

Microcopy Vet Burs®
(Non-Sterile, Single-Use Carbide & Diamond Veterinary Dental Burs)
Instructions for Use

PRODUCT DESCRIPTION

- **Carbide:** Microcopy Vet 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.
- **Diamond:** Microcopy Vet diamond burs are manufactured from a single piece of high-quality stainless steel plated at the operational end with a natural diamond grit. The diamond burs are further plated with a unique protective coating formula some of which contain a gold plating.
- **All:** Both the carbide and diamond ranges include patterns designed to meet the needs of all surgery and laboratory applications. The dental instrument 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, the burs require steam sterilization prior to use. The burs fit into a dental handpiece, which provides rotation, allowing the user to grind, cut or finish dental materials.

INTENDED USE

Microcopy Vet burs are indicated for veterinary dental procedures in companion animals, such as dogs and cats, requiring grinding, cutting or finishing of dental materials. Both Microcopy Vet carbide and diamond burs are intended for use on 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.

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

CONTRAINDICATIONS TO USE

- **Carbide:** The Microcopy Vet carbide burs are manufactured from a single piece of Tungsten Carbide or from a Tungsten Carbide tip brazed onto a surgical grade stainless steel stem. They contain 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 single-piece gold plated finishing 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.
- **Diamond:** The Microcopy Vet diamond dental burs are manufactured from a single-piece of stainless steel with nickel plating and diamond grit. 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.
- **All:** Use of Microcopy Vet burs is contraindicated on any patient who is allergic to any of the components of the product.

CLINICAL WARNINGS

Failure to follow the instructions below may cause the 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 bur.

- a) Microcopy Vet burs are single-use and are sold as cleaned non-sterile burs.
- b) Do NOT use any other sterilization method other than the method listed in this IFU before use.
- c) Attempts to re-process or re-sterilize will adversely affect the device's performance. 
- d) Do NOT use the product if the package is opened or damaged. 
- e) Do NOT use the products after their stated expiration date. 
- f) Do NOT use the product if the diamond grit, carbide blades, or shanks are damaged.
- g) Do NOT use rusted burs.

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- h) Do **NOT** use excessive force as this may cause the bur to break which may lead to patient injury.
- i) Do **NOT** exceed maximum speed as this may generate undesirable heat.
- j) Do **NOT** remove burs at a sharp angle to avoid leverage and breakage.
- k) Always keep track of lot numbers of Microcopy Vet burs to ensure traceability.

CLINICAL USE AND PRECAUTIONS WARNINGS

- a) Protect patient's eyes and vulnerable tissues when using dental burs.
- b) Clinicians should wear eye protection and facemask when using dental burs.
- c) Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
- d) Carefully read package labels to ensure use of the appropriate device. Failure to do so may cause procedural delays, or patient or user injury.
- e) Follow the handpiece manufacturer's instructions for use and maintenance, and service all handpieces appropriately.
- f) 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.
- g) Prior to use, inspect the bur for breakage or damage, discard any potentially defective burs. Do not use worn-out or dull devices. Discard any damaged burs immediately.
- h) Burs must be thoroughly sterilized prior to use to prevent the risk of infection.
- i) 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.
- j) 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.
- k) Never force a bur into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
- l) Before use, run the handpiece to check for any abnormalities including overheating.
- m) Do not apply excessive pressure on the bur as this could cause undesirable heat and/or may cause the bur to failure.
- n) 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.
- o) Avoid removing the bur at too sharp an angle to avoid leverage and breakage which could cause patient or user injury.
- p) Never exceed the maximum speeds as shown below as this may generate undesirable heat and damage the tooth pulp.

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

- q) In the unlikely event of a bur defect, **DO NOT** return to Microcopy. Please take pictures as Microcopy cannot accept used product.

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STORAGE (Pre-Sterilization/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 product to malfunction.

DISPOSAL

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

STERILIZATION PRIOR TO USE**Packaging**

- 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.
- **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:

Sterilization (Diamond Burs)

- The following parameters are validated for the diamond burs and should be used for the Pre-vacuum and Gravity Displacement methods:

Cycle Type	Exposure (min)	Temperature	Drying (minutes)
Pre-vacuum (4 pulses)	≥ 4	134°C ±0	≥ 15
Gravity Displacement	≥ 4	134°C ±0	≥ 15

- **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 (15 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 11737-2:2020.

Sterilization (Carbide Burs)

- The following parameters are validated for the carbide burs and should be used for the Pre-vacuum and Gravity Displacement methods:

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Cycle Type	Exposure (min)	Temperature	Drying (minutes)
Pre-vacuum (4 pulses)	≥ 3	134°C ±0	≥ 30
Gravity Displacement	≥ 10	135°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 (Post-Sterilization/Pre-Use)

- 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.

TRACEABILITY

- Each package includes the **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 Food and Drug Administration (FDA).
- To request a paper IFU free of charge, please contact Microcopy at sales@microcopydental.com or 800.235.1863, and an IFU will be delivered within seven (7) days.

APPLICABLE SYMBOLS

	Manufacturer	Indicates the medical device manufacturer.		Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.		Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.		Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Use-by date	Indicates the date after which the medical device is not to be used.		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	REF	Catalog Number	Indicates the manufacturer's catalog number so that the

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		from moisture.			medical device can be identified.
	Medical Device	Indicates device is designed and intended for medical use.		Max speed	Indicates Max speed
	Single Patient – Multiple Use	Indicates a medical device that may be used multiple times in a single operation.		Date of Manufacture	Symbol for date of manufacture.
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.		Keep Away from Sunlight	Indicates the product shall not be stored in direct sunlight.

CONTACT INFORMATION:



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