MyFlow

EN

Installation and Operating Instructions

CE 0297

2034100068L30

DÜRR DENTAL

1608V003

Contents

Important information

Product description

Operation

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Troubleshooting

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1 About this document

These installation and operating instructions form part of the unit.

If the instructions and information in these installation and operating instructions are not followed, Dürr Dental will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the unit.

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.

The following warning symbols are used:

General warning symbol

The warnings are structured as follows:

SIGNAL WORD

Description of the type and source of danger

Here you will find the possible consequences of ignoring the warning

› Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:

– **DANGER**
  Immediate danger of severe injury or death
– **WARNING**
  Possible danger of severe injury or death
– **CAUTION**
  Risk of minor injuries
– **NOTICE**
  Risk of extensive material/property damage

Other symbols

These symbols are used in the document and on or in the unit:

Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.

Take note of the accompanying documents.

CE labelling

Manufacturer

Dispose of correctly in accordance with EU Directive 2012/19/EU (WEEE).

Not sterile

Wear protective gloves.

Wear protective goggles.

Use a face mask.

Steam sterilise at 134 °C

Thermal disinfection and cleaning

1.2 Copyright information

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2 Safety

Dürr Dental has designed and constructed this device so that when used properly and for the intended purpose there is no danger to people or property. Nevertheless, residual risks can remain. You should therefore observe the following notes.

2.1 Intended use

Mobile powder-water jet handpiece for adaptation to the turbine coupling of a dental treatment unit. The device can be used to remove soft supragingival plaques and discolouration (pigments). The treatment spectrum ranges from periodontology and prophylaxis (dental cleaning) to cariology (conditioning of a fissure seal).

2.2 Improper usage

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damages resulting from this. In these cases the user/operator will bear the sole risk.

NOTICE
Device outage
Strongly abrasive jet materials can cause irreparable damage to the device.

› Strongly abrasive jet materials such as silicon carbide and aluminium oxide may not be used.

2.3 General safety information

› When operating this device always observe all guidelines, laws, and other rules and regulations that are applicable at the site of operation.
› Prior to each use, check condition of the device and make sure it is in perfect working order.
› Do not convert or modify the units.
› Observe the Installation and Operating Instructions.
› Make the Installation and Operating Instructions available to the person operating the device at all times.

2.4 Qualified personnel

Operation
Persons who operate the units must ensure safe and correct handling based on their training and knowledge.

› Instruct or have every user instructed in handling the unit.

Installation and repairs
› Installation, readjustments, alterations, upgrades and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

2.5 Only use genuine parts

› Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.
› Only use only genuine working parts and spare parts.

2.6 Transport

The original packaging provides optimum protection for the device during transport.
If required, original packaging for the unit can be ordered from Dürr Dental.

Dürr Dental does not accept any responsibility or liability for damage occurring during transport due to the use of incorrect packaging, even where the unit is still under guarantee.

› Only transport the device in its original packaging.
› Keep the packing materials out of the reach of children.

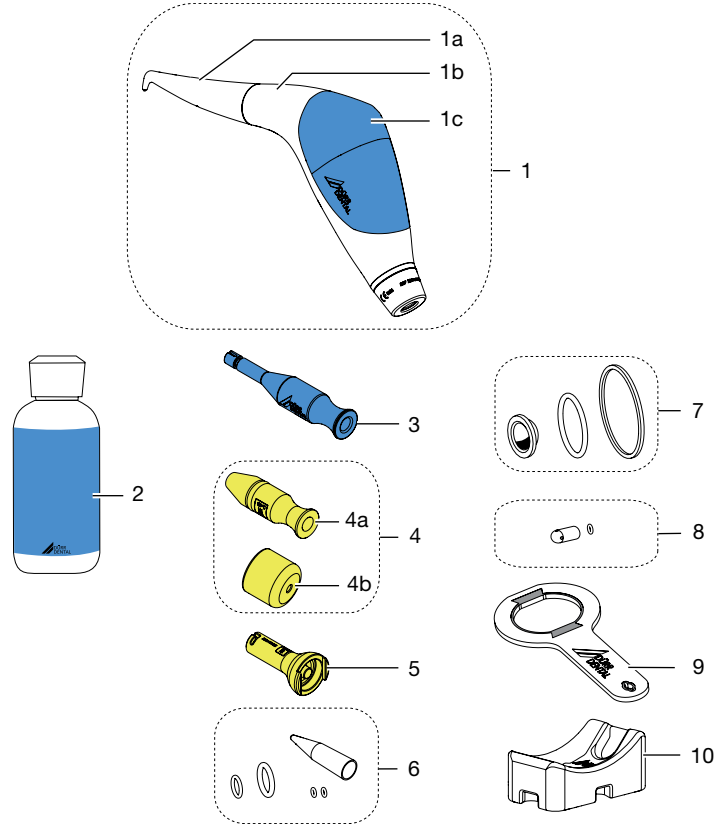
2.7 Disposal

Unit

The unit may be contaminated. Instruct the company disposing of the waste to take the relevant safety precautions in this case.

› Decontaminate potentially contaminated parts before disposing of them.
› Uncontaminated parts (e.g. electronics, plastic and metal parts etc.) should be disposed of in accordance with the local waste disposal regulations.
› If you have any questions concerning the correct disposal of parts, please contact your dental trade supplier.

3 Overview



1 Powder jet handpiece MyFlow Supra
1a Supra nozzle
1b Corpus
1c Powder container Supra (blue)
2 Lunos prophylaxis powder Gentle Clean
3 Rinse adapter for the nozzle (blue) for cleaning after ever treatment and following blockage
4 Rinse adapter set for use during reprocessing
4a Rinse adapter for nozzle (yellow) for use during reprocessing
4b Rinse adapter for corpus (yellow) for use during reprocessing
5 Function tool
6 O-ring set for corpus
7 O-ring set for powder container
8 O-ring and suction nozzle for the powder-air line
9 Combination wrench
10 Rest for powder container

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3.1 Scope of delivery

The following items are included in the scope of delivery (possible variations due to country-specific requirements and/or import regulations):

Scope of delivery powder jet handpiece MyFlow with "Supra nozzle"

for the versions

MyFlow 2034900050
Set: Supra / adapter: KaVo

MyFlow 2034900051
Set: Supra / adapter: Sirona

MyFlow 2034900052
Set: Supra / adapter: W&H

MyFlow 2034900053
Set: Supra / adapter: Bien Air

MyFlow 2034900054
Set: Supra / adapter: NSK

– Powder jet handpiece MyFlow Supra
– Rinse adapter for nozzle (blue)
– Rest for powder container
– O-ring set for corpus
– O-ring set for powder container
– Combination wrench
– Function tool
– Lunos prophylaxis powder Gentle Clean
– Installation and operating instructions
– Quick-start instructions

3.2 Special accessories

The following optional items can be used with the device:

Supra nozzle. 2034440000
Rinse adapter set
(yellow, manual reprocessing) 2034100155
Prophylaxis Cannula (qty 4) A070005850

3.3 Disposable materials

The following materials are consumed during operation of the device and must be ordered separately:

Lunos prophylaxis powder "Gentle Clean Neutral" nozzle CPZ610A2250
Lunos prophylaxis powder Gentle Clean Orange (4 x 180 g) CPZ620A2250
Lunos prophylaxis powder "Gentle Clean Spearmint" (4 x 180 g). . . .CPZ630A2250

3.4 Wear parts and spare parts

The following working parts need to be changed at regular intervals (refer to the "Maintenance" section):

Suction nozzle and o-ring for the powder-air line (set) 2034100148
O-ring set for corpus
with thread-on assistance 2034100160
O-ring set for powder container. . . 2034100150
Rinse adapter for nozzle 2034100161
Combination wrench. 2034100152
Function tool. 2034100154
Powder container Supra (qty. 2) . . 2034100104
Rest for powder container. 2034100147

Information on spare parts can be found on the website portal for authorised specialist dealers under: www.duerrdental.net.

4 Technical data

General technical data of device		
Dimensions (W x H x L)	mm	40 x 120 x 210
Weight, empty	g	200
Water pressure	kPa (bar)	70 - 200 (0.7 - 2)
max. water throughflow volume at 1 bar	ml/min	70
Air pressure	kPa (bar)	250 - 400 (2.5 - 4)
Air throughflow volume at 3.5 bar	Ln/min	10 - 20
Chamber volume powder container	cm^3	40
Filling volume powder container	g	max. 18

Noise level		
Device in operation	dB(A)	76*

* According to EN ISO 1680 (airborne noise emission); measured in noise-insulated room.

Classification		
Medical Devices Directive (93/42/EU)		Class IIa

Ambient conditions during storage and transport		
Temperature	°C	-40 to +60
Relative humidity	%	10 % to 90 %

Please refer to the labels on the packaging padding.

Ambient conditions during operation		
Temperature	°C	10 to 40
Relative humidity	%	20 to max. 75
Air pressure	hPa	700 - 1060

Turbine connections on treatment units
Sirona® R/F coupling
KaVo® MULTIflex Lux® Coupling
W&H® Roto Quick Lux® Coupling
NSK® MachLite / Phateleus Coupling
Bien-Air® Dental Unifix L® Coupling

® Registered trademarks of the corresponding company.

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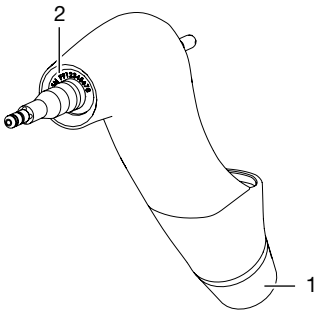
4.1 Type plate

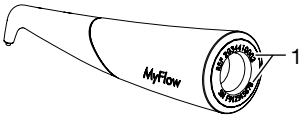
The type plate is located on the device packaging.

REF Order number

SN Serial number



1 Order number
2 Serial number



1 Order number and serial number

4.2 ID number powder container

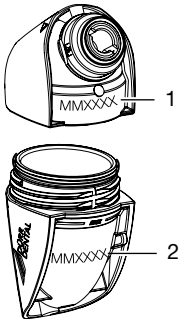
The identical ID number is located on the top and bottom parts of the powder container. The two parts belong together.

The ID number serves to document the reprocessing.

These parts may no longer be used after a certain number of reprocessing cycles / the end of the life span (see "13.1 Maintenance schedule").

The ID number is made up of the following marking: MMXXXX

MM	Date of manufacture: year and month
XXXX	Consecutive alphanumerical ID number



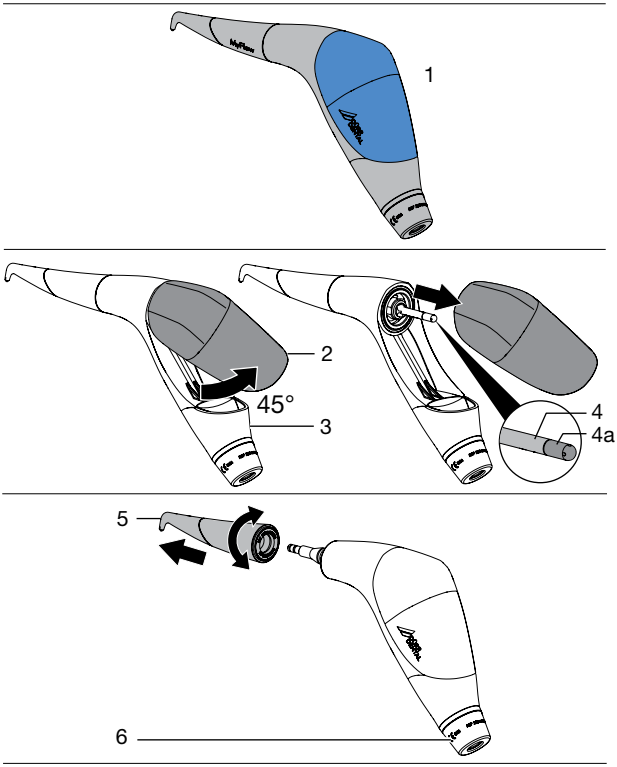
1 ID number powder container upper part
2 ID number powder container lower part

WARNING
Danger of injury
Exceeding the specified life span can result in defects, e.g. micro-fissures. Damaged powder containers can burst.
› Replace the powder container.

4.3 Conformity assessment

This device has been subjected to conformity acceptance testing in accordance with the current relevant European Union guidelines. This equipment conforms to all relevant requirements.

5 Operation



1 Powder jet handpiece MyFlow Supra
2 Powder container Supra (blue)
3 Corpus
4 Powder-air line
4a Suction nozzle on the powder-air line
5 Supra nozzle
6 Connection with an integrated coupling adapter for the turbine connection (treatment unit)

The powder jet handpiece MyFlow serves the removal of soft supragingival plaques and discolouration.

The powder jet handpiece is operated supragingivally with prophylaxis powders authorised for use in this area (e.g. "Gentle Clean Neutral" from Dürr Dental) the Supra powder container and the Supra nozzle.

The powder container can be changed quickly and easily via a a bayonet catch; the nozzle is changed equally easily using a push-fit fastening.

The powder jet handpiece MyFlow is available for various turbine couplings. The models are differentiated by the various integrated coupling adapters.

6 Indications

We recommend using the powder jet handpiece MyFlow Supra for removing soft supragingival plaques and discolouration:

- Before fluoride treatment
- Before tooth whitening
- Before applying seals
- Before determining the colour
- For orthodontics patients
- For preparing surfaces before the adhesion and cementing of inlays, onlays, crowns and facings
- For the preparation of surfaces prior to placing composite restorations
- Before the adhesion of orthodontic brackets

7 Contra indications

WARNING
Organ disorders
With serious conditions such as cardiovascular or renal impairment
- Do not treat patients with the powder water jet handpiece.

WARNING
Breathing difficulties
The powder water air mixture can cause respiratory problems in patients suffering from respiratory disorders.
- Do not treat patients with the powder water jet handpiece.

WARNING
The development of emphysema
Do not expose soft tissue to the powder jet; this could result in the formation of emphysema in the tissue.
- Do not direct the nozzle tip directly on the gums, the tongue or in the gum pockets.

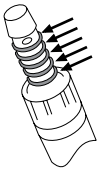
Comply with the specifications of the prophylaxis powder operating instructions. These may contain further safety instructions.

8 Preparing the device for treatment

8.1 Check the turbine connection

› Check the o-rings in the turbine coupling for their correct state.

Defective o-rings can cause damage to the device. Replace the o-rings if necessary.



› The powder jet handpiece is connected to the turbine connection of the treatment unit via an integrated adapter.

Established turbine connection (see "4 Technical data").

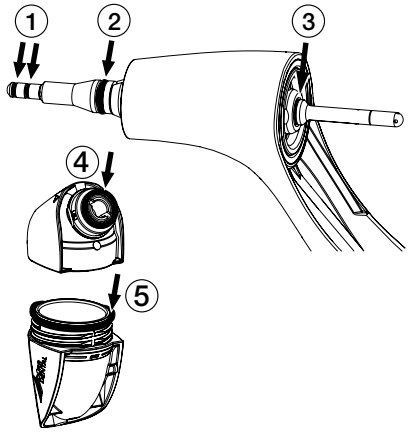
NOTICE
Damage to the device

Following use of an unsuitable turbine connection.

› Only operate the device using the correct turbine connection.

8.2 Check the o-rings

› Check the o-rings for damage before every treatment. Replace if necessary (see "13.2 Replace the o-rings on the corpus", or "13.7 Replace the dome valve and o-rings on the powder container").

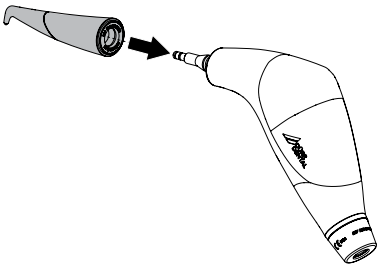


8.3 Connect the handpiece

– The treatment unit must be de-pressurised. Depressurise if necessary.
– Do NOT actuate the turbine foot switch.
– Should the turbine have a light, it must be switched off.

› The powder jet handpiece should be cleaned, disinfected and sterilised before first use and after every treatment (see "12 Reprocessing").

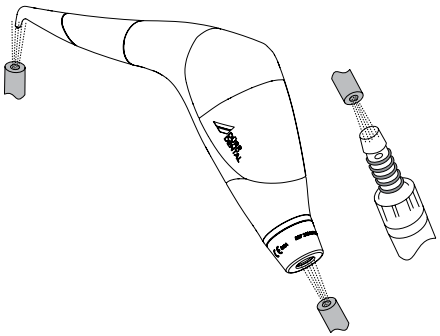
› Connect the nozzle to the corpus.



NOTICE
Danger of blockage

The powder jet handpiece and the turbine coupling must be dry before every use. Residual moisture can result in blockage of the air-water line.

› Blow the powder jet handpiece and the turbine coupling dry if required.



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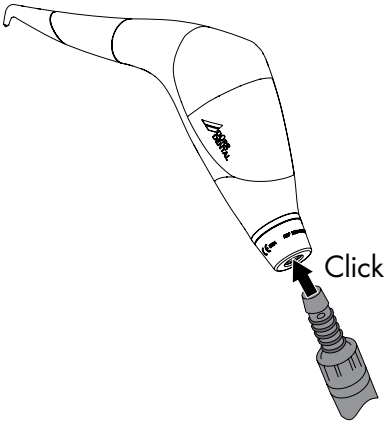
› Insert the turbine coupling in the powder jet handpiece coupling adapter.



Operate the device with an empty powder container for c. 10 seconds to remove any residual moisture in the powder container.

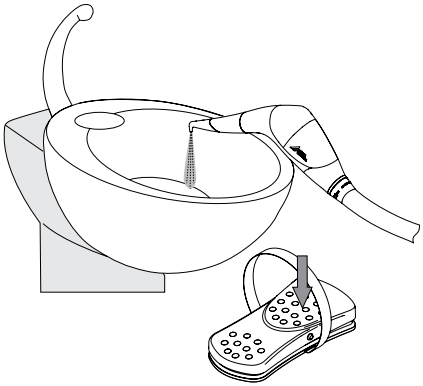
8.4 Set the water throughflow volume and air pressure

Always operate the powder handpiece with water flow.

Optimal treatment is only possible using powder, air and water.

It is easier to set the water throughflow volume when the powder container is empty. It is best to do this before first use.

› The nozzle in the powder jet handpiece is to be held in the damp spittoon with a clearance of c. 20 cm.



› If necessary, set the water flow volume on the turbine connection as required so as to ensure an equal, fine water flow.

› Set the air pressure on the treatment unit. Do not exceed the max. air pressure.

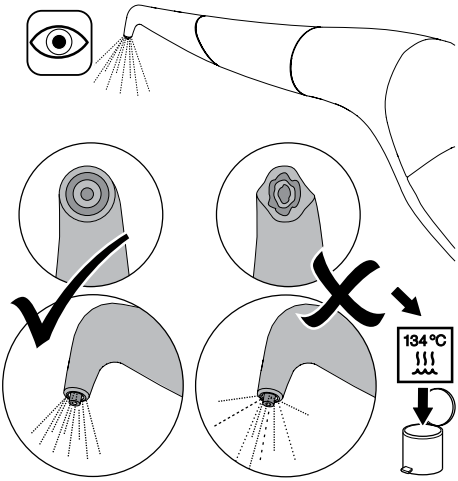
The treatment outcome varies depending on the setting of the air pressure:

The higher the air pressure, the greater the cleaning performance and the lower the polishing effect.

The lower the air pressure, the lower the cleaning performance and the lower the polishing effect.

8.5 Check the jet formation

› Check whether the nozzle openings are situated in a concentric pattern and that the jet pattern is concentric. An irregular jet pattern can be caused by blockage of the line. Remedy this if necessary.



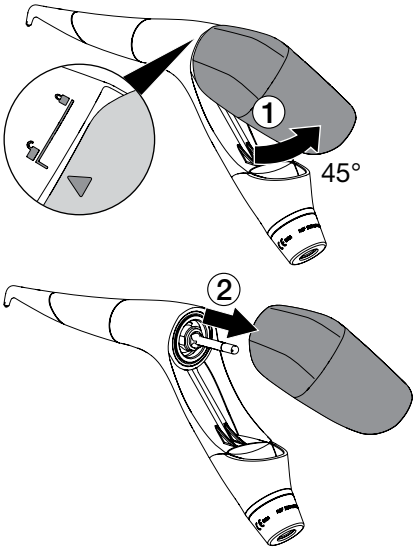
8.6 Fill the powder container

After removing the powder jet handpiece from the CD, insert the empty powder container.

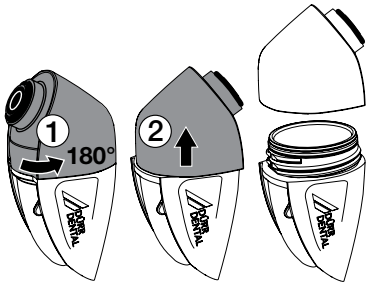
Activate the device x 1 with an empty powder container. This enables removal of the residual moisture in the powder-air line.

Remove and open the powder container

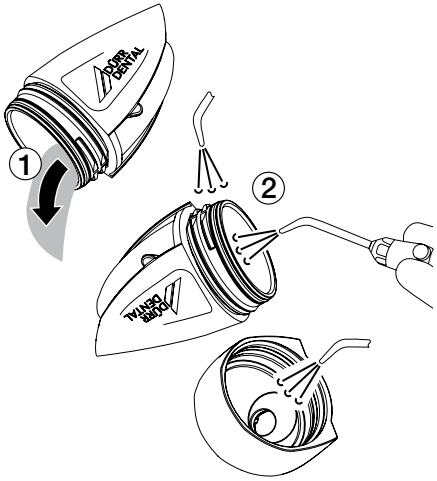
› Pivot the powder container through 45° then remove.



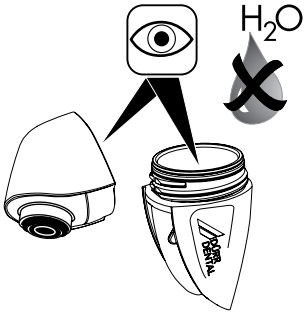
› Rotate the upper part of the powder container through 180° then remove.



› Remove any residual powder. Blow out the upper and lower parts of the container with compressed air.



› Check whether the powder container is dry.



› Check the o-rings for damage.

› Check the dome valve for damage (see "13.6 Check the dome valve").

WARNING
Danger of injury
Damaged powder containers can burst.
› Replace damages powder containers.

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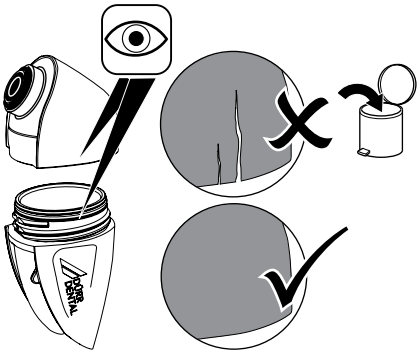
› Check the powder container for micro-fissures and use a new powder container if necessary.



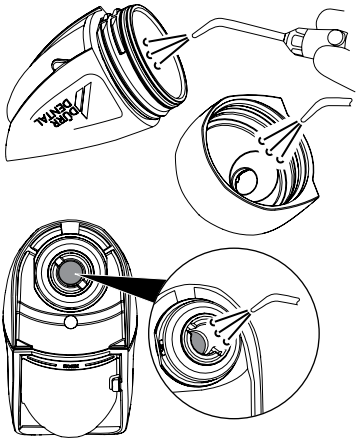
If a part of the powder container is defective, it is necessary to change both parts. Both parts have the same ID number (see "4.2 ID number powder container").

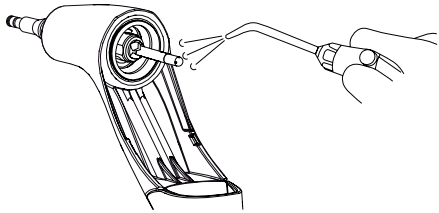
Fill the powder container

NOTICE
Moisture can cause the powder to clump together

› Check that the powder container is dry before filling it. Blow dry if necessary

› Check that the individual components are free of powder. Blow them free with compressed air if necessary. This helps to avoid blockages.

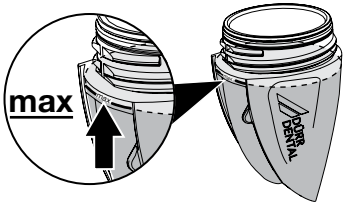


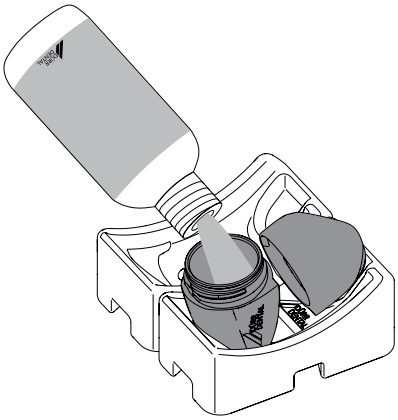


› Fill the jet powder in the lower part of the container.

Fill slowly to prevent the development of dust.

Comply with the maximum filling quantities. Do not exceed the max. filling quantities.

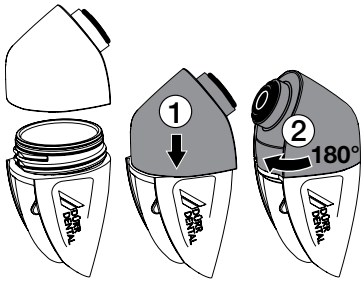




The best results are achieved when the **powder container is filled to the maximum**.

› Before screwing tight, remove any residual powder on the thread of the lower part of the container and on the bayonet catch of the sealing cap.

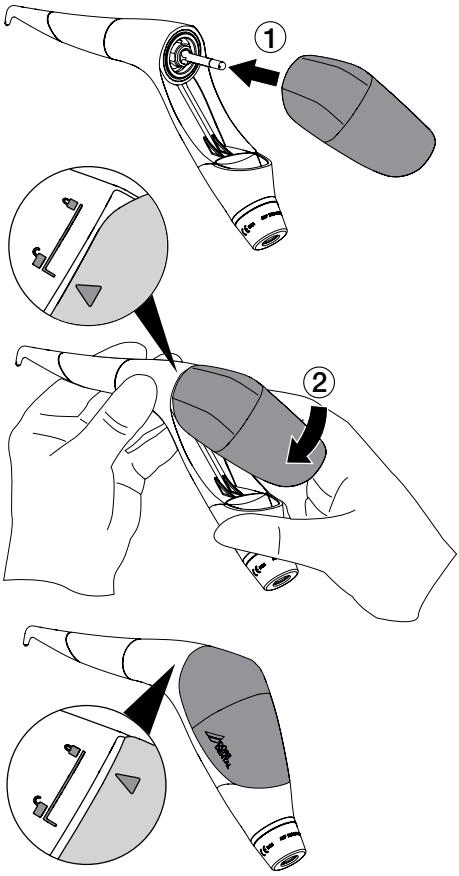
› Close the powder container. Ensure that the powder container has been closed correctly to prevent powder from escaping.



› Close the powder container to protect the powder from moisture.

Insert the powder container

› Slide the powder container onto the powder-air line, then turn until its end position has been reached. Consult the marking.

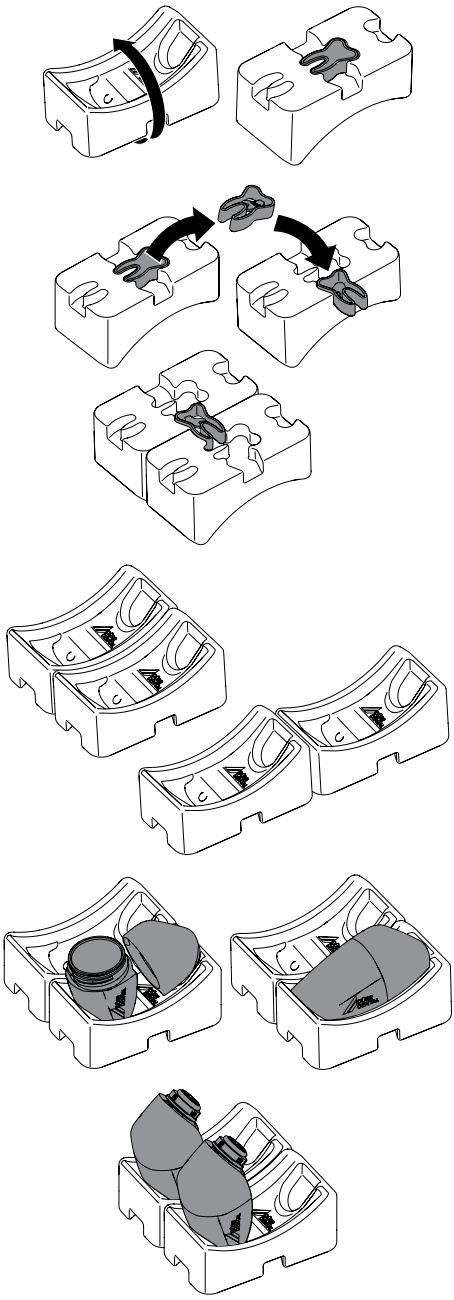


8.7 Possible applications of the powder container rest

Preparations for the treatment and "storage" can be simplified using a number of rests for the powder container (combined if required).

The rests are combined using the connection piece in the form of a tooth on the underside of the rest.

› Remove the tooth and insert as required.



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9 Precautionary measures

RKI recommendations:

Wear protective gloves.

Wear protective goggles.

Use a face mask.

WARNING
Risk of infection from contaminated products

Danger of cross contamination

› Reprocess the product correctly and promptly before its first use and after every subsequent use.

WARNING
Eye injuries

The powder flow can enter the eye by mistake.

› The operator, assistant and the patient should wear eye protection during the treatment.

› Never point the nozzle at a person either during or after treatment.

WARNING
Danger of infection!

To minimise the danger of infection and to avoid the inhalation of aerosols and powder

› Wear mouth and nose protection

NOTICE
Danger of soiling

The treatment can damage the patient's contact lenses or glasses.

› Remove contact lenses / glasses during the treatment.

NOTICE
Danger of soiling

The patient clothing can become soiled.

› Cover the clothing with a cloth during treatment.

10 Treatment with the Supra handpiece

RKI recommendations:

Wear protective gloves.

Wear protective goggles.

Use a face mask.

The device should be maintained at room temperature during treatment. Do not use a warm device, e.g. taken directly from the steam steriliser after reprocessing.

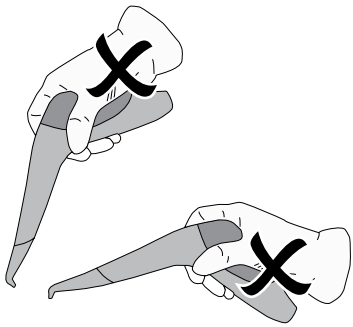
Following blockages, see "13.4 Free from blockages".

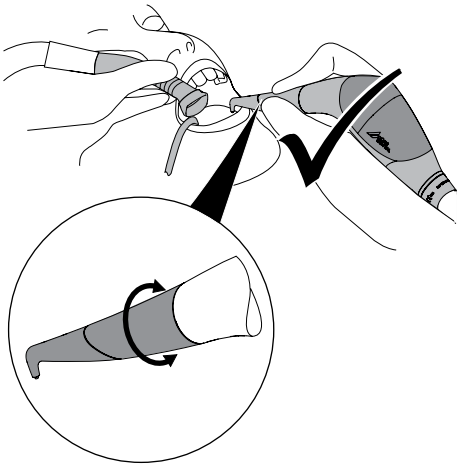
– Cover the patient's lips with Vaseline.
– Perform mucous membrane antisepsis for patients with an increased risk of infection.

› Position the small saliva cannula to suck from under the tongue.

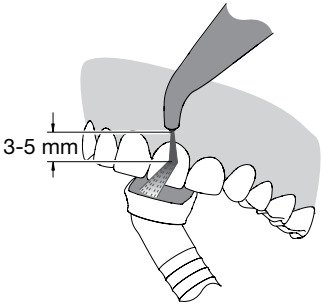
› Aspirate the impacting powder stream using the prophylaxis cannula or the large universal cannula.

› The handpiece and the suction cannula should be guided by the same person. Only in this way is it possible to ensure the best guidance of the suction cannula to the tip of the nozzle.

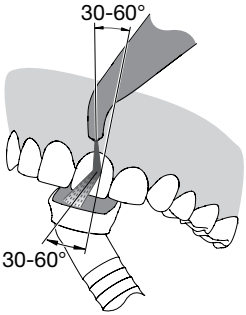




› Actuate the foot switch and remove the plaque with circular motions.
Move the tip of the nozzle in circular motions with a clearance of 3 - 5 mm from the tooth surface.



› Spray the tooth from the gum pocket to the cutting edge with an angle of 30 to 60 degrees.

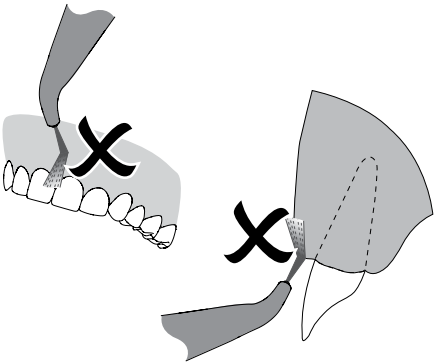


EN

WARNING
The development of emphysema
Do not expose soft tissue to the powder jet; this could result in the formation of emphysema in the tissue.
› Do not direct the nozzle tip directly on the gums, the tongue or in the gum pockets.

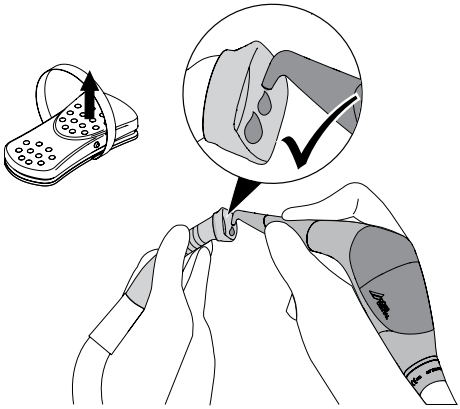
NOTICE
Damaging restorations
The jet powder could cause damage to restorations such as fillings, crowns and bridges
› Do not direct the powder flow towards restorations.

› The powder-air jet is very strong. It must not be misdirected otherwise it could damage the gums or result in the development of an emphysema (air blown into the blood circulation).



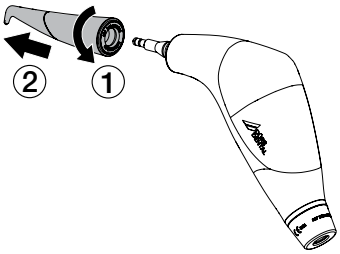
10.1 Precautionary measures after treatment

› The powder-air jet keeps flowing or a few seconds after the foot switch has been released.
Do not draw the handpiece over the face or clothes of the patient during this time.
We recommend retaining the nozzle tip in the suction cannula as long as it is in the patient mouth and until the spray has stopped.

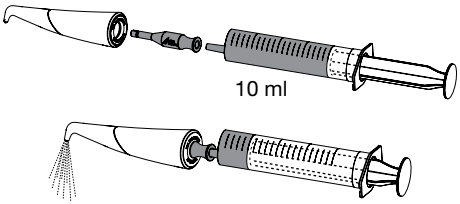


11 After every treatment

› Remove the nozzle with a slight twist movement.



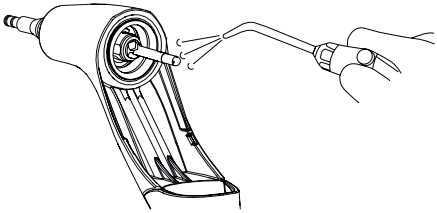
› Place the rinse adaptor (blue) on the nozzle and rinse with a 10-ml disposable pipette.



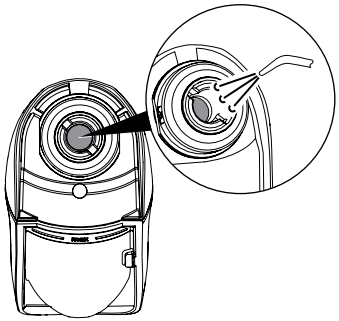
› Following blockages (see "13.4 Free from blockages").

› Blow the nozzle dry and clean.

› Blow the suction nozzle dry and clean.

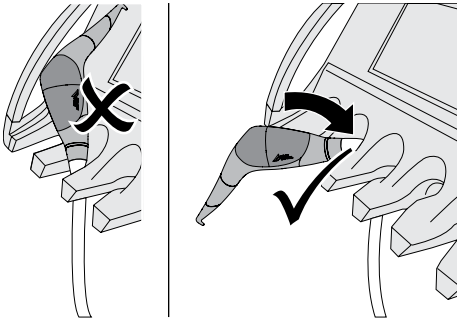


› Blow the dome valve in the powder container dry and clean.



11.1 Place down the handpiece

› Insert the handpiece in the treatment unit sheath so that the outlet aperture is facing downwards.



EN

12 Reprocessing

12.1 Risk analysis and categorisation

A risk analysis and categorisation of medical products often used in dentistry must be performed before their reprocessing by the operator. Comply with all national directives standards and specifications such as e. g. the "Recommendations from the Commission for Hospital Hygiene and Infection Prevention".

Accessories of the medical product are also subject to reprocessing.

Classification recommendation given intended use of the product: **semi-critical B to critical B**

Semi-critical medical product:
A medical product which comes into contact with mucous membrane or pathologically affected skin.

Critical medical product:
a medical product which also comes into contact with injured skin and blood.

12.2 Reprocessing procedure in accordance with EN ISO 17664

The process of reprocessing (cleaning, disinfection, drying and sterilisation) after each patient treatment is set according to the reprocessing procedure established by EN ISO 17664.

Important information!

The reprocessing notes in accordance with EN 17664 have been independently tested by Dürr Dental for the preparation of the device and its components and their reuse.

The person conducing the reprocessing is responsible for ensuring the reprocessing performed using the equipment, materials and personnel achieves the desired results. This requires validation and routine monitoring of the reprocessing process. Any negative consequences resulting from deviation from these instructions by the person performing the reprocessing are the responsibility of the member of staff performing the reprocessing.Frequent reprocessing has little effect on the device components. The end of the product life cycle is especially influenced by the amount of wear and tear or damage resulting from its use.

The use of soiled, contaminated and damaged components is at the sole responsibility of the person performing the reprocessing and the operator.

The reprocessing procedure was validated as follows:

Precleaning

ID 213 (Dürr Dental), 2%, 15 min.

Manual cleaning

ID 213 (Dürr Dental), 2%, 15 min.

Manual disinfection

ID 213 (Dürr Dental), 2%, 15 min.

Automatic cleaning and disinfection

Was performed in accordance with EN ISO 15883 with tested efficacy.

– Preclenaing with ID 213 (Dürr Dental), 2%, 15 min.
– Neodisher MediClean, RDG: G 7836 CD (Miele), Programme: D-V-MEDICLEAN at 90 °C (5 min)

Steam sterilization

Performed in accordance with EN ISO 17665 (valid IQ/OQ and product-specific performance appraisal PQ)).

Sterilise the parts for sterilisation (e. g. 20 min. at 121 °C, 4 min. at 132 °C or 4 min. at 134 °C).

EN

12.3 General information

NOTICE
Damage to the device
Care products containing oil will damage the device.
› The MyFlow powder jet handpiece must not be maintained with oil or a care system.

› Comply with all national directives, standards and specifications for the cleaning, disinfection and sterilisation of medical products as well as the specific specifications for dental practices and clinics.
› Comply with the specifications in "12.6 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying" and "12.7 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying" when selecting the cleaning and disinfectant agents to be used.
› Comply with the concentration, temperature, residence time and post-rinsing specifications issued by the manufacturer of the cleaning and disinfectant agent.
› Do not use any cleaning and disinfectant agents which contain chlorine, solvents, strong bases (pH >11) and oxidising agents.
› Use non-foaming, non-fixing and aldehyde-free cleaning and disinfectant agents.
› Do not use any rinse aid (danger of toxic residue on the components).
› Only use freshly-produced solutions.
› Use only distilled or de-ionised water with a low bacteria count (≤ drinking water quality).
› Use clean, dry, oil and particle-free compressed air.
› Do not exceed temperatures of 138 °C.
› Subject all the devices used (ultrasonic bath, cleaning and disinfection device (CD), sealing device, steam steriliser) to regular maintenance and inspections.

12.4 Preparation at the operating location

RKI recommendations:

Wear protective gloves.

Wear protective goggles.

Use a face mask.

WARNING
Risk of infection from contaminated products
Danger of cross contamination
› Reprocess the product correctly and promptly before its first use and after every subsequent use.

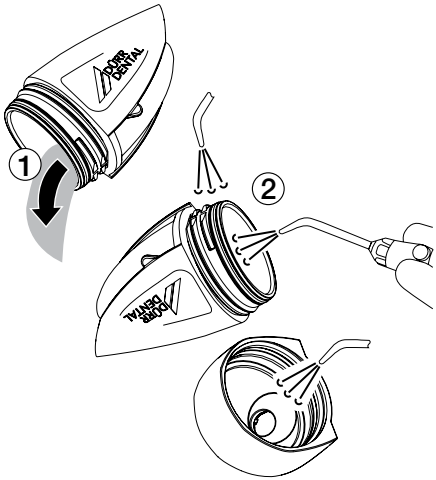
› Transport the device from the treatment location to the reprocessing location in such a way as to protect against contamination.
› Remove course organic soiling with a disinfectant cloth.

12.5 Pre-cleaning

› Remove any blood residue or coarse organic soiling immediately using fresh and moistened cellulose.
› Pre-clean the device max. 15 minute after use.

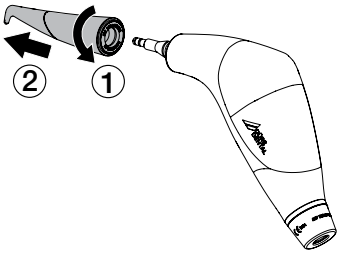
Prepare the powder jet handpiece

› Remove the powder container, open it and empty if necessary.



› Remove powder residue from the corpus and the nozzle.

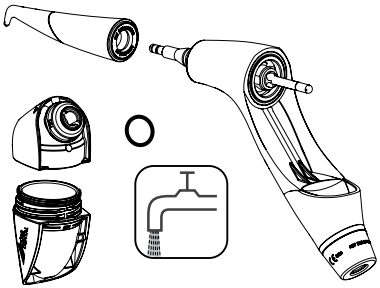
› Remove the nozzle with a slight twist movement.



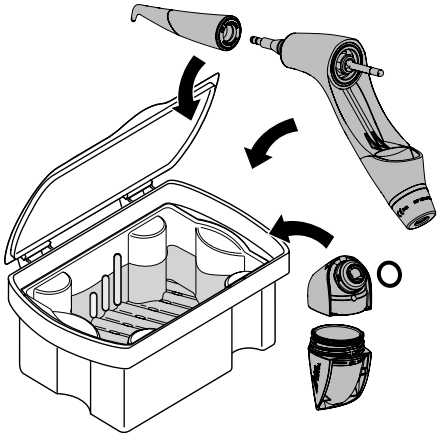
› Open the powder container.
› Remove the o-ring from upper part of the powder container.

Pre-cleaning the powder jet handpiece

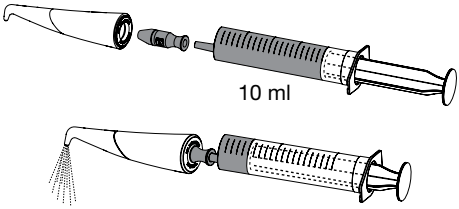
› Rinse all components under water for min. 1 minute (temperature < 35 °C).



› Insert all the individual components in a cleaning and disinfecting bath (non-fixing, aldehyde-free) for the foreseen residence time (max. 12 hours) so that they are all covered. See "12.3 General information".



› In the disinfectant bath, place the rinse adaptor (yellow) on the nozzle and rinse (min. three times) with a 10-ml disposable pipette.



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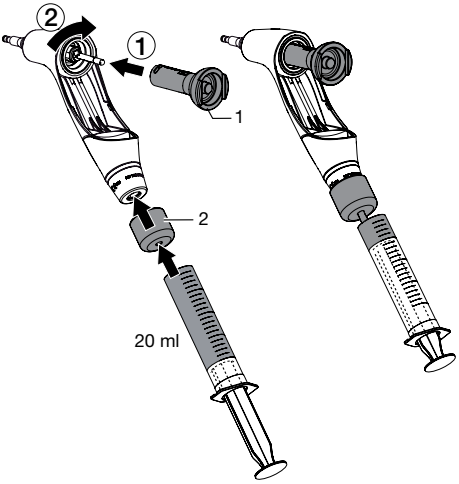
› Place the function tool (1) on the bayonet catch for the powder container and place them in the disinfectant bath.

Place the yellow rinse adaptor (2) for the corpus and rinse through at least 3 times using a 20-ml disposable pipette.



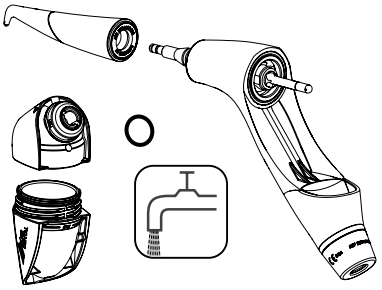
1 Function tool
2 Rinse adapter for the corpus

› Brush all exterior and interior surfaces completely with a soft clean brush.
› Remove all rinse adaptors.

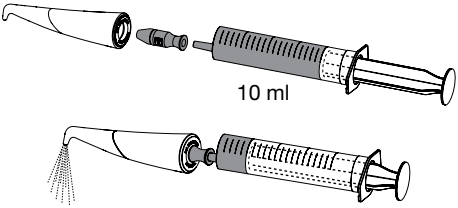
Rinse the powder jet handpiece

After the residence time prescribed by the manufacturer:

› Rinse all components under water for min. 1 minute (temperature < 35 °C).

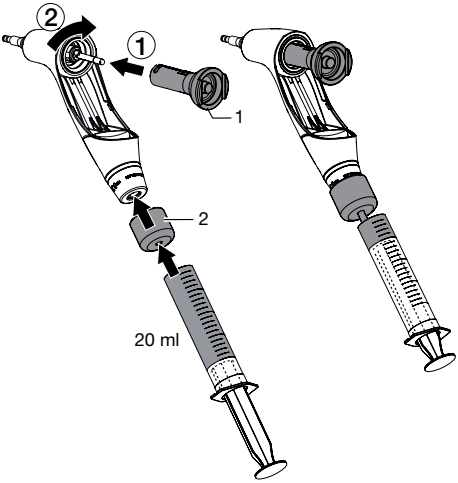


› Place the yellow rinse adaptor on the nozzle and rinse with water from a 10-ml disposable pipette at least three times.



› Place the function tool (1) on the bayonet catch for the powder container.

Place on the yellow rinse adaptor (2) for the corpus and rinse through with water at least 3 times using a 20-ml disposable pipette.



1 Function tool
2 Rinse adapter for the corpus

12.6 Manual cleaning, intermediate rinsing, disinfection, final rinse, drying

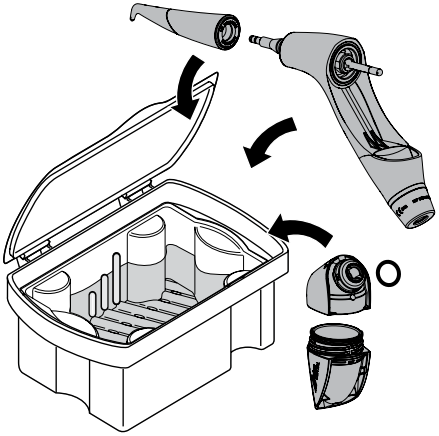
A combined cleaning and disinfectant agent is required for manual cleaning and disinfection. It must have the following properties:

– Checked, if necessary fully-viricidal effectiveness (VAH / CEN)
– Material compatibility with the product

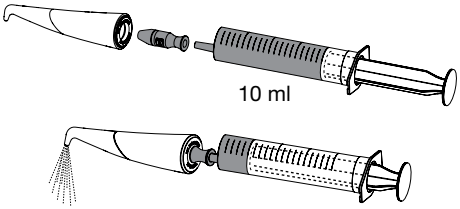
For further information, see: "12.3 General information".

Cleaning

› Place all the individual components in a cleaning and disinfecting bath (non-fixing, aldehyde-free) for the foreseen residence time (max. 12 hours) so that they are all covered. See "12.3 General information".

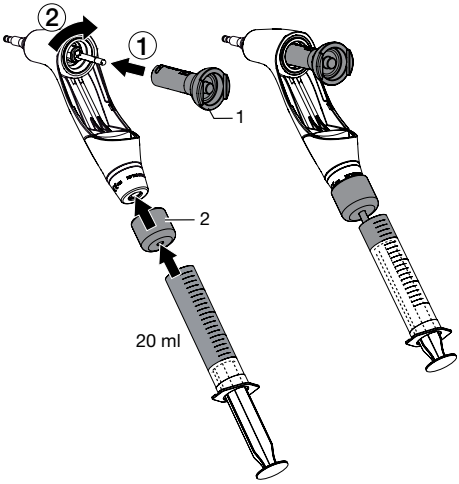


› In the disinfectant bath, place the rinse adaptor (yellow) on the nozzle and rinse (min. three times) with a 10-ml disposable pipette.



› Place the function tool (1) on the bayonet catch for the powder container and place them in the disinfectant bath.

Place the yellow rinse adaptor (2) for the corpus and rinse through at least 3 times using a 20-ml disposable pipette.



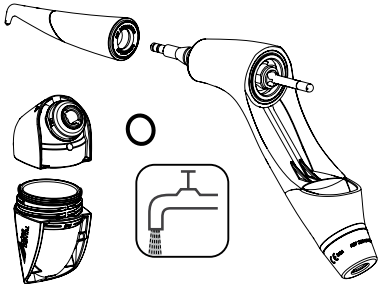
1 Function tool
2 Rinse adapter for the corpus

› Brush all exterior and interior surfaces completely with a soft hygienic brush.
› Remove all rinse adaptors.
› Comply with the residence times of the cleaning and disinfectant agent.

Intermediate rinsing

After the residence time prescribed by the manufacturer:

› Rinse all components under water for min. 1 minute (temperature < 35 °C).



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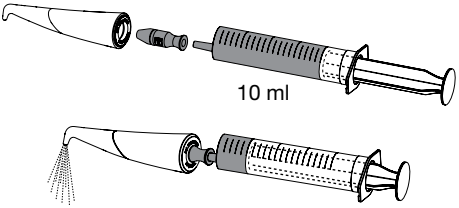
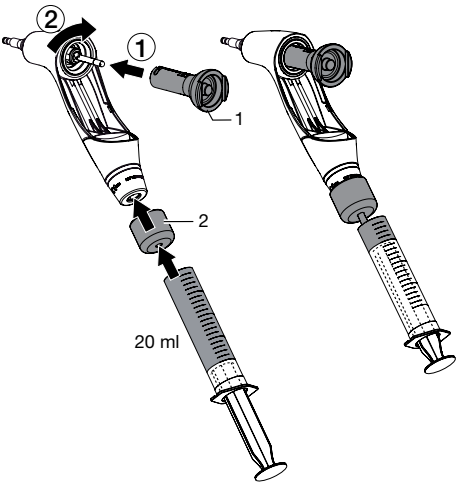
› Place the yellow rinse adaptor on the nozzle and rinse with water from a 10-ml disposable pipette at least three times.



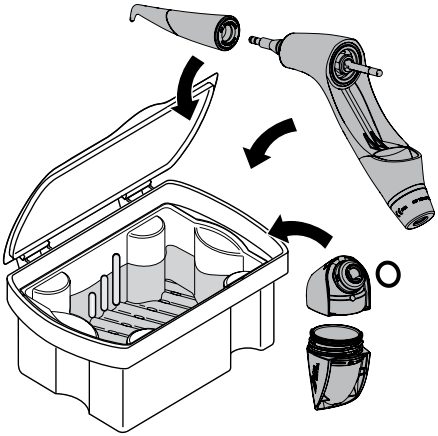
› Place the function tool (1) on the bayonet catch for the powder container.
Place on the yellow rinse adaptor (2) for the corpus and rinse through with water at least 3 times using a 20-ml disposable pipette.



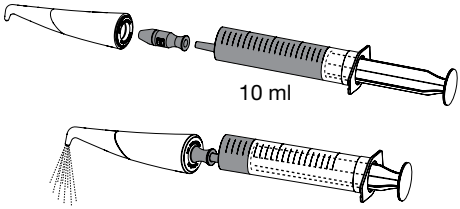
1 Function tool
2 Rinse adapter for the corpus

Disinfection

› Place all the individual components in a cleaning and disinfecting bath (non-fixing, aldehyde-free) for the foreseen residence time (max. 12 hours) so that they are all covered. See "12.3 General information".

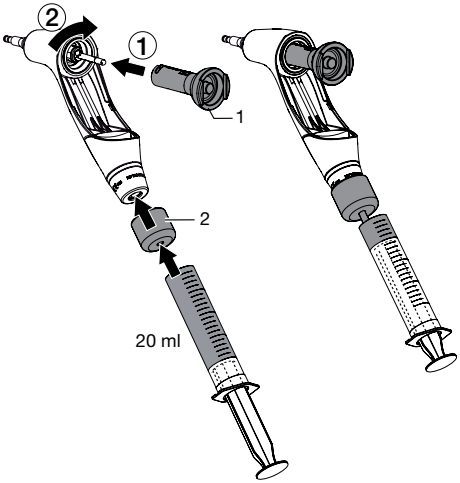


› In the disinfectant bath, place the rinse adaptor (yellow) on the nozzle and rinse (min. three times) with a 10-ml disposable pipette.



› Place the function tool (1) on the bayonet catch for the powder container and place them in the disinfectant bath.

Place the yellow rinse adaptor (2) for the corpus and rinse through at least 3 times using a 20-ml disposable pipette.

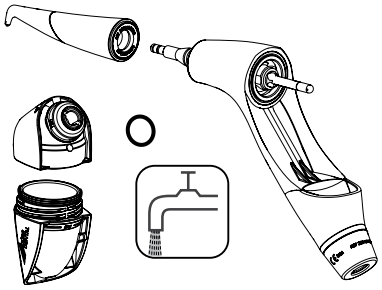


1 Function tool
2 Rinse adapter for the corpus

› Brush all exterior and interior surfaces completely with a soft hygienic brush.
› Remove all rinse adaptors.
› Comply with the residence times of the cleaning and disinfectant agent.

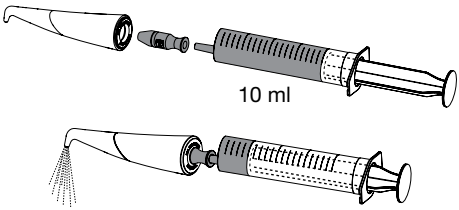
Final rinse

› Rinse all components under water for min. 1 minute (temperature < 35 °C).



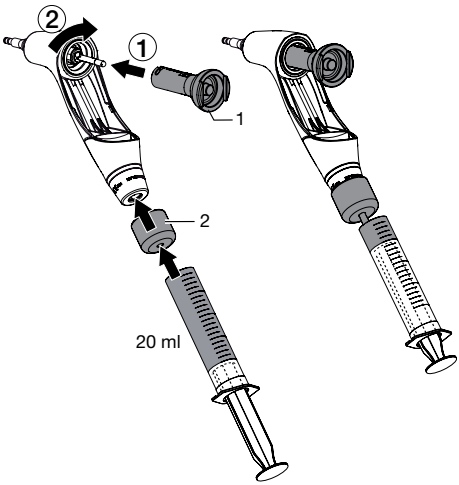
› Place in a water bath (filled with water) for 1 minute.

› Place the yellow rinse adaptor on the nozzle and rinse with water from a 10-ml disposable pipette at least five times.



› Place the function tool (1) on the bayonet catch for the powder container.

Place on the yellow rinse adaptor for the corpus (2) and rinse through with water at least five times using a 20-ml disposable pipette.



1 Function tool
2 Rinse adapter for the corpus

Drying

› Blow dry the components with compressed air.
› If necessary, re-dry at a clean location using a hygienic, lint-free cloth.

12.7 Automatic cleaning, intermediate rinsing, disinfection, final rinse, drying

Selection of the washer-disinfector

Automatic cleaning and disinfection requires a cleaning and disinfectant device (CD) with the following properties and validated processes:

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– Corresponds to and tested in accordance with EN ISO 15883
– Inspected program for thermal disinfection (A0 value > 3000 or min. 5 min at 90 °C)

Programme is suitable for the components and provides sufficient rinsing cycles.

For further information, see: "12.3 General information".

Selection of the cleaning agent automatic

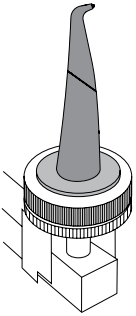
The following properties are required:

– Material compatibility with the product
– Corresponds with the manufacturer's specifications of the CD

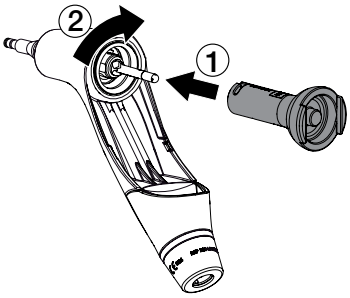
For further information, see: "12.3 General information".

Cleaning and disinfection

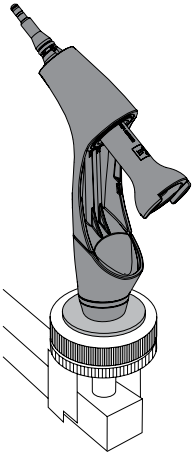
› Place the nozzle on the special bracket for transfer instruments (e.g. Miele: ADS 3 c. 22 mm Ø) in the CD.



› Place the function tool on the bayonet catch for the powder container and rotate in.



› Place the corpus on the special bracket for transfer instruments (e.g. Miele: ADS 3 c. 22 mm Ø) in the CD.



› Insert the upper and lower part of the powder container and insert the black o-ring in the small parts basket. The parts should not come into contact with each other and point downwards. Avoid unwashed areas.
› Fix components with a suitable fixing from the CD.

12.8 Check for function

› After the end of the cleaning and disinfection cycle, check the components for any residual soiling and moisture. If necessary, repeat the cycle.
› If necessary, replace any damaged parts.

Operate the device with an empty powder container for c. 10 seconds to remove any residual moisture in the powder container.

› The parts should be packaged as soon as possible after drying and checking.

12.9 Steam sterilising

Packing

CAUTION
Endangering the sterilisation success

The fitted components are not reached by the steam and as such are not sterilised.

› Do not fit the components before packaging.

For packaging of the components, only use transparent paper film sterilisation packaging that is approved for use in steam sterilisation according to the manufacturer's instructions. This includes:

– Temperature resistance up to 138°C
– Standards DIN EN ISO 11607-1/2
– The applicable sections of the standard series DIN EN 868

The sterilisation packaging must be sufficiently large. Once it is loaded, the sterilisation packaging may not be under any strain.

Steam sterilising

WARNING
Incorrect sterilisation reduces effectiveness and can damage the product.

› Only steam sterilisation is permitted.
› Comply with the specified process parameters.
› Comply with the manufacturer‘s instructions regarding use of the steam steriliser.
› Do not use any other methods.

Requirements placed on the steam steriliser:

– Suitable programme for the products listed (e. g. with hollow bodies, fractionated vacuum procedure in three vacuum steps)
– Sufficient product drying
– Validated process in accordance with DIN EN ISO 17665 (valid IQ/OQ and product-specific performance appraisal (PQ)

Perform the following steps:

› Sterilise the parts for sterilisation (e. g. 20 min. at 121 °C, 4 min. at 132 °C or 4 min. at 134 °C).
Do not exceed 138 °C.

Marking

› Mark the packaged, treated medical product in such a way as to ensure safe application.

12.10 Issue clearance for the parts for sterilisation

The reprocessing of the medical products ends with the documented clearance for storage and renewed use.

› Document the clearance of the medical product after reprocessing.

12.11 Storing parts for sterilisation

› Comply with the stated storage conditions:
– Store the parts protected against contamination
– Dust-protected, e.g. in a locked cabinet
– Protected against moisture
– Protected against excessive temperature fluctuations
– Protected against damage

Packaging for a sterile medical product can suffer damage as a result of a particular incident and the passage of time. Potential external contamination of the sterile barrier system should be taken into account in terms of aseptic preparation when establishing the storage conditions.

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13 Maintenance

To ensure proper operation and maintain the service life of the appliance, it is necessary to carry out cleaning and maintenance work diligently.

Inadequately or not carried out maintenance work can cause premature defects that are not covered by the warranty.

Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

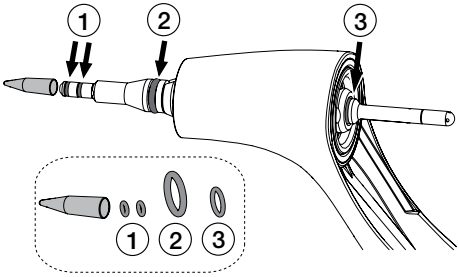
13.1 Maintenance schedule

Service interval	Maintenance work
Check before each treatment	– Check the jet formation for homogeneity – Check the powder container for damage (fissures) – O-rings for wear – Dome valve for wear
After every treatment	Clean and disinfect components.
After c. 1000 treatment cycles or after 2 years	Change the powder container. The identical ID number is located on the top and bottom parts of the powder container. Remember this when changing (see "4.2 ID number powder container").
Every 2 years	Send the device for inspection.

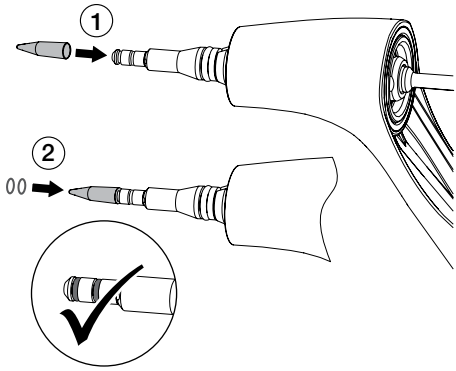
If necessary, all the components can be cleaned in an ultrasonic bath e.g. to avoid blockages.

13.2 Replace the o-rings on the corpus

› Check the o-rings for damage before every treatment. Replace if necessary.

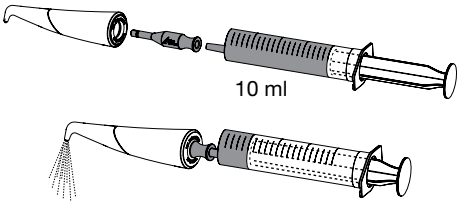


› Use the two small o-rings as assistance in tightening.



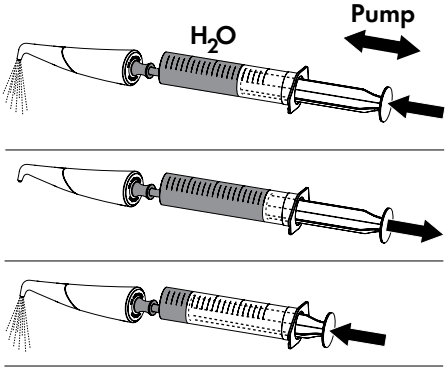
13.3 Clean the nozzles

› Place the rinse adaptor (blue) on the nozzle and rinse with a 10-ml disposable pipette.



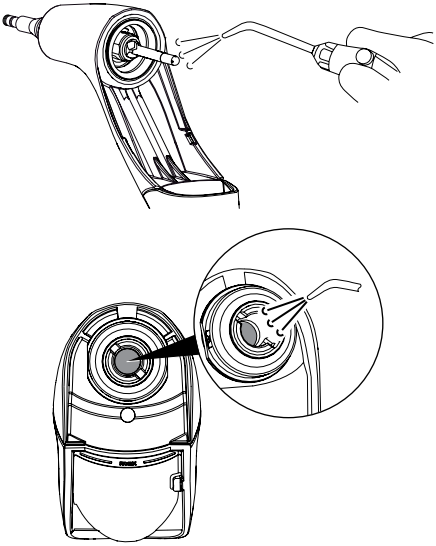
13.4 Free from blockages

› Place the rinse adaptor (blue) on the nozzle and pump in water with a 10-ml disposable pipette until the blockage has been rectified.



13.5 Clean the suction nozzle and dome valve

› Clean the suction nozzle and dome valve in the powder container with compressed air when changing the powder container.



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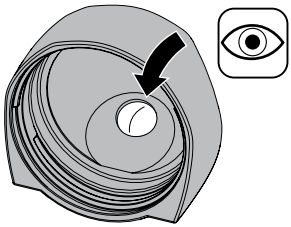
13.6 Check the dome valve

› Unscrew the powder container.

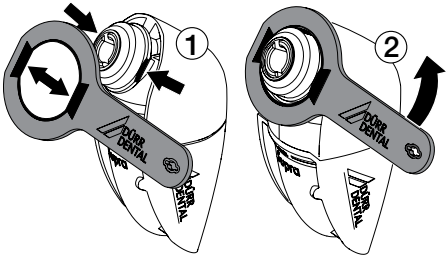
› Inspect the fitted dome valve / check whether is is possible to continue working with it.



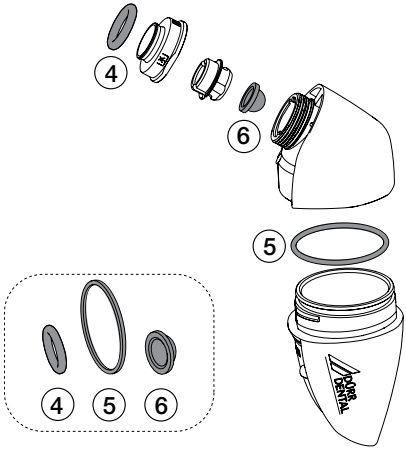
13.7 Replace the dome valve and o-rings on the powder container

› Apply the combination wrench to the powder container in accordance with the black markings on the powder container.

Loosen the union nut on the powder container with the combination wrench.



› Take apart the parts.



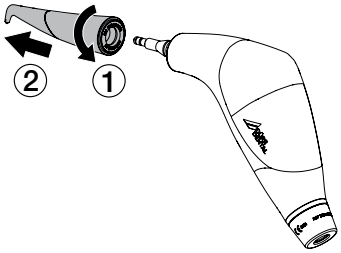
› Replace the o-rings and dome valve.

› Re-install the parts in reverse order.

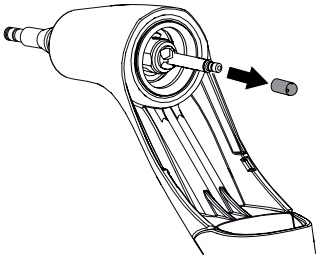
› Tighten the union nut hand tight using the combination wrench.

13.8 Free the powder-air line from blockages

› Remove the nozzle with a slight twist movement.



› Unscrew the suction nozzle from the powder-air line.

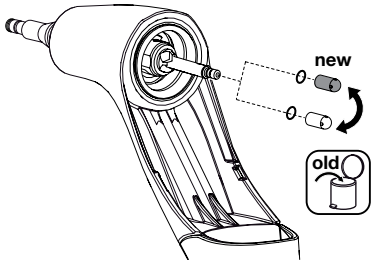


› Penetrate the powder-air line with a suitable instrument e.g. a needle and blow through with air.

› Screw the suction nozzle back on.

13.9 Replace the suction nozzle and the o-ring

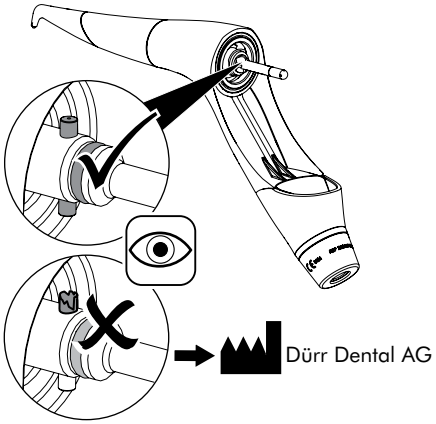
› Unscrew the suction nozzle from the powder-air line and remove the o-ring.



› Place on a new o-ring and screw on a new suction nozzle.

13.10 Check the bayonet catch for its function

› Check the bayonet catch regularly; the pins must not be damaged.



14 Tips for operators and service technicians

Any repairs above and beyond routine maintenance must only be carried out by suitably qualified personnel or by one of our service technicians.

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Problem	Probable cause	Solution
Water issued from between the corpus and the nozzle	O-ring between the corpus and the nozzle is defective.	› Check o-ring 2 and change if necessary (see "13.2 Replace the o-rings on the corpus").
Air jet falters	O-rings defective	› Check o-ring 1 and change if necessary (see "13.2 Replace the o-rings on the corpus").
Water flows into the powder container during operation	O-rings defective	› Check o-ring 1 and change if necessary (see "13.2 Replace the o-rings on the corpus"). › Check further o-rings and change if necessary › Device stored incorrectly
Too much noise	O-rings defective	› Check the o-rings and change if necessary (see "13.2 Replace the o-rings on the corpus").
Powder / air is issued	O-rings defective	› Check the o-rings and change if necessary (see "13.2 Replace the o-rings on the corpus").
No powder escapes from the nozzle	Nozzle blocked	› Remove the blockage on the nozzle (see "13.4 Free from blockages").
The powder container is difficult to open and close	Powder on the thread of the powder container	› Remove the powder on the thread before filling.
	O-ring defective	› Replace the o-ring (see "13.2 Replace the o-rings on the corpus").
Powder escapes from between the powder container and the corpus	O-ring or dome valve defective	› Check o-ring 3 and change if necessary (see "13.2 Replace the o-rings on the corpus"). › Check the dome valve and replace if necessary (see "13.6 Check the dome valve", or "13.7 Replace the dome valve and o-rings on the powder container").
The powder container moves considerably in the end position on the corpus	O-ring missing	› Fit o-Ring 4 and replace if necessary (see "13.7 Replace the dome valve and o-rings on the powder container").

Problem	Probable cause	Solution
Powder present in the coupling on the corpus	Corpus or nozzle blocked	› Remove the blockage on the nozzle (see "13.4 Free from blockages").
		› Clean the powder-air line (see "13.8 Free the powder-air line from blockages").
Fissures in the powder container	Treatment cycles exceeded.	› Use a new powder container.
	Damage resulting from incorrect handling and use	
Jet formation of the nozzle is irregular or formless	Nozzle is defective (the annular aperture is no longer concentric).	› Replace the nozzle (see "8.5 Check the jet formation" for jet form).
Fall in performance of the handpiece	Internal soiling	› Clean in the ultrasonic bath.
Insufficient removal	Powder container is empty or only half-full	› Fill the powder container.

DÜRR DENTAL AG
Höpfigheimer Strasse 17
74321 Bietigheim-Bissingen
Germany
Fon: +49 7142 705-0
www.duerrdental.com
info@duerr.de

DÜRR DENTAL