

CAUTION:

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

DESCRIPTION:

Microcopy NeoDiamond burs are manufactured from a single piece of high-quality stainless steel plated at the operational end with natural or synthetic diamond grit. Some diamond burs are further plated with gold plating. The range includes patterns designed to meet the needs of all surgery and laboratory applications. The diamond bur pattern and shape shall be selected by physician discretions and will be chosen according to the clinical application. The burs are packed in a plastic pouch in a dedicated cleanroom facility and terminally sterilized using Gamma Irradiation. **STERILE R** The diamond burs fit into a dental handpiece, which provides rotation, allowing the user to cut or finish dental materials.

INDICATIONS

NeoDiamond burs are indicated for anyone requiring cutting or finishing of dental materials. The burs are intended to cut and 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 ceramics 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 NeoDiamond is contraindicated on any patient who is allergic to any of the components of the product. NeoDiamond dental burs are manufactured from a single piece of stainless steel with nickel plating and diamond grit. Nickel plating is applied to gold plated NeoDiamond burs. 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) NeoDiamond pre-sterile burs are multi-use. The end of bur's life is determined by wear and damage in use. The burs should be inspected for defects during the preliminary cleaning process. Do not use worn or damaged burs.
- b) Do **NOT** use the product if the package is opened or damaged.
- c) Do **NOT** use the product if the diamond grit 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) Pediatric diamond burs shall be used with mini handpiece intended for use with short shank burs.
- i) 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.
- j) 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.
- 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 diamond burs.
- e) Clinicians should wear eye protection and facemask when using diamond 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) Handle packaging and product with care to ensure sterile barrier is maintained.
- j) Inspect sterile packaging for damage, tears, or punctures that may compromise sterile integrity. Given that the bur shows no sign of damage, the bur must be reprocessed according to instructions if the package is damaged or unintentionally open prior to use.
- k) For aseptic preparation open pouch immediately before use to prevent contamination.
- l) To open, hold the bur in the pouch by the operative end, push the shank end through the plastic to insert into handpiece collet and tighten before releasing the grip on the operative end and discard empty pouch.
- m) 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.
- n) Never force a bur into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
- o) When using short burs (up to 20mm in length) make certain the head/diamonds do not come in contact with the chucking mechanism and the neck is outside the chuck to prevent breakage.
- p) Prior to use inspect the bur for broken and/or damaged grit, discard any potentially defective burs. Do not use worn-out or dull devices.
- q) Discard any damaged diamond burs immediately.
- r) Before use, run the handpiece to check for any abnormalities including overheating.
- s) Read carefully the labels on the bur package.
- t) Do not apply excessive pressure on the bur as this could cause undesirable heat and/or may cause the bur to break.
- u) 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.
- v) Avoid removing the bur at too sharp an angle to avoid leverage and breakage which could cause patient or user injury.
- w) 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.
- x) Short burs are recommended to be used with a mini handpiece.
- y) Never exceed the maximum speeds as shown in the table below as this may generate undesirable heat.

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 (PRE-USE):

- Store in a dry and clean environment **at ambient temperature**. Protect instruments in general against chemicals, acids, heat and extreme temperature variations.

- Burs shall be stored within controlled conditions and away from direct sunlight.
- Improper storage conditions will shorten the shelf life and may cause products to malfunction.

DISPOSAL

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

TRACEABILITY:

- Each package includes **Lot 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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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.
MANUAL CLEANING, DRYING AND INSPECTION PROCEDURE	<p>If manual cleaning is implemented, the burs should be cleaned in a sink reserved for the purpose.</p> <p>Pre-clean under running water with a brush directly after use.</p> <ol style="list-style-type: none"> 1) Rinse the burs under running cold water and, keeping them immersed, brush thoroughly away from the body using a neutral cleaning or cleaning/disinfecting agent labeled for use on dental burs or other similar types of reusable medical instruments, following the agent manufacturer’s instructions. 2) Care should be taken to avoid spreading contaminants by spraying or splashing during the brushing process. 3) Wire brushes must be used with caution, as brass particles may result in galvanic corrosion and steel particles may cause discoloration of stainless steel. 4) After cleaning, inspect the burs, with the aid of magnification if necessary, to ensure that all contamination has been removed. Repeat the cleaning process if necessary. 5) Dry the burs using paper toweling or dry heat not exceeding 140°C. 6) Inspect the burs, with the aid of magnification if necessary and discard any damaged or corroded instruments. <p>Note: surface contamination on the burs must be removed prior to automatic reprocessing</p>
AUTOMATED CLEANING	<p>PRE-CLEANING –</p> <ol style="list-style-type: none"> 1) Prepare a 0.1% neutral/mild pH enzymatic detergent, according to manufacturer’s instructions. (in the lowest recommended concentrations). 2) Rinse the bur under running tap water for at least one (1) min. 3) Soak burs immediately into detergent solution, for two (2) minutes. 4) Scrub the burs under running water with soft nylon brush to remove any remaining blood or debris for at least one (1) minute. 5) Place the burs on a clean cloth to avoid any contact between them during the next cleaning procedure <p>AUTOMATED CLEANING PROCEDURE -</p> <p>Place the burs in the washer in a suitable small parts tray or on the load carrier such that all surfaces of the instruments will be cleaned and disinfected.</p> <ol style="list-style-type: none"> 1) Run the automatic wash cycle – Short cycle parameters. 2) Two (2) Minutes prewash at 30±5°C (86±41°F) with tap water. 3) Two (2) Minutes prewash at 30±5°C (86±41°F) with tap water. 4) Ten (10) Minutes main wash with natural pH detergent and tap water at 25±5°C (110±41°F). 5) One (1) Minute rinse with tap water at 30°C (86°F) 6) Ten (10) Minutes distilled water rinse at 30°C (86°F) 7) Twenty (20) Minutes air drying phase at high temperature of 100°C (414°F)

	<p>** The cleaning process was validated with short automatic wash cycle. Any cleansing and disinfecting agents used must be compatible with dental burs; otherwise accelerated corrosion or other damage may occur. The washer disinfectant and the cleaning agent manufacturers' instructions must be followed.</p> <p>POST AUTOMATED CLEANING PROCEDURE –</p> <ol style="list-style-type: none"> 1) Remove the instruments at the end of the washer program. 2) Check that the load is dry and, if necessary, dry with medical compressed air. 3) Visually inspect the burs for cleanliness. If contamination is still visible, reclean the burs again manually. 4) Subsequently, the recleaned burs must be reprocessed again automatically before sterilization 5) All instruments must be inspected visually for cleanliness, integrity and functionality, if necessary, by using an illuminated magnifying glass 6) All instruments are to be checked for damage and wear. Damaged medical devices may no longer be used and must be sorted out
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STEAM STERILIZATION

















PACKAGING FOR STERILIZATION	<p>If using an autoclave with a pre-vacuum cycle, pack the burs in appropriate instrument trays or pouches validated for steam sterilization.</p> <p>If using an autoclave without a pre-vacuum cycle, the burs should not be packed or wrapped but should be contained in appropriate bur stands with perforated lids.</p> <p>NOTE: Local legislation for sterilization may require that burs are wrapped in pouches for processing in either type of autoclave.</p>				
STERILIZATION	<p>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.</p> <p>The steam sterilization was validated in an autoclave without a pre-vacuum cycle (gravity displacement type) for a holding time of 3 minutes minimum and six minutes maximum at a temperature of 134 °C and drying time of 30 min.</p> <p>The holding time is the minimum time for which the minimum temperature is sustained.</p> <ol style="list-style-type: none"> 1) Place the packaged products in the sterilization chamber 2) Start the program <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;">Cycle duration minutes minimum (Min.)</td> <td style="width: 25%;">Cycle duration minutes maximum (Min.)</td> <td style="width: 25%;">Cycle temperature (°C)</td> <td style="width: 25%;">Drying time (Min.)</td> </tr> </table>	Cycle duration minutes minimum (Min.)	Cycle duration minutes maximum (Min.)	Cycle temperature (°C)	Drying time (Min.)
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3	6	134 °C	30		
	<p>3) Remove the burs at the end of the program and allow to cool down</p> <p>4) check the packaging for possible damage and screening effects</p> <p>5) Faulted packaging must be inspected as being non-sterile. The instruments must be repacked and re-sterilized.</p> <p>NOTE: Local infection control practice may recommend a different combination of holding time and temperature</p>				
STORAGE	<p>The burs should be stored in the sterilization container (bur stand or pouch) until required.</p> <p>Containers or pouches must be dried before opening to avoid recontamination of the contents with water.</p> <p>Storage should be in dry, clean conditions and at ambient temperature</p>				

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.

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 medical device can be identified		Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Authorized European representative	Indicates the Authorized representative in the European Union.		CE Marking	Indicates European Conformity Mark.
	Sterilized using irradiation	Indicates medical device that has been sterilized using irradiation.		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
	Importer	Indicates the entity importing the medical device into the locale		Distributor	Indicates the entity distributing the medical device into the locale
	Steam Sterilizable at 134°C.	Indicates that the instrument is sterilizable in a steam sterilizer (autoclave) at temperature 134°C.		Single Sterile Barrier System	Indicates a single sterile barrier system

	Keep Away from Sunlight	Indicates the product shall not be stored in direct sunlight
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