NeoBurr®
(Non-Sterile Multi-Use Dental Carbide Burs)
Instructions for Use

CAUTION:
Rx Only. These instructions, in whole or in part, are not a substitute for formal training in carbide dental burs. Appropriate professional education is REQUIRED prior to using this device clinically. NeoBurr carbides burs are intended to be used by qualified dental practitioners in dental clinics, hospitals, labs, or schools for dental applications.

DESCRIPTION:
Microcopy NeoBurr tungsten carbide burs are manufactured from either a single piece tungsten carbide or, from a tungsten carbide tip brazed to a surgical grade stainless steel stem. The carbide burs are further plated with a unique protective coating formula some of which contain gold plating. The range includes patterns designed to meet the needs of all surgery and laboratory applications. The burs are provided mechanically clean, but non-sterile and must be cleaned and sterilized before first use and may be reused following cleaning and sterilization instructions as described in the Reprocessing Section. The carbide burs fit into a dental handpiece, which provides rotation, allowing the user to cut or finish dental materials.

INDICATIONS
NeoBurr tungsten carbide burs are indicated for anyone requiring cutting or finishing of dental materials. NeoBurr burs are intended to cut or finish a wide variety of materials encountered in dentistry. These include tooth material such as enamel, dentin and bone, dental materials such as amalgam, composite, glass-ionomer cements, polymer and precious and non-precious alloys.
In the unlikely event of a bur defect, DO NOT return to Microcopy. Please take pictures as Microcopy cannot accept used product.

CONTRAINDICATIONS TO USE
Use of Microcopy NeoBurr is contraindicated on any patient who is allergic to any of the components of the product. NeoBurr dental burs are manufactured from a single-piece of Tungsten Carbide or from a Tungsten Carbide tip brazed onto a surgical grade stainless steel stem. NeoBurr has a 10% cobalt as a constituent which is a known allergen that can result in local or systemic allergic response and is therefore not recommended for use in those with an allergy or sensitivity. Nickel is used to braze the head of the bur to the shank and a nickel plating is applied to a single piece gold plated finishing NeoBurrs. A risk exists for those with a known nickel sensitivity suffering from an allergic response and therefore the nickel-plated burs are not recommended for use in those with a known allergy or sensitivity to nickel.

CLINICAL WARNINGS
a) NeoBurr carbide burs are multi-use and must not be used more than ten (10) times, based on the validated use report
b) Do NOT use the product if the package is opened or damaged.
c) Do NOT use the product if the carbide flutes or shank are damaged.
d) Do NOT use excessive force as this may cause the bur to break which may lead to injury.
e) Do NOT exceed maximum speed as this may generate undesirable heat.
f) Do NOT use any other cleaning and sterilization method other than what is listed in this IFU.
g) Do NOT use rusted burs.
h) Used burs shall be considered as contaminated and as such, appropriate precautions shall be taken during re-processing and disposal. Suitable eye protection, glove and a mask should be worn when re-processing.
i) Always keep track of lot numbers to ensure traceability.

Failure to follow these clinical warnings may cause the diamond bur to become dull, break, or become contaminated and result in the following: infection, preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the diamond bur.

CLINICAL PRECAUTIONS:
a) Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause procedural delays or patient or user injury.

NeoBurr®
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Instructions for Use

b) Clean and sterilize the burs supplied in accordance with the directions below before first use and before each reuse.
c) Always wear gloves when handling contaminated instruments.
d) Protect patient's eyes and vulnerable tissues when using these carbide burs.
e) Clinicians should wear eye protection and facemask when using carbide burs.
f) Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
g) Follow the hand piece manufacturer's instructions for use and maintenance and service all hand pieces appropriately.
h) Ensure handpieces are maintained in good working order and remain correctly lubricated at all times to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to procedural delays or injury of the patient or user, aspiration or swallowing of the device or damage to the preparation site due to vibration of a worn chuck or turbine.
i) Ensure the bur is fully seated and securely gripped in the handpiece collet prior to use. Failure to do so may cause the device to "walk out" of the handpiece and may lead to injury of the patient or user or aspiration or swallowing of the device.
j) Never force a bur into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
k) When using short burs (up to 20mm in length) make certain the head/flutes do not come in contact with the chucking mechanism and the neck is outside the chuck to prevent breakage.
l) Prior to use inspect the bur for broken and/or damaged flutes, discard any potentially defective burs. Do not use worn-out or dull devices.
m) Discard any damaged carbide burs immediately.
n) Before use, run the handpiece to check for any abnormalities including overheating.
o) Read the labels on the bur package carefully.
p) Do not apply excessive pressure on the bur as this could cause undesirable heat and/or may cause the bur to break.
q) Move the bur continuously when in use to avoid localized heating and/or damage to the bur. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
r) Avoid removing the bur at too sharp an angle to avoid leverage and breakage which could cause patient or user injury.
s) When cutting off zirconia crowns or endo access on zirconia, apply high water spray (>25ml/min) and use a light touch for pressure. Failure to do so may generate undesirable heat which may lead to damaged tooth pulp.
t) Short burs are recommended to be used with a mini handpiece.
u) Never exceed the maximum speeds as shown in the table below as this may generate undesirable heat. Do not exceed the maximum speeds tabulated below:

Instrument head diameter 01/10 (mm) - ISO	Maximum permissible speed (RPM)	Recommended operational 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
080 – 100	45,000	10,000 - 20,000

STORAGE

- In dry conditions and protected against contaminants. Protect instruments, in general, against chemicals, acids, heat and extreme temperature variations.

NeoBurr®
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Instructions for Use

- Bur shall be stored within controlled conditions.
- Improper storage conditions will shorten the shelf life and may cause product to malfunction.

DISPOSAL

- Each carbide bur must be disposed in a biohazard sharps waste container.
- Each unused carbide bur must be disposed in a sharps waste container.

TRACEABILITY:

Each package includes **Batch number** LOT on its label.
This number must be quoted in any correspondence regarding the product.

NOTICE: If a serious incident has occurred in relation to the device, the incident shall be reported to the manufacturer and if applicable, the competent authority of the Member State in which the user and/or patient is established.

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NeoBurr®
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Instructions for Use

REPROCESSING INSTRUCTIONS FOR DENTAL ROTARY INSTRUMENTS

LIMITATIONS OF RE-USE

a) Reprocessing will have little effect on Microcopy's dental burs. The end of a bur's life is determined by number of uses and the burs must be inspected for defects during the preliminary cleaning process.
b) Delay between use and reprocessing must be kept to a minimum to avoid contaminants drying, thereby making cleaning more difficult. Therefore, keep the unclean burs immersed in the cleaning/disinfecting agent in accordance with manufacturer instructions, but in any event, do not exceed 12 hours. Prolonged storage in disinfectant solutions may result in corrosion and should therefore be avoided.
c) 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.

WARNINGS

a) Used burs should be considered as being contaminated and appropriate handling precautions should be taken during reprocessing. Gloves, eye protection and a mask should be worn.
b) Other measures may be required if there are specific infection or cross contamination risks from the patient.

PREPARATION FOR CLEANING	There are no special requirements unless local infection controls require the use of a disinfectant immediately after use, in which case the selected disinfectant must be validated by the user for cleaning dental burs and the manufacturer's instructions followed. Delays between the use of and the reprocessing of a used bur, must be kept to under 1 hour so as to reduce the likelihood of contaminants drying and making cleaning more difficult.
AUTOMATED CLEANING AND DISINFECTION	Due to the reduced effectiveness and reproducibility of manual cleaning, automated cleaning and sterilization are the preferred processes for cleaning unused and soiled burs. The use of a washer-disinfector complying with EN ISO 15883 shall be used for the below process: **Step 1**: Pre-cleaning - for the removal of extensive contamination, prior to loading the burs into the washer-disinfector, rinse under cold tap water for ≥ 1 min. **Step 2**: Load the burs and dedicated bur block/stand (if applicable) into the washer-disinfector. **Step 3**: Clean using 0.5% cleaner at 55°C± 2°C for ≥ 5 min with demineralized water. **Step 4**: Rinse with demineralized water for ≥ 1 min. **Step 5**: Thermo-disinfection with demineralized water at 93°C± 2°C for ≥ 5 min. **Step 6**: Burs will dry be in-situ. **Inspection**: After cleaning, carefully inspect the burs to ensure all traces of contamination have been removed. Repeat cleaning steps if required.

NeoBurr®
(Non-Sterile Multi-Use Dental Carbide Burs)
Instructions for Use

	When using an automated washer-disinfector, the user should ensure that the process has been validated with the selected cleaning and disinfectant agents. Any cleaning and disinfectant agents must be compatible with the materials used in the bur. **Note**: for the purpose of Microcopy's reprocessing validation, proof of the general suitability for effective mechanical cleaning and disinfecting has been provided by an independent certified laboratory and carried out per ISO 15883-5:2005.
MANUAL CLEANING AND DISINFECTION	In the event that manual cleaning is the only option, the burs must be cleaned in a bath/sink reserved specifically for this purpose. **Step 1:** Clean the burs in a cleaning bath using a soft bristle brush until visibly clean for ≥10 seconds. **Step 2:** Place the burs (and bur block/stand) in a fresh bath using a neutral-pH cleaning solution, ensuring all burs are sufficiently immersed, follow the cleaning agent/manufacturer's instructions. Soak for at least 5 minutes. **Step 3:** after soaking and keeping the burs immersed, using a soft bristle brush, brush away from the body in a slow controlled manner to avoid spreading contaminants by spraying and/or splashing. **Step 4:** Rinse the instruments with clear tap water (drinking water quality) ≥10 seconds. **Step 5:** check all burs for signs of damage and/or deterioration, refer to section 9. **Disinfection:** **Step 1:** Immerse the instruments in a disinfection bath with 80% ethanol for 5 minutes. **Step 2:** Rinse the instruments with sterile water to remove all remaining chemicals. **Step 3:** dry as instructed in section 10.d. **Inspection:** After cleaning, carefully inspect the burs to ensure all traces of contamination have been removed. Repeat cleaning steps if required **Drying**: Burs may be dried using either a paper-towel or a non-shredding wipe.

NeoBurr®
(Non-Sterile Multi-Use Dental Carbide Burs)
Instructions for Use

STEAM STERILIZATION

STERILIZATION

NOTE: *Local legislation for sterilization may require that burs are wrapped in pouches for processing in either type of autoclave. Sterilization equipment complying with applicable international standards EN ISO 17995-1, EN ISO 13060 shall be used for the process below:*

If using a vacuum autoclave, pack the burs into a dedicated instrument tray or pouch in compliance with EN ISO 11607-1. **Or**

If using a non-vacuum autoclave, the burs shall be contained in a dedicated bur stand with perforated lid, or pouch in compliance with EN ISO 11607-1.

Use the following cycle times:

Cycle Time	Exposure (min)	Temperature	Drying (minutes)
Pre-vacuum (4 pulses)	≥ 3	134°C ±0	≥ 30
Gravity Displacement	≥ 10	134°C ±0	≥ 30

Note: The instructions from the autoclave manufacturer must be followed and adhered to at all times. Ensure that the maximum load as stipulated by the manufacturer of the sterilizer is NOT exceeded. Ensure that the minimum drying time (30 mins) is not compromised as failure to achieve this could result in a build-up of moisture and the burs corroding. National legislation may require burs to be wrapped in pouches for processing in either type of autoclave system.

Note: Local infection control practice may recommend a different combination of holding time and temperature

Note: for the purpose of Microcopy's reprocessing validation, proof of the general suitability for effective sterilization has been provided by an independent certified laboratory and carried out per ISO 11737-2:2009.

STORAGE

The burs should be stored in the sterilization container (bur stand or pouch) until required.
Containers or pouches must be dried before opening to avoid recontamination of the contents with water.
Storage should be in dry, clean conditions and at ambient temperature.
To minimize the risk of cross-contamination, avoid storing clean and soiled burs in the same bur block/stand or instrument tray.

VALIDATION OF CLEANING AND STEAM STERILIZATION

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

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Instructions for Use

APPLICABLE SYMBOLS:

	Manufacturer	Indicates the medical device manufacturer.		Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Catalog Number	Indicates the manufacturer's catalog number so that the medial device can be identified		Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Lot Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.		Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	Authorized European representative	Indicates the Authorized representative in the European Community.		CE Marking	Indicates European Conformity Mark.
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.		DEVICE for professional use only	(ref US FDA CDRH) Indicates device shall only be used by a trained professional.
	Keep Dry	Indicates a medical device that needs to be protected from moisture.		Importer	Indicates the entity importing the medical device into the locale
	Medical Device	Indicates device is designed and intended for medical use.		Max speed	Indicates Max speed
	Wear eye protection	Indicates that eye protection must be used.		Wear a mask	Indicates that a face mask must be worn.
	Distributor	Indicates the entity distributing the medical device into the locale			

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