

MDT's Carbide Cutters for Laboratory use **Instruction for use**

DESCRIPTION:

Carbide Cutters Rotary Instruments for Medical use and Cosmetic footcare and Nail design.
The Carbide Cutters intended to be use by professional dentists (chair side only) and dental technician in the dental laboratory.

Carbide Cutters for foot care/podiatry may only be used by podologists (medical podiatrists) who are familiar with the use of these instruments on the basis of state-certified training and experience. The instruments can be used universally for cosmetic foot care and the treatment of artificial nails.

Carbide Cutters are intended to be used by the Dental Technician for cutting, grinding and finishing of dental prosthetics or for cosmetic podiatry and manicure treatment used to debride excess toe nail and skin as well as extensive removal and shaping of thickened or mycotic nails.

Newly delivered unsterile instruments must be prepared accordingly before first use with patients.

SAFETY RECOMMENDATIONS:

- Until they are first used, rotating instruments should be kept in their original packaging, and protected from dust and moisture, at room temperature.
- Always keep the packaging so that the instruments are traceable if required.
- Always use fully functioning, correctly serviced and maintained handpiece.
- Insert the instruments as deeply as possible. Check for firm seating.
- Use respiratory and/or eye protection and an extraction system.
- Before starting to work on the workpiece, bring the instruments up to operating speed and make sure that they are running concentrically.
- **Clean and sterilize** instruments in accordance with the directions below before first use and before each reuse
- Always wear gloves when handling contaminated instruments.
- Surgical masks must be worn to avoid inhalation of aerosol or dust generated.
- Before each use, inspect the device for damaged or excessive wear. Discard worn device. Do not use rust instruments
- Observe the maximum speed. Risk of overheating and injury.
- Make sure that the instruments don't get jammed or levered.
- Excessive pressure can lead to damage to skin and tissue due to overheating.
- Only use the instruments in accordance with their intended use
- Failure to comply with or adhere to the following hygiene recommendations can lead to transmission of pathogens.
- If possible, use the entire length of the working part in order to avoid point overheating, e.g. of the tips (resulting excessive mechanical stress and local overheating).

INSTRUCTIONS FOR USE - CARBIDE CUTTERS IN THE DENTAL LABORATORY

1. Choice of instrument:

All rotary instruments can be used without restriction on dental laboratory materials in the dental laboratory.

2. Checking: The instrument should be checked for damage before use.

3. Practical use:

Set the handpieces to the correct operating speed for the material to be prepared before allowing the instrument to come into contact with the material.

Note: When preparing with a rotary instrument, it is essential to avoid excessive pressure.

4. Motor operating speeds:

Adhere strictly to the recommended motor operating speeds for the respective task and instrument.

5. Overheating of the material:

Overheating the material being prepared can have a detrimental effect on the properties of the material. At worst the material can lose the quality required for use in the oral cavity.

6. Overheating of the instruments:

Excessive motor speeds and excessive pressure cause overheating and tempering of the instrument, which can then lose its grinding and cutting capacity and damage the material.

To produce optimum results, run the rotary instruments at their recommended operation speed. The recommended operation speed must be adapted in line with the respective applications and medical circumstances. Lower speeds should be used when working in the dry technique in order to reduce the risk of heat building up. If the diameter of the working part exceeds that of the shank, powerful centrifugal forces may build up at higher speed which might bend the shank and/or fracture the instrument

SPEED RECOMMENDATION FOR LABORATORY USE - Guidance for RPM:

ISO-Ø Instrument head diameter 1/10 mm	Recommended Optimal permissible speed ↻	Recommended Maximum operational speed (RPM) ↻
008-023	25.000	40.000
025-045	20.000	30.000
050-080	15.000	20.000

7. Cleaning Laboratory Carbide Cutters:

The cutting blades of tungsten carbide instruments can be cleaned of surface dirt with a small toothbrush and in the case of ingrained dirt with the wire brush.

CARBIDE CUTTERS FOR BEAUTY / PODIATRY USE

REPROCESSING INSTRUCTIONS

1. Carbide Cutters for Beauty / Podiatric use are supplied mechanically clean, they are not sterile.
2. Prior to first use on the patient and immediately after every use (this is the only way to prevent drying of tissue substance)
3. The Cutters must be placed in a cleaning bath, disinfected, dried and inspected and, if necessary, sterilized.
4. The use of incorrect disinfectants and/or too long immersion in the disinfectant can lead to corrosion (increased risk of breaking) and to discoloration or the color ring may come off.

Always use an alkaline, aldehyde-free and alcohol-free cleaning and disinfection solution with corrosion protection (select agents which are expressly recommended as suitable by the manufacturer for the disinfection of rotating instruments (carbide)).

5. Place used instruments on a tray (for a maximum period of 1 hour).
6. Place the instruments in a covered container (free of bubbles) for pre-cleaning/pre-disinfection.
7. All podiatric instruments can also be cleaned in a thermal disinfectant.
8. Sterilization must be performed in an autoclave at 134°C/6 min (validated process):
 - a) Follow the autoclave manufacturer's instructions to sterilize the burs. In particular, care must be taken not to exceed the maximum recommended load for the autoclave.
 - b) MDT has validated steam sterilization in an autoclave without a pre-vacuum cycle (gravity displacement type) for a holding time of six (6) minutes at a temperature of 134°C. The holding time is the **minimum time** for which the minimum temperature is sustained.
 - c) Post sterilization allow drying time of 30 minutes.

***NOTE:** Local infection control practice may recommend a different combination of holding time and temperature.*

9. Only use fully deionized water for processing.
10. Observe the "Requirements for hygiene in the processing of medical devices". (Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) and the legal and hygiene requirements applicable in your country.

LIMITATIONS OF RE-USE

Reprocessing will have little effect on MDT's Cutters. The end of bur's/disc's life is determined by wear and damage in use and the burs/discs should be inspected for defects during the preliminary cleaning process.


Delay between use and reprocessing must be kept to minimum to avoid contaminants drying, thereby making cleaning more difficult. Therefore, keep the unclean burs immersed in the cleaning/disinfecting agent in accordance with its manufacturer Instructions, but in any event do not exceed 12 hours.

Caution: Do **not** leave burs immersed in disinfectants that have a fixative action (such as aldehyde-based products) unless the burs have been thoroughly cleaned first.

STORAGE

Storage should be in dry, clean conditions and at ambient temperature.


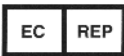




TRACEABILITY

Each package bears **Lot number**  on its label.
This number must be quoted in any correspondence regarding to the product.

SYMBOLS INTERPRETATION

Symbols on the product package should be interpreted as follows:

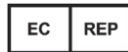
SYMBOLS:

	Manufacturer	Indicates the medical device manufacturer.		Authorized Representative in the European Community
	Lot Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.		Indicates the need for the user to consult the instructions for use.
	CE marking	Signifies European technical conformity		For Professional Use

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