REPROCESSING INSTRUCTIONS



AIRFLOW MAX ES





PIEZONLED



EMS

RELATED ACCESSORIES



SUMMARY

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BEFORE USE

Please read these Operating Instructions carefully as they explain all the most important details and procedures. Please pay special attention to the safety precautions.

Always keep these Instructions close at hand.

These Instructions are only applicable to the equipment they were delivered with.

To prevent injury to persons or damage to property, please observe the corresponding directives and symbols.

This instruction follows the recommendations of RKI Robert Koch Institut, Germany.

Translations in this manual are based on the English version. Thus the English text will be referred to in case of discrepancy.

CLEANING AND DISINFECTION FOR DEVICES AND HANDPIECE CORDS

The following instructions have been validated for all reusable products¹ of EMS dental devices. It remains the responsibility of the processor to ensure that the processing, as actually performed using the equipment, materials and personnel in the processing facility, achieves the desired result. This requires validation and/or validation and routine monitoring of the process. Likewise any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse effects.



(1) (2) CLEAN AND DISINFECT

Use a cleaning and disinfecting wipe (less than 35% alcohol) that complies with the standards applicable in the country.

Follow carefully the instructions provided by the wipes manufacturer.

On NOT use CaviWipes™ or Advantaclear wipes. It damages EMS products.

INTRODUCTION

EMS recommends compliance with cleaning, disinfection, packaging for sterilization and sterilization procedures according to ISO 17664.

Always report adverse events related to device reprocessing directly to EMS.

Products must be cleaned, disinfected and, if applicable, sterilized prior to first use. Do not reprocess the products over the authorized number of sterilization cycles. To replace, refer to the "Service life" section of these Instructions.

Concentrations and contact times specified by the manufacturer of the cleaning and disinfection agent must be observed.

Remember that sterilization mustn't be achieved unless assembly components are cleaned and disinfected first.

If parts of these instructions are not clear or seem to be inadequate, do not hesitate to contact/inform EMS.

Users shall also observe any legal requirements applicable in their country as well as the hygiene regulations in effect at the hospital or clinic.

This applies especially with regard to additional requirements for the inactivation of prions.

SERVICE LIFE

The products have been designed for a large number of sterilization cycles. The materials used in their manufacture were selected accordingly. However, with every renewed preparation for use, thermal and chemical stresses will result in ageing of the products.

Always replace products that present signs of wear or early degradation, regardless of the number of sterilization cycles left unused.

DO NOT expose the products to temperature exceeding 138°C.

EMS handpieces must not be lubricated or otherwise exposed to oil whether directly or indirectly.

Lifetime: see product's Instructions for Use.

SYMBOLS

A Caution / Danger - Risk of property damage or injury

🚺 Please note - Useful additional information and hints

Prohibited

Wear personal protective equipment

Refer to instruction manual

📆 Sterilizable at up to 135°C in the autoclave

M Suitable for thermal disinfection

 $\bigotimes_{\text{S (second)}} \text{Required time - Abbreviations used: min (minute) ;}$

PROCESS FOR RELATED PRODUCTS MENTIONED ON PAGE 3



✓ 01 PREPARE

At the point of use: Immediately after patient treatment, rinse the lumen(s) line of the handpiece/instrument with cold tap water. Coarse soiling must be removed by wiping the products.

Special attention need to be paid to cracks, crevices and hard to reach areas.

Place the products on an appropriate rack to transport them to the reprocessing area to avoid any product damage and contamination to the environment and people involved in the reprocessing process.

Always carry out **AIRFLOW®** and **PERIOFLOW®** Handpiece powder unclogging and check for both lumens (water and powder) clearance before proceeding. Use Easy Clean².



Products have to be disassembled as shown below:



Remove any installed file.
Remove the screw and separate the small O-ring.



Remove any installed instrument.
Remove the nose cap and separate the light guide and O-ring.



PIEZON® Instruments with CombiTorque®:

Separate the PIEZON® Instrument and the CombiTorque® but keep each original instrument and CombiTorque® together throughout their life.

Cleaning is to be performed within 1 hour from use.

Wear personal protective equipment according to the type of preparation.

Any product must be cleaned manually or automatically by washer or disinfector. Follow the dedicated cleaning part according to your dental equipments.

EMS recommends the use of an ISO 15883 compliant automatic washer-disinfector (WD) for optimal effectiveness and service life.

A EMS handpieces must not be lubricated or otherwise exposed to oil whether directly or indirectly.



EITHER () () 02 03 04 AUTOMATIC CLEAN, DISINFECT AND DRY WITH WASHER DISINFECTOR

🚺 The washer-disinfector must comply with ISO 15883, must have suitable baskets to hold small products and must have rinsing connections with diameter of approximately 16mm for the attachment to product lumen.

Correctly place the product into a suitable rack, connect all lumens to the rinsing connectors and start the automated cleaning.

💔 Instructions of the manufacturer of the washer disinfector must also be observed.

🛕 Carefully follow the instructions provided by the disinfection solution manufacturer.

The following automated process³ can be used to achieve an A0 Level of 3000:

⊘2 min Pre-clean with cold tap water4. Drain

Clean at 55°C with tap water and 0.5% neodisher MediClean Dental (Dr Weigert) solution. ⊙ 5 min

Drain

Rinse and neutralize with cold demineralized water⁵.

Drain

Rinse with cold demineralized water⁵. **⊙**2 min

Drain

Perform thermal disinfection (final rinse) with deionized water at 93°C minimum. ⊗ 3 min

Drain

Dry at 100°C.

OR



02 MANUAL CLEAN + (3) 03 DISINFECTION + (11) 04 DRY







The following validated EMS process can be used with and without ultrasound.

OD NOT use any ultrasound bath cleaning procedure with the handpieces: it may destroy the products. It is ONLY intended to be used with EMS PIEZON® Instruments and file holders. In case of ultrasound bath cleaning, place products in a metal sieve and sonicate 10 minutes.

Validated product	Process	EMS products to clean/ disinfect	Process		
0.5%		all EMS products EMS PIEZON® Instruments and file holders	Brush the devices in a cleaning solution of 0.5% neodisher in deionized water at 40°C with a suitable soft bristled brush until all visible residue has been removed.		
neodisher MediClear	without ultrasound bath		⊙15 s	For products with lumens, flush all lumens with a spray gun (water jet gun, with a static water pressure of 2 bar) with cold tap water.	
(Dr. Weiger) Datii		⊘15 min (10 min with ultrasound)	Place the product in 0.5% solution of neodisher with deionized water at 40°C. Make certain that all lumens are filled with cleaning solution (use a syringe if needed).	
0.5%	with		⊙15 s	Rinse all lumens by flushing with a spray gun (water jet gun, with a static water pressure of 2 bar) with cold deionized water ⁵ .	
neodisher MediClear	ultrasound		⊙10 s	Rinse the whole product under cold running deionized water.	
(Dr. Weiger	l hath⁵		At room temperature (15-25°C), use an air pistol (compressed air, max. 3 bars) to fully dry the lumen and the whole product until no more residues of water are present (visible or detectable).		

Then disinfect:

💶 ASP CIDEX® OPA solution must be used undiluted, within its useful and shelf life, and in compliance with the manufacturer's warnings and instructions for use.

Immerse the product completely into CIDEX® OPA solution at minimum 20°C. Make certain that all lumens are filled ⊙5 min with disinfectant solution (use a syringe if needed).

The ASP CIDEX® OPA disinfectant requires a total of three rinses: keep the product totally immersed, and use a large ↑ 1 min (each rinse) volume⁷ of fresh water.

Do not reuse the water for rinsing or any other purpose. Residues of disinfectant may cause serious side effects.

And dry

At room temperature (15-25°C), use an air pistol (compressed air, max. 3 bars) to fully dry the lumen and the whole product until no more residues of water are present (visible or detectable).



(Q) 05 INSPECT

🛕 If stains are still visible on the product after cleaning/disinfection, the entire cleaning/disinfection procedure must be repeated. Products with visible damage, chip/flake loss, corrosion or deformation must be disposed of (no further use is allowed). Check also the integrity of O-rings and gaskets and replace if damaged or deformed.

Uverify the product to be fully dry. In case of detection of residues of water, remove these using an air pistol (clean compressed air). Fully dry the lumen and the whole product until no more residues of water are present (visible or detectable).