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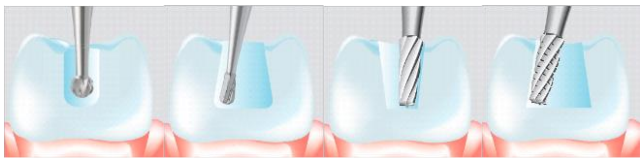

**SRN: LI-MF-000011937**

# Tungsten carbide and steel drills / finishers

Tungsten carbide drills / crown separators / PowerCut / finishers / periodontics / amalgam removers / steel drills

Basic UDI-DI: **++ E31210521CQ**

Use: reusable instruments, supplied non-sterile - reprocess before first use.

**Detailed reprocessing recommendations in accordance with DIN EN ISO 17664 www.edenta.com**

Storage: protect packaged instruments from high temperatures and UV radiation. Store in a dry and clean place, do not store in a room with solvents or chemicals. Storage temperature: 15°C - 25°C | Transport temperature: 10°C - 35°C.

**Intended purpose:**
Tungsten carbide/steel drills and finishers for the preparation and finishing of restorations in the dental practice / clinic. For use by medical professionals with a degree in dentistry.
Tungsten carbide/steel drills and finishers for removing carious tooth substance, for preparing retention, resistance and contour forms, for finishing crown stumps and cavity margins, for smoothing fillings during cavity preparations, for excavating cavities, for drilling out old fillings, for separating crowns and bridges and for dental measures to prepare a tooth for fitting a crown.

**Description:**
Tungsten carbide/steel drills and finishers are rotary instruments with a stainless steel shank and a working part made of tungsten carbide or steel with teeth. The instruments are available in different shapes, head diameters and working lengths. The shanks are designed to fit into standard dental handpieces. The shanks of the instruments are designed exclusively for use in motors (straight/contra-angle handpieces and turbines) in accordance with standard EN ISO 14457:2017.

**Application:**
Tungsten carbide/steel drills and finishers for restorative and prosthetic work in the dental practice / clinic. The instruments can be used to cut or finish a variety of dental materials. This includes tooth materials such as enamel, dentine and bone, dental materials such as amalgam, composite, glass ionomer cements, polymer and ceramic veneers as well as precious and non-precious metal alloys.

| | | | | | |
|---|---|---|---|---|---|
| Cavity preparation | | Crown separation | | Root smoothing | |
| Drilling out old fillings | | Root canal preparation | | Crown preparation | |
| Filling processing | | Orthodontics | | | |

**Safety instructions:**

- Use of instruments only by specialised personnel (degree in dentistry).
- The instruments must be disinfected, cleaned, dried and sterilised before being used on patients for the first time and immediately after each use.
- see validated procedure under

**Detailed reprocessing recommendations in accordance with DIN EN ISO 17664 www.edenta.com**

- Tungsten carbide/steel drills must not be sterilised with chemical agents or dry heat, as these methods have not been validated for use.

- Instruments made of tool steel (steel drills) are neither suitable for machine reprocessing nor for steam sterilising and can only be disinfected manually with a suitable agent. It is recommended to change to an appropriate tungsten carbide instrument.
- Unfavourable instrument shapes result in incorrect preparation shapes.
- Observe the operating speed (rpm) - the maximum speed is indicated on the product packaging. Using the instruments outside the speed range can lead to instrument breakage and injury to the patient and user. Excessively high speeds close to the pulp jeopardise its vitality.
- Ensure sufficient water spray cooling **(min. 50 ml/min)** on the working part at all speeds above 1500 rpm. Additional external cooling is required for instruments with an overall length of >19 mm and a head diameter >1.8 mm (ISO -018).
- Depending on the type of preparation, work with a contact pressure of 0.3 - 2N.
- Avoid blocking the instruments due to excessive contact pressure as well as tilting and levering (increased risk of breakage).
- The motor systems (dental handpieces) must be in a technically flawless condition.
- Clamp the instruments as deeply as possible into the dental handpieces and check that they are firmly seated.
- Damaged, bent or out-of-round instruments must be sorted out immediately and no longer used.
- The use of a rubber dam is recommended.
- The use of safety goggles is recommended.

**Possible side effects:**
The information on instrument handling, especially on water-spray cooling, contact pressure, disinfection, cleaning and sterilisation given in the section on safety instructions must always be observed and complied with. The instruments may only be used for their intended purpose (application symbols). Failure to observe the safety instructions may result in injuries such as heat necrosis, tissue or nerve damage, as well as biological width violations or infections. Failure to observe the safety instructions can also result in damage to the instrument motor.

**Storage of reprocessed instruments:**
Reprocessed instruments should be stored in hygienically maintained racks, trays or other suitable containers and in their original packaging at room temperature until they are used for the first time. The same applies to sterilised instruments and those with sterilisation packaging. Storage must be protected from dust, moisture and recontamination.

**Disposal:**
For safe disposal, the instruments must be placed in break-proof, puncture-proof and sealed containers (contamination protection). The local, official regulations for the disposal of medical instruments must be observed!

Enthält gefährliche Substanzen

**CAS** 7440-48-4: Cobalt

**Contains hazardous substances:**
The products labelled with the CAS number (CAS:7440-48-4) contain more than 0.1 mass percent cobalt, which is classified as a CMR substance of Class 1B as possibly carcinogenic, mutagenic and/or toxic to reproduction. Tests have shown that the quantities of cobalt released by medical devices used for their intended purpose are so low that they pose no danger and no precautionary measures need to be taken.

**Serious incidents:**
Notice to the user and/or patient that any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is resident.

**Description of the symbols used:**

| | | | | | |
|---|---|---|---|---|---|
| MD | Medical device | | Manufacturer | 2019-09 | Date of manufacture |
| | Packaging unit | | Follow the instructions for use www.edenta.com | REF | Order number |
| ISO | ISO number | LOT | Lot number - for traceability of the batch | max. | Maximum permissible speed |
| opt. | Speed recommendation | | Ultrasound | | Thermal disinfector |
| 134 °C | Autoclave | | | | |

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