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DIATECH HP Polishers

Instructions for Use **EN**

Please read the Instructions for Use carefully before using the product. Keep for later reference.

PRODUCT DESCRIPTION
Polishers are rotary devices that consist of a silicone/synthetic rubber polishing head impregnated with abrasive material. Polishers are used in conjunction with dental hand pieces for dental restoration procedures. Polishers are available in various head shapes and sizes, shank types and lengths as well as abrasive grits.

INTENDED USE
Polishers are intended to be used for the purpose of fine contouring and polishing dental restorations extraorally.

COMPOSITION
Shank: stainless steel (may contain nickel)
Matrix: silicone or synthetic rubber, pigments
Abrasives: diamonds, silicon carbide, aluminium oxide

INDICATIONS
Extraoral treatments requiring contouring or polishing of restorations.

CONTRAINDICATION
Patient use.

SAFETY INSTRUCTIONS
- Use personal protective equipment during use or handling of instruments.
- The instruments can be cleaned, sterilized, 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 HP polishers may only be undertaken by specialist personnel such as dental technicians or dentists.
- Don't use instruments showing signs of wear or damage (i.e. deterioration, non-concentric rotation, etc.). This 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 discarded.
- Exceeding the maximum specified speed and/or contact pressure may result in excessive heat generation and/or damage to the instrument.

⚠WARNING
- Only use a cleaning agent/disinfectant suitable for polishers.
- Prolonged disinfection can damage the polisher or cause discoloration. Follow the manufacturer's specifications of the disinfectant with regard to the concentration and reaction time. Ensure that the process is effective.
- Strongly acidic and alkaline cleaning agents can damage the instrument. It is recommended to use pH neutral cleaning agents.
- Use a cleaning agent containing a corrosion inhibitor.
- Use sterilizing devices according to the manufacturer's recommended procedure.
- 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.

SIDE EFFECTS / INTERACTIONS
No side effects or interactions are known to the manufacturer.

USER- / PATIENT GROUP
Use by qualified dental professionals only. Not suitable for use on patients.

PREPARATION
- Only use technically flawless handpieces and instruments.
- The instruments must be selected based on shape, size and type according to the type of application.
- Ensure that the instrument is securely connected to the handpiece.

PROPER USE
- The recommended speeds are indicated on the packaging label. Do not exceed the maximum speed indicated.
- Before applying the instrument to the restoration, bring it up to working speed. Ensure that the instrument rotates without imbalance.
- During use, move the instrument continuously.
- To achieve best results, use the polishers in the indicated sequence when using multiphase polishing systems.
- Do not apply pressure exceeding 1.5 N.
- Choose the polishing system according to the application as indicated in the table below.

Polishing System	Application
Acrypol	Acrylics
Cerapol	All Ceramics

TESTMETHOD FOR CORRECT APPLICATION
- Check concentric rotation
- RPM of device is within the recommended speed range

REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE
General remarks
The instructions provided below have been validated by the manufacturer of the polishers as being capable of preparing a polisher 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.

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, then place instrument in container.

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

Pre-Treatment (optional)
1. For pre-cleaning, place instruments in a bath with suitable enzymatic cleaning agent (e.g. BioSonic UC32, manufactured by COLTENE, 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 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 (optional)
1. Fill the ultrasonic device with a suitable enzymatic cleaning agent (e.g. BioSonic UC32, manufactured by COLTENE).
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.

⚠ **Polishers cannot be properly sterilized unless they have been thoroughly cleaned and are free from visual contamination.**

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

Sterilization (optional)
Device: Sterilizer according to DIN EN 285 or small steam sterilizer according to DIN EN 13060, type B process or ANSI/AAMI ST55.

Process: Steam sterilization with fractionated pre-vacuum, 132 °C (270 °F) (parameter of validation) or 134 °C with holding and drying time according to the manufacturer of the sterilizer (e.g. 4 and 20 minutes).

1. Place the packaged products in the sterilization chamber.
2. Start the program.
3. Remove the products at the end of the program and allow to cool down.
4. Then check the packaging for possible damage and screening effects. Faulted packaging must be regarded as being non-sterile.

⚠ **The instruments are not suitable for hot air or chemiclave sterilization.**

Storage after sterilization
Store the sterilized instrument packed and protected from recontamination in the sterilization bag until use.

SHELF LIFE / STORAGE
Expiry date: see packaging
Storage temperature: 2-28 °C (36-82 °F)

Store in dry environment. Protect against exposure to heat and sun. Avoid extreme temperature fluctuations. 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 HP polishers must be stored in a suitable sharps container and disposed of according to applicable legislation. Special country-specific regulations may apply. Dispose only of completely emptied packages together with household waste in compliance with official 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.
In the unlikely event of inhalation, ingestion, eye contact, or similar incidents seek immediate medical attention from an appropriate medical specialist to mitigate potential harm.

CE 0123

Application Information

pxl.coltene.com/diatech-polishers

GLOSSARY	
	Consult instructions for use
CE	**Marking of Conformity Europe**
Rx ONLY	**Restricted device for professional use only**
MD	**Medical Device**
	Legal Manufacturer
EC REP	**European Authorized Representative**
	Importer
REF	**Reference Number**
	Manufacturing Date
	Expiry Date
LOT	**Batch Code**
UDI	**Unique Device Identifier**
	Keep dry
	Keep away from sun light
	Temperature limitation
NON STERILE	**Non-sterile**
	Packaging size
ISO	**ISO Code of instrument:** **000 00 0 000 000 000** **A B C D E F** **A. Material of working part** **B. shank type or bore diameter** **C. overall length** **D. shape** **E. specific characteristics: grit size** **F. nominal size of working part (head diameter)**
max.	**Max. pressure**
132 °C	**Sterilizable in a steam sterilizer (autoclave) at the temperature specified**
1/min	**Maximum Speed RPM**
	Caution. Please follow general application and safety instructions

COLTENE International Dental Group

Dent4You AG
Bahnhofstrasse 2
CH-9435 Heerbrugg

Made in Switzerland by
Coltène/Whaledent AG
Feldwiesenstrasse 20
CH-9450 Altstätten

Customer Center
service@coltene.com

COLTENE