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DIATECH Diamond Instruments

Instructions for use **EN**

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

PRODUCT DESCRIPTION
Diamond burs are rotary grinding devices used in conjunction with dental handpieces 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
Coating: gold

INDICATIONS FOR USE / CLINICAL BENEFIT
Treatment or modification of hard structures in the mouth i.e. due to:
- Caries
- 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.

SAFETY 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 subsequent re-use.
- Federal law restricts this device to sale by or on the order of a licensed healthcare 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 damage (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.
- Tilting 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.

PREPARATION
- 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.

PROPER 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 water cooling functions properly.
- 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.

Head diameter (ISO)	RPM Speed Range (min-1)
007 – 011	75000 – 150000
012 – 015	60000 – 110000
016 – 019	45000 – 88000
020 – 023	40000 – 75000
024 – 028	30000 – 65000
029 – 032	25000 – 56000
033 – 041	22000 – 45000
042 – 054	20000 – 37000
055 – 060	17000 – 32000

TEST METHOD FOR CORRECT APPLICATION
- Consistent material removal
- 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.

⚠ **WARNING**
- DIATECH Diamond Instruments are supplied non-sterile and must be reprocessed 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 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 procedure.
- 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.

Reprocessing limitations
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.

Instructions:
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.
2. 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.
4. Remove the instruments from the ultrasonic device at the end of the program.
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.

⚠ 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))

⚠ The instruments are not suitable for sterilisation with hot air or in chemiclaves.

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.

DISPOSAL
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.

CE 0123 UA.TR.120

Glossary

	Digital Instruction
CE	**Marking of Conformity Europe**
	Conformity mark Ukraine
Rx ONLY	**Restricted device for professional use only**
MD	**Medical Device**
	Legal Manufacturer
EC REP	**European Authorized Representative**
REF	**Reference Number**
	Manufacturing Date
LOT	**Batch Code**
UDI	**Unique Device Identifier**
NON STERILE	**Non-sterile**
	Keep dry
	Type Code: 0000 – 000 – 000 – 000 **A B C D**
#	**A. Head No. May vary in length.** **B. Type of shank incl. overall length** **C. Nominal size of working part (head diameter)** **D. Nominal size of working part (head length)**
	Packaging size
	ISO Code of instrument: **00 0 00 0 000 000 000** **A B C D E F G**
ISO	**A. Material of working Part** **B. Coating** **C. Type of shank** **D. Overall length** **E. Shape** **F. Specific characteristics: Grit size** **G. Nominal size of working part (head diameter)**
max.	**Max pressure**
H_2O	**Spray H_2O**
132 °C	**Sterilisable in a steam steriliser (autoclave) at the temperature specified**
1/min	**Maximum Speed RPM**
	Open here
	Caution. Please follow general application and safety instructions
	Importer – entity importing the medical device into the locale
▽OPEN▽	**Peel in arrow direction to open blister**

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