

Instruction for use

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1 Introduction

These instruction for use and safety recommendation are to be strictly observed. Non-observance of these instructions may lead in increasing the risk of injury and impair the proper function of the devices. The devices are intended for dental use only.

The instruments are sold in unsterile condition and should be cleaned, disinfected and sterilised prior each application.

The instruments are multi use so they can be re-used. However, it is the sole responsibility of the doctor using the instruments to decide whether, depending on the respective case and the potential wear and tear of the products, he can re-use the products and how frequently he uses them.

2 Storage

Prior to the first use of the device, the product should be stored in its original packaging at room temperature in dust- and humidity-free conditions. This will maintain the useful life of the devices. As re-usable instruments the useful life depends on their wear and tear.

After sterilisation, the devices need to be stored in sterilisation wrapping in a dry and dust-free place. Please note that the shelf-life of the sterilisation state of the device depends from the validation of the sterilisation wrapping. After expiration of the defined date the devices need to be re-sterilised.

3 Cleaning and disinfecting

If possible, an automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the instruments. A manual procedure (even in case of application of an ultrasonic bath) should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered. The pre-treatment step is to be performed in both cases.

When choosing an appropriate cleaning and disinfecting agent you need to ensure

- fundamental suitability for the cleaning and disinfection of instruments made of metallic material
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- application of a disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA clearance or CE marking) compatible with the used cleaning detergent.
- avoid aggressive products (hydrochloric acid, hydrogen peroxide...), they may corrode the instruments.

Pre-treatment:

Abrasive impurities need to be removed from the instruments directly after use (within two hours maximum).

Manual Cleaning and disinfection procedure:

Immediately place used instruments in a special anti-corrosive disinfectant bath for a short time otherwise their colour code may come off. Do not use too aggressive products (hydrochloric acid, hydrogen peroxide...), they may corrode the instruments.

Clean the instruments in an ultrasonic bath or under running water.

Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F).

Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

Automated cleaning/disinfection (disinfector/ WD (Washer-Disinfector)):

Please consider the following points during selection of the WD:

- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA clearance)
- possibility for an approved program for thermal disinfection (A0 value ≥ 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water - only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
- regularly maintenance and check/calibration of the WD

4 Sterilisation

Before sterilization, place the instruments in stands and trays suitable for sterilization.

Sterilize the instruments. Autoclave: 18 min. 134°C, 2 bars.

5 Use

- Use adequate supply of water spray in order not to damage the tooth and contiguous tissues. The water should be distributed over the entire length of the working part. A deflection of the coolant jet can cause heat related damages.
- Additional cooling is required for instruments with a total length exceeding 19 mm and for instruments with a head diameter exceeding 2 mm.
- Immediately remove any instruments that are damaged, bent or don't run concentrically.
- Pressure should be 0.3 – 2N (30 – 200p) for FG instruments and 2 – 5N (200 – 500p) for HP instruments, in other words work with as little pressure as possible.
- The turbine, right angle and hand-piece must be in perfect technical conditions.
- Insert the instruments carefully and without using force. Miniature instruments should be inserted no further than the end of the cylindrical part.
- Avoid canting or levering when grinding.
- Observe the min./max. speeds indicated in the table below and on the packages
- Full speed should be reached outside the mouth of the patient. Technicians should run the hand-piece at full speed before applications to the product on which is being performed.

VELOCITÀ DI ROTAZIONE - VITESSES DE ROTATION - DREHZAHLEN ROUND SPEEDS - VELOCIDADES - СКОРОСТЬ ВРАЩЕНИЯ				
ISO \varnothing (1/10 mm)	Maximum permitted speed (min^{-1})		Recommended operational speed (min^{-1})	
	FG	HP	FG	HP
007 - 010	450.000	250.000	100.000 - 220.000	100.000 - 190.000
012 - 014	450.000	250.000	70.000 - 220.000	70.000 - 140.000
016 - 018	450.000	120.000	55.000 - 160.000	55.000 - 110.000
021 - 023	300.000	120.000	40.000 - 120.000	45.000 - 85.000
025 - 027	160.000	80.000	35.000 - 110.000	35.000 - 70.000
029 - 031	140.000	80.000	30.000 - 95.000	32.000 - 64.000
033 - 040	120.000	80.000	25.000 - 75.000	25.000 - 50.000
042 - 050	95.000	60.000	15.000 - 60.000	20.000 - 37.000
055 - 070	60.000	60.000	12.000 - 40.000	17.000 - 34.000
080 - 100	45.000	40.000	10.000 - 20.000	10.000 - 25.000
120 - 140		30.000		8.000 - 16.000
160 - 180		25.000		6.000 - 11.000
200 - 220		20.000		5.000 - 9.000
Round speeds for grit sizes F and C:				
F	40.000		10.000 - 20.000	
C	25.000		8.000 - 12.000	
Round speeds for specially marked instruments:				
◆	300.000		70.000 - 140.000	
★	160.000		40.000 - 85.000	
●	140.000		30.000 - 60.000	
▲ RA	15.000		7.500 - 10.000	