

<b>Title:</b>	<b>Instructions for Use (IFU) – The Vet Bur Co. Non-Sterile, Single-Use Carbide &amp; Diamond Veterinary Dental Burs</b>	
<b>Doc #:</b>	<b>MCD-IFU-024</b>	<b>Rev: 1</b>
<b>Originator:</b>	David Honeycutt	<b>Effective Date:</b> 15Aug2024
<b>Owner:</b>	Quality	<b>DCN#:</b> DCN-24-114

**PRODUCT DESCRIPTION**

- **Carbide:** The Vet Bur Co. 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:** The Vet Bur Co. 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**

The Vet Bur Co. burs are indicated for anyone requiring grinding, cutting or finishing of dental materials. Both The Vet Bur Co. 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. The Vet Bur Co. 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 Vet Bur Co. 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 Vet Bur Co. 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 The Vet Bur Co. 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.

- The Vet Bur Co. burs are single-use and are sold as cleaned non-sterile burs.
- Do NOT use any other sterilization method other than the method listed in this IFU before use.
- Attempts to re-process or re-sterilize will adversely affect the device’s performance.  
- Do NOT use the product if the package is opened or damaged. 
- Do NOT use the products after their stated expiration date. 

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- f) Do **NOT** use the product if the diamond grit, carbide blades, or shanks are damaged.
- g) Do **NOT** use rusted burs.
- 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 The Vet Bur Co. 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.

<b>Instrument Head Diameter 01/10 (mm) - ISO</b>	<b>Maximum Permissible Speed (RPM)</b>	<b>Recommended Operational Speed (RPM)</b>
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

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q) In the unlikely event of a bur defect, DO NOT return to The Vet Bur Co. Please take pictures as The Vet Bur Co. cannot accept used product.

**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 an autoclave with a pre-vacuum cycle, pack the burs in appropriate instrument trays or pouches validated for steam sterilization.
- 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.
- **NOTE:** Local legislation for sterilization may require that burs are wrapped in pouches for processing in either type of autoclave.

**Sterilization**

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.

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.

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

- 1) Place the packaged products in the sterilization chamber.
- 2) Start the program:

Cycle Duration Minutes Minimum (Min.)	Cycle Duration Minutes Maximum (Max.)	Cycle Temperature (°C)	Drying Time (Min.)
3	6	134 °C	30

- 3) Remove the burs at the end of the program and allow to cool down.
- 4) Check the packaging for possible damage and screening effects.
- 5) Faulted packaging must be inspected as being non-sterile. The instruments must be repacked and re-sterilized.
- 6) **NOTE:** Local infection control practice may recommend a different combination of holding time and temperature.

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**STORAGE (Post-Sterilization/Pre-Use)**

1. The burs should be stored in the sterilization container (bur stand or pouch) until required.
2. Containers or pouches must be dried before opening to avoid recontamination of the contents with water.
3. 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 The Vet Bur Co. at [Sales@TheVetBurCo.com](mailto:Sales@TheVetBurCo.com) or 800.237.7025, 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.
<span style="border: 1px solid black; padding: 2px;">LOT</span>	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 from moisture.	<span style="border: 1px solid black; padding: 2px;">REF</span>	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
<span style="border: 1px solid black; padding: 2px;">MD</span>	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.

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	<b>Non-Sterile</b>	Indicates a medical device that has not been subjected to a sterilization process.		<b>Keep Away from Sunlight</b>	Indicates the product shall not be stored in direct sunlight.
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**CONTACT INFORMATION:**



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800.237.7025