

PREMIUM ROTARY INSTRUMENTS

These Instructions for use and reprocessing apply to all DIATECH diamond instruments used on patients.

Definition

DIATECH diamond instruments are rotary grinding instruments for dentists, for the treatment of hard tooth substances, composites, metals, ceramics and similar dental restorative materials. DIATECH diamond instruments consist of a working part with diamond grains in a galvanic nickel bond on a stainless steel shaft.

Indications

- Preparation of cavities
- Preparation of crowns Removal of old fillings
- Fine adjustment
- Crown separation
- · Endo-access

Contraindications

DIATECH diamond instruments contain small amounts of nickel. The instruments should not be used in patients with a known nickel allergy, as hypersensitivity may occur in extreme cases.

Safety Information

- WARNING · Only supplied to dentists and dental laboratories or upon their instructions.
- Wear safety glasses to protect eyes from emitted particles.
- Wear respiratory protection and use suction to prevent inhalation of aerosol and/or dust generated during application.
- The use of non-sterile diamond instruments increases the risk of infection. The diamond instruments must be cleaned and sterilised in accordance with the reprocessing instructions below, before the first and each subsequent application

- · The use of blunt, damaged or no longer smooth-running diamond instruments increases the risk of injury and can have a negative effect on the work result.
- Tilting the diamond instrument and using the diamond instrument with a wedge or lever action can increase the risk of breakage.
- The development of heat during preparation can lead to damage of the tooth substance, pulp and adjacent fillings.
- Exceeding the maximum specified speed may result in excessive heat generation and/or damage to the diamond instrument.
- The use of diamond instruments with excessive contact pressure can lead to excessive heat development and/or damage to the diamond instrument.
- The use of a technically faulty handpiece increases the risk of injury and can have a negative effect on the work result.
- Dental material or other residues that are detached during application can be aspirated or swallowed.

Application

- Only use technically and hygienically perfect handpieces and diamond instruments. Diamond instruments with blank areas on the working part as well as blunt, damaged, bent or no longer smooth-running diamond instruments must be sorted out immediately and disposed of properly.
- Use a rubber dam to prevent aspiration or swallowing. The diamond instruments have to be selected (shape, size,
- type) primarily according to the type of preparation. Diamond instruments with coarse grain are suitable for gross reduction. Diamond instruments with fine grain are suitable
- for fine finishing. Secure the diamond instruments carefully and completely into the handpiece.
- Check that the diamond instrument is securely connected to the handpiece.
- Before applying the diamond instrument to the preparation site, bring it up to working speed. Ensure that the instrument rotates without unbalance and that the water cooling functions properly.
- Place the diamond instrument rotating at working speed on the preparation site and begin with preparation. The ergonomic principles must be taken into account during the working procedures. Do not use the instrument with a wedge or lever action. Once the preparation has been completed, remove the rotary instrument from the site and allow it to come to a standstill.
- During use, move the diamond instrument continuously and use with sufficient water cooling (min. 50ml/min).
- Use speeds as indicated on the packaging label. The recommended force applied (reference value 1.5 N) is
- based upon the diameter of the diamond instrument and the substrate to be worked on.

Storage

DIATECH Diamond grinding instruments for the dental practice

Whenever possible, the diamond instruments should be stored in their original packaging to enable them to be identified and traced.

Marking:

The LOT number is shown on the package label.

REPROCESSING INSTRUCTIONS

The instructions given below were validated by the manufacturer of the medical device as being suitable for the preparation of a medical device for its reprocessing. The reprocessor is responsible for ensuring that the actual reprocessing with the equipment, materials and personnel employed in the reprocessing plant delivers the desired results. This requires verification and/or validation and routine monitoring of the process.

▲ Safety instructions

- DIATECH diamond instruments are supplied non-sterile and must be reprocessed before the first and each further use. If not cleaned and sterilised properly, there is a risk of infection.
- · Protective clothing, gloves and goggles must be worn at all times during reprocessing.
- Only use a cleaning agent/disinfectant suitable for diamond instruments.
- Strongly acidic and alkaline cleaning agents can lead to impairment of the diamond instruments. It is recommended to use pH neutral detergents.
- Simple cold disinfectant solutions are unsuitable for repro cessing. Such solutions do not result in sufficient sterility and may contain corrosive substances that reduce the performance and resistance of the diamond instrument.
- Use a cleaning agent containing a corrosion inhibitor. The cleaning agent manufacturer's instructions must be followed.
- Use sterilizing devices according to the manufacturers recommended procedure.
- It is the responsibility of the user to ensure that sterilisation is effective.

Reprocessing limitations

Repeated reprocessing has a minimal effect on the diamond instruments

The end of use is determined by the wear and damage of the diamond instrument during its use. Diamond instruments must be checked for wear and damage before each use.

INSTRUCTIONS

Initial treatment at the site of use

Remove surface contamination immediately after use on the patient using a disposable cloth, then place diamond instruments in container

Storage and transport:

Transport diamond instruments in a closed container to the reprocessing site immediately. Start cleaning immediately.

riangle The drying of impurities makes cleaning of diamond instruments more difficult.

Ultrasonic cleaning

- 1. For pre-cleaning, place diamond instruments in a bath with a suitable enzymatic cleaning agent (e.g. BioSonic UC32, man-ufactured by Coltène/Whaledent Inc., contact time: 5 minutes). Ensure that the diamond instruments are completely covered by the cleaning agent and do not come into contact with each other.
- 2. Remove remaining impurities with a soft brush. A Special attention must be taken to ensure that difficult-toaccess areas of the diamond instruments are cleaned and that spreading of germs through spraying is prevented.
- 3. Remove the diamond instruments from the cleaning agent and rinse with cold water for 2 minutes. 4. Dry the diamond instruments with a fibre-free cloth.
- 5. Fill the ultrasonic device with a suitable enzymatic cleaning agent (e.g. BioSonic UC32, manufactured by Coltène/ Whaledent Inc.).
- 6. To avoid damage, insert the diamond instruments into a suitable instrument holder and place in the ultrasonic device
- 7. Treat the diamond instruments in an ultrasonic bath for 10 minutes.
- 8. Remove the diamond instruments from the ultrasonic device at the end of the program and rinse under cold water for 2 minutes.

Drying

Dry the diamond instruments with a fibre-free cloth.

Maintenance, inspection and testing

Visual inspection for cleanliness and integrity, using magnification if necessary. In case of visible contamination, the process must be repeated. Damaged or rusting diamond instruments must be disposed of.

riangle Diamond instruments cannot be properly sterilised unless they have been thoroughly cleaned and are free from contamination.

Packaging for sterilisation

Pack diamond instruments in bags which have been validated for sterilisation (e.g. self-adhesive bags from SPSmedical).

Sterilisation

Diamond instruments can be sterilised by applying a sterilisation cycle with dynamic air removal. Sterilise in a bag at full cycle with a minimum holding time of 3 minutes at 132 °C (270 °F).

▲ DIATECH diamond instruments are not suitable for sterilisation with hot air or in chemiclaves, as these reprocessing methods have not been validated.

Storage

Store the diamond instrument in the sterilisation bag until use.

Recommended Speeds

Head diameter in 1/10 mm	Speed range (r.p.m.)
007-011	75.000-150.000
012-015	60.000-110.000
016-019	45.000-88.000
021-023	40.000-75.000
024-028	30.000-65.000
029-032	25.000-56.000
033-041	22.000-45.000
042-054	20.000-37.000
055-060	17.000-32.000

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Keep out of the reach of children.

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Diamond instruments should be stored in a dry environment.