

## Instructions for use / Application and safety precautions

### Separation strips

DISTRIBUTED BY	MANUFACTURER	REV. STATUS	LANGUAGE
EVE Ernst Vetter GmbH Neureutstr. 6 75210 Kelttern, Germany	Dr. Hopf GmbH & Co KG Bayernstr. 9 30855 Langenhagen, Germany	01	English



#### SCOPE OF THIS INFORMATION:

Unless stated otherwise, the following information applies to the separating strips below offered by Dr. Hopf GmbH & Co. KG under the brand name EVE when used as intended.

#### INTENDED USE:

All the instrument groups listed above are for multiple use during dental treatments. They are used for reduction or for surface conditioning of dental tissues such as dental enamel and dental materials such as composites, metal alloys, ceramics and dental resins.

They are intended for use by trained technicians and dentists. Separating strips are used manually.

#### TRANSPORT, STORAGE AND TREATMENT OF NEW INSTRUMENTS PRIOR TO FIRST USE:

There are no particular conditions necessary for transport.

Please store all original packaged instruments at a clean and dry place at room temperature.

New instruments are not packaged in sterile condition and must be cleaned, disinfected and sterilized according to preparation instructions before each use.

With unpacking longer, thinner instruments and discs, take care not to bend them. It is best to open blister packaging with scissors; with rigid packages, both labels should be cut before lifting the cap.

#### DISPOSAL:

All our instruments are free of hazardous substances ex works. Only the requirements for protection against infection and contamination need be considered for disposal.

#### INSTRUCTIONS FOR USE:

All our instruments are developed and manufactured with care for their particular application. Improper use can endanger the user, the patient and possibly other persons as well as damage the instrument.

Prior to use, ensure that:

1. Users and assistance where mouth protection, goggles and gloves and that the environment (treatment unit, etc.) is appropriately disinfected.
2. Processing extraneous materials in the mouth, such as filling materials, can release nanoparticles of these. Depending on the starting material, these may be bioactive. Thus suction and possibly other protective measures such as a dental rubber dam, etc. are recommended.
3. Please work with as little pressure as possible (about 50 g, corresponding to the pressure applied when writing) and do not twist the instrument. Higher pressure only leads to greater heat development, faster wear and inferior work results. If the instrument jams, carefully remove the instrument without twisting it and check for damage before using it again.
4. Dull and damaged instruments must no longer be used. Please check the instruments prior to each use. Signs of damage with diamond instruments are blank spots on the working part, bent instruments which changes in the original form.

If the safety instructions are not followed, damage can occur to the tooth and surrounding tissue or the workpiece, possibly endangering the user, the patient and other persons.

#### NOTE REGARDING THE OBLIGATION TO REPORT:

According to the relevant statutory regulations, serious incidents which occur in conjunction with a product from us must be reported to Dr. Hopf (at the address end of next page) and to the responsible national authorities of the country in which the user works.

In terms of the law, incidents are subject to mandatory reporting if the use of the instrument directly or indirectly caused or could have caused the death or serious damage to health of the patient, user or another person (source: the German Safety Plan for Medical Devices [MPSV], Section 2).

#### DECLARATION OF ICONS USED ON THE LABELS:



Manufacturing date



Address of manufacturer



Consult instructions



134 °C  
To be sterilized  
in the autoclave

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#### GENERAL INFORMATION:

The following instructions contain the minimum requirements for reprocessing of which have been validated for safety. In addition, there are processing steps marked as recommendations (in italics), which can improve the result of the controls, particularly after cleaning and disinfection. Furthermore, there is also a validated manual method provided for cleaning and disinfection. It is considered as an alternative for regions with poor infrastructure or for cases where technical equipment fails. Fundamentally, all equipment used must meet the relevant standards and regulations and be in proper technical and hygienic condition.

#### BASIC LEGAL AND REGULATORY INFORMATION:

These preparation instructions were produced in accordance with the EU medical device regulation (MDR/2017), DIN EN ISO 17664: 2004 and the recommendations of the commission for hospital hygiene and infection prevention at the Robert Koch Institute (RKI): "Infection prevention in dentistry – requirements for hygiene" (2006) and "Hygiene Requirements for the Reprocessing of Medical Devices" (2012)

#### SCOPE OF THIS INFORMATION:

Unless stated otherwise, the following information applies to the separating strips below offered by Dr. Hopf when used as intended.

#### RISK ASSESSMENT AND CLASSIFICATION OF THE PRODUCT GROUPS ACCORDING TO THE GUIDELINE CITED ABOVE:

Due to their area of application and abrasive surface, separating strips are to be classified as semi-critical B for polishing, with particular requirements for preparation. The separating strips are technically suitable for preparation in most types of ultrasonic baths, cleaning and disinfection equipment and autoclaves. Cleaning and disinfection equipment can be insufficient for sole use in cleaning under some circumstances due to the aforementioned special considerations (please refer to critical process steps as well.). Our instruments are not suited for Chemiclav or hot air sterilization.

#### CRITICAL PROCESS STEPS:

The post-cleaning check is to be considered a critical process step (critical control point). The rough surfaces from diamond coating result in a risk that tissue remains and other impurities are not removed completely. This can reduce the effectiveness of disinfection and sterilization. Therefore, drying of impurities is to be avoided, and the post-cleaning check should be performed with particular care using aids such as a magnifier or microscope.

#### EXPERTISE AND PROTECTION OF THE PERSON PERFORMING PREPARATION:

The separating strips must only be prepared by persons with the necessary expertise. The requirements for this are defined in the relevant regulations and statutes. Gloves, mouth protection, safety glasses and protective clothing must be worn to avoid contact with potentially infectious material.

#### SUITABLE MEDIA FOR CLEANING AND DISINFECTION:

Only certified media produced according to the relevant standards may be used. The manufacturers of these cleaning and disinfection materials check whether a product is fundamentally usable for rotary instruments. Thus all media for which the manufacturer indicates a corresponding approval can be used. They should contain corrosion protection agents. Cleaning and disinfection media which contain strong acids and bases or hydrogen peroxide and sodium hypochlorite, are not suited for use.

#### STORAGE AND PREPARATION OF NEW INSTRUMENTS:

Please store all original packaged instruments in a clean and dry place at room temperature. New instruments are not packaged in a sterile condition and must be disinfected and sterilized according to the following instructions before use.

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#### PREPARATION OF USED INSTRUMENTS:

Separating strips must be prepared prior to each use according to the following steps.

<b>1. CLEANING AND DISINFECTION:</b>	<p>Cleaning should begin as soon as possible after use, no later than 6 hours, to avoid drying contaminants which are difficult to remove. Before storing used instruments, procedures for occupational safety (involving the risk of infection and contamination) must be followed.</p> <p><b>A) Automated cleaning and disinfection:</b>  <b>Recommendation:</b> Pre-cleaning in an ultrasonic bath can significantly improve visual inspection results. Please note the information from the device manufacturer.            Clean and disinfect the cleaning and disinfection equipment according to the instructions of the manufacturer. It should be ensured that the instruments are held in place so that they do not rub against anything and in particular so that the heads are not in a dead zone for rinsing. Instruments with blind holes (polishing equipment) should be stored flat.</p> <p><b>B) Manual cleaning and disinfection:</b>            Place instruments in cold water for at least five minutes, rinse under flowing water, remove any tissue remains with the aid of a brush, then rinse again. Repeat brushing and rinsing as needed after inspection with a magnifier.            After that, disinfect strips in a chemical disinfection bath. Please use only disinfectants which contain corrosion protection agents and comply with the concentrations and treatment times prescribed by the manufacturer.            All instruments must be rinsed after disinfection with water which is microbiologically and chemically safe, and then dry thoroughly with medical-grade compressed air.</p>
<b>2. FOLLOW-UP INSPECTION:</b>	<p>Prior to sterilization, all instruments must be inspected for cleanliness and functionality, preferably with a magnifier or microscope. For each kind of impurity, particularly on the diamond coating or serration or in blind holes, the cleaning and disinfection process must be repeated or the instrument must be discarded. Worn, bent or damaged instruments must be excluded.</p>
<b>3. STERILIZATION:</b>	<p><b>Recommendation for semi-critical (nonsurgical) instruments used:</b> we recommend unpackaged sterilization in autoclaves as a minimum.            Critical (surgical) instruments used must be packaged according to regulations and marked for sterilization in the autoclave. Generally, a partial pre-vacuum and dwell time of five minutes at 134 °C and about 2 bar pressure are used. The information from the equipment manufacturer is authoritative for this.</p> <p><b>Note:</b> Galvanic corrosion can occur in autoclaves with steel holders. This can lead to surface rust on the stainless steel shafts of instruments which, however, does not adversely affect the function of the instrument. To avoid this, all holders and the interior of the autoclave should be checked regularly for corrosion.</p>
<b>4. RELEASE:</b>	<p>The preparation must be documented according to regulations and the instruments released for reuse or storage.</p>
<b>5. STORAGE:</b>	<p>Prepared and packaged instruments must be stored at room temperature in a clean, dry place, protected from dust and free of vermin. The period of storage is subject to regulations, the quality of the packaging material, the permeability of sealed seams and storage conditions and generally comprises no more than six months.</p>
<b>CONTACT INFORMATION TO MANUFACTURER:</b>	<p>Dr. Hopf GmbH &amp; Co KG            Bayernstr. 9            30855 Langenhagen, Germany            Telephone: +49 (0)511 78 53 394            Fax: +49 (0)30 833 29 95            E-mail: info@sunshine-dental.de            www.sunshine-dental.de</p>
<b>CONTACT INFORMATION TO DISTRIBUTOR:</b>	<p>EVE Ernst Vetter GmbH            Neureutstr. 6            75210 Kelttern, Germany            Telephone: +49 (0) 72 31 97 77 -0            Fax: +49 (0) 72 31 97 77 -99            E-mail: info@eve-rotary.com            www.eve-rotary.com</p>

#### DECLARATION:

The manufacturer has validated that the instructions given above are suitable for preparing a device for reuse. The person performing the preparation is responsible to ensure that the reprocessing actually performed with the equipment used, materials and personnel in the reprocessing facility achieves the desired results. This usually requires validation and routine monitoring of the procedure so that the recommended guidelines from the corresponding institutions (such as the Robert Koch Institute) are complied with. Deviations by the person performing the preparation from the instructions provided should be carefully evaluated for their effectiveness and possible advantageous consequences.