Take-off the O-ring.
- Replace defective parts.
- Follow the reverse sequence for assembly.

8 Accessories and consumables

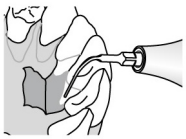
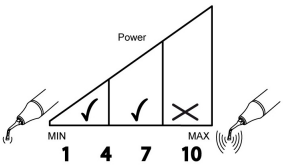
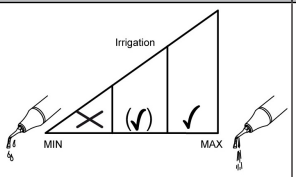
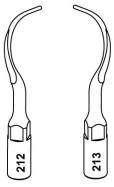
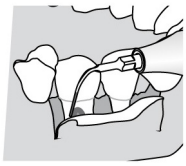
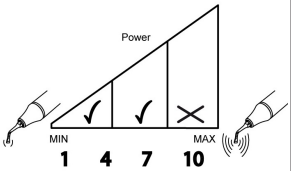
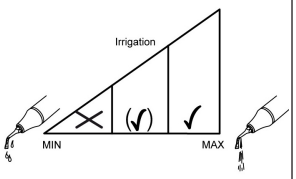
Mat. No.	Material summary
1.007.4004	Piezo Scaler Tips
1.007.4006	Piezo Paro Tips tip set
1.007.4008	Piezo Implant Tips tip set
1.007.4011	Piezo Endo Tips file set
1.007.4014	Piezo Implant Refill
1.007.4015	Cem attachment
1.007.4024	PIEZO Scaler Tips 201 (incl. torque wrench)
1.007.4026	PIEZO Scaler Tips 202 (incl. torque wrench)
1.007.4027	PIEZO Cem Tips 225 (incl. torque wrench)
1.007.4028	PIEZO Scaler Tips 203 (incl. torque wrench)
1.007.4032	PIEZO Paro Tips 212 (incl. torque wrench)
1.007.4033	PIEZO Paro Tips 213 (incl. torque wrench)
1.007.4034	PIEZO Paro Tips 214 (incl. torque wrench)
1.007.4035	PIEZO Prep Tips 226 (incl. torque wrench)
1.007.4036	PIEZO Prep Tips 227 (incl. torque wrench)
1.007.4037	PIEZO Prep Tips 228 (incl. torque wrench)
1.007.4038	PIEZO Prep Tips 229 (incl. torque wrench)
1.007.4039	PIEZO Paro Tips 210 (incl. torque wrench)
1.007.4040	Piezo Endo Tips 220 (incl. torque wrench)
1.007.4041	Piezo Endo Tips 221 (incl. torque wrench)
1.007.4042	PIEZO Paro Tips 211 (incl. torque wrench)
1.007.4043	Piezo Endo Tips 222 (incl. torque wrench)
1.007.4016	Piezo tip card
1.007.4020	PIEZO ENDO wrench
1.007.3004	Piezo torque wrench
1.007.3995	PiezoLED handpiece
1.007.4002	PIEZO Scaler hose R1300
1.007.3997	Steri-Box 5pcs
1.007.3998	Steri-Box 6pcs
1.007.4917	PiezoLED sleeve
1.007.4021	PiezoLED fibre optic conductor sleeves
1.007.4916	PiezoLED flat gasket
1.007.6959	O-ring 1.15 x 1.0
1.007.4793	Piezo Endo 222 nut
1.007.4794	Piezo Endo 222 O-Ring 1.5 x 1.0
1.007.6936	Module PiezoLED for ESTETICA E50/70/80
2.000.1969	Module PIEZOscaler for ESTETICA E30/Primus 1058

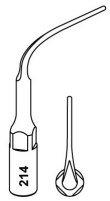
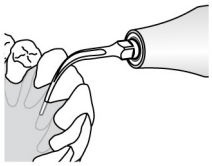
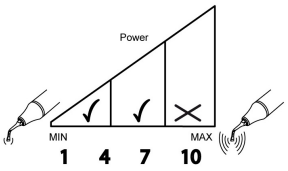
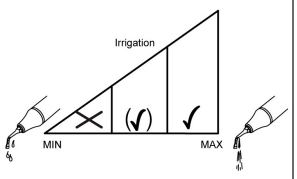
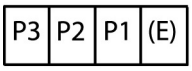
9 Tips: Rapid Overview

Piezo Scaler Tips

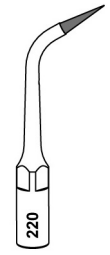
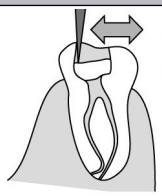
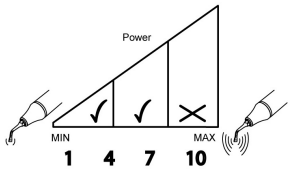
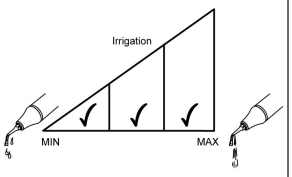
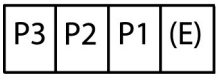
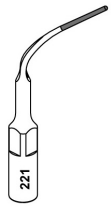
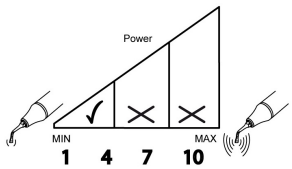
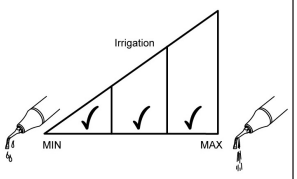
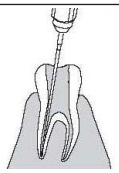
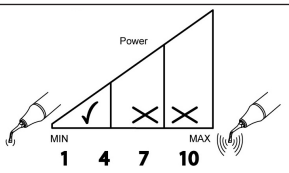
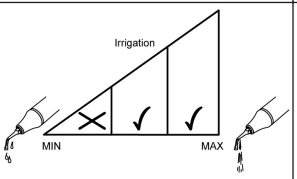
Product identification	Indication	Permissible power setting	Permissible spray water volume	Operating mode
 Scaler 201				P3 P2 P1 (E)
 Scaler 202				P3 P2 P1 (E)
 Scaler 203				P3 P2 P1 (E)

Piezo Paro Tips

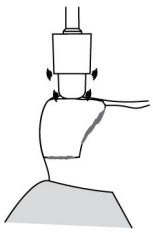
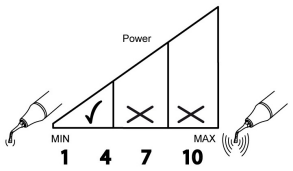
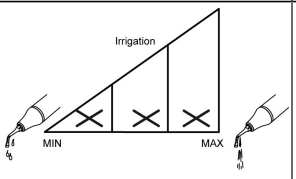
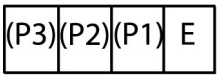
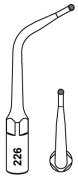
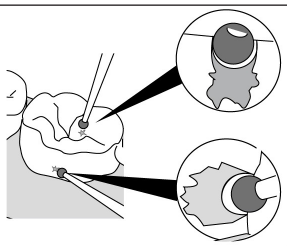
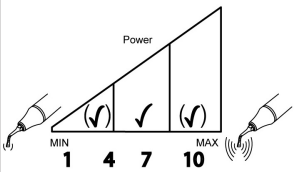
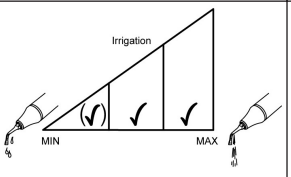
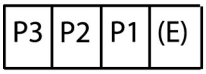
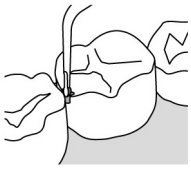
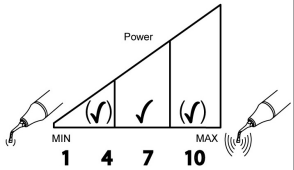
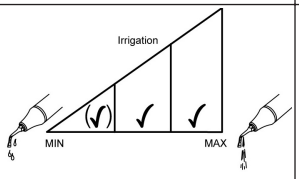
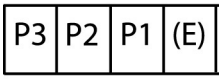
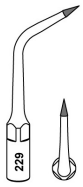
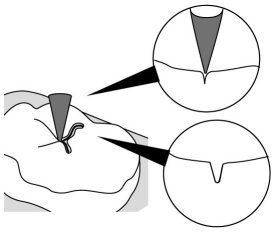
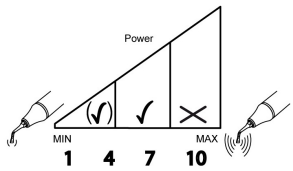
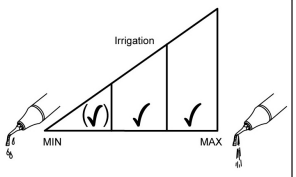
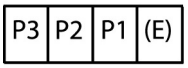
Product identification	Indication	Permissible power setting	Permissible spray water volume	Operating mode
 Paro 210 + 211				P3 P2 P1 (E)
 Paro 212 + 213				P3 P2 P1 (E)

Product identification	Indication	Permissible power setting	Permissible spray water volume	Operating mode
 Paro 214				

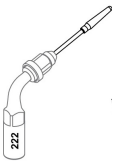
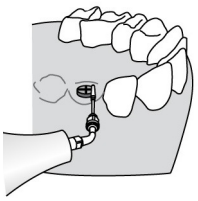
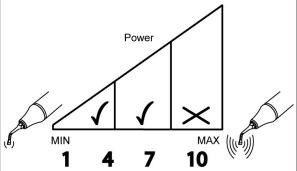
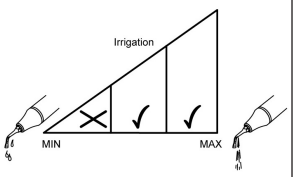
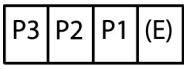
Piezo Endo Tips

Product identification	Indication	Permissible power setting	Permissible spray water volume	Operating mode
 Endo 220				
 Endo 221				
 Endo files				

Piezo Prep Tips

Product identification	Indication	Permissible power setting	Permissible spray water volume	Operating mode
 Cem 225				
 Prep 226				
 Prep 227 + 228				
 Prep 229				

Piezo Implant Tips

Product identification	Indication	Permissible power setting	Permissible spray water volume	Operating mode
 Implant 222				

10 Terms and conditions of warranty

The following warranty conditions apply to this KaVo medical device:
KaVo provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and processing for a period of 12 months from the date of the invoice, subject to the following conditions:
In case of justified complaints, KaVo will honour its warranty with a free replacement or repair. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.
KaVo shall not be liable for defects and their consequences that have arisen or may arise from natural wear, improper handling, cleaning or maintenance, non-compliance with operating, maintenance or connection instructions, calcination or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with KaVo's instructions for use or other manufacturer's instructions. The warranty granted does not usually extend to lamps, optical fibres made of glass and glass fibres, glassware, rubber parts, and the colourfastness of plastic parts.
All liability is excluded if defects or their consequences originate from manipulations or changes to the product made by the customer or a third party that is not authorised by KaVo.
Warranty claims will only be accepted if the product is submitted along with proof of purchase in the form of a copy of the invoice or note of delivery. The dealer, purchase date, type, and serial number must be clearly evident from this document.

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