

NeoDiamond® Non-Sterile, HP Diamond Burs Instructions for Use


CAUTION:

The device is to be used as per the following instructions by physician or licensed practitioner Rx Only. These instructions, in whole or in part, are not a substitute for formal training. Appropriate professional education is **STRONGLY RECOMMENDED** prior to using this device clinically.

DESCRIPTION:

The HP Diamond Burs are intended to be used by professional dentists and dental technician in the dental laboratory.

The HP Diamond Burs are a rotary abrading device made of stainless steel coated with diamond particles on the working end and designed to fit into a dental handpiece. The handpiece connection provides the rotation, allowing the user to abrade hard structures like metal, plastics, porcelains, and similar materials. The HP Diamond Burs are provided non-sterile and can be reused, therefore read the following cleaning and sterilization instructions carefully.

The HP Diamond Burs are provided mechanically clean, but non-sterile  and may be reused following cleaning and sterilization instructions as described in this IFU.

INDICATIONS

Microcopy HP Diamond Burs are intended to be used by dentists in dental labs for the removal of small amounts of outer substrate surface between two adjacent structures (Interproximal reduction). It is a means to acquire additional space to create ideal tooth alignment.

CONTRAINDICATIONS TO USE

- a) Used HP Diamond 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.
- b) In the event of an HP Diamond Bur will be returned to Microcopy, please ensure any contaminated and/or potentially contaminated HP Diamond Bur have been effectively cleaned and are appropriately packaged for return.

STORAGE

Store in a dry and clean environment at ambient temperature.

PRECAUTIONS:

- a) Carefully read package labels to ensure appropriate use of the HP Diamond Bur. Failure to do so may cause procedural delays or user injury.
- b) Failure to follow these instructions may cause the following: preparation site damage and injury to the user.
- c) Clean and sterilize the HP Diamond Bur supplied in a non-sterile condition in accordance with the directions below before first use and before each reuse.
- d) Always wear gloves when handling contaminated instruments.
- e) Clinicians should wear eye protection and facemask when using the HP Diamond Bur.
- f) Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
- g) Prior to use inspect the HP Diamond Bur for broken and/or damaged grit, discard any potentially defective burs. Do not use worn-out or dull devices.
- h) Ensure handpieces are maintained in good working order and remain correctly lubricated at all times according to the manufacturer's instructions.
- i) Discard any damaged HP Diamond Bur immediately.
- j) Do not use rusted HP Diamond Bur.
- k) Carefully read the labels on the package.
- l) Follow the hand piece manufacturer's instructions for use and maintenance and service all hand pieces appropriately.
- m) Before use, run the handpiece to check for any abnormalities including overheating.

- n) Do not apply excessive pressure on the HP Diamond Bur as this could cause undesirable heat and/or may cause the HP Diamond Bur to fail.
- o) Move the bur continuously when in use to avoid localized heating and/or damage to the bur. Undesirable heat generation can cause damage to the material.
- p) 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 to the user.
- q) Never force a HP Diamond Bur into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
- r) Always refer to the product packaging for the Maximum RPM. Never exceed the maximum speeds as shown in the table as this may generate undesirable heat.
- s) Do not exceed the maximum speeds tabulated below:

Instrument head diameter 01/10 (mm) – ISO	Maximum permissible speed (RPM)
007 - 046	50,000
047 - 049	45,000
050 - 054	40,000
055 - 064	35,000
065 - 074	30,000
075 - 094	25,000
095 - 119	20,000
120 - 139	18,000
140 - 159	16,000
160 - 179	14,000
180 - 199	12,000
200 - 220	10,000

REPROCESSING INSTRUCTIONS FOR HP DIAMOND BURS

Limitations of Re-Use

Reprocessing will have little effect on Microcopy's HP Diamond Burs. The bur shelf 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 minimum to avoid contaminants drying, thereby making cleaning more difficult. Therefore, keep the unclean burs immersed in the cleaning/disinfecting agent in accordance with its manufacturer Instructions, but in any event do not exceed 12 hours.

WARNINGS

Used HP Diamond 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. Used HP Diamond Burs are considered bio-hazard and need to be discarded as bio-hazard waste unless reprocessing.

CLEANING, DRYING, AND INSPECTION PROCEDURE FOR LABORATORY USE

Manual Cleaning:

If manual cleaning is implemented, the HP Diamond Burs should be cleaned in a sink dedicated for the purpose. Microcopy has validated the procedure detailed below:

1. Rinse the instruments 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 instruments, preferably with the aid of magnification, to ensure that all contamination has been removed. Repeat the cleaning process if necessary
5. Dry the instruments using paper toweling or dry heat not exceeding 140°C
6. After cleaning, inspect the instruments, preferably with the aid of magnification, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.

Steam Sterilization:Scope

These sterilization instructions are applicable to HP Diamond Burs initially provided non-sterile and to non-sterile burs that are about to be reused.

Packaging for Sterilization

If using an autoclave with a pre-vacuum cycle, pack the burs in dedicated 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 dedicated bur/disc stands with perforated lids.

Note: *Local legislation may require that burs/discs will be wrapped in pouches for processing in either type of autoclave.*

Sterilization Process

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.

Microcopy has validated steam sterilization in an autoclave without a pre-vacuum cycle (gravity displacement type) for a holding time of 10 minutes at a temperature of 135 °C and 30 minutes drying. The holding time is the minimum time for which the minimum temperature is sustained.

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


Storage

The HP Diamond Burs should be stored in the sterilization container (bur stand or pouch) until use. 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.











Validation of Cleaning and Steam Sterilization

The above detailed processes have been validated as being Microcopy recommended process for preparing Microcopy's dental burs 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, achieve the required results. This may require validation and monitoring of the process. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.

TRACEABILITY:

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

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 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.
	Medical Device	Indicates device is designed and intended for medical use.		Importer	Indicates the entity importing the medical device into the locale

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