

1 Symbols

	See Section 2 Safety	
	Important information for users	
	Can be steam-sterilised in an autoclave	
	Can be thermo-disinfected	
	CE mark – indicates that the product complies with the Medical Device Directive	
REF.	Reference number	
SN	Serial number	
	Intensity Level 1: low (1/3) Level 2: medium (2/3) Level 3: high (3/3)	Spray Level 1: 20 – 40 ml Level 2: 41 – 50 ml Level 3: max. 60 ml

2 Safety

2.1 Description of risk levels

	CAUTION
	CAUTION is used for situations in which a lack of care can endanger patients, users or others.
	WARNING
	WARNING is used for situations that can lead to serious injury.

2.2 Safety instructions

	CAUTION
	Please be sure to observe all of the information in your scaler handpiece's operating instructions.
	CAUTION
	Ensure that the tip, key and handpiece are compatible. Combinations that do not fit can cause damage.



The type of the instrument is stated on the tip. MK-dent scaler tips are only intended for the area of use described (see **3.1 Definition of purpose**). Make sure that the scaler tip is correctly positioned each time you use it.

3 Product description

MK-dent scaler tips combined with an ultrasonic scaler can be used in a very wide range of areas.

3.1 Definition of purpose

Scaling	Removing stains and supragingival scale, removing crowns
Periodontics	Scaling and periodontal therapy
Endodontics	Preparation of root canals, rinsing root canals, cleaning root canals, compressing gutta-percha
Restoration	Minimally invasive cavity preparation

For details see **7 Areas of use**.

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. Check the condition of the scaler tip using MK-dent scaler tip testers (included with every MK-dent scaler handpiece and available online at www.MK-dent.com/download-center/Gebrauchsanweisungen).

Please refer to the appropriate operating instructions for information about how to use the scaler handpieces properly.

4 General information

 WARNING	WARNING
	Damage to pulp and tooth Too little spray water can cause the instrument to overheat and lead to injury. → Set the water quantity for spray cooling to at least 20 ml/min, unless stated otherwise.
 WARNING	WARNING
	Risk of infection for patients and users due to non-sterile instruments → The instrument and its accessories must be prepared in accordance with these instructions the first time they are used, and after every treatment; see Section 8 Cleaning and disinfecting in compliance with ISO 17664 .
 CAUTION	CAUTION
	Do not use on any metal or ceramic crowns, or prosthetics, otherwise you may damage them.

5 Getting started and using

5.1 Preparing to get started

Check that the scaler handpiece and accessories are complete and undamaged. To use a tip, refer to the scaler handpiece's operating instructions.

5.2 Operation



Before beginning each treatment, rinse the water-carrying systems for at least two minutes without instruments on.


You should also rinse them for 20 to 30 seconds with the tip attached after each patient.

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. Then remove the scaler tip.


6 Use

MK-dent scaler handpieces are distinguished by a lateral radius of movement which allows to treat the patient very gently.

To ensure this remains the case, always hold the instrument at a tangent and press it sideways against the surface of the tooth.

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


6.1 Using diamond-covered scaler tips

 WARNING	WARNING
	Damage to tooth Diamond-covered scaler tips should always be used with enough water so that they remain cool. → Set the water quantity for spray cooling to at least 20 ml/min.


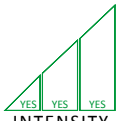
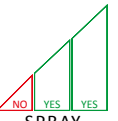


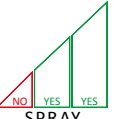


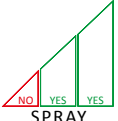


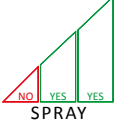
i Check the condition of the diamond layer before use. A worn diamond layer reduces efficiency.

7 Areas of use

7.1 Scaling




 WARNING	WARNING
	Damage to tooth Diamond-covered scaler tips should always be used with enough water so that they remain cool. → Set the water quantity for spray cooling to at least 20 ml/min.

Products in this category:


	Item no. for EMS®	Item no. for Acteon-Satelec®	Areas of use
  INTENSITY  SPRAY	ST01E / ST01ED	ST01S / ST01SD	Universal, for removing supragingival calculus.
  INTENSITY  SPRAY	ST03E / ST03ED	ST03S / ST03SD	
  INTENSITY  SPRAY	ST02E / ST02ED	ST02S / ST02SD	Universal, for removing supragingival, interproximal calculus.
  INTENSITY  SPRAY	ST04E / ST04ED	ST04S / ST04SD	For removing coatings, dental cement and coarse residue.

7.2 Prosthetics



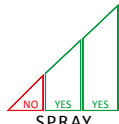

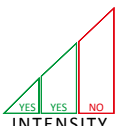
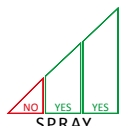

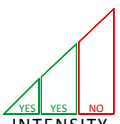
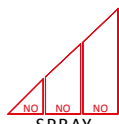

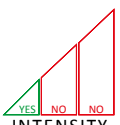
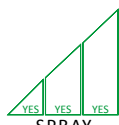

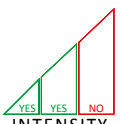
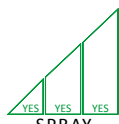

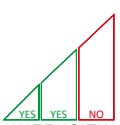
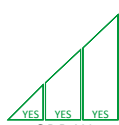
Products in this category:

	Item no. for EMS®	Item no. for Acteon-Satelec®	Areas of use
  INTENSITY  SPRAY	ST05E	ST05S	For removing crowns and bridges.


7.3 Periodontics

 WARNING	WARNING
	Damage to tooth Diamond-covered scaler tips should always be used with enough water so that they remain cool. → Set the water quantity for spray cooling to at least 20 ml/min.


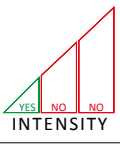
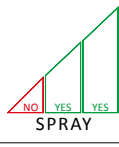

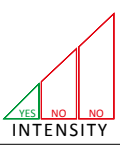
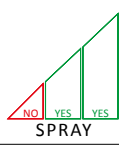

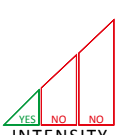
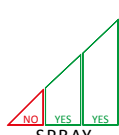
Products in this category:

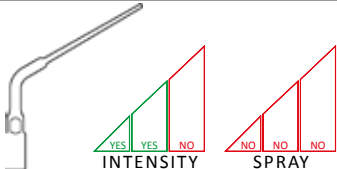
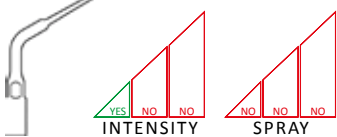
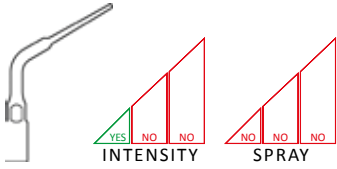
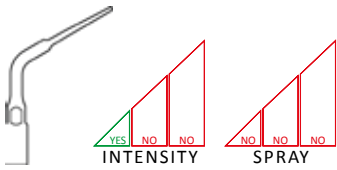
	Item no. for EMS®	Item no. for Acteon-Satelec®	Areas of use
  	ST06E / ST06ED	ST06S / ST06SD	Precision tip for cleaning and rinsing periodontal pockets.
  	ST07E	ST07S	Diamond-coated precision tip (40µm) for smoothing.
  	ST08E / ST08ED	ST08S / ST08SD	For melting gutta-percha (in conjunction with an appropriate solution).
  	ST09E	ST09S	Diamond-coated precision tip (40µm) for widening the root canal and removing broken file fragments.
  	ST10E / ST10ED	ST10S / ST10SD	Cleaning tip for removing shallow calculus.
  	ST11E	ST11S	Diamond-coated tip for removing shallow supragingival calculus.

7.4 Endodontics


 WARNING	WARNING
	Damage to tooth Diamond-covered scaler tips should always be used with enough water so that they remain cool. → Set the water quantity for spray cooling to at least 20 ml/min.

Products in this category:

	Item no. for EMS®	Item no. for Acteon-Satelec®	Areas of use
  	ST12E	ST12S	Endo file holder with 120° angle. Recommended for cleaning root canals. For the versatile use of different endo files with diameters of 0.7 mm and 0.8 mm. An Endo Torque is needed to attach.
  	ST13E	ST13S	Endo file holder with 95° angle. Recommended for cleaning root canals. For the versatile use of different endo files with diameters of 0.7 mm and 0.8 mm. An Endo Torque is needed to attach.
  	ST14E	ST14S	Endo file holder with 180° angle. Recommended for cleaning root canals. For the versatile use of different endo files with diameters of 0.7 mm and 0.8 mm. An Endo Torque is needed to attach.

	Item no. for EMS®	Item no. for Acteon-Satelec®	Areas of use
	ST15E	ST15S	For removing root treatment residue during root treatment.
	ST16E	ST16S	Diamond-coated precision tip (40µm) for removing excess fill material during root treatment. For widening and cleaning root canals.
	ST17E	ST17S	For removing root treatment residue during root treatment.
	ST18E	ST18S	Diamond-coated precision tip (40µm) for removing excess fill material during root treatment. For widening and cleaning root canals.

7.5 Cavity preparation

 WARNING	WARNING
	Damage to tooth Diamond-covered tips should always be used with enough water so that they remain cool. → Set the water quantity for spray cooling to at least 20 ml/min.

Products in this category:

	Item no. for EMS®	Item no. for Acteon-Satelec®	Areas of use
	ST19E	ST19S	For treating occlusal cavities.
	ST20E	ST20S	For treating mesial cavities.
	ST21E	ST21S	For treating distal cavities.
	ST22E	ST22S	Instrument with tip angled 45° to the left.
	ST23E	ST23S	Instrument with tip angled 45° to the right.



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

8 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.

8.1 Preparations in the place of use



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.

8.2 Cleaning



WARNING

Cleaning in an ultrasonic unit may cause damage

→ Only clean the instrument as described below.

8.2.1 Manual cleaning

- ☞ Brush the instrument under running water using a disposable toothbrush until you cannot see any more dirt.
- ☞ Remove the scaler tip from the handpiece using the Prophy Torque or the endodontic tip using the Endo Torque, and rinse all the parts 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.
- ☞ Place scaler tip and fitting tool into a cleaning solution afterwards (dose: 1%, e.g. neodisher Medi® Clean Forte) and allow to soak for ten minutes..
- ☞ After that, rinse the Prophy Torque and scaler tip using demineralised water to remove the cleaning solution.
- ☞ Blow the parts dry using compressed air until no more drops of water are visible.

8.3 Disinfection

8.3.1 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 all of the parts of 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.

8.3.2 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 **10 Validating cleaning and disinfecting**.

- ☞ Place scaler tips into a sieve.
- ☞ 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 use.
- ☞ Ensure the instrument is dry after the end of the cycle, otherwise there might be adverse effects.

8.4 Drying

8.4.1 Manual drying

- ☞ Blow dry the inside and outside of the scaler tips and fitting tool using compressed air until no more drops of water are visible.

8.4.2 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.


9 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 the parts into a sterilisation package.

9.1 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.



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.

10 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.

11 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.

12 Tools

Prophy Torque fitting tool	SC21KEY
Endo Torque fitting tool	SC22KEY



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