



EDENTA AG, Hauptstrasse 7, CH-9434 AU/SG – Switzerland
Tel.: +41 71 747 25 25 Fax: +41 71 747 25 50 e-mail: info@edenta.ch

User Information for rotating dental and surgical Instruments

- Use of improper instruments can cause insufficient preparation results.
- Excessive speeds while using instruments with overly large heads endanger the stability of the instruments.
- Excessive speeds applied near to the dental pulp can endanger its vitality. The same can be the result when using an inadequate supply of water spray.
- Observe permissible speeds indicated on packaging.
- The handpiece must be in proper working condition. The use of an adequate supply of water spray of a minimum of 50 ml/min on the working part is necessary in the 1500 min⁻¹ speed range to ensure reliable cooling of the material being worked on.
- Additional external cooling is needed for Instruments with a total length of > 19 mm and a head diameter of 1.8 mm (ISO -018).

- Moistening of the surfaces to be prepared must not be impaired by an incorrect suction system. Deflection of the coolant jet can also cause heat related damage.
- The recommended applied contact pressure range is 0.3 – 2 N (30 – 200 p) depending on the kind of preparation.
- Avoid tilting, levering, or blocking the instruments up by using too much contact pressure (increased danger of fracture).
- Insert the instruments as deeply as possible without excessive use of force into the chuck and check to ensure that they are secure.
- Extremely tapered instruments will wear faster at the tip due to the smaller size. To maintain the longevity of these instruments, careful preparation with less contact pressure is important.
- Apply Turbo instruments over their entire grinding surface.
- Roughness obtained with a diamond coating >ISO 524 has to be finished.
- Immediately remove any instruments that are damaged, bent or no longer run concentrically.
- Depending on the application, the use of protective goggles is recommended.
- Rotating instruments have to be disinfected, cleaned, dried and sterilised before the first application on the patient and immediately after every use.

Manual preparation							
Cleaning and Disinfection				Preparation for sterilization	Sterilization		Approval for use and storage
Instruments	Process	Substance	Exposure time				
Considering the restriction and the material compatibility							
Diamond grinding tools TC Cutters / burs Steel burs Polishers ¹⁾ Abrasives with ceramic bond Brushes / Flexi-Snap ³⁾	After mechanical cleaning, chemical disinfection and cleaning	Aldehyde-free disinfectant, DGHM or FDA approved and CE mark, may be used with ultra-sonic cleaner ²⁾ , concentrations according to the manufacturer's instructions.	According to manufacturer's instructions.	Remove residual disinfectant with water and dry. Visual check and functional test; if necessary reclean and condition steel drills with anti-corrosion spray. Packaging complies with EN ISO 11607 / DIN EN 868-2ff.	semi-critical B Steam sterilization 121°C / 1.1 bar; 20 min. 134°C / 2.1 bar; 5 min. Steam sterilizer should comply with DIN EN 13060, class B or DIN EN 285	critical B	Approval or rejection in the case of an incorrect procedure to be carried out by specialist. Storage in suitable sterile packaging.

Mechanical preparation							
Cleaning and Disinfection				Preparation for sterilization	Sterilization		Approval for use and storage
Instruments	Process	Substance	Exposure time				
Considering the restriction and the material compatibility							
Diamond grinding tools TC Cutters / burs Steel burs Polishers ¹⁾ Abrasives with ceramic bond Brushes / Flexi-Snap ³⁾	After mechanical cleaning, mechanical disinfection and cleaning in a cleaning and disinfection machine	Cleaning agent DGHM (German Society for Hygiene and Microbiology) or FDA approval and CE Mark, concentration according to the manufacturer's instructions.	Cleaning and disinfection machine programme according to the manufacturer's instructions	Remove residual moisture	semi-critical B Subsequent sterilisation in a steam steriliser can be omitted with verifiable disinfection in a cleaning and disinfection machine	critical B Steam sterilization 121°C / 1.1 bar; 20 min. 134°C / 2.1 bar; 5 min. Steam sterilizer should comply with DIN EN 13060, class B or DIN EN 285	Approval or rejection in the case of an incorrect procedure to be carried out by specialist. Storage in suitable sterile packaging.

semi-critical B Non-invasive use
Instruments come into contact with mucosa or pathologically changed skin.

This manufacturer's information applies for all instruments, which are used for the following non-invasive (preventive/ restorative/ dental prosthetic/ orthodontic treatments) measures: these are polishers, ceramic abrasives, rotary ceramic, tungsten and diamond instruments, which are used for cavity and crown preparations, for filling removal and preparation or for crown cutting.

critical B Invasive use
Instruments, which penetrate the skin or mucosa and consequently come into contact with blood, inner tissues or organs, including wounds.
This manufacturer's information applies for all instruments, which are used for surgical, periodontal or endodontic measures: these are tungsten-carbide and diamond rotary instruments and also rust-proof stainless steel or ceramic instruments as well as steel or nickel-titanium root canal instruments (including manual root canal instruments).

Detailed recommendations for preparation in accordance with DIN EN ISO 17664 www.edenta.ch

1. Sterilisation for polishers at 134°C / 2.1 bar; 5 min. is recommended.
2. The use of bur stands or trays is necessary to avoid contact damage. The use of inappropriate disinfectants and/or keeping the instruments too long in the disinfectant can result in corrosion (increased danger of breakage) and discolouration of the instruments or the colour coding can come off. No alkaline disinfectant must be used for the disinfection of silicon rubber polishers.
Do not place polishers in alcohol!
3. Use brushes / Flexi-Snap as single-use products!

Storage and Keeping Conditions:

In dry conditions and protected against contaminants. Protect instruments in general against chemicals, acids, heat and extreme temperature variations. Do not use polishers after expiration date indicated.

Observe guidelines from Robert-Koch-Institut - ch. E3, (Hygiene Requirements in Dentistry) or the valid legal and hygiene regulations in the respective country!

Steel instruments are unsuitable for both mechanical preparation and the steam steriliser. They should be replaced by corresponding tungsten-carbide instruments. **Single-use products** (identified on the packaging with) are not approved for reuse. Safe use cannot be guaranteed if these products are reused, as there is the risk of infection and/or the products are no longer safe to use. The end of the product's service life is generally determined by wear and damage due to use.

Colour-anodised aluminium units (e.g. Bur block 40500 to 40580 and Retopin mandrel) lose their colour during use of standard cleaning procedures and in a cleaning and disinfection machine. Cleaning and disinfectant agents, which are specifically designed for these materials should be used during preparation.