CE 0123

1 Symbols

CAUTION	See Section **2 Safety**
	Important information for users
135°C	Can be steam-sterilised in an autoclave
	Can be thermo-disinfected
CE	CE mark – indicates that the product complies with the Medical Device Directive
REF.	Reference number
SN	Serial number

2 Safety

2.1 Description of risk levels

CAUTION	**CAUTION**
	CAUTION is used for situations in which a lack of care can endanger patients, users or others.

WARNING	**WARNING**
	WARNING is used for situations that can lead to serious injury.

2.2 Safety instructions

WARNING	**WARNING**
	The scaler handpiece may not be used in conjunction with gaseous anaesthetics in operation rooms.

WARNING	**WARNING**
	Functional test before every use If you discover any damage, irregular running noises, heavy vibrations, unusual warming or other defects: → Notify service

CAUTION	**CAUTION**
	Do not use the ultrasonic scaler to work on prosthetics made of ceramic or metal since the high frequencies may cause damage.

WARNING	**WARNING**
	You should always use sufficient quantities of water during treatment to prevent the instrument tip from heating up. If you do not, it may seriously damage the device, tooth, dental root or gum. A water throughput of at least 20 ml/min is needed to prevent the device from heating up. Refer to the instructions for each scaler tip for more details.

WARNING	**WARNING**
	This product may not be used near people who carry pacemakers or suffer from haemophilia. Care is also advised around pregnant women and children.

3 Product description

These Operating Instructions apply to the following MK-dent products:

Scaler handpieces in the Prophy Line series	
Scaler handpieces with lights	**Scaler handpieces without lights**
22021, 22019	**22016, 22020, 22017**

3.1 Definition of purpose

This medical product is exclusively for use on patients in dental practices, especially for the following applications:
removing subgingival and supragingival scale; cavity preparation; cleaning and rinsing root canals; preparing root canals; loosening inlays, crowns and bridges; and periodontal therapy. The scaler handpiece may not be used in conjunction with gaseous anaesthetics in operation rooms.

3.2 Intended use

This product should be used exclusively in compliance with its defined purpose by expert, trained personnel and in accordance with the specifications, notices and warnings in these Operating Instructions.
Using the product in any other way can endanger patients, users or others, and is not allowed.
You should check it every time you use it to make sure it is working properly. You may not use scaler handpieces that are in anything but perfect condition.
Maintenance, repairs and modifications must be done by the MK-dent repair service or by a repair workshop authorised by MK-dent. Please refer to the appropriate operating instructions for information about how to use the scaler tips properly.

3.3 Technical specifications

	22016, 22017 (EMS® connector)	22020, 22021 (Acteon-Satelec® connector)	22019 (KaVo® connector)
Electronic input voltage (V)	190 – 230	190 – 230	190 – 230
Instrument's range of motion (pm)	1 ~ 100	1 ~ 100	1 ~ 100
Instrument's oscillation frequency (kHz)	28 ± 3	28 ± 3	28 ± 3
Power output (W)	3 – 20	3 – 20	3 – 20
Spray water pressure (bar)	0.1 - 5.0	0.1 - 5.0	0.1 - 5.0
Spray water consumption (ml/min) as per EN ISO 14457	> 20	> 20	> 20

KaVo®, EMS® und Acteon-Satelec® are registered trademarks.
MK-dent has no economic links with the aforementioned companies.

3.4 Storage and transport conditions

CAUTION	**CAUTION**
	The instrument may not work if used after being stored very cold. → Allow heavily refrigerated instruments to warm up to room temperature before use.

CAUTION	**CAUTION**
	Always protect the medical product against moisture! → Make sure that the connection between the tube and handpiece is dry.

The following applies to storing and transporting the products:

Temperature	+5 °C - +40 °C (41 °F - +104 °F)
Relative air humidity	<80%, non-condensing
Air pressure	500 hPa - 1060 hPa (7.2 psi - 15 psi)

4 Getting started and using

4.1 Preparing to get started

Check that the scaler handpiece and accessories are complete and undamaged. Before beginning each treatment, rinse the water-carrying systems for at least two minutes without instruments on.

4.2 Putting on an instrument

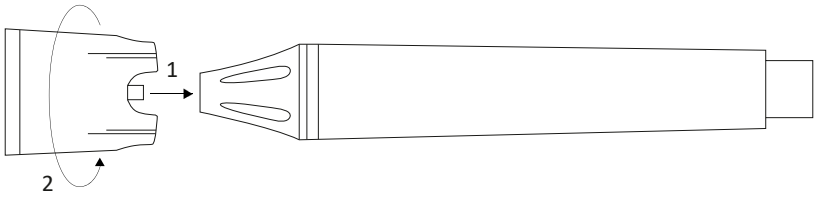
☞ Use the scaler tip card to ensure that the scaler tip is in sufficiently good condition before you use it. If it is not, replace it with a new one.
☞ Screw the scaler tip you require into the handpiece before you slot it onto the tube (see **4.3 Inserting the scaler tip**).
☞ Place the instrument exactly onto the tube connector. Make sure the contacts are in the right position.
☞ Pull lightly to ensure that the instrument is firmly attached to the tube.
☞ To remove the instrument, hold it tight and pull the tube sleeve off.

4.3 Inserting the scaler tip

CAUTION	**CAUTION**
	The treatment unit's foot controls may not be switched on when removing the scaler tip.

WARNING	**WARNING**
	Placing the scaler tip perpendicular to the tooth during treatment can damage the tooth.

Always use the MK-dent Prophy Torque for inserting the scaler tip so that you do not overtighten the thread.

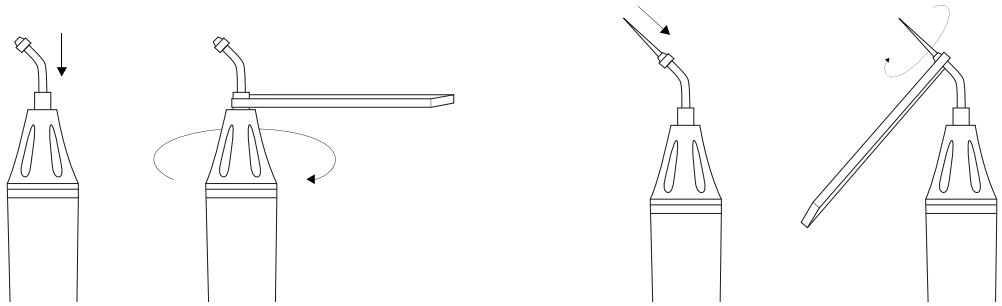


☞ Insert the scaler tip into the MK-dent Prophy Torque and place this onto the thread at the top of the scaler handpiece.
☞ Turn clockwise to tighten the scaler tip.
☞ Pull the fitting tool off. The instrument is now ready to use.
☞ Hold the handpiece between your thumb and index finger to work accurately. You can now switch on the scaling unit.
☞ Set the vibration intensity and water supply to suitable levels. Refer to the appropriate scaler tip operating instructions for more information.

4.4 Inserting the endo tip

WARNING	**WARNING**
	Do not start using the handpiece until the scaler tip is inserted into the root canal.

WARNING	**WARNING**
	Always use low-intensity vibrations otherwise you may damage the tooth. Do not exert too much pressure.



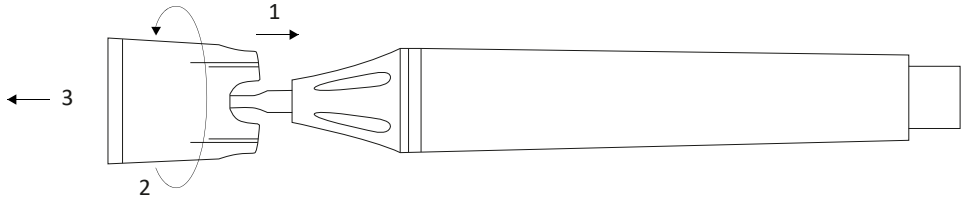
☞ Screw the file holder onto the thread and tighten by hand.
☞ Tighten the file holder using the MK-dent Endo Torque.
☞ Insert the file into the file holder and tighten it with the Endo Torque as well.
☞ Set the vibration intensity and water supply to suitable levels. Refer to the appropriate scaler tip operating instructions for more information.
☞ Next, insert the file into the root canal and begin the treatment.

4.5 Removing the scaler tip

CAUTION	**CAUTION**
	The treatment unit's foot controls may not be switched on when removing the scaler tip.

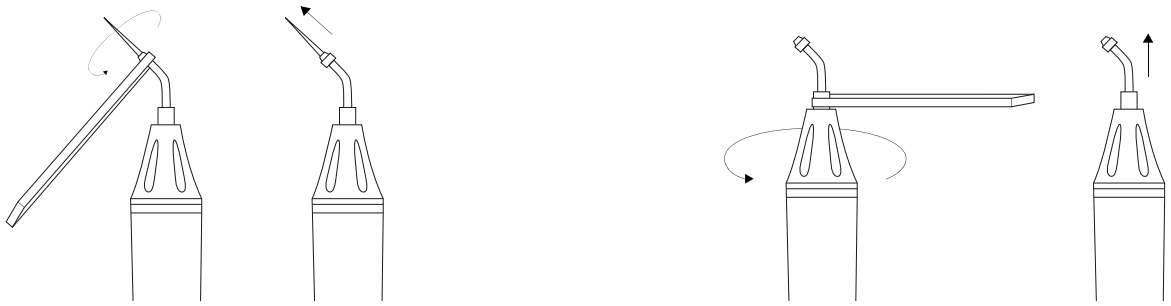
Always use the MK-dent Prophy Torque for removing the scaler tip so that you do not damage the thread.

☞ Rinse out the scaler after every scaling procedure for at least 30 seconds, so that you clean any coarse particles out of the tip and handpiece.



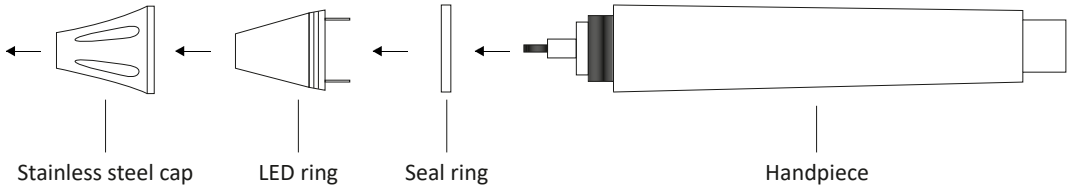
☞ Place the MK-dent Prophy Torque onto the scaler tip but without touching it.
☞ Turn anticlockwise to loosen the scaler tip from the thread.

4.6 Removing the endo tip



☞ To remove the file, place the MK-dent Endo Torque onto the file holder and turn anticlockwise to loosen the connection.
☞ Then remove the file.
☞ To remove the endo tip, place the Endo Torque onto the thread and turn anticlockwise to loosen the connection.
☞ Then remove the endo tip.

4.7 Disassembling the scaler handpiece



☞ Screw the stainless steel cap anticlockwise off the handpiece.
☞ Remove the LED ring (only on scaler handpieces with lights) and the blue seal ring by pulling them off.

5 Cleaning and disinfecting in compliance with ISO 17664

The scaler handpiece and scaler tips, including the MK-dent Prophy Torque and Endo Torque, have to be cleaned and disinfected after every treatment.

5.1 Preparations in the place of use

WARNING	**WARNING**
	Risk of infection through non-sterile instruments → Wear gloves.

☞ Clean and disinfect the instrument within an hour after the treatment.
☞ Immediately remove remnants of cement, blood and composite.
☞ Take the instrument for cleaning and disinfecting when it is dry.

5.2 Cleaning

WARNING	**WARNING**
	Cleaning in an ultrasonic unit may cause damage → Only clean the instrument as described below.

5.2.1 Manual cleaning

☞ Brush the instrument under running water using a disposable toothbrush until you cannot see any more dirt.
☞ Remove the scaler tip or endodontic tip from the handpiece using the appropriate fitting tool (see **4.5** or **4.6**) and rinse it under running water. Also rinse the spray hole and thread thoroughly.
☞ Use a jet needle to clean the spray channel in the scaler tip so as to remove any potential blockages.
☞ Now disassemble the scaler handpiece as described in **4.7 Disassembling the scaler handpiece**.
☞ Place all of the parts of the disassembled handpiece and fitting tool, including the scaler tip, into a cleaning solution afterwards (dose: 1%, neodisher Medi® Clean Forte) and allow to soak for ten minutes.
☞ After that, rinse all the parts using demineralised water to remove the cleaning solution.
☞ Blow all of the parts dry using compressed air until no more drops of water are visible.

5.3 Disinfection

5.3.1 Manual disinfection

Always use disinfectants whose microbiological effect is guaranteed by the manufacturer (such as VAH/DGHM registration or CE labelling).

☞ Rinse the handpiece and the tip completely and use a spray to rinse any places that are difficult to get at.
☞ Place the disassembled handpiece and the tip with its fitting tool into the appropriate alcohol-based disinfectant (such as 70% isopropyl alcohol).
☞ Allow them to soak in the solution for ten minutes.
☞ After that, rinse all the parts using demineralised water to remove the disinfecting solution.

5.3.2 Mechanical cleaning and disinfection

MK-dent recommends thermo-disinfectors that meet the requirements of EN ISO 15883-1. Cleaning should be done at at least 55 °C (131 °F) for at least six minutes, and disinfection at at least 90 °C (194 °F) for at least five minutes (for A0 value > 3000).
For cleaning we recommend a mildly alkaline cleaning agent, pH 9 to 11, such as neodisher Medi® Clean Forte.
For details of validating this process, see **7 Validating cleaning and disinfecting**.

☞ Connect the scaler handpieces to the thermo-disinfector's luer lock adapter using a silicon tube.
☞ If visible dirt remains after treatment in the thermo-disinfector, then the process must be repeated.
☞ The instrument must be dry and free of residue before it is re-used.
☞ Ensure the instrument is dry after the end of the cycle, otherwise there might be adverse effects.

5.4 Drying

5.4.1 Manual drying

☞ Blow the inside and outside of the instrument dry using compressed air until no more drops of water are visible.

5.4.2 Mechanical drying

Drying should normally be part of your thermo-disinfector's cleaning cycle. Please refer to your thermo-disinfector's operating instructions.

☞ If the instrument still shows signs of moisture after the end of the cycle, blow it using compressed air until it is completely dry.

6 Sterilisation

The sterilisation bag has to be big enough for the instrument so that the packaging is not under tension. Packaging for items being sterilised has to meet the applicable standards of quality and use and must be suited to the sterilisation process.

☞ Seal each instrument into a separate sterilisation package.

6.1 Sterilisation in an autoclave in compliance with EN 13060/ISO 17665-1

CAUTION	**CAUTION**
	Moisture causes contact corrosion Damage to product. → Remove the instrument from the autoclave immediately after the sterilisation cycle.

135°C The medical product is resistant to temperatures up to 135 °C (275 °F).

Use the following sterilisation procedure:
Autoclave with fractional pre-vacuum (recommended): min. 4 minutes at min. 132 °C (270 °F)

☞ Refer to the manufacturer's operating instructions.

7 Validating cleaning and disinfecting

Mechanical cleaning and disinfecting was validated using a WD BHT INNOVA® M3 device and Dr. Weigert neodisher Medi® Clean Forte cleaning agent.

Settings:
- 1 minute pre-rinsing at 30 °C (86 °F)
- 6 minutes cleaning at 55 °C (131 °F) with a dose of 0.5% neodisher Medi® Clean Forte
- 1 minute neutralisation
- 1 minute post-rinsing
- 5 minutes disinfecting at 90 °C (194 °F)

Mechanical disinfection was validated using 70% isopropyl alcohol and 10 minutes of soaking.
Sterilisation was validated using a W&H® LISA 517 unit with fractional pre-vacuum at 132 °C (270 °F) for 4 minutes.
Please note that the treatment process used at your practice also needs to be validated.

8 Storage

☞ Store treated instruments in a dry, dark, cool room protected from dust and, as far as possible, from bacteria.
☞ Please note the expiry date of sterilised items.

9 Tools and accessories

Prophy Torque fitting tool	SC21KEY
Endo Torque fitting tool	SC22KEY
Jet needle	AC0001

10 Terms of warranty

MK-dent guarantees to the end customer fault-free function, material and workmanship for twelve months starting from the invoice date.

In the event of a justified complaint, MK-dent will fulfil the warranty by repairing or replacing the unit for free. There may be no other claims of any kind whatsoever, especially claims for compensation. In the event of delay, reckless culpability or intentional action, this only applies if compelling legal regulations do not state otherwise.

The warranty does not apply to defects or their consequences if they came about or could have come about as a result of natural wear; incorrect handling, cleaning or maintenance; non-adherence to maintenance, operating or connecting instructions; corrosion; contamination in media supply; or chemical or electrical influences that are abnormal or not permitted according to operational regulations.
The warranty generally does not apply to lamps, light guides made of glass or glass fibre, glass items, rubber parts or the colour-fastness of plastic parts. The warranty shall be null and void if defects and their consequences could be a result of interference in or alteration of the product.

Guarantee claims can only be asserted if the product is presented with proof of purchase in the form of a copy of the invoice or delivery note. This has to clearly show the retailer, the date of purchase, the type of device and its serial number.
If you wish to claim during the warranty period, we will arrange for the product to be collected from you.
To organise this, please contact us on +49 (0) 4532 40049-0. Please include the aforementioned documents (copies) with the product, as well as a brief description of the fault.

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