# **DIATECH Diamond Instruments**

Please read the instructions for use carefully before using the product.

Diamond burs are rotary grinding devices used in conjunction with dental hand-pieces for dental restoration procedures. They are made of stainless steel plated with diamond abrasive grit at their working end. Diamonds burs are available in various head shapes and sizes, shank types and lengths as well as abrasive grits.

INTENDED USE
Diamond burs are intended to be used for the purpose of grinding or finishing hard structures in the mouth including teeth and dental restorations.

### COMPOSITION

Shank: stainless steel Binder: nickel Abrasive grit: diamond

### INDICATIONS FOR USE / CLINICAL BENEFIT

Treatment or modification of hard structures in the mouth i.e. due to:

- Endodontic treatment
- Replacement or modification of dental restorations Tooth defects requiring prosthetic treatment Cosmetic dental treatment

### CONTRAINDICATION

Don't use in patients with a known nickel allergy. Don't use on metal and amalgam.

- ARELI INSTRUCTIONS

  Use personal protective equipment during use or handling of instruments

  Use a rubber dam to prevent aspiration or swallowing of wear debris, disconnected instruments or parts of broken instruments

  The instruments must be cleaned, sterilised, and checked in accordance with
  the reprocessing instructions below before the initial use and each subse-
- the reprocessing instructions below below the notice of a licensed health-quent re-use. Federal law restricts this device to sale by or on the order of a licensed health-care practitioner. The use of DIATECH Diamond Instruments in the patient's mouth may only be undertaken by specialist personnel such as dentists. Don't use instruments showing signs of wear or dramage (i.e. blunt, broken tips, deterioration, discolouration, inconsistent material removal, deformed/ non-concentric rotation, etc.). Increases the risk of injury, breakage, and can have a negative effect on the work result. Instruments showing signs of wear or damage should be removed from service and discarded. Illting the instrument and using it with a wedge or lever action can increase the risk of breakage.
- Illing the instrument and using it with a wedge or lever action can increase the risk of breakage.
  The generation of heat during preparation can lead to damage of the tooth substance, pulp and adjacent fillings.
  Exceeding the maximum specified speed and/or contact pressure may result in excessive heat generation and/or damage to the instrument.
  Don't use a technically faulty handpiece.

- Dental material or other residues that are detached during application can be aspirated or swallowed.

SIDE EFFECTS / INTERACTIONS
Hypersensitivity may occur in patients with a nickel allergy.

**USER / PATIENT GROUP**Use by qualified dental professionals only. Suitable for all patient groups.

- Always place a rubber dam Only use technically and hygienically flawless handpieces and instruments. The instruments must be selected based on shape, size and type according to the type of preparation. Ensure that the instrument is securely connected to the handpiece.

- NOPER USE

  Use speeds as indicated in the table below. The application speeds are also indicated on the packaging label. Do not exceed the maximum speed indicated.

  Before applying the instrument to the preparation site, bring it up to working
- speed. Ensure that the instrument rotates without imbalance and that the wa
- During use, move the instrument continuously and use with sufficient water cooling (min. 50ml/min). Ensure that the effectiveness of the water cooling is
- not impaired by an incorrect suction system or deflection of the water spray. Do not apply pressure exceeding 1.5N. Tapered instruments will wear faster at the narrower tip portion. The longevity of these instruments may be increased by using less contact pressure.

RPM Speed Range (min-1)
75000 – 150000
60000 - 110000
45000 – 88000
40000 – 75000
30000 - 65000
25000 – 56000
22000 – 45000
20000 – 37000
17000 – 32000

## TEST METHOD FOR CORRECT APPLICATION

- Concentric rotation RPM of device is within the recommended speed range
- Sufficient water cooling

# REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE

General remarks

The instructions provided below have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Special country-specific reprocessing and hygiene regulations may apply. The reprocessor is responsible to comply with the local regulations.

- DIATECH Diamond Instruments are supplied non-sterile and must be repro-cessed before the initial use and each subsequent re-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 re-

- 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 instrument. It is recommended to use pH neutral cleaning agents.
   Simple cold disinfectant solutions are unsuitable for reprocessing DIATECH Diamond Instruments. Such solutions do not result in sufficient sterility and may contain corrosive substances that may damage the instrument.
- Use a cleaning agent containing a corrosion inhibitor.

  The cleaning agent manufacturer's instructions must be followed.

- · Use sterilising devices according to the manufacturer's recommended proce-
- It is the responsibility of the user to ensure that reprocessing is effective
- The drying of contaminants can impede proper cleaning of the instrument. Prolonged exposure of instruments to contaminants such as blood residues can lead to corrosion damage.

Repeated reprocessing has a minimal effect on the instruments. The end of use is determined by the wear and damage of the instrument due to use. Instruments showing signs of wear or damage must be sorted out immediately and disposed of properly.

Place of use:
Remove surface contamination immediately after use on the patient, then place instrument in container.

Storage and transport: Transport instruments in a closed container to the reprocessing site immediately. Start cleaning immediately.

- Pre-Treatment:

  1. For pre-cleaning, place instruments in a bath with a suitable enzymatic cleaning agent (e.g. BioSonic UC32, manufactured by Coltène/Whaledent Inc., contact time: 5 minutes). Ensure that the instruments are completely covered by the cleaning agent and do not come into contact with each other.
- Remove remaining residues with a soft brush. Special attention must be taken to ensure that difficult to access areas of the instruments are cleaned and that
- spreading of germs through spraying is prevented.

  3. Remove the instruments from the cleaning agent and rinse with cold water for 2 minutes and dry with compressed air.

- Ultrasonic cleaning

  1. Fill the ultrasonic device with a suitable enzymatic cleaning agent (e.g. BioSonic UC32, manufactured by Coltène/Whaledent Inc.).

  2. Place the instruments into a suitable instrument holder to avoid damage and ensure all surfaces are cleaned and disinfected. Place instrument holder with instruments in the ultrasonic device and ensure it is fully submerged into the
- cleaning agent.

  3. Start the ultrasonic device and treat the instruments for a duration of 10 minutes.
- utes.

  4. Remove the instruments from the ultrasonic device at the end of the prog

  5. Rinse under cold water for 2 minutes and dry with compressed air.

- Maintenance, inspection and testing:
  Visual inspection for cleanliness and integrity, using magnification if necessary.
  In case of visible contamination, the process must be repeated.
  Instruments showing signs of wear or damage must be sorted out immediately and disposed of properly.

 $\triangle$  Diamond instruments cannot be properly sterilised unless they have been thoroughly cleaned and are free from visual contamination.

### Packaging for sterilisation:

Pack instruments in bags suitable for sterilisation (e.g. self-adhesive bags from SPSmedical).

Sterilisation:
The 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). (e.g. Statim G4 (SciCan))

Storage after sterilisation:
Store the sterilised instrument packed and protected from recontamination in the sterilisation bag until use.

# SHELF LIFE / STORAGE

Store in dry environment. Store in original packaging until first use to facilitate identification and traceability. Ensure identification and traceability after instrument has been removed from its original packaging.

DIATECH Diamond Instruments must be sterilized after use, stored in a suitable sharps container, and disposed of in accordance with local regulations. Used, unsterilized DIATECH Diamond Instruments must be classified as biohazardous, stored in a suitable sharps container, and disposed of in accordance with local regulations. The disposer is responsible to comply with the local regulations.

# REPORTING OBLIGATION

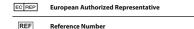
All serious incidents occurring in conjunction with this product must be reported immediately to the manufacturer as well as to the competent authority.



### Glossary

UDI

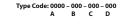




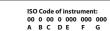


NON STERBLE	Non-sterile	
*	Keep dry	

**Unique Device Identifier** 



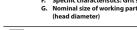
- Head No. May vary in length. Type of shank incl. overall length Nominal size of working part А. В. С. (head diameter)
- Nominal size of working part

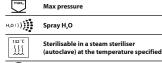


Material of working Part

Packaging size

- Coating
  Type of shank
  Overall length
- Shape Specific characteristics: Grit size





Maximum Speed RPM

7 Caution. Please follow general application  $\triangle$ and safety instructions

Importer – entity importing the medical device into the local

Peel in arrow direction to open blister

# COLTENE International Dental Group

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∇ OPEN ∇

Made in Switzerland by Coltène/Whaledent AG CH-9450 Altstätten

Customer Center

