Instructions for Use Burs & Discs (EN)

Language Variant English

1. APPLICATION NOTES

1.1 SCOPE

These document provide general instructions for rotatecs rotary devices and specific reprocessing recomondation that are applicable to the cleaning and steam sterilization of the multi-use Diamond Burs/Discs and Tungsten Carbid Dental Burs burs prior to initial use, and there after rotatecry subsequent re-use. The multi-use Diamond Dental Burs/Discs and TC burs are supplied mechanically clean, but NOT sterile.

rotatec Diamond Dental Burs are manufactured from stainless steel coated with Diamond.

The Diamond dental burs are part of rotatec Dental Rotary instruments portfolio available to its customers including diamond coated burs, TC dental burs, discs and dental polishers.

The rotary instrument are supplied as non-sterile for multi-use as follow.

1.2 DENTAL ROTARY INSTRUMENT – INDICATION FOR USE

These rotary instruments are intended for a wide variety of restorative procedures including but not limited to removal of caries or old restorations, preparation of cavities for restoration, finishing of restorations, interproximal reduction (IPR), removal of crowns, orthodontic device procedure and any other dental operation. It can be used to cut, grind or polish a wide variety of dental materials, including tooth material such as enamel, dentine, as well as dental materials such as amalgam, composite, zirconia, Lithium di silicate, glass cements, polymer and ceramic veneers and various alloys.

1.3 INTENDED PURPOSE

The dental rotary instrument is intended for laboratory and dental applications in clinics and hospitals both chair side and within the dental oral orifice.

1.4 INTENDED USERS

Professional use - Dental Rotary Instruments are intended for dentistry and must only be used by dentists and other qualified professionals who are familiar with use of these instruments based on their training and experience. Therefore, user training is not needed to ensure specified performance and safe use of the medical device.
For laboratory applications, the use of these instruments must be by a licensed technician.

1.5 INTENDED PATIENT POPULATION

All patients in need for dental care.

1.6 CONTRAINDICATIONS AND WARNINGS

- For the use of rotatec Diamond burs, TC burs or Diamond discs is contraindicated on any patient with known allergy to Nickel.
- The use of Tungsten Carbide burs in patients with known sensitivity to cobalt is not recommended; in these cases, the use of alternative devices should be considered.

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1.7 STORAGE (BEFORE USE):

Store in a dry and clean environment at ambient temperature.
The bur pattern selected will be chosen to cut a specific material in a specific application.
The following table gives guidance and provides **recommended RPM** for the user.

For FG diamond burs:

Diameter of the instrument head 1/10 mm	Maximum permissible speed (rpm)	Recommended operating speed (rpm)
007 – 010	450,000	100,000 – 220,000
011 – 014	450,000	70,000 – 220,000
015 – 018	450,000	55,000 – 160,000
019 – 023	300,000	40,000 – 120,000
024 – 027	160,000	35,000 – 110,000
028 – 031	140,000	30,000 – 95,000
032 – 040	120,000	25,000 – 75,000
041 – 054	95,000	15,000 – 60,000
055 – 070	60,000	12,000 – 40,000
071– 100	45,000	10,000 – 20,000

The following table applies to HP burs and HP diamond discs:

Process	Coarse reduction	Contouring	Finishing	Polishing
Standard colour code	blue	green	yellow	white
Speed, rpm	7,000 – 10,000	7,000 – 10,000	2,000 – 3,000	2,000 – 3,000

The following recommendations apply to carbide burs:

Application	Carbide bur type	Material	Size (mm)	rotatec ID number	Recommended operating speed (rpm)
Cavity preparation	Standard	Enamel/dentine	010 – 023	FG.TC0002-0008 / 0057 / 0556-0557	< 450,000
Removal of fillings	Standard	Amalgam/composite	010 – 018	FG.TC0330-0331	60,000 – 120,000
Excavation	Standard	Enamel/dentine	010 – 023	FG.TC0002-0008 / 0035	< 2,000
Finishing of margins	Finishing	Enamel	010 – 016	FG.TC0057	10,000 – 20,000
Finishing of restorations	Finishing	Amalgam	012 – 023	FG.TC0245	18,000 – 30,000
Finishing of restorations	Finishing	Composite	012 – 023	FG.TC 557 / 057	10,000 – 20,000
Finishing of restorations	Finishing	Glass ionomer	012 – 023	FG.TC 557 / 057	10,000 – 20,000
Finishing of crowns and bridges	Finishing	C&B acrylic	010 – 016	FG.TC 557 / 057	40,000 – 80,000
C&B metal grinding	Standard	Metals	018 – 027	FG.TC1157-1158 / 1557-1558	< 30,000
Grinding of acrylic dentures	Standard	Acrylic	018 – 027	FG.TC 1157 / 1158 / 330	< 20,000

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1.8 CLINICAL PRECAUTIONS AND WARNINGS:

Read carefully:

- **a)** The instrument shall be used by a dentist or an authorized dental technician in accordance with the following instructions.
- **b)** Read the packaging labels carefully to ensure correct use of the instrument. Failure to do so may result in procedural delays or injury to patients or users. Before use, check the integrity of the sterile packaging for damage and cracks that could impair the sterility of the product.
- **c)** Failure to follow these instructions for use may result in: possible damage to the tooth/restoration, injury to the patient or user, or possible aspiration or swallowing of the instrument.
- **d)** Clean and sterilize instruments supplied non-sterile before first use and before each reuse according to the instructions below to avoid any risk of contamination.
- **e)** Always wear gloves when handling contaminated instruments.
- **f)** The pouch of sterile products must only be opened immediately before use. The pouch should be retained until the end of the treatment to allow correct identification.
- **g)** Protect the patient's eyes and sensitive tissue when using these instruments.
- **h)** Dentists should wear eye protection and a face mask when using these instruments.
- **i)** Surgical masks must be worn to avoid inhaling aerosols and/or dust generated during the procedure.
- **j)** Ensure that the instrument is fully seated and gripped in the handpiece chuck. Failure to follow these instructions may result in possible damage to the tooth, injury to the patient or user, or possible aspiration or swallowing of the instrument.
- **k)** Before use, inspect the instrument for rust, broken and/or damaged flutes and dispose of any possibly defective burs/discs. Do not use worn or blunt instruments.
- **l)** Do not apply excessive pressure to the instrument as this may result in undesired heating and/or failure of the instrument.
- **m)** Keep the instrument in constant motion during use to avoid local heating and/or damage to the instrument. Undesired heat generation may cause discomfort, tooth or tissue necrosis or burns to the patient.
- **n)** Avoid removing the instrument at too sharp an angle in order to prevent leveraging effects and fractures that could injure the patient or user.
- **o)** Never force an instrument into a handpiece, as this could damage the handpiece chuck and lead to a delay in the procedure.
- **p)** Do not exceed the maximum speeds indicated on the label, as this may result in undesired heat generation or reduced effectiveness.
- **q)** Paediatric **diamond** burs should be used with a mini-handpiece intended for the use of short-shank burs and standard burs up to 20 mm in length.

The type and shape of the dental instruments are selected at the dentist's discretion and according to the required application.

2. REPROCESSING RECOMMENDATION FOR DIAMOND BURS/DISCS AND TC BURS

2.1 SCOPE

The reprocessing instructions detailed below apply only to reusable burs/discs. Burs shall be reprocessed upon initial use and prior to being reused.

2.2 LIMITATIONS OF REUSE

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

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

Prolonged storage in disinfectant solutions may result in corrosion and should therefore be avoided.

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

2.3 WARNINGS

Used instrument should be considered as being contaminated and appropriate handling precautions should be taken during reprocessing. Gloves, eye protection and a mask should be worn. Other measures may be required if there are specific infection or cross-contamination risks from the patient. Used burs are also considered as biohazard and need to be discarded as bio-hazard waste unless reprocessing procedures has been done according to the instructions.

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2.4 STERILIZATION – WITH STEAM

Packaging for Sterilization

When using either an autoclave with a pre-vacuum cycle or gravity displacement, place the instruments in appropriate instrument trays or pack them in pouches validated for steam sterilization.

NOTE: *Local legislation for sterilization may require that dental instruments are wrapped in pouches for processing in either type of autoclave.*

Sterilization

Follow the autoclave manufacturer's instructions to sterilize the instruments. In particular, care must be taken not to exceed the maximum recommended load for the autoclave.

rotatec has validated steam sterilization in an autoclave for both pre vacuum as well as in a gravity displacement type for a holding time of 4 minutes at a temperature of 134 °C and drying time of 15 Min.

The holding time is the minimum time for which the minimum temperature is sustained.

Note: For the purpose of rotatec dental instruments, steam sterilization validation a Yipak self-sealing sterilization pouches were used.

1. Place the packaged instruments in the sterilization chamber
2. Start the program (The validated time was four (4) minutes as a minimum, longer time is also possible)

Cycle duration minutes minimum (Min.)	Cycle temperature (^{0}C)	Drying time (Min.)
4	134 °C	15

1. Remove the instruments at the end of the program and allow them to cool down
2. Check the packaging for possible damage and screening effects
3. Faulted packaging must be inspected as being non-sterile. The instruments must be repacked and re-sterilized.

NOTE: Instrument blocks (stand) can be used for sterilization purposes for immediate use only.

Storage

The device should be stored in the sterilization pouch until required.

Storage

Duration of storage according to own specifications.

It is recommended to store instruments packed and protected from recontamination in proven suitable sterile packaging, cassettes or retainers.

2.5 VALIDATION OF CLEANING AND STEAM STERILIZATION

The above detailed processes have been validated as being capable of preparing rotatec's dental burs and discs for reuse. It remains the responsibility of the reprocessor to ensure that the reprocessing as actually performed, using the equipment, materials and personnel in the reprocessing facility, achirotatec the required results. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.

2.6 DISPOSAL

Used burs are considered as biohazard and need to be discarded as bio-hazard waste in accordance with local regulations.

2.7 TRACEABILITY

Each package includes **Lot number** 

on its label. This number must be quoted in any correspondence regarding to the product.

3. CONTACT ROTATEC

Any serious incident that has occurred in relation to our instrument must be reported to **rotatec** (at the address shown below) and to the competent authority of the Member State in which the user/patient is established.

If you return burs to rotatec, please ensure that all contaminated and/or potentially contaminated burs have been effectively cleaned and properly packaged for return.

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4. GLOSSARY OF SYMBOLS

Symbol	Meaning
	Manufacturer
	CE conformity
	Authorized Representative in the European Community / European Union
	Use-by date (Expiration date)
	Batch code
	Catalogue number / Part number
	Unique Device Identifier
	Medical device
0483	Identification number of the Notified Body
	ISO number
	Global Trade Item Number (GTIN)
	Maximum permissible rotational speed
	Pack size
	Country of manufacture
REVX	Label revision level

ⓘ **Hinweis:** Die tatsächlichen ISO-Symbole können als Bild in die Symbol-Spalte eingefügt werden (Kopieren & Einfügen). Die Tabelle ist vollständig editierbar.

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5. CONTACT INFORMATION

Symbol	Address
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