



Instruction for Use

MK-dent Propphy Line Air Polishing Device

Version: 2022-12-01

CE 0123

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1 About these Instructions for Use

This Instruction for Use is applicable for the MK-dent air polishing devices PR1011K, PR1011S, PR1011W, PR1011N, PR1011B

1.1 Explanation of warnings

These Instructions for Use are intended to assist users in the safe and effective operation of the product described. Before attempting to operate the product, you must read these Instructions for Use, noting and strictly observing all WARNING and CAUTION notices. Pay special attention to all the information given and procedures described in the "Safety" section.

These Instructions for Use are part of the system. They shall be kept in the immediate vicinity of the system so that they are accessible at any time.

To avoid personal injury and damage to property, observe the warnings and safety information contained in this document. These are specially marked:



WARNING

A **WARNING** alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.



CAUTION

A **CAUTION** alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury, and/or cause environmental pollution.

NOTICE

NOTICE

This is used to identify special advice, for example to assist the operator or to improve an operating sequence.

1.2 Compliance

This Medical Device meets the provisions of the Directive 93/42/EWG.

CE 0123

This product complies with these international standards:

- ISO 14971 Application of risk management to medical devices
- IEC 62366-1 Application of usability engineering to medical devices

If you have further questions regarding the applicable national or international standards, please address them to the manufacturer:



MK-dent GmbH
Marie-Curie-Str. 2
22941 Bargtheide
Germany

2 Intended Use

2.1 Intended Use

The ProphyLine is intended to generate a powder jet with glycine powders that are used during supragingival prophylaxis procedures to remove dental biofilms, plaque, stain and discoloration from tooth surface.

2.2 Indications for Use

The ProphyLine is a powder jet device intended for supragingival air polishing in the course of professional cleaning of teeth during a prophylaxis treatment by dental professionals to remove dental biofilms, plaque, stain and discoloration from tooth surface.

2.3 Contraindications

Never use the ProphyLine on patients with:

- low salt diet (due to hypernatremia, edema, pregnancy toxemia, etc.),
- serious ulcer in digestive organs,
- renal dysfunction,
- cardiac dysfunction,
- asthma or chronic pulmonary disease,
- electrolyte abnormality due to hypochloric alkalosis,
- an intraoral injury or disease,
- hyperemia, inflammation or bleeding in the intraoral cavity,
- oral mucosa inflammation or bleeding,
- allergies
- contact lenses

2.4 Intended Patients

Patients in need of supragingival air polishing during general prophylactic treatment (professional dental cleaning). However, the decision to use supragingival air polishing is the responsibility of the dentist or dental hygienist, respectively.

2.5 Intended Operator Profile

The ProphyLine is an air polishing handpiece for use by dentists or dental hygienists with the appropriate training.

2.6 Intended Use Environment

The ProphyLine is an air polishing handpiece for use in dental practices or dental hospitals.

3 Safety and Requirements

3.1 General safety regulations



WARNING

- This product is not sterilized in the delivery condition. Sterilize in an autoclave before first use.
- Sterilization must be done before first use and after every patient in order to prevent direct and cross infection.
- This product must be used only by qualified dental professionals and only for dental treatment.
- Never dismantle or modify this product.
- In case of trouble, do not repair by yourself, ask your dealer for repair.
- In case of deterioration or malfunction, do not use this product.
- Do not use this product when in an unmaintained condition.
- To operate correctly and safely, keep the cautions for use.
- Use glycine powder for dental prophylaxis only. Other powder (for example, alumina powder) will cause a decrease in cleaning efficiency, patient injury, powder clogging, or damage to the polisher.
- Use the powder only once



CAUTION

- Patients with contact lenses must remove them before treatment.
- Depending on the patient physical conditions, allergy symptoms or stomatitis may seldom occur. In such a case, stop using this product immediately.

NOTICE

NOTICE

Air polishing should be avoided on or near the following:

- Porcelain, gold alloy, and glass ionomer restorations to prevent surface roughness, staining, pitting, and loss of marginal integrity.
- Dental implants, except with glycine or erythritol powder, which can be used safely on implant surfaces.

3.2 Reporting obligation

If the use of this product leads to a serious deterioration in the patient's state of health, then report this to your dealer or to us as the manufacturer and to the BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte).

Our contact details can be found in these instructions for use. The contact details of the notified body will also be communicated to you on request.

3.3 Side effects

Depending on the patient physical conditions, allergy symptoms or stomatitis may seldom occur, depending on the chosen powder. In such a case, stop using this product immediately.

The following side effects may occur if the ProphyLine is not used as intended:

- patient discomfort
- abrasion of cementum and dentine
- epithelial abrasion of the gums
- subcutaneous emphysema

3.3 Risk patient groups

Never use this product on patients with:

- low salt diet (due to hypernatremia, edema, pregnancy toxemia, etc.),
- serious ulcer in digestive organs,
- renal dysfunction,
- cardiac dysfunction,
- asthma or chronic pulmonary disease,
- electrolyte abnormality due to hypochloric alkalosis

Avoid using this product on patients with:

- intraoral injury or disease,
- hyperemia, inflammation or bleeding in the intraoral cavity,
- oral mucosa inflammation or bleeding,
- allergies,
- contact lenses

4 Product description

4.1 Description

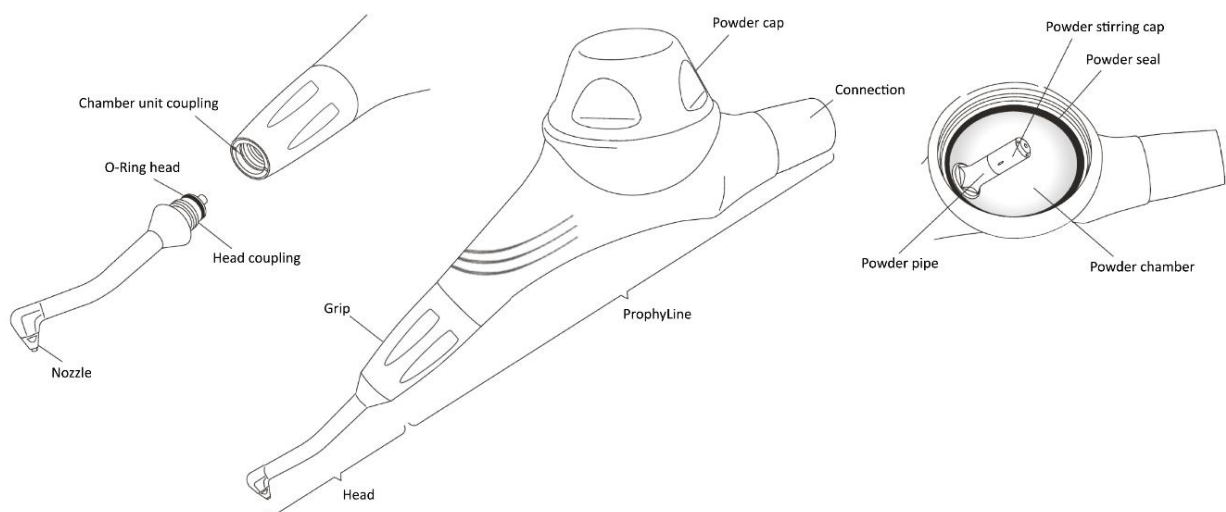
The Prophy Line is a dental air polishing device to clean tooth surfaces.

- The compact form of the ProphyLine handpiece allows easy movement between dental units and takes up little space for storage.
- The quick-disconnect system permits easy replacement with turbines and immediate use. No need for cumbersome installation and allowing easy integration into your treatment system.
- The contra-angled head rotates 360 degrees, allowing excellent access to all areas.
- The detachable head allows easy maintenance in case of powder clogging.
- Driven by compressed air and water from the dental unit, the ProphyLine neither effect other medical devices and is not effected by electromagnetic waves.

4.2 Combination with other products

REF Prophy Line	PR1011K	PR1011S	PR1011W	PR1011N	PR1011B
Coupling	QC4012K QC4014K QC5015K QC5016K QC5016KW QC5116K QC5116KW QC6016K QC6016KW QC6116K QC6116KW	QC5016SW QC6016SW	QC4014W QC5016W	QC4014NT QC5016NT QC6016NT	N/A
Connection	KaVo®	Sirona®	W&H®	NSK®	Bien Air®

4.3 Product components

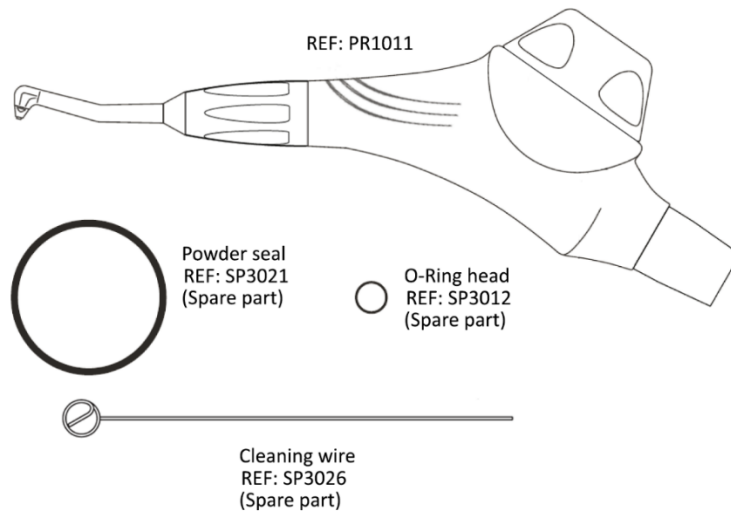


4.4 Scope of delivery

The scope of delivery components and accessories below are included in the delivery kit:

- PR1011
- Powder seal (SP3021)
- O-ring head (SP3012)
- Cleaning wire (SP3026)
- Instructions for use (IFU).

When you open the delivery package the first time, confirm all components are included in the package. If something is missing, contact your dealer immediately.



4.5 Materials needed that are not included

NOTICE

NOTICE

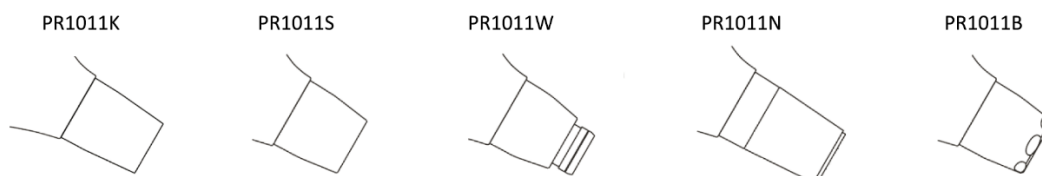
No powder is included in the delivery package.

No coupling is included in the delivery package.

4.6 Configurations

The configuration of the PR1011 is as described in **4.3 Product components**, only the connection options differ. The different connections are described as follows:

REF Prophy Line	PR1011K	PR1011S	PR1011W	PR1011N	PR1011B
Connection	KaVo®	Sirona®	W&H®	NSK®	Bien Air®



5 Accessories, tools, consumables and spare parts

5.1 Accessories

N/A

5.2 Tools

Key: KE2021
Assembly / disassembly
Connection sleeve, KaVo®
connection



Key: KE2022
Assembly / disassembly
Powder pipe



Key: KE2023
Assembly / disassembly
Hollow screw



5.3 Consumables

- 3M ESPE, Clinpro Glycine Prophy Powder, grain size 20-25 µm

5.4 Spare Parts

- Powder seal (SP3021)
- O-ring head (SP3012)
- Cleaning wire (SP3026)

6 Installation

6.1 Requirements for the environment

To supply polisher with clean and dry air, clean the air filter of the compressor in your dental office. Do not supply compressed air containing moisture. For drainage and regular maintenance of your compressor, please refer to your air compressor's instruction manual. Confirm the compressor is maintained according to its instructions for use.

6.2 Unpacking

When unpacking the package first time, confirm all contents in **4.4 Scope of delivery** are included in the package. Confirm polisher has no defect or damage such as cracks.

6.3 Assembly



WARNING

Powder cap and powder seal must be attached firmly. An unstable attachment will cause the powder cap to undo during use and may cause injuries or powder scattering.

The head and powder cap must not be detached during operation. This may cause injuries due to the instrument becoming disconnected, or powder scattering.



CAUTION

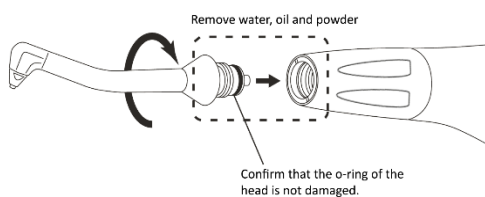
Do not fill the powder yet. Water due to sterilization must be expelled by an idle run beforehand.

Polisher must be disconnected from a turbine hose of dental unit when attaching and detaching the head. If it is connected, disconnect from the turbine hose first. If water, oil, or powder adheres to head or inside the chamber unit's coupling, wipe off with a cotton swab or dry cloth.

The powder cap must be attached or detached when polisher is not connected to a turbine hose. If connected, detach from the turbine hose. If water, oil, or powder adheres to inside chamber unit, powder cap, or powder seal, wipe off with a dry cloth.

Step 1:

Attaching the head

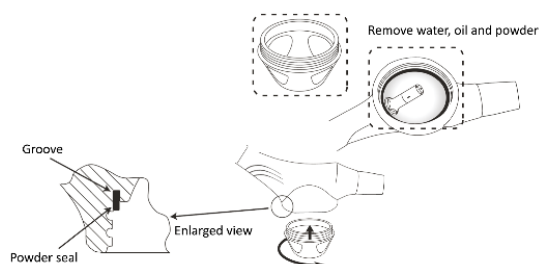


Confirm the o-ring of the head is not damaged.

Align the head to the thread of the chamber unit's coupling, turn the head in the direction of the arrow in the illustration until it stops. Confirm secure attachment.

Step 2:

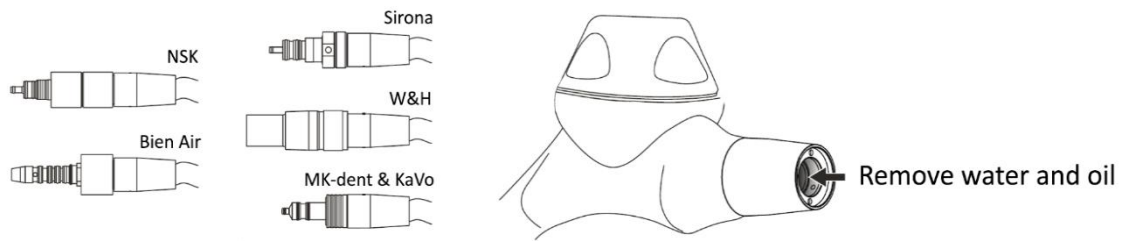
Attaching the powder cap



Confirm the powder seal (blue) is fully engaged in the groove of chamber unit shown in the illustration.

Turn the powder cap in the direction of the arrow in the illustration. Confirm secure attachment.

6.4 Preparation for connection



When a handpiece (air turbine, air scaler, etc.) is detached, water and oil remain at the joint. Remove the water and oil without fail. Confirm no water or oil remains in the coupling on your turbine hose. Remove with a dry cloth if remains.

Confirm no water or oil remains in the joint of polisher. Remove with a cotton swab if remains.

6.4.1 Air pressure test

Connect a pressure gauge to the coupling on your turbine hose until you hear a locking sound. Make sure the meter is securely attached. If you do not have a pressure gauge, contact your dealer.

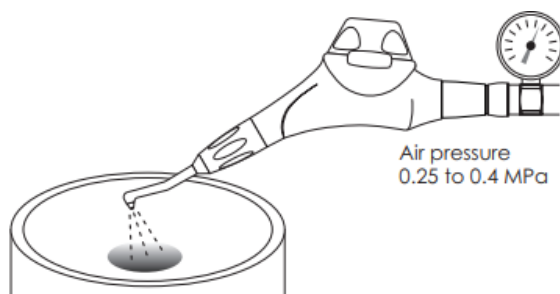
Connect the instrument to the manometer coupler until you hear a locking sound. Make sure the meter is seated firmly.

6.4.2 Air pressure setting



WARNING

The air pressure at the coupling must be set within 0.25 to 0.4 MPa (about 36 to 58 psi; 2.5 – 4.0 bar; 2.5 to 4.1 kgf/cm²). Excess air pressure will damage tooth surface and cause patient pain. It may also cause trouble during use such as injuries due to instrument damage, or powder scattering.



Turn off the water supply of your dental unit. Direct polisher to your cuspidor and depress your foot control to activate the dental unit.

Adjust the air pressure of the unit until the gauge shows 0.25 to 0.4 MPa (about 36 to 58 psi; 2.5 – 4.0 bar; 2.5 to 4.1 kgf/cm²). Detach the pressure gauge and polisher after pressure adjustment.

6.4.3 Connecting to the coupling system

Connect a coupling (separately sold) compatible with your polisher to your turbine hose. Confirm secure connection.

6.5 Putting into service and operation

6.5.1 Operator protection



WARNING

When using, the operator and assistants must wear gloves, protective eyewear and anti-dust masks full-time.

If the powder gets into the eyes, wash your eyes with plenty of water and consult an eye doctor.

6.5.2 Before use



CAUTION

Water removal in the channels.

If water remains inside of the main body, powder will become damp and cause clogging.

After reprocessing, run polisher for 1 minute without powder before use. This idle run will expel remaining water inside.



Make sure no powder remains within the powder chamber.

Direct the nozzle to your cuspidor. Depress your foot control without water supply from the dental unit. Run for 1 minute to remove water remaining in the channels of polisher.

6.5.3 Powder filling



WARNING

Remove powder remaining in/on the screw threads of the powder chamber, powder cap, and sealing surface of the powder seal. Remaining powder may cause premature wear of the threads and insufficient sealing which may cause powder scattering.

In case of screw thread failure of the chamber unit including wear and/or deformation, stop using the polisher. Ask for repair of the chamber unit together with the powder cap.

If the powder cap has a crack or fissure, replace with a new one.



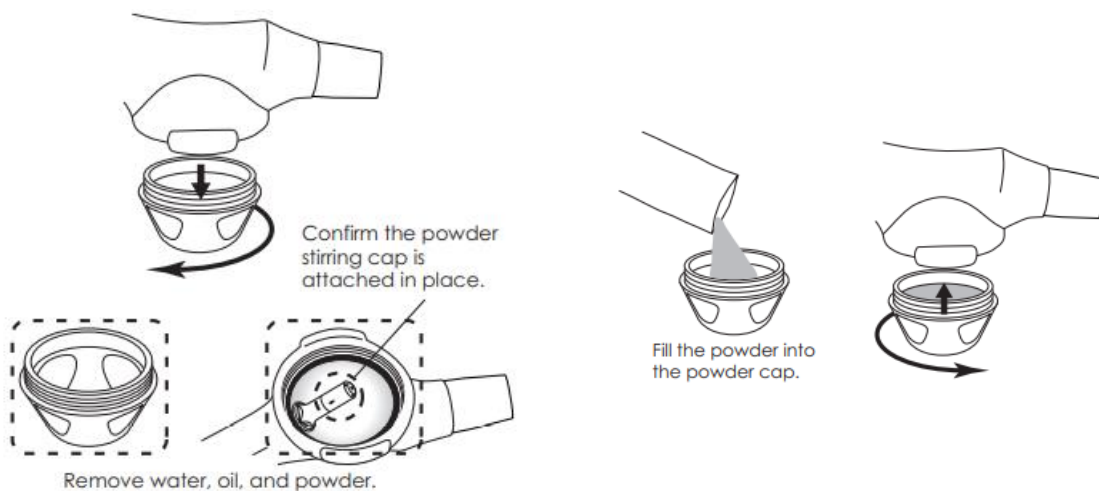
CAUTION

Do not fill more powder than the prescribed quantity.

Do not shake polisher after filling the powder. The powder may leak from the nozzle.

Always use dry compressed air and dry powder. Use of air and powder containing moisture or oil will cause powder clogging.

Make sure the powder stirring cap is attached in place. Improper attachment will lower the prophylaxis efficiency.



Remove polisher from the turbine hose before refilling/filling the powder. Detach the powder cap by turning in the direction of the arrow in the illustration above.

Confirm the powder stirring cap is attached in place.

If water, oil, or powder remains inside of powder chamber or powder cap, remove it with a dry cloth.

Fill powder not exceeding 15 g into the powder cap.

Take care not to spill the powder over the thread of the powder cap. If the powder is spilt over the thread, wipe it off with a dry cloth.

Hold the chamber unit downward and the powder cap upward as shown in the illustration. Turn the powder cap in the direction of the arrow until it stops. Confirm the powder cap is screwed securely in place.

6.5.4 Confirming correct operation



WARNING

When connecting your coupling to this product, confirm secure connection after hearing a locking sound. Make sure the head and powder cap are firmly screwed in. An unstable attachment will invite injuries due to fall of the body and such parts, or powder scattering.

Confirm no damage, no cracks, no breakage or no major corrosion is present on the product and it is safe to use.

Never pull the handpiece out of your coupling while the powder jet device is in operation. This can lead to injuries.



Confirm the handpiece is firmly seated. Direct the nozzle to your cuspidor. A lot of powder might be sprayed immediately after filling powder. Before using on a patient, spray into your cuspidor for one second one or two times to confirm proper operation.

Depress the foot control of your dental unit one or two times for about one second and confirm, if air, water, and powder are sprayed, water supply is sufficient as well as no leak of air, powder, and water from polisher can be detected.

When using for the first time, grasp the spraying area and cleaning effect with an extracted tooth or tarnished coin.

If you have trouble, refer to Chapter **11 Trouble shooting**. For water supply adjustment, use the water volume control of your dental unit.

7 Treatment

7.1 Patient, operator, and assistant protection



WARNING

Before the first contact with the patient, the product must be properly processed to avoid infection, refer to Chapter 8 Reprocessing.

Before using, protect the patient with towels and protective eyewear so that the powder does not enter mucous membranes (eyes, nose, tracheae) other than intraoral.

When using, the operator and assistants must wear gloves, protective eyewear and anti-dust masks full-time to avoid infection.

If the patient wears contact lenses, the patient must remove them before treatment. If the powder gets into the eyes, wash your eyes with plenty of water and consult an eye doctor.

Protect the patient's face (other than oral cavity) with towels and protective eyewear. When spraying into an area around soft tissues such as gingiva, protect it with cotton in advance.

7.2 Spraying



WARNING

Never spray into the subgingival, root canal, or extraction socket. It can cause accidental symptoms such as emphysemas.

Never spray directly into the intraoral soft tissues (gingiva, mucosa). It can cause accidental symptoms such as surface damages. Protect the soft tissues with cotton in advance.

Do not put this product close to heat. It will cause damage on the body and malfunction and may invite injuries or powder scattering during use.



CAUTION

Always use with sufficient water. If the water is insufficient, the powder will scatter and the cleaning efficiency will decrease.

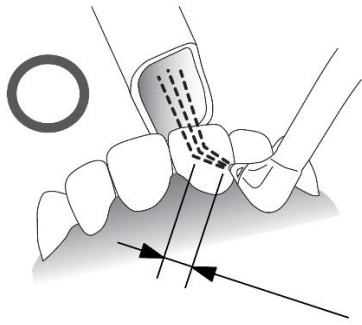
Make your vacuum suction system ready to remove scattered powder. Direct the nozzle to tooth surface and depress your foot control to start spraying.

The powder may be sprayed for a few seconds after releasing your foot control due to the residual pressure in the powder chamber. Collect the powder with your vacuum suction system to avoid damaging soft tissues. Take care so that the patient does not swallow powder.

Avoid prolonged continuous use. Have the patient rinse out his/her mouth enough as needed.

Do not spray directly to restorations such as crowns. It may scratch restorations.

The tooth cuticle is removed during the cleaning procedure and the prevention ability of tooth against discoloration is decreased. The tooth cuticle will be re-created by protein contained in saliva. To avoid discoloration, instruct the patient not to smoke or have foods or beverages with strong coloring effect such as example tea, coffee, and red wine for two or three hours after treatment.



Keep distance of 2 to 5 mm from the tooth surface.

Suction the spray with your vacuum suction system and avoid soft tissues.

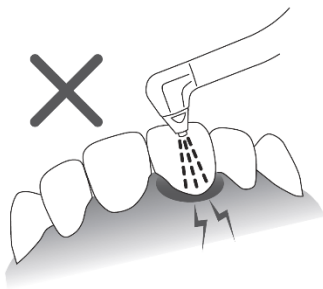
Spray from gingival margin to occlusal surface.

When cleaning a large area, spray while moving the nozzle minutely.

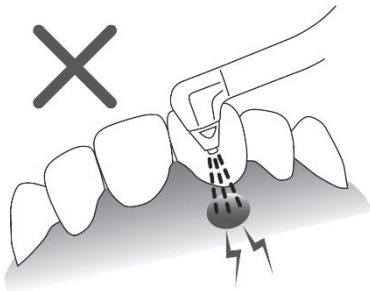
The powder may be sprayed for a few seconds after releasing your foot control due to the residual pressure within the powder chamber.

Collect the powder with your vacuum suction to avoid damaging soft tissues.

Have the patient rinse out his/her mouth as needed or after treatment



Never spray into the subgingival, root canal, or extraction socket. It can cause accidental symptoms such as emphysemas.



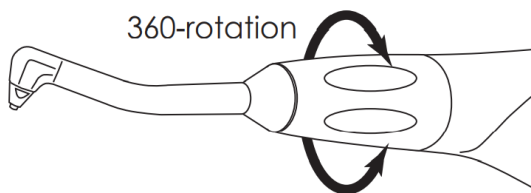
Never spray directly into the intraoral soft tissues (gingiva, mucosa). It can cause accidental symptoms such as surface damages.

7.3 Turning the head



WARNING

The head must be rotated by holding and turning the grip, not the head. Otherwise, the head will loosen and this may invite injuries or powder scattering during use.



Rotate the head by turning the grip.

The head rotates 360 degrees.

7.4 Disconnecting after use



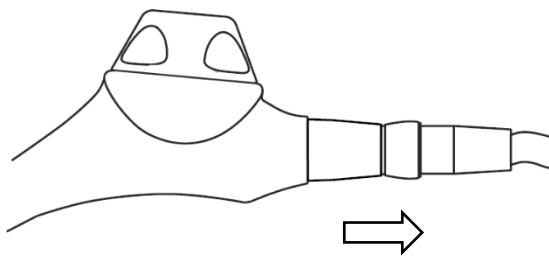
WARNING

The product must not be dropped.



CAUTION

Remove remaining water, oil or powder remaining in and on the head, coupling of the chamber unit, powder chamber and powder cap. Otherwise the powder will get damp and cause clogging.



Detach the handpiece according to the instruction manual of your coupling.

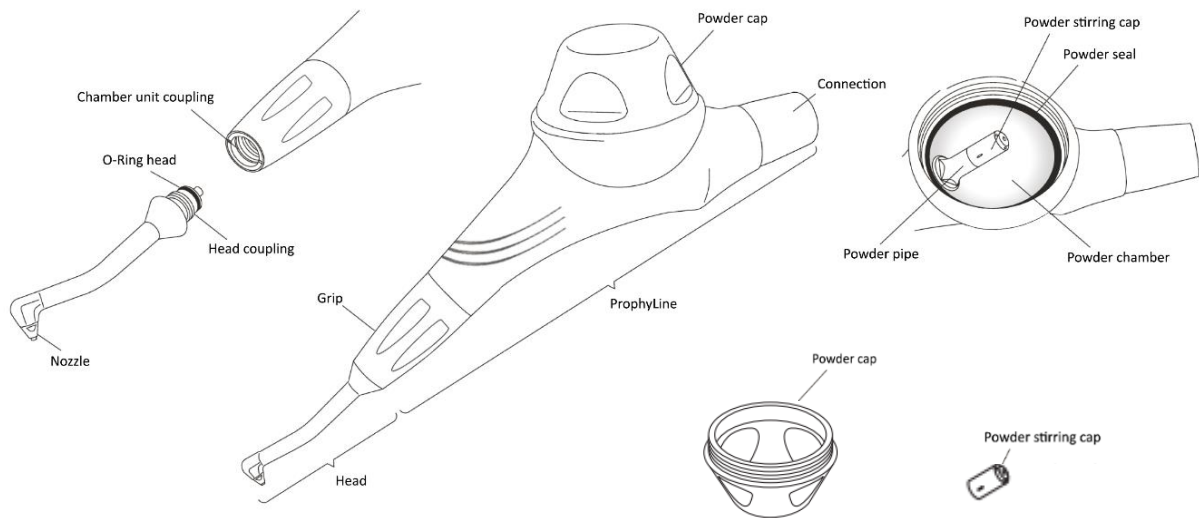
When reconnecting, clean the coupling, turbine hose and inside of chamber unit's joint in advance referring to **6.4.3 Connection to the coupling system**.

8 Reprocessing according to ISO 17664-1

NOTICE

NOTICE

Assembling and disassembling is described in chapter 6.3, 8.1.1 and 8.1.2



8.1 Processing at the location of use



WARNING

Risk of infection due to non-sterile instruments. Always wear gloves.



CAUTION

Do not use ultrasonic cleaners to clean this product. This will cause malfunction or damage.

Remove powder remaining inside and on the surface of polisher between treatment and sterilization.

NOTICE

NOTICE

Before reconnecting, clean the coupling on your turbine hose and inside of chamber unit's joint in advance referring to 6.4 Preparation for connection.

Immediately remove any debris of blood or powder. Wipe off saliva and blood on the polisher.

Do not put the instrument in any kind of liquid.

Process the instrument within one hour after each treatment in order to prevent piling.

Ensure a dry storage and transport of the instrument to the place of processing.

8.1.1 Detaching the head

The head must be attached or detached when polisher is not connected to a turbine hose. If polisher is connected to a turbine hose, disconnect it from the turbine hose.

Turn the head in the opposite direction of the arrow as shown in **6.3 Assembly** and detach.

Before reattaching, clean the head and inside of chamber unit's coupling in advance referring to **6.3 Assembly**.

8.1.2 Detaching the powder cap

The powder cap must be attached or detached when polisher is not connected to a turbine hose. If polisher is connected to a turbine hose, disconnect it from the turbine hose.

Hold polisher keeping the powder cap downward. Turn the powder cap to detach. Detach the powder cap above your cuspidor, as the powder in the powder chamber may scatter when the powder cap is released.

Discard the leftover powder out of the powder cap.

Before refilling the powder and reattaching the powder cap, clean the inside of powder chamber and powder cap referring to **6.3 Assembly**.

8.1.3 Powder disposal

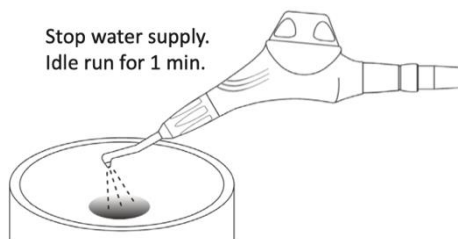


CAUTION

The leftover powder must be discarded after treatment. When the powder gets damp, it will cause clogging.

Detach the powder cap referring to **8.1.2 Detaching the powder cap**. Discard the leftover powder.

8.1.4 Removal of remaining powder within polisher



Attach the emptied powder cap to the chamber unit.

Connect polisher to the coupling on your turbine hose.

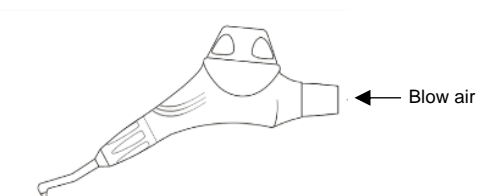
Direct the nozzle to your cuspidor.

Depress your foot control without water supply from the dental unit.

Run for 1 minute to remove the powder remaining within the channels of polisher.

Disconnect polisher from your coupling.

8.1.5 Water draining



Attach the powder cap and head to the emptied chamber unit.

Direct the nozzle to your cuspidor.

Blow air into the joint of chamber unit to drain the water channels.

8.2 Manual pre-cleaning



CAUTION

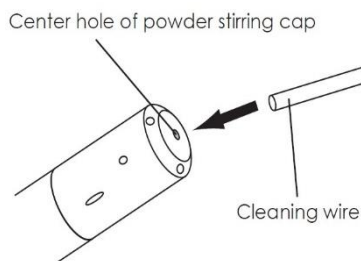
Insufficient cleaning of the surface and the water- and air pipes

In order to ensure a successful cleaning a thorough manual pre-cleaning, must be done.

The use of manual pre-cleaning requires training of the employees who carry out these reprocessing instructions. This is necessary to guarantee successful cleaning.

Cleaning must be done when polisher is disconnected from the coupling on your turbine hose. After disassembling the head and powder cap from the chamber unit wash each part (in particular, where powder adheres) with running water.

8.2.1 Manual cleaning powder stirring cap



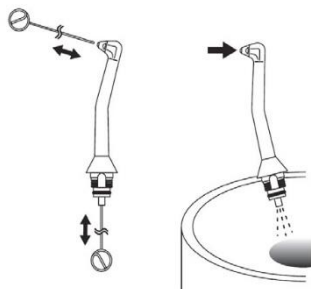
Remove the powder stirring cap from the powder pipe.

(The cleaning wire does not pass through the center hole when the powder stirring cap is connected.)

Remove powder adhered on the center hole of the powder stirring cap with a cotton swab or dry cloth.

Clean the center hole with the attached cleaning wire to remove the powder blocking the center hole.

8.2.2 Manual cleaning head



Remove the head from the chamber unit.

Insert the cleaning wire into the spraying orifice of the nozzle and center hole of the connection.

Remove powder remaining within the channels using the cleaning wire.

Blow air into the spraying orifice of the nozzle to remove powder remaining inside.

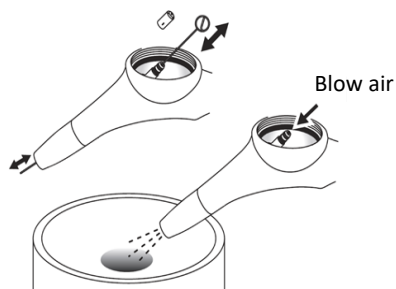
If water, oil or powder remains at the surface of the head, remove with a dry cloth.

8.2.3 Manual cleaning chamber



Detach the head and powder cap from the chamber unit.

Loosen the powder stirring cap from the powder pipe by turning in the direction of the arrow in the illustration and detach it.



Insert the cleaning wire into the powder pipe and remove powder remaining in the pipe.

Blow air into the powder pipe of the nozzle with a three-way syringe to remove powder remaining inside.

If powder remains inside coupling of the chamber unit, remove with a cotton swab or dry cloth.

If water, oil or powder remains inside chamber unit or in the powder cap, remove with a cotton swab or dry cloth.

Attach the powder stirring cap to the powder pipe by turning in the opposite direction of the arrow in the illustration.



CAUTION

Make sure the powder stirring cap is attached in place after cleaning. Improper attachment will lower the cleaning efficiency.

8.2.4 Manual drying

Blow on the instrument with compressed air from the inside and the outside until no visible drops are left.

8.3 Automatic cleaning

8.3.1 Cleaning, disinfection and rinsing

NOTICE



NOTICE

MK-dent recommends thermal disinfectors that fulfill the EN ISO 15883-1 requirements and are approved by the manufacturer for dental handpieces. The cleaning should be carried out at a minimum of 55 °C and for at least 6 minutes, the disinfection at a minimum of 90 °C and for at least 5 minutes (for an A0-value > 3,000). For the cleaning a mild alkaline cleaning agent with a pH of 9 to 11 is recommended, like e.g. Dr. Weigert Neodisher® MediClean forte.

The Prophy Line can be mechanically reprocessed in the assembled state. For the mechanical reprocessing the adapters specified by the manufacturer of the thermal disinfectant and compatible with your polisher must be used. For information about the positioning refer to the operator's manual of your device.

The validation of the automatic cleaning and disinfection was carried out with the device WD BHT INNOVA® M3 in the program Nr. 03 Thermodisinfection with the cleaner Dr. Weigert Neodisher® MediClean forte 0,5 %. The Instruments were connected to a Luer-Lock adapter of the machine via a silicone tube.

Parameters for automatic cleaning and disinfection:

Cleaning for 1 minute with cleaner 0,5 % MediClean forte at 30 °C / 86 °F

Cleaning for 6 minutes with cleaner 0,5 % MediClean forte at 55 °C / 131 °F

Rinsing for 1 minute with demineralized water

Thermodisinfection for 5 minutes with demineralized water at 90 °C / 194 °F (for an A0-value > 3000).

NOTICE**NOTICE**

The final rinse water must be of drinking water quality in accordance with the EU Drinking Water Ordinance (total germ count max. 100 CFU/ml).

Repeat the process if visible contaminations still exist after the treatment in a thermal disinfectant.

8.3.2 Mechanical drying

The drying process normally is part of the cleaning process of your thermal disinfectant. Please follow the instructions for your thermal disinfectant.

To prevent any kind of impairments of the instrument, make sure after every cycle that the instrument is dry on the inside and the outside. In case of moisture remaining on the instrument after the cleaning process, blow with compressed air until completely dry.

8.4 Sterilization in an autoclave

8.4.1 Wrapping

NOTICE**NOTICE**

The sterilization bag must be big enough for the head of the ProphyLine so that the packaging doesn't is under tension. The sterilization packaging must comply with EN ISO 11607-1 and must be suitable for the sterilization method. Wrap each instrument individually in a single sterilization bag and check the weld seam for leaks.

Remove the head from the chamber unit. Confirm no powder remains in the head. Put the head into a single sterilization bag and seal it.

8.4.2 Sterilization

**WARNING**

Only the head of the ProphyLine is sterilizable in autoclave.

Sterilization must be done before first use and after every patient in order to prevent direct and cross infection.

To avoid infection, wear suitable protective wears such as mask, gloves and eyewear. This medical product has a temperature resistance of up to max. 135 °C / 275 °F.

**CAUTION**

To avoid trouble and damage on the product, follow the instructions when sterilizing.

Do not sterilize with powder remaining.

Do not sterilize the head with instruments on which some medicine or chemical agent remains.

Do not immerse polisher in disinfectant liquids.

Dry heat sterilizers generate high heat that exceeds the maximum sterilization temperature of this product. Do not use in order to avoid mechanical trouble or damage.



CAUTION

Depending on the conditions of your sterilizer or sterilizing methods, this product may discolor.

NOTICE

NOTICE

Pay close attention to the manufacturer's instruction.

Place the sealed head in the sterilization bag on a sterilization tray to avoid direct contact with sterilizer's inner chamber surface, and put into the autoclave.

8.4.3 Sterilization parameters

Only apply the following sterilization parameters:

Autoclave with a fractionated pre-vacuum (recommended): minimum of 5 minutes at a minimum of 134 °C / 273 °F

The sterilization was validated with the device W&H LISA 517, Serial No. 08-0794, in a fractionated pre-vacuum process at 134 °C (273 °F) for 5 minutes. According to the Operating Instructions of the manufacturer of the sterilizer for every sterilization process the software of the autoclave calculates the time of the drying process.

The instructions listed above have been validated by the medical device manufacturer as being suitable for preparing a medical device for its reuse. The processor is responsible for ensuring that the actually carried out processing with the equipment, materials and personnel used in the processing facility achieved the desired result. This requires verification and/or validation and routine monitoring of the process.

8.4.4 After Sterilization

When the sterilization cycle is finished, take out sterilized head from the autoclave.

8.5 Storage

After sterilization and natural drying, confirm no water beading remains and store. Store in a place of low temperature and moisture.



CAUTION

The chamber unit and head must be dried completely before storage. If water remains, discoloration, rust, or powder clogging will occur.

Store and take care of polisher properly to keep it out of reach of persons other than dental professionals.

Do not store polisher in a place where it may be exposed to water.

Keep polisher in a place where it is not affected by barometric pressure, temperature, humidity, ventilation, strong sunshine, dust, salt or sulfurous air.

Keep polisher in places without vibration or shock.

Do not store polisher in a place where chemical agents are kept or some gas exists.

9 Maintenance

9.1 Regular maintenance and checks



WARNING

Inappropriate maintenance or service may result in dysfunctions and/or deterioration. Always perform proper maintenance and service.



CAUTION

To use safely, check and maintain this product according to this instruction.

9.2 Cleaning in case of problems

In case of problems with air or powder pipes clean each part of the polisher. Cleaning must be done when polisher is disconnected from the coupling. For instruction go to Chapter 7.4 **Disconnecting after use**.

10 Disposal

Dispose of this product in accordance with local rules and regulations, or return this product cleaned in accordance with Chapter 8 **Reprocessing** of this instruction to the manufacturer.

11 Trouble shooting

NOTICE

NOTICE

This product must not be repaired by the user in case of malfunction. Contact your dealer for repair.

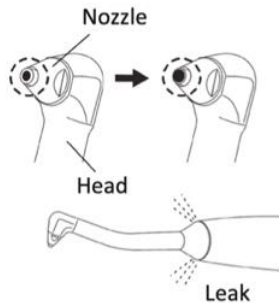
If this product does not operate as stated in this manual, check your problem according to the list below. If your trouble is not corrected, or if your trouble is not listed below, contact your dealer.

Symptoms	Possible causes	Countermeasures
1) No powder spray. Low cleaning efficiency.	<ul style="list-style-type: none"> The center hole of the powder stirring cap is clogged with powder. Powder clogging within the channels. The powder stirring cap is not attached properly. No air supply. Low air pressure at the coupling. The control system of the dental unit does not work. 	<ul style="list-style-type: none"> Clean the powder stirring cap according to 8.2.1 Manual cleaning Powder stirring cap. Clean the head and chamber unit according to 8.2.2 Manual cleaning Head and 8.2.3 Manual cleaning Chamber. Attach the powder stirring cap properly according to 8.2.3 Manual cleaning Chamber. Set coupling pressure between 0.25 and 0.4 MPa. Check the control system using other handpiece.

Symptoms	Possible causes	Countermeasures
2) No water	<ul style="list-style-type: none"> Water supply system of your dental unit is shut off. Water does not reach turbine hose. Water channels of polisher are clogged. O-ring(s) on your coupling is/are damaged. 	<ul style="list-style-type: none"> Activate the water supply system of your dental unit. Check the water supply system of your dental unit. Ask your dealer for repair. Replace the o-ring(s) on your coupling (separately sold or included in delivery).
3) Leak (air, water, and powder) from powder chamber coupling.	<ul style="list-style-type: none"> The head is not firmly attached. The o-ring in the head is worn or damaged. 	<ul style="list-style-type: none"> Attach the head firmly according to 6.3 Assembly. Replace the attached head o-ring according to 12.2 Replacement of the head o-ring.
4) Air and/or powder leak from near of the powder chamber.	<ul style="list-style-type: none"> The powder cap is not firmly attached. The powder seal is not properly attached in the powder chamber. The powder seal is worn or damaged. Powder adheres to the sealing surface (of the powder seal and/or powder cap). 	<ul style="list-style-type: none"> Attach the powder cap firmly according to 6.3 Assembly. Attach the powder seal properly according to 12.4 Replacement of the powder seal. Replace with the attached new powder seal according to 12.4 Replacement of the powder seal. Fill the powder into the powder cap properly according to 6.5.3 Powder filling.
5) Water leak from around the coupling on the turbine hose.	<ul style="list-style-type: none"> O-ring(s) on your coupling is/are damaged (for PR1011K/W/S/B). O-ring(s) on your joint is/are damaged (for PR1011N). 	<ul style="list-style-type: none"> Replace the o-ring(s) on your coupling (separately sold or included in delivery package). Replace the o-ring(s) on the joint (separately sold).
6) Polisher can not be connected to your coupling.	<ul style="list-style-type: none"> Polymer is not compatible with your coupling. The light cover at the front of the coupling is loose (if you use coupling with light). 	<ul style="list-style-type: none"> Use polisher compatible with your coupling according to 4.2 Combination with other products Turn the light cover at the front of the coupling to fix securely.

12 Repair

12.1 Replacement of the head



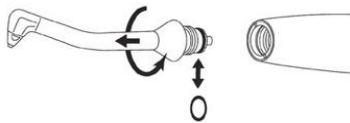
The nozzle of the head will wear out with use. A broadened spraying orifice will cause decrease in cleaning efficiency and difficulty in pinpoint spraying.

When the spraying orifice has become larger like shown in the illustration, the work efficiency will be recovered by replacement of the head (separately available).

The entire head must be replaced, not only the nozzle. Attach the head properly according to **6.3 Assembly**.

12.2 Replacement of the head o-ring

In case the o-ring at the coupling of the head is damaged or worn, air, water, or powder leaks from the joint, replace the used o-ring with the provided head o-ring (spare part).



Head o-ring (spare part)

Attach the o-ring properly in place. Do not damage the surface of the o-ring when replacing.

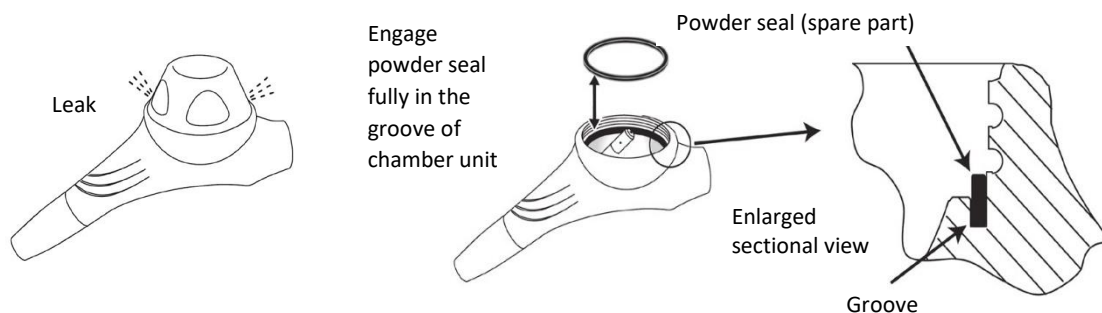
12.3 Replacement of the powder cap

The transparency of the powder cap will lower with use and may result in decreased visibility inside the powder cap. In case you cannot see powder in the powder chamber, replace the powder cap (separately available). If the powder cap is cracked, it must be replaced with a new one. Attach the powder cap properly according to **6.3 Assembly** when replacing.

12.4 Replacement of the powder seal

In case the powder seal attached into the thread of the powder chamber is damaged or worn out, air or powder leaks between the powder cap and powder seal, replace the used powder seal with the provided powder seal (spare part). Follow the procedure below:

If powder or something remains in the groove of the powder chamber, in which the powder seal is attached (see the illustration below), remove it with air from a three-way syringe. Clean the groove and attach the powder seal properly so that the powder seal fully seats in the groove (see the illustration below). Do not damage the surface of the powder seal when replacing.














WARNING

When replacing o-rings and powder seal, be careful about the correct mounting location and direction. Incorrect mounting may cause injuries due to disconnection of the head or powder cap, powder scattering, leakage of air, water, or powder during use.

13 Technical data

ProphyLine	PR1011				
REF	PR1011K	PR1011S	PR1011W	PR1011N	PR1011B
Device Length	201 mm (7.9 inch)	196 mm (7.7 inch)	200 mm (7.9 inch)	208 mm (8.2 inch)	196 mm (7,7 inch)
Weight	142 g (5.0 oz.)	137 g (4.8 oz.)	136 g (4.8 oz.)	144 g (5.1 oz.)	133 g (4.7 oz.)
Connection	KaVo®	Sirona®	W&H®	NSK®	BienAir®
Powder consumption volume	4 g / min (air pressure on coupler 0.4 MPa / 4 bar)				
Coupling air pressure	0.25 - 0.4 MPa (36 - 58 psi, 2.5 - 4.0 bar, 2.5- 4.1 kgf/cm²)				
Air consumption volume	10 L / min (air pressure on coupler 0.4 MPa / 4 bar)				
Water flow volume	40 ml / min (water pressure on coolant 0.2 MPa / 2 bar)				

14 Explanation of symbols

	See Chapter 1 Explanation of warnings
	See Chapter 1 Explanation of warnings
	Product can be sterilized in a steam sterilizer (Autoclave)
	Can be used in thermal disinfectors
	CE-mark – Confirms that this product fulfills all applicable requirements with applicable EU legislation in force (e.g., Directive 93/42/EEG).
	Reference number
	Serial number
	Legal manufacturer
	Medical device
	Consult instructions for use
	Unique Device identifier

15 Warranty

MK-dent provides the end user a warranty for proper function, immaculate material and workmanship for a period of 24 months after purchasing. Relevant for this is the invoice date.

In case of justified complaints MK-dent carries out a free repair or a possible free replacement. This will be decided by MK-dent. Other claims of any kind, in particular damage compensation is excluded. In the event of default, gross negligence, or intent, this shall only apply unless there are compelling legal regulations.

MK-dent is not liable for defects and their consequences that have arisen whose arising may be due to natural wear, improper handling, improper cleaning, or maintenance, non-compliance with operating or manual instructions, calcination or corrosion, contaminated air and water supply or chemical or electrical influences that are unusual or not permitted according to MK-dent's instruction for use or to other manufacturer's instructions.

The warranty does usually not cover, rubber parts and the color fastness of plastic parts.

All liability is excluded if defects or their consequences arise because of interventions or modifications on the product by the end user or by a third party not authorized by MK-dent.

Warranty claims will only be accepted if the product is submitted with a proof of purchase in the form of an invoice or a copy of the delivery note. Dealer, purchase date, model and serial number must be clearly visible.