Scope of this information
Unless stated otherwise, the following information applies to the groups of products below offered by Hopf, Ringleb & Co. GmbH & Cie. under the brand name HORICO® when used as intended: Separating strips, Diamond burs, Carbide burs, Polishers

Intended use
All the instrument groups listed above are for multiple use during dental treatments. They are used for reduction, excavation and cutting or for surface conditioning of dental tissues such as bone, dentin and 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. All other instruments are powered by a handpiece or angle attachment.
Note: There are handpiece and angle attachment drives with collets for handpiece, right angle shank and friction grip (FG) shanks. These must comply with the relevant ISO standards.

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 and handpiece.

Prior to use, ensure that:

1. Users and assistance wear mouth protection, goggles and gloves and that the environment (treatment unit, etc.) is appropriately disinfected, because infection particles can be scattered by the fast rotation and spray water.
2. Use only drives which are in good technical and hygienic condition. Please follow the operating instructions from the handpiece manufacturer!
   Please note explicitly that most preprocessing units generally do not lubricate the collet and bearings. Most handpiece manufacturers usually require this after 20 to 30 minutes of operation.
3. Please clamp the shaft of the instrument as deeply as possible. If instruments are loose or protrude too far, they can fly off, bend or break, causing injuries, or be swallowed or aspirated.
4. Select the speed such that the maximum allowed RPM is not exceeded (see the table for maximum speed). Exceeding the maximum speed increases safety risks, reduces the quality of work and generates heat. The recommended speed, which is generally about half the maximum speed, produces the best work results and reduces undesirable secondary effects to a minimum.
5. Ensure sufficient air/water cooling (minimum 60 ml/min).
6. 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.
7. Please bring the instrument up to working speed outside of the mouth or prior to contact with the workpiece. If vibrations occur, the instrument is bent and can no longer be used!
8. 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.
9. If the instrument jams, stop the handpiece, carefully remove the instrument without twisting it and check for damage before using it again.
10. 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 produce vibrations when starting and changes in the original form. Carbide instruments exhibit damaged and deformed cutting edges or breaks.
11. Long instruments are not suited for canals with curvature: there is a risk of breakage.

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.

Maximum speed

Diamant-Schleifinstrumente - DIAMOND INSTRUMENTS
INSTRUMENTS DIAMANTES - INSTRUMENTOS DIAMANTADOS

ISO Ø [1/10 mm]	– FG, W, RA, CA – [UPM – RPM – TPM]	– H, HP, PM – [UPM – RPM – TPM]
005–014 016–023	450 000 300 000	50 000 50 000
025–045 047–065 066–093	120 000 80 000 60 000	50 000 50 000 40 000
100–127 130–300 450	30 000 25 000	30 000 25 000 20 000

Sinter-Diamanten -
SINTERED DIAMONDS
DIAMANTS FRITTES
DIAMANTADOS SINTERIZADOS

ISO Ø [1/10 mm]	– H, HP, PM – FG – [UPM – RPM – TPM]
016–070	25 000
080–310	15 000

Hartmetall-Instrumente
TUNGSTEN CARBIDE INSTRUMENTS
INSTRUMENTS EN CARBURE DE TUNGSTENE
INSTRUMENTOS DE CARBURO DE TUNGSTENO

ISO Ø [1/10 mm]	- FG – W, RA, CA - [UPM/RPM/TPM]	- H, HP, PM - [UPM/RPM/TPM]
003–027	200 000	50 000
031	120 000	50 000
040	70 000	50 000
045	65 000	50 000
050	60 000	40 000
060	50 000	35 000
070	30 000	30 000

The optimal working speed recommended by HORICO is usually about 50% of the maximum permitted speed. However, the speed should be adjusted according to the material (refer to the information for the item in the catalog).

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 us (at the address below) 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 · to be sterilized in the autoclave · mouth gard · eye protection · empf. recommended turning speed · max. maximum turning speed

Reprocessing instructions

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 groups of products below offered by us when used as intended: Separating strips, Diamond burs, carbide burs, Polishers.

Risk assessment and classification of the product groups according to the guideline cited above
Due to their area of application and abrasive surface and/or blind holes, separating strips and polishiers are to be classified as semi-critical B for polishing, with particular requirements for preparation. Diamond burs and carbide burs are to be classified as semi-critical B (nonsurgical) or critical B (surgical) depending on the application and due to services with particular requirements for preparation. All the aforementioned product groups 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 or serration of instruments and blind holes in polishers 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 aforementioned product groups 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.

Preparation of used instruments
All product groups must be prepared prior to each use according to the following steps.

1. Cleaning and disinfection
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.

Recommendation: All typs of burs should be stored in a "bur's bath" as soon as possible after use until reprocessing. The bur bath should contain a disinfectant for better protection of the person responsible for reprocessing.

A) Automated cleaning and disinfection:
Recommendation: 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.

B) Manual cleaning and disinfection
Place instruments in cold water for at least five minutes, rinse under flowing water, remove any tissue remains with the aid of a brush or DIACLEAN cleaning stone (the latter for diamond grinding instruments only), then rinse again. Repeat brushing and rinsing as needed after inspection with a magnifier.
After that, disinfect strip, diamond and carbide instruments 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.

2. Follow-up inspection
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 (for polishers), the cleaning and disinfection process must be repeated or the instrument must be discarded. Worn, bent or damaged instruments must be excluded.

3. Sterilization
Recommendation for semi-critical (nonsurgical) instruments used: 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.

Note: 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.

4. Release
The preparation must be documented according to regulations and the instruments released for reuse or storage.

5. Storage
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.

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.

Contact information for the manufacturer
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