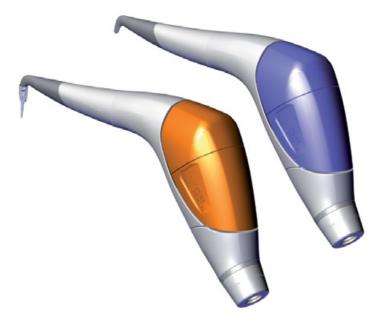
# MyLUNOS Pro



Installation and operating instructions







# Contents



# Important information

Abou	t this document
1.1	Warnings and symbols
1.2	Copyright information 4
Safety	
2.1	Intended purpose 4
2.2	Intended use
2.3	Improper use4
2.4	General safety information 5
2.5	Qualified personnel 5
2.6	Only use original parts 5
2.7	Transport
2.8	Disposal
	1.1 1.2 <b>Safet</b> 2.1 2.2 2.3 2.4 2.5 2.6 2.7



# **Product description**

3	Over	<b>view</b>
	3.1	Scope of delivery8
	3.2	Optional accessories 8
	3.3	Consumables
	3.4	Wear parts and replacement
		parts
4	Tech	nical data 10
4	<b>Tech</b> 4.1	nical data
4		
4	4.1	Type plate 11



# Usage

6	Indica	ations	1
	6.1	Supra	1
	6.2	Perio14	1
7	Cont	ra indications 14	1
8	Prepa	aring the device for treatment 15	5
	8.1	Check the turbine connection 15	5
	8.2	Check the o-rings 15	5
	8.3	Connect the handpiece15	5
	8.4	Set the water throughflow volume	
		and air pressure16	3
	8.5	Check the jet formation 16	3

	8.6	Fill the powder container 17
	8.7	Possible applications of the
		powder container rest
9	Preca	utionary measures 21
10	Treatr	nent
	10.1	Treatment with the powder jet handpiece Perio
	10.2	Treatment with the powder jet handpiece Perio
	10.3	Precautionary measures after treatment
	10.4	Place down the handpiece 26
11	After	every treatment
	11.1	Removing the single-use tip "LUNOS Perio Tip"
	11.2	Check the rinsing adapter 28
	11.3	Cleaning and drying
12	Repro	cessing
	12.1	Risk analysis and categorisation 30
	12.2	Reprocessing procedure in
		accordance with EN ISO 17664 30
	12.3	General information
	12.4	Preparation at the operating location
	12.5	Pre-cleaning
	12.6	Manual cleaning, intermediate rinsing, disinfection, final rinse,
		drying
	12.7	Automatic cleaning, intermediate rinsing, disinfection, final rinse,
		drying
	12.8	Check for function
	12.9	Steam sterilising
		Issue clearance for the parts for sterilisation
	12.11	Storing parts for sterilisation 38
13	Maint	enance
	13.1	Maintenance schedule
	13.2	Clean the nozzles 40
	13.3	Clean the suction nozzle and dome valve
	13.4	Free from blockages 40
	13.5	Free the powder-air line from blockages
	13.6	Check the bayonet catch for its function
	13.7	Check the dome valve 41

13.8	Replace the dome valve and
	o-rings on the powder container 41
13.9	Replace the o-rings on the
	corpus
13.10	Replace the suction nozzle and
	the o-ring 42



# Troubleshooting

14	Tips for operators and service		
	technicians	43	

# Important information

# 1 About this document

These installation and operating instructions represent 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 risks of personal injury or material damage.

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 a description of 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
- ATTENTION

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.



Observe the operating instructions.



 $_{\alpha}$  CE labelling with the number of the notified body



Manufacturer



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



Not sterile



Do not reuse



Do not re-sterilise



Do not use if packaging is damaged



Expiry date



Thermal disinfection and cleaning



Steam sterilise at 134 °C



Lower and upper temperature limits



Lot designation



Sterilised with ethylene oxide (STERILE EO)

HIBC Health Industry Bar Code (HIBC)



SN Serial number

Caution: By virtue of Federal Law, the

**Rx**only unit may only be sold to dentists or on behalf of a dentist.



Wear protective gloves.





EN

Use a mask.

Use protective clothing

# 1.2 Copyright information

All circuits, processes, names, software programs and units mentioned in this document are protected by copyright.

The Installation and Operating Instructions must not be copied or reprinted, neither in full nor in part, without written authorisation from Dürr Dental.

# 2 Safety

Dürr Dental has designed and constructed this unit so that when used properly and for the intended purpose it does not pose any danger to people or property. Nevertheless, residual risks can remain. You should therefore observe the following notes.

# 2.1 Intended purpose

This device is a powder jet handpiece for use in dental applications. It is used predominantly for the removal of plaques, deposits and discolourations on teeth, as well as for the cleaning of brackets, dental braces, crowns and bridges. In addition, the device can also be used to assist with the treatment of periodontal defects.

# 2.2 Intended use

Mobile powder-water jet handpiece for adaptation to the turbine coupling of a dental treatment unit.

It can be used to remove supragingival plaques (mainly soft ones) and discolourations (pigments, the basic colour of the tooth remains unaffected) and subgingival biofilm. The treatment spectrum ranges from periodontology and periimplantitis through prophylaxis (professional dental cleaning) to cariology (conditioning of fissure sealing).

We recommend working with Lunos® prophy powder Gentle Clean (only supragingival) or Lunos® prophy powder Perio Combi (supragingival and subgingival).

When using other powders, the properties of the powder materials and the grain size will need to be considered. Approved powder materials for medium grain size (14 to 70 µm) are sodium bicarbonate, glycine, trehalose and erythrit.

We recommend working with Lunos® prophy powder Gentle Clean (only supragingival) or Lunos® prophy powder Perio Combi (supragingival and subgingival).

When using other powders, the properties of the powder materials and the grain size will need to be considered, see "4 Technical data".

#### 2.3 Improper use

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

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.

## 2.4 General safety information

- Always comply with the specifications of all guidelines, laws, and other rules and regulations applicable at the site of operation for the operation of this unit.
- > Check the function and condition of the unit prior to every use.
- > Do not convert or modify the unit.
- > Comply with the specifications of the Installation and Operating Instructions.
- The Installation and Operating Instructions must be accessible to all operators of the unit at all times.

## 2.5 Qualified personnel

#### Operation

Unit operating personnel 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.

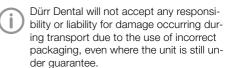
# 2.6 Only use original parts

- Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.
- Only use only original wear parts and replacement parts.

# 2.7 Transport

The original packaging provides optimum protection for the unit during transport.

If required, original packaging for the unit can be ordered from Dürr Dental.



- > Only transport the unit in its original packaging.
- Keep the packing materials out of the reach of children.

## 2.8 Disposal

#### Unit

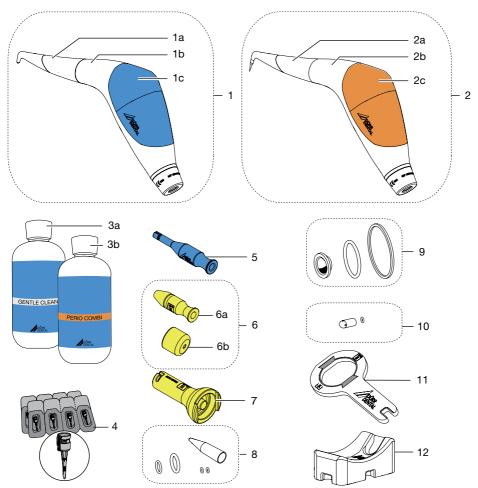


The unit may be contaminated. Instruct the company disposing of the waste to take the relevant safety precautions.

- > 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 about the correct disposal of parts, please contact your dental trade supplier.

# Product description

# 3 Overview



- 1 Powder jet handpiece MyLUNOS Supra
- 1a Supra nozzle
- 1b Corpus
- 1c Powder container Supra (blue)
- 2 Powder jet handpiece MyLUNOS Perio
- 2a Perio nozzle
- 2b Corpus
- 2c Perio powder container (orange)
- 3a Lunos Prophy Powder Gentle Clean (Supra)
- 3b Lunos Prophy Powder Perio Combi (Perio)
- 4 LUNOS Perio Tips

- 5 Rinsing adapter for the nozzle (blue) for cleaning after ever treatment and following blockage
- 6 Rinsing adapter for use during reprocessing
- 6a Rinsing adapter for nozzle (yellow) for use during reprocessing
- 6b Rinsing adapter for corpus (yellow) for use during reprocessing
- 7 Function tool
- 8 O-ring set for corpus
- 9 O-ring set for powder container
- 10 O-ring and suction nozzle for the powder-air line
- 11 Combination wrench
- 12 Tray for powder container

#### 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 of the powder jet handpiece with Supra nozzle

for the versions

MyLUNOS ...... 2034900050 Set: Supra / adapter: KaVo

MyLUNOS ...... 2034900052 Set: Supra / adapter: W&H

#### MyLUNOS ..... 2034900054

#### Set: Supra / adapter: NSK

- Powder jet handpiece MyLUNOS Supra
- Rinsing adapter for nozzle (blue)
- Rinsing adapter for nozzle (yellow)
- Tray for powder container
- O-ring set for corpus
- O-ring set for powder container
- Combination wrench
- Function tool
- Prophylaxis cannula
- LUNOS Prophy Powder Gentle Clean
- Installation and operating instructions
- Quick start instructions

#### Scope of delivery of the powder jet handpiece with Perio nozzle

for the versions

MyLUNOS ...... 2034910053 Set: Pro / Adapter: Bien Air

#### 

- Powder jet handpiece MyLUNOS Perio
- Rinsing adapter for nozzle (blue)
- Rinsing adapter for nozzle (yellow)
- Tray for powder container
- O-ring set for corpus
- O-ring set for powder container
- Combination wrench
- Function tool
- Prophylaxis cannula
- Perio powder container
- LUNOS Perio Tips
- Lunos Prophy Powder Perio Combi
- Installation and operating instructions
- Quick start instructions

#### 3.2 Optional accessories

The following optional items can be used with the device:

Supra nozzle
Perio nozzle
Rinsing adapter set
(yellow, manual reprocessing) 2034100155
Prophylaxis Cannula (qty 4) A070005850
Tray for powder container 2034100147
Retrofitting set Perio 2034900100

#### 3.3 Consumables

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

Lunos Prophy Powder Gentle Clean Neutral (4x 180 g).....CPZ610A2250 Lunos Prophy Powder Gentle Clean Orange (4x 180 g)....CPZ620A2250 Lunos Prophy Powder Gentle Clean Spearmint (4x 180 g)....CPZ630A2250 Lunos Prophy Powder Perio Combi (4x 100 g)....CPZ640A1950 LUNOS Perio Tips (40 piece)....2034100020

# 3.4 Wear parts and replacement parts

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



Information about replacement parts is available from the portal for authorised specialist dealers at: www.duerrdental.net. EN

# 4 Technical data

General technical data of device		
Dimensions (W x H x D)	mm	50 x 70 x 230
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 <sup>3</sup>	40
Filling volume powder container	g	max. 18
Noise level		
Device in operation	dB(A)	77*

In accordance with EN ISO 19402; measured in a noise-insulated room.

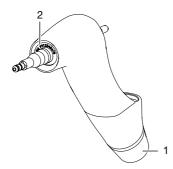
Classification		
Medical Devices Directive (93/42/EEC	)	Class Ila
Ambient conditions during storage	and transport	
Temperature	°C	0 to +25
Relative humidity	%	max. 95
Air pressure	hPa	700 - 1060
Ambient conditions during operatio		
Temperature	°C	10 to 40
Relative humidity	%	20 to max. 75
Air pressure	hPa	700 - 1060
Turbine connections on treatment u	nite	
	mits	
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 corres	ponding company.	
Prophy powder properties		

riophly portion proportion		
Grain size (average)	μm	14 to 70
Approved powder materials		Sodium bicarbonate, glycine, trehalose, erythritol

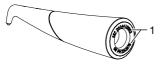
## 4.1 Type plate

The type plate is located on the device packaging.

- REF Order number
- SN Serial number



- 1 Order number on corpus
- 2 Serial number on corpus



1 Order number and serial number on nozzle

### 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



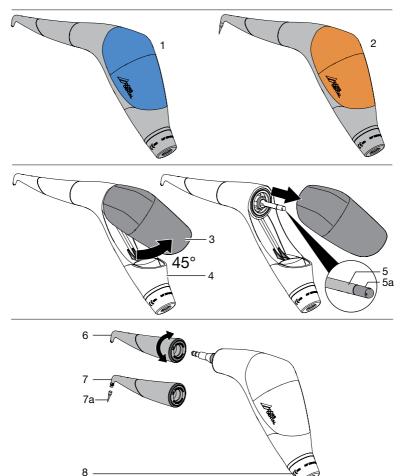
#### WARNING Risk of injury

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

# 4.3 Evaluation of conformity

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 MyLUNOS Supra
- 2 Powder jet handpiece MyLUNOS Perio
- 3 Powder container (Supra blue, Perio orange)
- 4 Corpus
- 5 Powder-air line
- 5a Suction nozzle on the powder-air line
- 6 Supra nozzle
- 7 Perio nozzle
- 7a LUNOS single-use tip (for Perio nozzle)
- 8 Connection with an integrated coupling adapter for the turbine connection (treatment unit)

The powder jet handpiece MyLUNOS serves the removal of soft, supragingival plaques and discolouration as well as for the removal of subgingival biofilm.

The powder containers can be changed quickly and easily via a a bayonet connection; the nozzles are changed equally easily using a push-fit fastening and the Perio single-use tips via a combination wrench.

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

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

The *Perio* powder jet handpiece is operated *supragingivally* with prophy powders authorised for use in this area (e.g. Prophy Powder Perio Combi from Dürr Dental), the Perio powder container and the Perio nozzle.

For subgingival treatment, the Perio single-use tip (LUNOS Perio Tip) is placed on the Perio nozzle to remove subgingival biofilm in gingival pockets.

# 👤 Usage

# 6 Indications

# 6.1 Supra

We recommend using the Supra powder jet handpiece MyLUNOS 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

# 6.2 Perio

We recommend using the powder jet handpiece MyLUNOS Perio for the removal of subgingival biofilm, e.g. in the scope of periodontitis treatment:

- > on subgingival gingival pockets
- > for cleaning of implant surfaces

# 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.

# 

#### The development of emphysema

Do not expose soft tissue to the powder flow during the Supra application as this could result in emphysema formation 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

#### Check the turbine connection 8.1

> 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.



Figure 1: Example Sirona coupling

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

Conventional turbine connections (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.

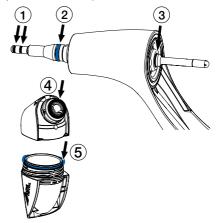
# 8.2 Check the o-rings



#### CAUTION Personal injury

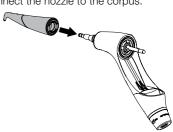
Check the O-rings for damage before every treatment

- > Only operate the device with intact O-rings.
- > Check the o-rings for damage before every treatment. Replace if necessary (see "13.9 Replace the o-rings on the corpus", or "13.8 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 initial use and after every treatment (see "12 Reprocessing").
- > Connect the nozzle to the corpus.



#### NOTICE

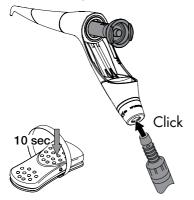
# Danger of blockage Moisture can cause the powder to clump together

Ensure that after reprocessing or flushing of the inner lumen, all residual moisture in the interior powder-air line line is removed. The air/powder line must be dry before the powder jet handpiece is used.

- Remove the residual moisture by blowing the air/powder line and blow dry for 10 seconds before using the handpiece.
- > Inserting the function tool



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



> Operate the device for around 10 seconds to remove any residual moisture.

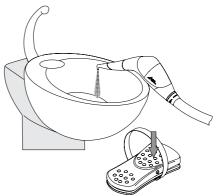
### 8.4 Set the water throughflow volume and air pressure



# Always operate the powder handpiece with a water flow rate.

Optimal treatment is only possible using the media powder-air and water. It is easier to set the water flow rate when the powder container is empty. It is best to do this before first use.

> Hold the nozzle of the powder jet handpiece in the moist spittoon with a clearance of approx. 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.

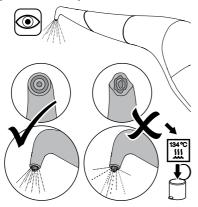
The lower the air pressure, the lower the cleaning performance and the lower the polishing effect.

16

# 8.5 Check the jet formation

#### Supra nozzle

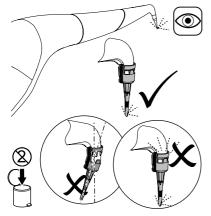
Check whether the nozzle openings are situated in a concentric pattern and that the jet pattern is concentric. An irregular jet pattern can be caused by blockage of the line. Remedy this if necessary.



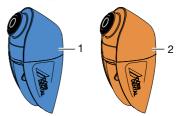
#### Perio nozzle

After pushing on the Perio single-use tip, hold the nozzle in the spittoon and check whether the single-use tip has been correctly attached: The powder-air flow must emerge through the openings of the single-use tip. If the powder-air flow emerges anywhere else, it is possible that the single-use tip has not been correctly attached or that it is defective.

Correctly attach the single-use tip or change it if required.



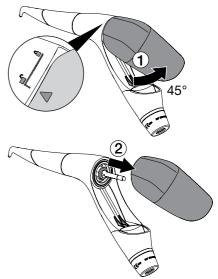
8.6 Fill the powder container



- 1 Supra powder container (blue) for supragingival treatment
- 2 Perio powder container (orange) for subgingival treatment

#### Remove and open the powder container

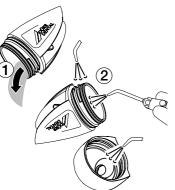
> Pivot the powder container through 45° then remove.



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.

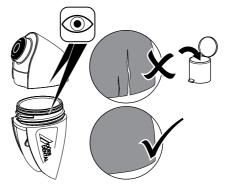
> Check the dome valve for damage (see "13.7 Check the dome valve").



#### CAUTION Risk of injury

Damaged powder containers can burst. > Replace damages powder containers.

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

We recommend working with Lunos® prophy powder Gentle Clean (only supragingival) or Lunos® prophy powder Perio Combi (supragingival and subgingival).

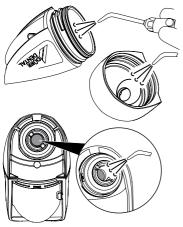
When using other powders, the properties of the powder materials and the grain size will need to be considered, see "4 Technical data".

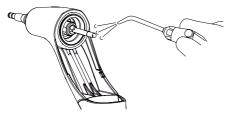
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# NOTICE

# 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.

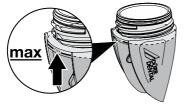


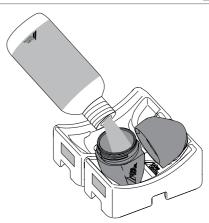


> Fill the jet powder in the lower part of the container.

Fill slowly to prevent the development of dust.

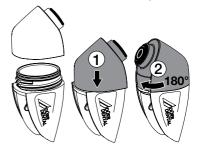
Comply with the maximum filling quantities. Do not exceed the max. filling quantities.





EN

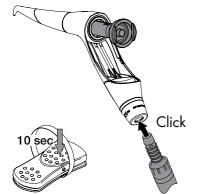
- The best results are achieved when the powder container is filled to the maximum.
- > Before screwing tight, remove any residual powder on the thread of the lower part of the container and on the bayonet connection of the sealing cap.
- Close the powder container. Ensure that the powder container has been closed correctly to prevent powder from escaping.



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

#### Insert the powder container

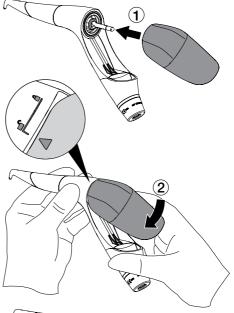
After removing the powder jet handpiece from the washer-disinfector and before inserting the powder container, first insert the function tool.

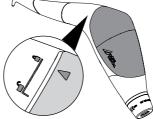


> Operate the device 1x for 10 sec. with the function tool inserted.

This enables removal of the residual moisture in the powder-air line.

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

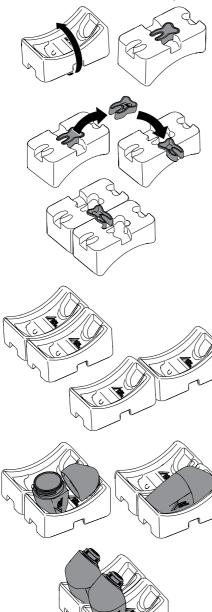




# 8.7 Possible applications of the powder container rest

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.



# 9 Precautionary measures

- Wear protective gloves.
  - Wear protective goggles.



Use a mask.



Use protective clothing.



#### CAUTION Risk of infection from contaminated products

Risk of cross contamination

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



#### WARNING Eye injuries

The air/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 before or after treatment.
- Observe the run-after time of the air/ powder flow! Do not remove the nozzle from the mouth until no air/powder flow is visible.

# WARNING

# Danger of infection!

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

> Wear mouth and nose protection

# 

# Danger of soiling

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

Remove contact lenses / glasses during the treatment.



#### Danger of soiling

NOTICE

The patient clothing can become soiled.

Cover the clothing with a cloth during treatment.

# 10 Treatment



Wear protective gloves.



Wear protective goggles.



Use a mask.



Use protective clothing.



#### CAUTION Risk of allergic reaction

Patients with a corresponding predisposition can react sensitively to the powder.

> Stop the treatment immediately if any allergic reaction is observed.

# NOTICE

#### Danger of blockage Moisture can cause the powder to clump together

Ensure that after reprocessing or flushing of the inner lumen, all residual moisture in the interior powder-air line line is removed. The air/powder line must be dry before the powder jet handpiece is used.

Remove the residual moisture by blowing the air/powder line and blow dry for 10 seconds before using the handpiece.



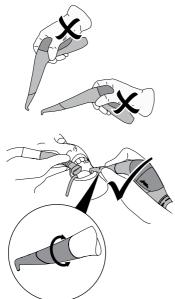
The device should be maintained at room temperature during treatment. Do not use a warm device, e.g. taken directly from the steam steriliser after reprocessing.

In case of blockage, 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.
- Should the turbine have a light, it must be switched off.

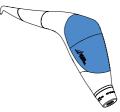
ΕN

- > 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.



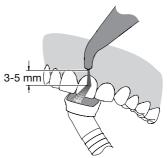
# 10.1 Treatment with the powder jet handpiece Perio

Using the handpiece with the Supra nozzle fitted

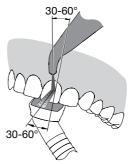


Actuate the foot switch and remove the plaque with circular motions.

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.



#### 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.

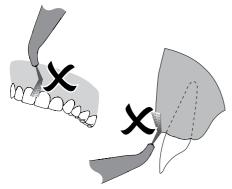
Do not direct the nozzle tip directly on the gums, the tongue or in the gum pockets.

#### 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.
- It air/powder flow must not be misdirected otherwise it could damage the gingiva or result in the development of an emphysema (air blown into the soft tissue).

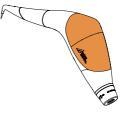


Release the foot switch and wait until the jet stops. Allow for this delay, blow into the suction cannula if necessary.

For the next steps, refer to "10.3 Precautionary measures after treatment".

# 10.2 Treatment with the powder jet handpiece Perio

Use the handpiece with the Perio nozzle fitted





#### WARNING Risk of cross contamination

> A new and sterile "LUNOS Perio single-use tip must be fitted before every treatment.



#### WARNING Risk of aspiration

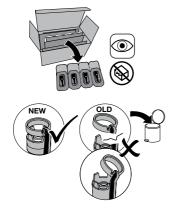
The mechanical safety concept serves to avoid unintentional detachment of of the single-use tip "LUNOS Perio Tip" from the nozzle.

> A new single-use tip must be fitted before every treatment.

#### CAUTION Gingivitis

Incorrectly stored "LUNOS Perio Tips" single-use tips could be unsterile.

For correct storage, see "LUNOS Perio Tips" type plate > Take a new single-use tip "LUNOS Perio Tip" from the packaging, and check its integrity and make sure it is within its expiry date. If the product is used after its expiry date, sterility can no longer be ensured.



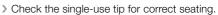


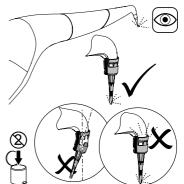
#### WARNING Risk of injury

Parts could become detached from the nozzle if the "LUNOS Perio Tip" single-use tip is not fitted properly. Aspiration of small parts is possible.

- > Check the single-use tip for correct seating.
- > Push on the single-use tip.









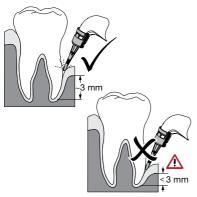
#### WARNING The development of emphysema

The soft tissue can be damaged as a result of careless handling.

- Carefully slide the single-use tip "LUNOS Perio Tip" into the gingival pocket. In order to avoid the risk of an emphysema as far as possible, it must be ensured that there is still 3mm of bone substance at the apex.
- > Observe the probing depth according to the marking (markings compliant with the WHO probe)



Insert the single-use tip "LUNOS Perio Tip" into the gingival pocket. The depth of penetration depends on the depth of the gingival pocket.



- > When the single-use tip is in the gingival pocket, press the foot switch for 5 seconds.
- > Use circular motions to remove subgingival biofilm from the tooth surfaces.

In contrast to the Supra nozzle, cleaning of gingival pockets with a probing depth of more than 5 mm is possible.

5 sec

- Release the foot switch and wait until the jet stops. Allow for this delay.
- Pull the "LUNOS Perio TIP" single-use tip out of the gingival pocket and treat the next gingival pocket. For the next steps, refer to "10.3 Precautionary measures after treatment".

# 10.3 Precautionary measures after treatment

> The powder-air jet keeps flowing or a few seconds after the foot switch has been released.

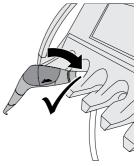
Do not draw the handpiece over the face or clothes of the patient during this time. We recommend retaining the nozzle tip in the suction cannula as long as it is in the patient mouth and until the spray has stopped.



# 10.4 Place down the handpiece

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





ΕN

# 11 After every treatment

### 11.1 Removing the single-use tip "LUNOS Perio Tip"



### WARNING

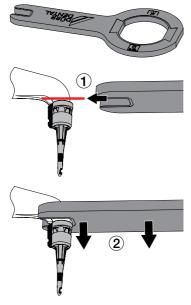
# Material failure due to steam sterilisation

The single-use tip "LUNOS Perio Tip" cannot be steam-sterilised and must be removed after every treatment.

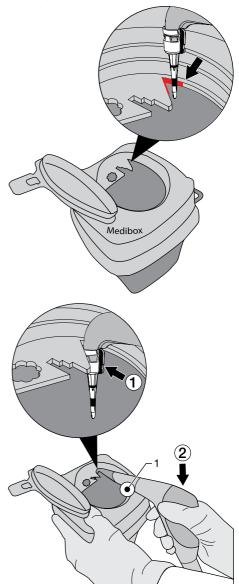
Single-use tips must only be used once.

> We recommend using the combination wrench to remove the single-use tip, or a sharps container or dental flat pliers:

#### Combination wrench (Dürr Dental)



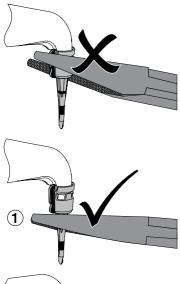
Sharps container (e. g. Medibox, from Braun)

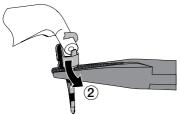


1 Pivot

#### Dental flat pliers

Ensure that you use the flat pliers correctly, see 1 - 3





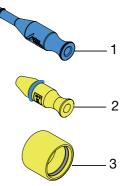
> Only use LUNOS Perio Tips once!



# 11.2 Check the rinsing adapter

> Check that the O-rings are properly seated on the rinsing adapters.

The rinsing adapters must be replaced if the O-rings are lost.



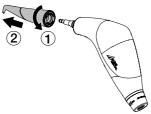
- 1 Rinsing adapter for the nozzle (blue) for cleaning after ever treatment and following blockage
- 2 Rinsing adapter for nozzle (yellow) for use during reprocessing
- 3 Rinsing adapter for nozzle (yellow) for the corpus, for use during reprocessing

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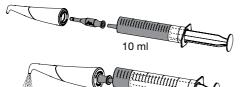
ΕN

# 11.3 Cleaning and drying

Remove the nozzle with a slight twist movement.



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



- In case of blockage (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.



# 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 device are also sub-

EN

ject to reprocessing. Classification recommendation given intended use of the product: **semi-critical B to critical B** The operator is responsible for correct classification of the medical products, defining the reprocessing steps and performing the reprocessing.

# 12.2 Reprocessing procedure in accordance with EN ISO 17664

The reprocessing procedure after each patient treatment is carried out according to the reprocessing procedure established by EN ISO 17664.

#### Important information!

The reprocessing notes in accordance with EN ISO 17664 have been independently tested by Dürr Dental for the preparation of the device and its components for 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 deviation from the instructions described herein by the staff preparing the equipment could lead to lower effectiveness and possible negative consequences: these lie solely with the staff responsible.

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:

#### Pre-cleaning

- ID 213 Instrument disinfection (Dürr Dental)
- Manual cleaning
  - ID 213 Instrument disinfection (Dürr Dental)
- Manual disinfection
  - ID 213 Instrument disinfection (Dürr Dental)
- Automatic cleaning and disinfection

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

- Pre-cleaning with ID 213 instrument disinfection (DürrDental)
- Cleaning agent: Neodisher MediClean, washer-disinfector RDG: G 7836 CD (Miele), programme:
   D-V-MEDICLEAN at 90 °C (5 min)
- Steam sterilisation

was performed in accordance with EN ISO 17665 with the fractionated vacuum procedure.

Sterilise the parts for sterilisation, e.g.

- 20 minutes at 121°C
- 4 minutes at 132 °C (also valid for 5 minutes at 134 °C)

# 12.3 General information

# NOTICE

Equipment damage due to unsuitable products

Oils and care products containing oil will damage the device.

- The handpiece must not be maintained with oil or with a care system that contains oil.
- 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.
- > Clean and disinfect all parts a maximum of two hours after use.
- Comply with the specifications (see "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.
- Only use cleaning agents that are non-fixing and aldehyde-free and display material compatibility with the product.
- Only use disinfectants that are aldehyde-free and display material compatibility with the product.
- > Do not use any rinse aid (danger of toxic residue on the components).
- > Only use freshly-produced solutions.
- Only use distilled or deionised water with a low bacterial count (at least drinking water quality) that is free from facultatively pathogenic microorganisms (e.g. legionella bacteria).
- > Use clean, dry, oil and particle-free compressed air.
- > Do not exceed temperatures of 138 °C.
- Subject all 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



Wear protective gloves.



Wear protective goggles.

Use a mask.



Jse protective clothing.



#### 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 and inorganic soiling with a disinfectant cloth.



#### WARNING

#### Material failure due to steam sterilisation

The single-use tip "LUNOS Perio Tip" cannot be steam-sterilised and must be removed after every treatment.

Single-use tips must only be used once.

Check that the O-rings are properly seated on the rinsing adapters (see).

The rinsing adapters must be replaced if the O-rings are lost or damaged.

# 12.5 Pre-cleaning

Do not leave the pre-cleaning more than 15 minutes after the unit has been used.

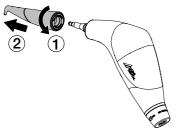
- Clean the exterior surfaces completely with two cleaning cloths. Make sure that the surfaces are sufficiently moistened.
- > Note the action time of the cleaning agent.
- > Perform the procedure twice.

#### Preparation of powder jet handpiece

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



- > Remove powder residue from the corpus and the nozzle.
- > Attach powder container again.
- Blow compressed air through the powder jet handpiece for at least 1 minute.
- Remove the nozzle with a slight twist movement.

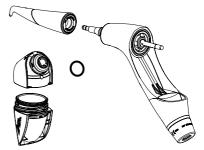


- > Remove and open the powder container.
- Remove the O-ring from upper part of the powder container.

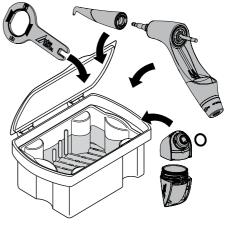


#### Pre-cleaning of the powder jet handpiece

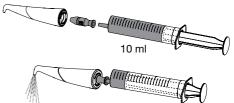
Rinse all components under water for min. 1 minute (temperature < 35 °C).</p>



Place all the individual components in a cleaning and disinfecting bath (non-fixing, aldehyde-free) for the foreseen reaction time (max. 2 hours) so that they are all covered. See "12.3 General information".



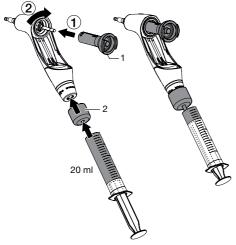
In the disinfectant bath, place the rinse adapter (yellow) on the nozzle and rinse (min. three times) with a 10-ml disposable pipette.



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

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

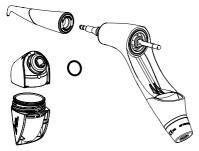


- 1 Function tool
- 2 Rinsing adapter for the corpus
- > Brush all exterior and interior surfaces completely with a soft clean brush.
- > Remove all rinse adapters.

#### Rinse the powder jet handpiece

After the action time prescribed by the manufacturer:

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



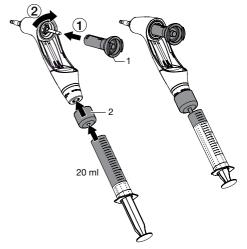
Place the yellow rinse adapter on the nozzle and rinse with water from a 10-ml disposable pipette at least three times.





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

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



- 1 Function tool
- 2 Rinsing adapter for the corpus

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

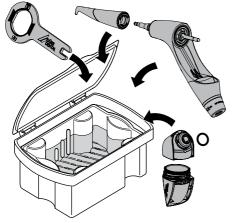
A combined cleaning and disinfectant agent is required for manual cleaning and disinfection. It must have the following properties:

- certified, possibly virucidal efficacy (DVV/RKI, VAH or European Standards)
- without chlorine, solvents, strong alkaline solutions (pH >11) or oxidising agents
   For further information, see: "12.3 General information".

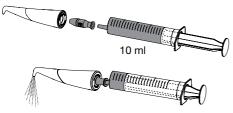
ΕN

#### Cleaning

Place all the individual components in a cleaning and disinfecting bath (non-fixing, aldehyde-free) for the foreseen residence time (max. 2 hours) so that they are all covered. See "12.3 General information".

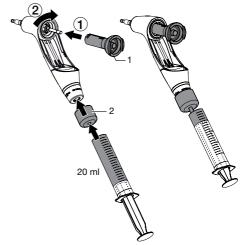


In the disinfectant bath, place the rinse adapter (yellow) on the nozzle and rinse (min. three times) with a 10-ml disposable pipette.



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

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



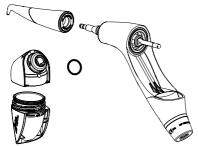
- 1 Function tool
- 2 Rinsing adapter for the corpus
- > Brush all exterior and interior surfaces completely with a soft hygienic brush.
- > Remove all rinse adapters.
- > Comply with the action times of the cleaning agent and disinfectant.

ΕN

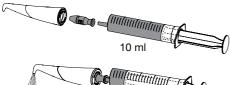
#### Intermediate rinsing

After the action time prescribed by the manufacturer:

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



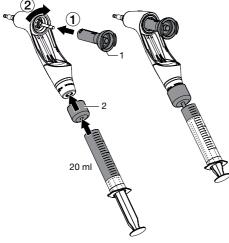
Place the yellow rinse adapter on the nozzle and rinse with water from a 10-ml disposable pipette at least three times.





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

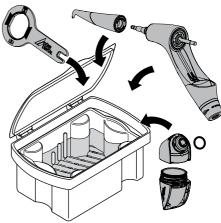
Place on the yellow rinse adapter (2) for the corpus and rinse through with water at least 3 times using a 20-ml disposable pipette.



- 1 Function tool
- 2 Rinsing 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. 2 hours) so that they are all covered. See "12.3 General information".



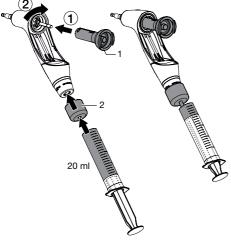
In the disinfectant bath, place the rinse adapter (yellow) on the nozzle and rinse (min. three times) with a 10-ml disposable pipette.





- Usage
- Place the function tool (1) on the bayonet connection for the powder container and place them in the disinfectant bath.

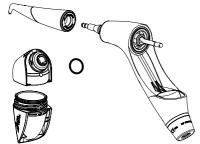
Place the yellow rinse adapter (2) for the corpus and rinse through at least 3 times using a 20-ml disposable pipette.



- 1 Function tool
- 2 Rinsing adapter for the corpus
- Brush all exterior and interior surfaces completely with a soft hygienic brush.
- > Remove all rinse adapters.
- Comply with the action times of the cleaning agent and disinfectant.

### Final rinse

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



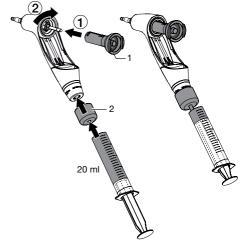
Place in a water bath (filled with water) for 1 minute. Place the yellow rinse adapter on the nozzle and rinse with water from a 10-ml disposable pipette at least five times.





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

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



- 1 Function tool
- 2 Rinsing adapter for the corpus

### Drying

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

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

#### Selection of the washer-disinfector

Automatic cleaning and disinfection requires a washer-disinfector with the following properties and validated processes:

- Corresponds to and tested in accordance with EN ISO 15883
- Certified program for thermal disinfection (A<sub>0</sub> value ≥ 3000 or at least 5 minutes at 90°C)

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

For more information "12.3 General information".

#### Selection of the cleaning agent automatic

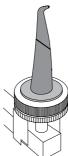
The following properties are required:

- 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

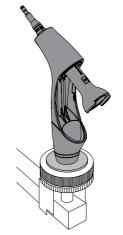
Place the nozzle on the special bracket for transfer instruments (e.g. Miele: ADS 3 c. 22 mm Ø) in the CD.



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 their openings should be pointing downwards. Make sure there are no hidden areas that are missed by the rinsing process.
- > Secure the components with a suitable fixture of the cleaning and disinfection unit.

#### Drying

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

EN

# 12.8 Check for function

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

Operate the device with the function tool inserted for around 10 seconds to remove any residual moisture from the corpus and nozzle.

> 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, use only sterile barrier systems made of transparent paper film that are approved for use in steam sterilisation according to the manufacturer information. 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 sterile barrier system must be large enough. Once it is loaded, the sterile barrier system must 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:

- Corresponds to EN 13060 or EN 285 and/or ANSI AAMI ST79
- 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 (at least 20 minutes at 121°C, at least 4 minutes at 132°C or at least 5 minutes 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 device 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.

ΕN

# 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

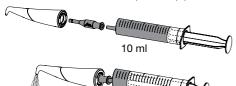
Service interval	Maintenance work
Check before each treatment	<ul> <li>Check the jet formation for homogeneity</li> <li>Check the powder container for damage (fissures)</li> <li>O-rings for wear</li> <li>Dome valve for wear</li> <li>Check the single-use tip "LUNOS Perio Tip" for correct seating</li> </ul>
Before every reprocessing	Check that the O-rings are properly seated on the rinsing adapters. The rinsing adapters must be replaced if the O-rings are lost or damaged.
After every treatment	<ul> <li>Clean and disinfect components.</li> <li>Dispose of the single-use tip "LUNOS Perio Tip" after single use.</li> </ul>
Every three months	<ul> <li>Replace the dome valve and O-rings on the powder container (see "13.8 Replace the dome valve and o-rings on the powder container").</li> <li>Replace the O-rings on the corpus (see "13.9 Replace the o-rings on the corpus").</li> </ul>
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.

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## 13.2 Clean the nozzles

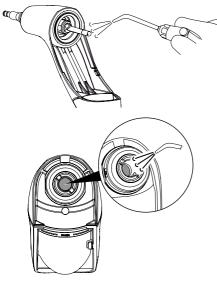
> Place the rinse adaptor (blue) on the nozzle and rinse with a 10-ml disposable pipette.



- Remove all the residual moisture by blowing
- the powder-air line dry for 10 seconds before using the handpiece.

## 13.3 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.

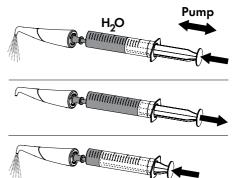


# 13.4 Free from blockages

> In the event of blockage, vent the entire system before pulling off the nozzle from the corpus:

Wait approx. 4 seconds before disconnecting the device from the turbine coupling.

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



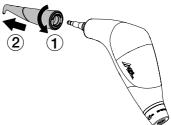
Remove all the residual moisture by blowing the powder-air line dry for 10 seconds before using the handpiece.

## 13.5 Free the powder-air line from blockages

> In the event of blockage, vent the entire system before pulling off the nozzle from the corpus:

Wait approx. 4 seconds before disconnecting the device from the turbine coupling.

> Remove the nozzle with a slight twist movement.



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



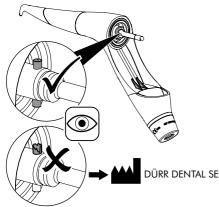
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- > Penetrate the powder-air line with a suitable instrument e.g. a needle and blow through with air.
- > Screw the suction nozzle back on.
- Reprocess the corpus manually or with a machine.



# 13.6 Check the bayonet catch for its function

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

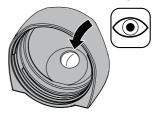


# 13.7 Check the dome valve

> Unscrew the powder container.



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

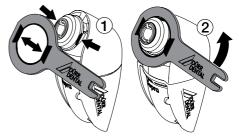


## 13.8 Replace the dome valve and o-rings on the powder container

### Replace every 3 months

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.

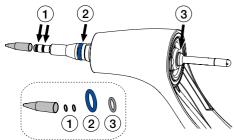


- > Replace the o-rings and dome valve.
- > Re-install the parts in reverse order.
- > Tighten the union nut hand tight using the combination wrench.

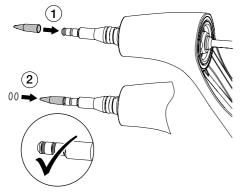
# 13.9 Replace the o-rings on the corpus

## Replace every 3 months

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

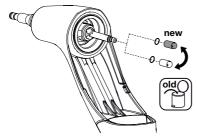


> Use the two small o-rings as assistance in tightening.



# 13.10 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.

# Troubleshooting

# 14 Tips for operators and service technicians



Any repairs exceeding routine maintenance may only be carried out by qualified personnel or our service.

Fault	Probable cause	Solution
Water issued from be- tween the corpus and the nozzle	O-ring between the corpus and the nozzle is defective.	Check the O-ring 2 and change if necessary (see "13.9 Replace the o-rings on the corpus").
Air jet falters	O-rings defective	Check O-rings 1 and change if necessary (see "13.9 Replace the o-rings on the corpus").
Water flows into the pow- der container during op- eration	O-rings defective Device stored incorrectly	<ul> <li>Check O-rings 1 and change if necessary (see "13.9 Replace the o-rings on the corpus").</li> <li>Check further O-rings and change if necessary</li> </ul>
	The corpus and nozzle were not dried properly after reprocessing or rinsing, i.e. there is still residual moisture in the internal pow- der-air line.	Blow-dry the powder-air line for 10 seconds in order to eliminate the residual moisture (see "12.8 Check for function").
Too much noise	O-rings defective	Check the O-rings and change if necessary (see "13.9 Replace the o-rings on the corpus").
Powder / air is issued	O-rings defective	Check the O-rings and change if necessary (see "13.9 Replace the o-rings on the corpus").
No powder exits from the nozzle	Nozzle blocked	<ul> <li>Remove the blockage on the nozzle (see "13.4 Free from blockages").</li> <li>Vent the entire system: wait approx. 4 seconds before disconnecting the device from the turbine coupling.</li> </ul>
The powder container is difficult to open and close	Powder on the thread of the pow- der container	Remove the powder on the thread before filling.
	O-ring defective	Replace the o-ring (see "13.8 Replace the dome valve and o-rings on the powder contain- er").

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Fault	Probable cause	Solution
Powder escapes from be- tween the powder contain- er and the corpus	O-ring or dome valve defective	Check o-ring 3 and change if necessary (see "13.9 Replace the o-rings on the corpus").
		Check the dome valve and replace if necessary (see "13.7 Check the dome valve", or "13.8 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 nec- essary (see "13.8 Replace the dome valve and o-rings on the powder container").
Powder container does not engage in the end po- sition on the conus	Powder residue in the area around the bayonet connection	<ul> <li>Remove all powder residue in the area around the bayonet connection</li> <li>Reprocess the powder containe and corpus</li> </ul>
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 "13.5 Free the powder-air line from blockages").
		<ul> <li>Reprocess the corpus and noz- zle (see "12 Reprocessing").</li> </ul>
Coupling of turbine hose	Powder in the coupling	> Reprocess the corpus.
does not engage	Spring washer in the powder jet handpiece defective	> Send the unit for repair.
Turbine connection is defective	The light on the turbine is not switched off (excessive heat development)	Notify customer service or send the device to be repaired.
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	Internal soiling	> Clean in the ultrasonic bath.
handpiece		<ul> <li>Reprocess the corpus and nozzle.</li> </ul>
Insufficient removal	Powder container is empty or only half-full	> Fill the powder container.



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