NeoDiamond®
(Non-Sterile Dental Diamond Burs)
Instructions for Use (IFU)

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 in diamond dental burs. Appropriate professional education is STRONGLY RECOMMENDED prior to using this device clinically.

DESCRIPTION:
Microcopy NeoDiamond 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. The range includes patterns designed to meet the needs of all surgery and laboratory applications. The burs are packed in a plastic slider.

These burs are provided non-sterile and must be sterilized before first use and can be reused following cleaning and sterilization instructions as following described.

INDICATIONS
Microcopy NeoDiamond diamond burs can be used to cut 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.

CONTRAINDICATIONS TO USE
Use of Microcopy NeoDiamond is contraindicated on any patient who is allergic to any of the components of the product.

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) Failure to follow these instructions may cause the following: preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the diamond burs.
c) Clean and sterilize the burs 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) Protect patient's eyes and vulnerable tissues when using these diamond burs.
f) Clinicians should wear eye protection and facemask when using diamond burs.
g) Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
h) Ensure the bur is fully seated and gripped in the handpiece collet.
i) 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.
j) Ensure handpieces are maintained in good working order and remain correctly lubricated at all times.
k) Discard any damaged diamond burs immediately.
l) Do not use rusted burs.
m) Read carefully the labels on the bur package.
n) Follow the hand piece manufacturer's instructions for use and maintenance and service all hand pieces appropriately.
o) Before use, run the handpiece to check for any abnormalities including overheating.
p) Move the bur continuously when in use so as to avoid localized heating.
q) Do not apply excessive pressure on the bur as this could cause undesirable heat and/or may cause the bur to fail.
r) 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.
s) Avoid removing the bur at too sharp an angle to avoid leverage and breakage which could cause patient or user injury.
t) Maintain handpieces in good working condition 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.

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u) 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.

v) Never force a bur into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.

w) 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.

x) 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

CLINICAL USE:

Microcopy NeoDiamond burs can be used to cut a wide variety of materials encountered in dentistry. These include tooth material such as enamel and dentin, dental materials such as composite, glass-ionomer cements, polymer and ceramic and precious and non-precious alloys. Our range of diamond burs provide maximum cutting efficiency and effortless access through tough diamond for both endodontic treatment and crown removal.

REPROCESSING INSTRUCTIONS FOR DENTAL ROTARY INSTRUMENTS

LIMITATIONS OF RE-USE

Reprocessing will have little effect on Microcopy's dental burs. The end of a bur's 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 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.

Caution: 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

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. Other measures may be required if there are specific infection or cross contamination risks from the patient.

Used burs are also considered as bio-hazard and need to be discarded as bio-hazard waste unless reprocessing procedures have been done according to the above instructions.

PREPARATIONS 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 organization for reprocessing dental burs, and the disinfectant manufacturer's instructions must be followed.

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CLEANING, DRYING, AND INSPECTION PROCEDURE

If manual cleaning is implemented, the burs should be cleaned in a sink reserved for the purpose.

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.

Ultrasonic cleaning may also be used prior to sterilization, but only cleaning agents recommended for ultrasonic cleaning should be used and the user must validate the process.

Cleaning by means of an automated washer disinfector is also possible, but the user should validate the process with the selected cleansing and disinfection agents. Any cleansing and disinfecting agents used must be compatible with the materials used in the dental burs; otherwise accelerated corrosion or other damage may occur. The washer disinfector and the cleaning agent manufacturers' instructions must be followed.

STERILIZATION – USING STEAM

PACKAGING FOR STERILIZATION

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. Microcopy has validated steam sterilization in an autoclave without a pre-vacuum cycle (gravity displacement type) for a holding time of six minutes at a temperature of 134 ºC. 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 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.

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 reprocessor to ensure that the reprocessing is actually performed, using the equipment, materials and personnel in the reprocessing facility, to 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.

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TRACEABILITY:

Each package includes **Lot number** LOT 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.
REF	Catalog / Part Number	Indicates the manufacturer's catalog number so that the medial device can be identified	LOT	Lot Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
EC REP	Authorized European representative	Indicates the Authorized representative in the European Community.	CE	CE Marking	Signifies European technical conformity.
	Non-Sterile Product	Indicates a medical device that has not been sterilized.			

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