

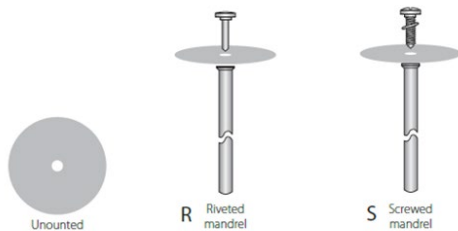
NeoDiamond® Non-Sterile, Diamond Discs Instructions for Use

CAUTION:

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

DESCRIPTION:

Microcopy NeoDiamond Discs are manufactured from a single piece of high-quality stainless steel plated at the operational end with natural or synthetic diamond grit. The discs are available mounted or unmounted. The mounted discs are available mounted on Mandrels with two options: Riveted or Screwed. The unmounted discs shall be mounted on a standard Screwed Mandrel before use.



The Diamond Discs are provided mechanically clean, but non-sterile and must be cleaned and sterilized before first use and can be reused following cleaning and sterilization instructions as described in the Reprocessing Section.

INTENDED USE

NeoDiamond Discs are indicated for anyone requiring grinding or finishing of dental materials. The discs are intended to remove 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.

In the unlikely event of a disc defect, DO NOT return used product to Microcopy. Please take pictures as Microcopy cannot accept used product.

CONTRAINDICATIONS TO USE

Use of Microcopy NeoDiamond discs is contraindicated on any patient who is allergic to any of the components of the product. NeoDiamond dental discs are manufactured from a single-piece of stainless steel with nickel plating and diamond grit. Nickel plating is applied to gold plated NeoDiamonds. A risk exists for those with a known nickel sensitivity suffering from an allergic response and therefore the nickel plated discs are not recommended for use in those with a known allergy or sensitivity to nickel.

PRODUCTS IN COMBINATION WITH MICROCOPY'S DENTAL DISCS

The diamond discs are compatible with any approved medical device handpiece that can be operated with RA or HP shanks. Maintain handpieces in good working conditions 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.

STORAGE (PRE-USE)

Store in a dry and clean environment at ambient temperature.

CLINICAL WARNINGS

- Do **NOT** use the product if the package is opened or damaged.
- Do **NOT** use the product if the diamond grits or shanks are damaged.
- Do **NOT** use excessive force as this may cause the disc to break which may lead to patient injury.
- Do **NOT** exceed maximum speed as this may generate undesirable heat.
- Do **NOT** use any other cleaning and sterilization method other than what is listed in this IFU.

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- f) Do **NOT** use rusted discs.
- g) Do **NOT** remove discs at sharp angle to avoid leverage and breakage.
- h) Used discs 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.
- i) Always keep track of lot numbers of NeoDiamond 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 USE AND PRECAUTIONS:

- a) Carefully read package labels to ensure appropriate use of the Diamond Disc. Failure to do so may cause procedural delays or user injury.
- b) Clean and sterilize the discs 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 diamond discs.
- e) Clinicians should wear eye protection and facemask when using the diamond discs.
- 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) Ensure the disc 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.
- j) Never force a disc into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
- k) Prior to use inspect the discs for broken and/or damaged grit, discard any potentially defective discs. Do not use worn-out or dull devices.
- l) Discard any damaged diamond discs immediately.
- m) Before use, run the handpiece to check for any abnormalities including overheating.
- n) Carefully read the labels on the package.
- o) Do not apply excessive pressure on the discs as this could cause undesirable heat and/or may cause the disc to fail.
- p) Move the disc continuously when in use to avoid localized heating and/or damage to the disc. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
- q) Avoid removing the disc at too sharp an angle to avoid leverage and breakage which could cause patient or user injury.
- r) Do not exceed the maximum speeds tabulated below:

Instrument head diameter 01/10 (mm) – ISO	Maximum permissible speed (RPM)
100 - 127	30,000
130 - 300	25,000

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.
- Improper storage conditions will shorten the shelf life and may cause product to malfunction.

DISPOSAL

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

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

TRACEABILITY:

- Each package includes **Batch number** 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 DIAMOND DISCS

LIMITATIONS OF RE-USE

Reprocessing will have little effect on Microcopy's Diamond Discs. 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 discs immersed in the cleaning/disinfecting agent in accordance with its 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.

Caution: Do **NOT** leave discs immersed in disinfectants that have a fixative action (such as aldehyde-based products) unless the burs have been thoroughly cleaned first.

WARNINGS

Used Diamond Discs 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 Diamond Discs are considered bio-hazard and need to be discarded as bio-hazard waste unless reprocessing performed according to the instructions.

CLEANING

Preparation For Cleaning

There are no special requirements for pre-cleaning 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 discs and the manufacturer's instructions followed.

Due to limited reproducibility of manual cleaning, automated cleaning and steam sterilization are the preferred processes for the cleaning stage.

Manual Cleaning, Drying, and Inspection Procedure:

If manual cleaning is implemented, the Diamond Discs should be cleaned in a sink dedicated for the purpose. Pre-clean under running water with a brush directly after use, particularly at the difficult to access points (grooves, bristles, holes, rough surfaces).

Microcopy has validated the procedure detailed below:

1. Rinse the instruments under running cold water at least one (1) minute.
2. Soak in a 0.1-0.3% enzymatic neutral cleaning or cleaning/disinfecting detergent labeled for use on dental rotary instruments or other types of reusable medical instruments, following the agent manufacturer's instructions. Soak for at least 2 minutes.
3. Then, keeping them immersed, brush thoroughly away from the body in a slow controlled way to avoid spreading contaminants by spraying or splashing during the brushing process.
4. In all cases soft nylon brush is recommended in order to avoid possible device damage.
5. Take the instruments out of the bath and rinse them under warm running water for at least 2 minutes and until visibly clean.

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6. After cleaning, inspect the cleanliness of the instruments with the aid of magnification, to ensure that all contamination has been removed. Repeat the cleaning process if necessary.
7. Dry the instruments using a non-shedding wipe or clean compressed air.
8. Inspect the instruments, with the aid of magnifying glass if necessary for any signs of damage and/or deterioration such as corrosion. Pay particular attention to the diamond grit and shanks for any chips/cracks, chatter marks, distortion, and general wear & tear. Any instrument found in condition which causes concern, must be discarded.

Automated Cleaning

Pre-Cleaning

1. Prepare a 0.1-0.3% neutral/mild pH enzymatic detergent, according to manufacturer's instructions.
2. Rinse the instruments under running tap water for at least one (1) minute.
3. Soak instruments immediately into detergent solution, for at least two (2) minutes.
4. Scrub under running water with soft nylon brush to remove any remaining blood or debris for at least one (1) minute on each disc side (two (2) minutes total).
5. Place the instruments on a clean cloth to avoid any contact between them during the next cleaning procedure.

Automated Cleaning Procedure

Place the instruments 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.

1. Run the automatic wash cycle – Short cycle parameters.
2. Two (2) Minutes prewash at 30±5°C (86±9°F) with tap water.
3. Ten (10) Minutes main wash with neutral pH detergent and tap water at 45±5°C (113±9°F).
4. One (1) Minute rinse with tap water at 30°C (86°F).
5. Ten (10) Minutes distilled water rinse at 30°C (86°F).
6. Twenty (20) Minutes air drying phase at high temperature of 80°C (176°F).
7. Five (5) minutes air drying phase at high temperature of 110°C (230°F).

Note: For the purpose of Microcopy instruments automated reprocessing validation, a Miele PROFESSIONAL washer (model PG8593) and the cleaning agent Power Zyme (Deconex) were used. Other equivalent reprocessing cleaning agents can be used upon local validation by the user. Any cleaning and disinfecting agents used must be compatible with dental discs; otherwise, accelerated corrosion or other damage may occur. The washer disinfectant and the cleaning agent manufacturers' instructions must be followed.

Post Automated Cleaning Procedure

1. Remove the instruments at the end of the washer program.
2. Check that the instruments are dry, if necessary, dry with medical grade compressed air.

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3. Visually inspect the discs for cleanliness. If contamination is still visible, reclean the instruments again manually.
4. Subsequently, the recleaned instruments 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.

STEAM STERILIZATION

Scope

These sterilization instructions are applicable to Diamond Discs initially provided non-sterile and to non-sterile discs that are about to be reused.

Packaging for Sterilization

When using either an autoclave with a pre-vacuum cycle or gravity displacement, place the instruments in appropriate instrument trays or pack them in pouches validated for steam sterilization.

Note: Local legislation may require that dental instruments are wrapped in pouches for processing in either type of autoclave.

Sterilization

Follow the autoclave manufacturer's instructions to sterilize the discs. 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 4 minutes at a temperature of 134 °C and drying time of 15. The holding time is the minimum time for which the minimum temperature is sustained.

Note: For the purpose of Microcopy dental instruments, steam sterilization validation a Yipak self-sealing sterilization pouches were used.

1. Place the packaged instruments in the sterilization chamber.
2. Start the program (The validated time was four (4) minutes as a minimum, longer time is also possible).

Cycle duration minutes minimum	Cycle temperature (°C)	Drying time minimum
4	134	15

3. Remove the instruments at the end of the program and allow them 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.

Note: Instrument blocks (stand) may be used for sterilization purposes for immediate use only.

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Storage

The Diamond Discs should be stored in the sterilization pouch until required. 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 discs for reuse. It remains the sole responsibility of the reprocessor to ensure that the reprocessing is 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.

DISPOSAL

Used discs are considered as biohazard and need to be discarded as bio-hazard waste in accordance with local regulations.

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.		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
	Wear eye protection	Indicates that eye protection must be		Wear a mask	Indicates that a face mask must be worn.
	Distributor	Indicates the entity distributing the medical device into the locale		Max speed	Indicates Max speed
	DEVICE for professional use only	(ref US FDA CDRH) Indicates device shall only be used by a trained professional.		Date of Manufacture	Symbol for date of manufacture.

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CONTACT INFORMATION:

**Microcopy**

3120 Moon Station Rd. NW

Kennesaw, GA 30144, USA

sales@microcopydental.com

800.235.1863

**Obelis s.a.**

Bd. Général Wahis 53

1030 Brussels, Belgium

mail@obelis.net

+ (32) 2. 732.59.54

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