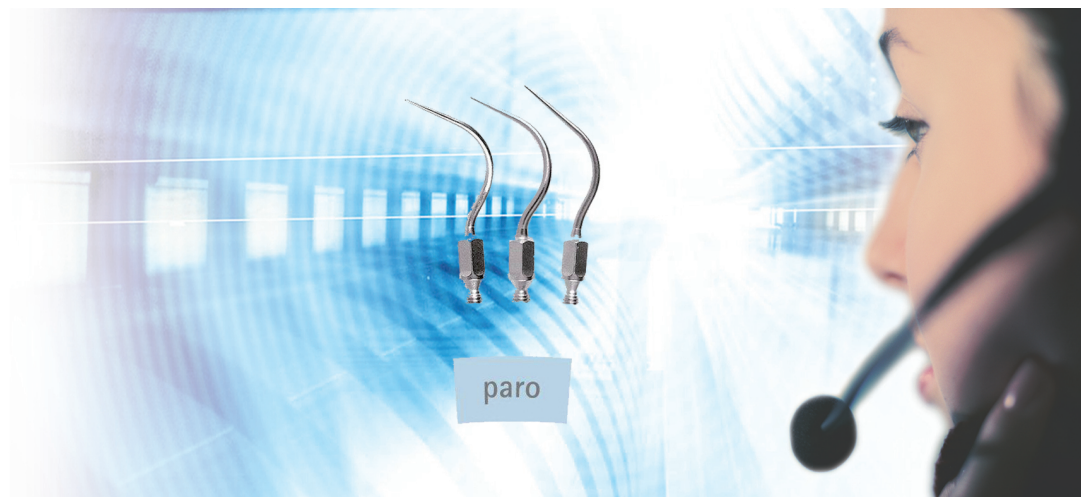


Instructions for use

For SONICflex tips paro - REF 0.571.0371,
paro A - REF 1.006.2020



Always be on the safe side.



KaVo. Dental Excellence.

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1 User instructions

Dear User

Congratulations on purchasing this KaVo quality product. By following the instructions below you will be able to work smoothly, economically and safely.

Symbols

	Refer to the chapter on Safety/Warning symbol
	Important information for users and service technicians
	Action request
	CE mark (European Community). A product bearing this mark meets the requirements of the applicable EC directive.
	Can be steam-sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
	Thermodisinfected

Target group

This document is intended for dentists and their assistants. The section on starting up is also intended for service technicians.

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 the potential consequences of non-observance. ► The optional step includes necessary measures for hazard prevention.

2.1.3 Description of danger levels

The safety instructions listed here, together with the three levels of danger will help avert property damage and injury.

	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 cause death or serious injury.

	DANGER
	DANGER indicates a hazardous situation that can directly cause death or serious injury.

2.2 Purpose – Proper use

This medical device is

- only intended for dental treatment. Any other type of use or alteration to the product is impermissible and can be hazardous.
The SONICflex paro tips are used in combination with the SONICflex for periodontal plaque removal. Also see the instructions for use.
- A medical device according to relevant national statutory regulations.

According to these provisions, the medical device is only for the described use in conformance with:

- the applicable health and safety regulations,
- the applicable accident prevention regulations
- and these instructions for use.

According to these regulations, the user is required to:

- only use properly operating equipment,
- use the equipment for the proper purpose,
- to protect himself, the patient and third parties from danger,
- to avoid contamination from the product.

2.3 Safety instructions

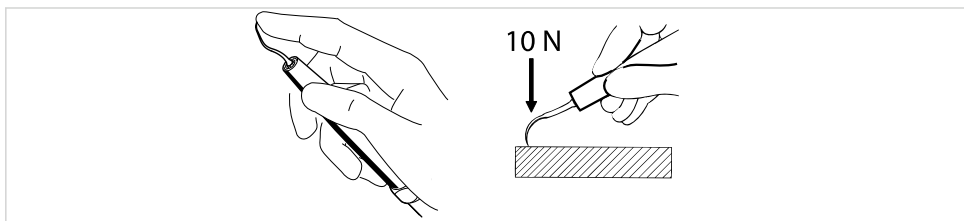
	⚠ CAUTION Premature wear and malfunctioning from improper storage during long periods of nonuse. Reduced product life. ▶ The medical device should be cleaned, serviced and stored in a dry location, according to instructions, before long periods of nonuse.
	⚠ WARNING Hazards for the care provider and the patient. In the case of damage, irregular running noise, excessive vibration, un-typical warming or when the cutter or grinder cannot be held. ▶ Do not use further and notify Service.
	⚠ CAUTION Hazard from using non-KaVo equipment. This can damage the product and cause malfunction. ▶ The tips may not be used on non-KaVo equipment.



Note

When the SONICflex is in the holder, the torque wrench should be placed on the tip to protect against injury.

	⚠ CAUTION
	Breakage of the SONICflex tips. A fracture may occur as a result of long-term use or damage (dropped to the floor or mechanical change of the original shape). ▶ Before each use, check the tips by pressing on them gently with your thumb or forefinger. ▶ In addition, expose the tips to approx. 10 N (1 kg) mechanical load without function.



	⚠ CAUTION
	Hazard from worn SONICflex paro tips. SONICflex paro tips can break or become contaminated. ▶ We recommend changing the SONICflex paro tips every 9-12 monthsSONICflex paro Spitzen auszutauschen.

	⚠ CAUTION
	Risk of injury and infection when changing the SONICflex tips. This can substantially endanger the user. ▶ Use gloves or finger stalls whenever you check, insert or remove the SONICflex tips.

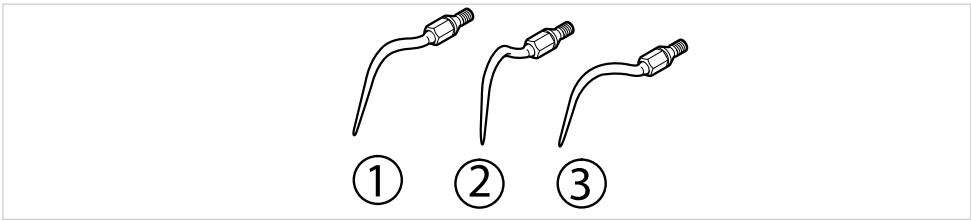
	⚠ CAUTION
	The SONICflex tips may break if the wrong or excessive output is used. This can endanger the user and patient. ▶ Do not use the wrong or excessive output setting.



Note

Regularly check the wear of the tip with the tip test card (**Mat. no. 1.001.6958**).

3 Product description



SONICflex par tip set – REF 0.571.0371
SONICflex paro tip set A – REF 1.006.2020

3.1 Technical data

- ① Tip no. 60 straight – REF 0.571.7402
- ① Tip no. 60 A straight – REF 1.006.1934
- ② Tip no. 61 left – REF 0.571.7412
- ② Tip no. 61 A left – REF 1.006.1935
- ③ Tip no. 62 right – REF 0.571.7422
- ③ Tip no. 62 A right – REF 1.006.1936

3.1.1 Identification tip type

Tips with long thread for use with:

KaVo SONICflex LUX 2000 L / LX / N / NX, 2000 NM / LM, 2004 LM, 2003 / 2003 L



Tip identification by:
① 2-digit number

Tips with short thread for use with:

KaVo SONICflex quick 2008



Tip identification by:
② 2-digit number and capital letter A

3.2 Transportation 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).
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3 Product description | 3.2 Transportation and storage conditions

	Temperature: -20°C to +70°C (-4°F to +158°F)
	Relative humidity: 5% RH to 95% RH absence of condensation
	Air pressure: 700 hPa to 1060 hPa (10 psi to 15 psi)
	Protect from moisture

4 First use

	⚠ WARNING
	Hazard from non-sterile products. Risk of infection to the care provider and patient. ▶ Before first use and after each use, prepare and sterilise the medical device.

4.1 Inserting the SONICflex tips



- ▶ Insert the desired tip with the tip end pointing down into the torque wrench and screw it into the handpiece by turning it clockwise.

	⚠ CAUTION
	Hazard from a tip which has been incorrectly inserted in the torque wrench. This may result in a risk of injury for the user. ▶ When inserting the tip into the torque spanner, make sure that the tip's end always faces into the opening of the torque spanner.



The torque wrench is for changing the working tips of the SONICflex and to protect against injury. The torque wrench can be screwed in more quickly by holding it at the rear, thin grip area ①. The large diameter ② is used for tightening and removal.



Note

The tip is properly gripped when the torque wrench slips.



Note

When the SONICflex is in the holder, the torque wrench should be placed on the tip to protect against injury.

4.2 Removing the SONICflex tip

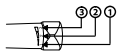


- ▶ Place the torque wrench on the SONICflex tip, and unscrew it anticlockwise.

5 Operation

5.1 Power settings for the SONICflex

	⚠ CAUTION
	Hazard from not maintaining the recommended settings. The tips can break if the recommended setting is not used. The product will malfunction if the tip breaks. ▶ Always observe the recommended setting for the KaVo SONICflex in the table.



Use the control ring of the SONICflex to select power level 1, 2, or 3.

Recommending power levels for the SONICflex paro tips:

LEVEL 1 =	✓
LEVEL 2 =	✓
LEVEL 3 =	Short-term ✓

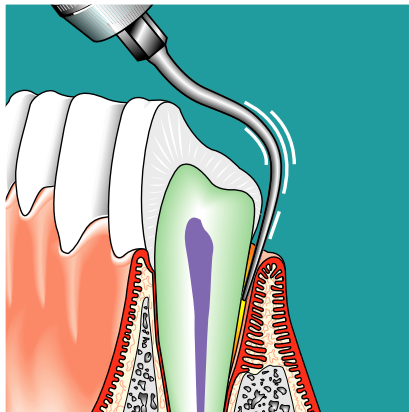
	⚠ DANGER
	Level 3 = Short-term. Hazard from damage to the enamel and premature breakage of the tip. ▶ Level 3 should only be used briefly.

5.2 Instructions for use

This tip set can be used for initial treatment and regular recall. Regular recall treatments are very important for successful periodontal treatment to remove pathogenic plaque and to clean the root surface. This should reduce the formation of plaque. Previously the dentist only had sharp-edged tips or hand instruments available for this purpose.

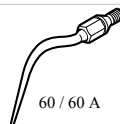
With this new set of tips, subgingival plaque and endotoxins can be removed from the root surface and efficiently flushed out with the internally channelled spray. The SONICflex paro tips were specially developed for initial periodontal treatment, recall and finishing following root cleaning under flap surgery. Hard plaque

and concretions can be removed with diamond-coated SONICflex rootplaner tips.



The SONICflex paro tips are rounded and have no sharp edges. The tips are available in three different versions in the set. The straight SONICflex paro tip is suitable for universal use in every quadrant. The angled SONICflex paro tips can be used for hard-to-reach pockets. If the tip is held in the hand with the thread visible, the angle to the right or left is easy to identify.

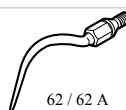
The SONICflex paro tips are designed for use in the following areas:



SONICflex paro, straight, no. 60 / 60 A
- all quadrants



SONICflex paro, left angled, no. 61 / 61 A
- mandible left - vestibular
- mandible right - lingual
- maxilla right - vestibular
- maxilla left - lingual



SONICflex paro, right angled, no. 62 / 62 A
- mandible left - lingual

- mandible right - vestibular
- maxilla right - lingual
- maxilla left – vestibular

In order to avoid damage to the root surface, the working end of the SONICflex paro tip should not be placed on the root surface. Only the side surfaces of the SONICflex paro tips should be used for working.

You can receive information at www.kavo.com.

6 Preparation methods according to ISO 17664

	⚠ WARNING
	Hazard from non-sterile products. Risk of infection to the care provider and patient. ▶ Before first use and after each use, prepare and sterilise the medical device.



Note

The following preparation procedures apply for the SONICflex tips, torque spanner and nozzle needle.

6.1 Preparation 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.



Note

Do not place the tips in the drill bit bath, as the fine capillaries would corrode badly, making it impossible to rinse them under running water.



Note

If a sterile coolant is used, the SONICflex tips must be rinsed with spray water after each use to prevent crystallisation in the tips.

- ▶ 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 similar.
- ▶ Reprocess the medical device as soon as possible after treatment.
- ▶ Prepare the SONICflex instrument according to the manufacturer's instructions for use.

6.2 Preparation before cleaning

- ▶ Remove the tip from the SONICflex using the torque wrench.

6.3 Cleaning

	⚠ CAUTION
	Malfunctions from cleaning in the ultrasonic unit. Defects in the product. ▶ Only clean manually or in a thermodisinfectior.

6.3.1 Manual cleaning of the exterior

Accessories required:

- Tap water 30 °C +/- 5 °C (86 °F +/- 10 °F)
- Nozzle needle
- Rubber eraser
- Brush, e.g. medium-hard toothbrush



Brush the SONICflex tip under running tap water using, e.g., a toothbrush of medium hardness. Clean the cone of the tip with a rubber eraser. If necessary, clear the water passage at the tip with a nozzle needle.

6.3.2 Manual cleaning of the interior

To effectively set up, the inside of the machine must be cleaned automatically in a cleaning and disinfection unit in accordance with ISO 15883-1. (The interior of this product is not to be cleaned manually).

6.3.3 Mechanical cleaning of the exterior and interior



Note

Before setting up, screw the SONICflex tips clockwise onto the SONICflex instrument.

KaVo recommends thermidisinfectors in accordance with ISO 15883-1, e.g. Miele G 7781 / G 7881.

(Validation was performed with the program "VARIO-TD", the cleaner "neodisher® mediclean", the neutraliser "neodisher® Z" and rinse "neodisher® mielclear" and only refers to the material compatibility with KaVo products.)



Note

Insert the instrument with tip screwed on into the adapter for interior cleaning in the thermidisinfector (e.g. Miele accessories for dental silicon adapters).

- The program settings and cleansers and disinfectants that must be used can be found in the instructions for use of the thermidisinfector.

6.4 Disinfection



⚠ CAUTION

Malfunctioning from using a disinfectant bath or disinfectant containing chlorine. Defects in the product.

- Only disinfect in a thermidisinfector or manually.

6.4.1 Manual disinfection of the the exterior

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

- ▶ Mikrozyd AF made by Schülke & Mayr (liquid or cloths)
- ▶ FD 322 made by Dürr
- ▶ CaviCide made by Metrex

Consumables required:

Cloths for wiping off the medical device.

Spray the disinfectant on a cloth, then wipe down the medical device and allow the disinfectant to act according to the instructions of the disinfectant manufacturer.



Note

Follow the instructions for use of the disinfectant.

6.4.2 Manual disinfection of the interior

For the effective re-preparation, the inside of the device must be cleaned automatically in a cleaning and disinfection unit in accordance with ISO 15883-1. The interior of this product is not designed for manual disinfection.

6.4.3 Mechanical disinfection of the exterior and interior



Note

Before setting up, screw the SONICflex tips clockwise onto the SONICflex instrument.

KaVo recommends thermidisinfectors in accordance with ISO 15883-1, e.g. Miele G 7781 / G 7881.

(Validation was performed with the program "VARIO-TD", the cleaner "neodisher® mediclean", the neutraliser "neodisher® Z" and rinse "neodisher® mielclear" and only refers to the material compatibility with KaVo products.)



Note

Insert the instrument with tip screwed on into the adapter for interior cleaning in the thermidisinfector (e.g. Miele accessories for dental silicon adapters).

- ▶ The program settings and cleansers and disinfectants that must be used can be found in the instructions for use of the thermidisinfector.

6.5 Drying

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 disinfection program of the thermodesinfector.



Note

Follow the instructions for use of the thermodesinfector (compressed air quality according to ISO 7494-2).

6.6 Packaging



Note

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



Note

The SONICflex can also be sterilised in the sterilisation tray.



- ▶ Individually weld the medical device in the sterilised item packaging (such as KaVo STERlclave bags **Mat. no. 0.411.9912**).
- ▶ Tips with short thread and marked A only fit in green mounts.
Tips with long thread fit in blue and green mounts.

6.7 Sterilisation

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



⚠ CAUTION

Contact corrosion due to moisture.
Damage to product.

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



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

6 Preparation methods according to ISO 17664 | 6.8 Storage

KaVo recommends, e.g.

- STERlclave B 2200 / 2200P made by KaVo
- Citomat/ K-series made by Getinge

Autoclave with a triple prevacuum for at least 4 minutes at
 $134\text{ }^{\circ}\text{C} \pm 1$ ($273^{\circ}\text{F} \pm 1.8$)

Autoclave using the gravitation method for at least 10 minutes at
 $134\text{ }^{\circ}\text{C} \pm 1$ ($273\text{ }^{\circ}\text{F} \pm 1.8$)

Autoclave using the gravitation method for at least 60 minutes at
 $121\text{ }^{\circ}\text{C} \pm 1$ ($250\text{ }^{\circ}\text{F} \pm 1.8$)

Follow the manufacturer's instructions for use.

Autoclave with a pre-vacuum for least four minutes at $134^{\circ}\text{C} \pm 1^{\circ}\text{C}$
($273^{\circ}\text{F} \pm 1.8^{\circ}\text{F}$)

Drying time: 20 min.

Autoclave with the gravitation method for at least 10 minutes at $134^{\circ}\text{C} \pm 1^{\circ}\text{C} \pm 1^{\circ}\text{C}$
($273^{\circ}\text{F} \pm 1.8^{\circ}\text{F}$)

Drying time: 30 min.

Autoclave with the gravitation method for at least 60 minutes at $121^{\circ} \pm 1^{\circ}\text{C}$
($250^{\circ}\text{F} \pm 1.8^{\circ}\text{F}$)

Drying time: 30 min.

Follow the manufacturer's instructions for use.

6.8 Storage

Prepared products must be stored, protected from germs (as far as possible) and dust, in a dry, dark, cool room.



Note

Comply with the expiry date of the sterilised items.

7 Tools

7 Tools

Obtainable from the dentalmed. specialist supplier

Material summary	Mat. no.
Torque wrench	1.000.4887
Nozzle needle	0.410.0911
Sterilisation tray	0.411.9101
STERIclave bags	0.411.9912

