

Instructions for sterilization



Procedure code : H



WARNINGS :

Exceeding maximum rotation speed allowed would increase risks to security.
Insufficient water cooling can irreversibly damage the tooth and its surrounding soft tissues.

INSTRUCTIONS :

■ Indications :

Therapeutic application field is indicated on the label.

■ Contra-indications :

None to our knowledge.

■ Side effects :

None to our knowledge.

■ Working place :

Remove all dirt on surfaces using a paper towel.

■ Storage and transportation :

No special requirements. We recommend reconditioning these polishers immediately after use.

■ Pre-cleaning steps :

See "Disinfection" and "sterilization". No dismantling needed.

■ Manual cleaning

Material required : cleaning product (NaOH solution, 1 mole, 1 hour//hypochlorite solution, 12%, 1 hour// Helipur H plus N 4 %, 1 hour), brush and running water.

Procedure :

1. Remove all dirt from instrument by rinsing it (temp. : < 30° C).
2. Apply cleaning solution on all instrument surfaces with a brush.

NOTE : An adequate brush should be used for correct cleaning of places difficult to reach such as cannulation or blind holes.

3. Hold the instrument three minutes under running water and ensure that running water flows several times into and out of the cannulation and blind holes.

■ Automatic cleaning :

Material required : cleaning/disinfecting machine and cleaning product (BIB forte, for instance).

1. Place instruments in the machine.
2. Set the machine on standard cycle and clean for at least 5 minutes and rinse for at least 3 minutes.
3. After removing the instruments, check that cannulation and blind holes are free of dirt. If necessary, start a new cycle or clean manually.

■ Disinfection

A disinfection solution can be used, according to instructions on label (NaOH solution, 1 mole, 1 hour// hypochlorite solution, 12 %, 1 hour// Helipur H plus N 4 < 4 %, 1 hour). In case of automatic cleaning, 10 minutes rinsing at 80°C can be performed as last step.

■ Maintenance :

Discard any blunt or damaged polisher.

■ Checking of the instruments :

For all instruments : ensure that the instrument is neither damaged nor worn. Its' edges and corners must have no notches and be regular in shape. Long and narrow instruments (especially the rotary ones) must be checked for deformations. If the instrument is a component of another instrument, both components should be checked

■ Instructions regarding rotation speed

Never exceed the maximum rotation speed stated. The recommended and maximum speeds allowed can vary between products. For that reason, please refer to the rotation speeds indicated on the packaging and in our product catalog. Exceeding maximum rotation speed allowed, will tend to vibrate the polisher. Such vibrations can deform the polisher or its shaft and cause them to break. In the latter case, could occur to the user, the patient and other individuals.

■ Restrictions regarding instrument reconditioning :

Frequent reconditioning of these instruments will have little impact on them since their life expectancy first and foremost depends on wear and possible damages to them during use.

■ Packaging :

Single instrument : polyethylene bags may be used. These bags should be big enough to accommodate the instrument without putting the sealing system of the bag under tension. Instrument sets : sort out the instruments using appropriate trays, or place them on an all-purpose tray. Corners and edges must be protected, and the weight per tray should not exceed 12 kg. Insert size : (18 x 14 x 2 cm or 25 x 10 x 5 cm); wrap using the CSR-double-wrapping procedure according to AAMI standards.

■ Sterilization :

Vacuum autoclaving at 134°C for 20 minutes. Temperature must not exceed 150°C. Do not use a chemiclave or a hot air disinfectant.

■ Storage :

No special requirements.

■ Additional information

If several instruments are to be sterilized in the autoclave, ensure that the maximum weight allowed by the autoclave manufacturer is not exceeded.

■ How to contact the manufacturer

Phone number and address of the local distributor are provided in the prospectus. You can also call the following number : +49 (0) 7231-9777-0.

■ The manufacturer has validated the fact that the above specified instructions ARE SUITED FOR reconditioning these polishers so that they can be re-used.

The individuals who are responsible for reconditioning must ensure proper reconditioning by using the appropriate equipment and products, as recommended by the RKI (Robert Koch Institute). Any deviation from the given instructions would have to be thoroughly examined as to its impact and possible negative effects.

Directions for Use & safety rules



Recommendations for use of EVE polishers :

All EVE polishers are exactly tailored to your specific needs. Improper use can lead to tissue damage, early wear or destruction of the polisher, not to mention the risks to the user, the patient or other persons.

Proper use

- These instruments must only be used with turbines, hand-pieces and contra-angles that are technically and hygienically perfect, meaning that they should be well maintained and correctly cleaned. The turbines and contra-angles used for these instruments must ensure precise and regular rotation.
- Insert the instrument shaft into the driving unit as far as possible.
- Before applying the instrument on the surface to be treated, bring it to the rotation speed needed.
- In order to avoid deformations, use circular movements with the instrument.
- Do not bend the instrument or use it as a lever because this would lead to increased risk of breaking the instrument.
- Immediately discard any deformed, non-concentric rotating instruments.
- Unmounted polishers must be centered after shaft mounting in order to avoid vibrations during use and only high quality mandrels should be used. Using mandrels of inferior quality could break them and cause injuries.
- Protective glasses should be worn at all times. In case of improper use or material failure, the mandrel, shaft or work-piece can break and could become a dangerous flying object. Instead of wearing protective goggles, you can work behind a protective glass pane.
- Wearing a respiratory mask will prohibit inhaling dust from polishers or workpieces. We recommend a dust aspiration system.

Improper use of these instruments leads to bad quality results and more risks. This is why they must be used only by qualified persons.

Instructions regarding rotating speed

- Never exceed the maximum rotation speed stated. The recommended and maximum rotation speeds allowed can vary between products. For that reason, please refer to the rotation speeds indicated on the packaging and in our product catalogue.
- In case of non-observance of the maximum rotation speed allowed, the polisher will tend to vibrate. Such vibrations can deform the polisher or its shaft and cause them to break. In the latter case, the user, the patient and other persons can be injured.
- Observing rotation speeds ensures optimum results.

Non observance of the maximum rotation speed allowed increases safety risks

Pressure on the polisher

- Excessive pressure on the polisher can destroy it.
- Excessive pressure results in more heat produced.
- Excessive pressure can cause early wear of the polisher.

Always avoid excessive pressure on the instrument because this will cause overheating, which could damage the pulp. Additionally, in case of very excessive pressure, the instrument can break and, as a result, persons can be injured.

Water cooling

- In order to avoid the overheating of a tooth, sufficient water cooling must be ensured (50 ml/min).

Insufficient water cooling can lead to irreversible damages to the tooth and its surrounding tissues.

Storage, cleaning, disinfection and sterilization

- EVE instruments should be stored in their original packaging, at room temperature, in a place protected against dust, moisture and recontamination. Label on the packaging ensures proper identification of the product.
- Before taking the polishers out of their packaging and putting them into other containers, please read information regarding use, rotation speed, LOT-number and safety aspects like protective goggles or respiratory mask. Then, put the instruments in hygienically well maintained stands or in other appropriate containers.
- These instruments must be disinfected and sterilized before they are used on the patient.
- After use, disinfect the instruments immediately. The next steps are cleaning, disinfection and sterilization.
- Always wear protective clothes and gloves while reconditioning contaminated instruments.
- An appropriate disinfection product must be used, and Directions for Use should be followed according to the technique to be used, as well as working time and indications of this product. Please note that using aggressive products to clean, over-working the product or improper dosage of the product can destroy these polishers.
- Sterilization : vacuum autoclaving at 134°C for 20 minutes (or according to RKI recommendations). Temperature must not exceed 150°C. Do not use a chemiclave or a hot air disinfectant.

Before implementing the disinfecting and sterilizing technique, make absolutely sure it is the appropriate one for the specific instruments to be used.

Zur Angabe des bestimmungs gemäßen Gebrauchs werden auf unseren Verpackungen genormte Symbole verwendet.

EVEFLEX

Wear-resistant polisher, medium grain, for precious metals, amalgam and composite materials

made in Germany

REF 14023 - BV2K		10			
LOT 213199		7000 - 12000			
ISO 653 204 243 513 030					

07/2009 0124 134 °C

EVE Ernst Vetter GmbH
Rastatter Str. 30 / D- 75179 Pforzheim
www.eve-rotary.com / info@eve-rotary.com

see Directions for use/Product Catalogue	Disposable item	Filling
Single packaging	Order number	Rotation speed
Date of manufacture	ISO number	134°C Autoclave
Manufacturer : Ernst Vetter GmbH, D-Pforzheim	Lot number for product traceability	Protective goggles
Prophylaxis	CE marking	Respiratory mask