

NeoDiamond® IPR Strips (Multi-Use) 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 IPR Strips are intended to be used by qualified dental practitioners in dental clinics, hospitals, labs, or schools for dental applications.

DESCRIPTION

Microcopy NeoDiamond® IPR Strips are comprised of Single-Patient-Use stainless steel strips that are solid or have multiple holes and are coated on one or both sides with the same (varying grit size) diamond as Microcopy's NeoDiamond® burs. The coating is applied to the entire strip surface except for a small ("neutral") area in the middle of the strip. There are also non-diamond coated strips that have a serrated edge to aid in insertion into the interproximal space. These IPR Strips are provided mechanically clean, but non-sterile and must be cleaned and sterilized before first use and re-use.

INDICATIONS

NeoDiamond® IPR Strips are intended to be used by dentists in dental clinics/hospitals/labs. The strips are intended for manual use in multiple dental treatments to pre-polish, contour, finish polish and high shine polish interproximal areas of composite restorations and/or used in interproximal reduction of enamel. In addition, NeoDiamond® IPR Strips may be used to finish restorations interproximally along with interproximal enamel reduction during orthodontics.

In the unlikely event of a strip defect, DO NOT return to Microcopy. Please send a picture by email as Microcopy cannot accept used product.

CONTRANDICATIONS TO USE:

Use of Microcopy NeoDiamond Strips is contraindicated on any patient who is allergic to any of the components of the product. The diamond strips are manufactured from Stainless Steel, Diamonds, and Nickel. A risk exists for those with a known nickel sensitivity suffering from an allergic response and therefore not recommended for use in those with a known allergy or sensitivity to nickel.

Any serious incident that has occurred in conjunction with our device, must be reported to Microcopy (at the address listed below) and to the competent authority of the Member State in which the user/patient is established.

CLINICAL WARNINGS

- a) When unpacking, take care not to bend Strips.
- b) Always wear gloves when handling contaminated instruments.
- c) Do not reuse more than **fifteen (15)** times as patient or user injury may result from device wear.
- d) Do **NOT** use the product if the package is opened or damaged.
- e) Do **NOT** use a NeoDiamond® IPR Strip if it is damaged.
- f) NeoDiamond® IPR Strips must be cleaned and sterilized prior to first use and after each re-use.
- g) Always keep track of Lot Numbers of NeoDiamond® IPR Strips to ensure traceability.

Failure to follow these instructions may cause the strip 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 strip.

STORAGE

Store in a dry and clean environment at ambient temperature.

CLINICAL USE AND PRECAUTIONS

- a) The device is to be used as per the following instructions by dental professional or licensed practitioner.
- b) Strips must be thoroughly cleaned and sterilized in accordance with the directions below prior to the first use to prevent the risk of infection.
- c) Always wear gloves when handling contaminated instruments.
- d) Clinicians should wear eye protection and facemask when using NeoDiamond® IPR Strips.

**NeoDiamond®
IPR Strips (Multi-Use)
Instructions for Use**

- e) Surgical masks must be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
- f) Failure to properly remove the accumulated debris may cause the device to break causing user harm.
- g) Always inspect the strip before use as the use of a damaged strip could cause procedural delays, injury to the patient or user, or aspiration or swallowing of a broken device by the patient.

REPROCESSING INSTRUCTIONS FOR DIAMOND COATED STAINLESS STEEL IPR STRIPS

Strips shall be reprocessed upon initial use and prior to reuse.

Limitations of Re-Use

- a. Reprocessing will have little effect on Microcopy’s IPR dental diamond strips.
- b. The strips may be used up to **fifteen (15)** uses.
- c. The strips should be inspected for defects during the preliminary cleaning process.
- d. Delay between use and reprocessing must be kept to a minimum to avoid contaminants.
- e. Prolonged storage in disinfectant solutions may result in corrosion as well as device damage and should therefore be avoided.
- f. Do not leave strips immersed in disinfectants that have a fixative action (such as aldehyde-based products) unless the strips have been thoroughly cleaned first.

WARNINGS

- a. Cleaning agents with chlorine or chloride as the active ingredient are corrosive to stainless steel and must not be used. Cleaning agents with neutral pH are recommended.
- b. Used strips should be considered as contaminated after use and as such, appropriate handling precautions should be taken during re-processing and disposal. Suitable gloves, eye protection, and a mask should be worn when reprocessing. Other measures may be required if there are specific infection or cross-contamination risks from the patient.
- c. Used strips are also considered as biohazard and need to be discarded as bio-hazard waste accordance with local regulations unless reprocessing procedures was performed per the instructions.
- d. Do not use cold sterilizing methods for the sterilization of strips. These agents often contain strong oxidizing chemicals that may attack the substrate that bonds the diamond particles to the steel blanks.

CLEANING AND STERILIZATION INSTRUCTIONS FOR DIAMOND DENTAL STRIPS

Preparation for Cleaning	<p>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 for cleaning dental instruments shall be used and the manufacturer’s instructions followed.</p> <p>Due to limited reproducibility of manual cleaning, automated cleaning followed by steam sterilization are the preferred processes for reprocessing.</p>
Pre-use and Re-use Manual Cleaning and Drying Procedure	<p>If manual cleaning is implemented, the strips should be cleaned in a sink reserved for the purpose.</p> <ol style="list-style-type: none"> 1. Pre-clean under running water with a soft nylon brush directly after use. 2. Prepare a fresh bath of neutral-pH cleaning solution following the manufacturer’s instructions. Immerse the device and soak for at least ten (10) minutes 3. After soaking, while immersed, brush thoroughly away from the body using the neutral cleaning agent for at least one (1) minute. 4. Thoroughly rinse the device under running warm water for at least one (1) minute and until visibly clean. 5. Dry the device using a non-shedding wipe or clean compressed air.
Ultrasonic Cleaning Procedure	<ol style="list-style-type: none"> 1. This procedure should always follow the manual cleaning.

**NeoDiamond®
IPR Strips (Multi-Use)
Instructions for Use**

	<ol style="list-style-type: none"> 2. Prepare a fresh pH-neutral cleaning solution following the manufacturer’s instructions for correct concentration, exposure time, water temperature and quality. 3. Place the device in a sonication unit ensuring the device is completely submerged and sonicate for at least fifteen (15) minutes. 4. Perform a thorough final rinse of the device under running warm water for at least (1) minute. 5. Visually inspect to confirm the removal of gross debris from perforations, crevices and other hard to reach areas. Repeat the cycle if needed until visibly clean. 6. Dry the device using a non-shedding wipe or clean compressed air. <p>NOTE: For the purpose of Microcopy dental strips manual reprocessing validation, the cleaning agent Power Zyme (Deconex) was used.</p>
<p>Pre-Cleaning (Before the Automated Procedure)</p>	<ol style="list-style-type: none"> 1. Prepare a neutral/mild pH enzymatic detergent following the manufacturer’s instructions. 2. Rinse the strip under running tap water for at least one (1) min. 3. Soak strips immediately into detergent solution, for two (2) minutes. 4. Scrub the strips under running water with soft nylon brush to remove any remaining blood or debris for at least one (1) minute for each side and one (1) minute for each surface side. 5. Place the strips on a clean cloth to avoid any contact between them during the next cleaning procedure.
<p>Automated Cleaning Procedure</p>	<p>Place the strips 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.</p> <ol style="list-style-type: none"> 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 natural 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) <p>NOTE: Microcopy validated the cleaning process with short automatic wash cycle. Any cleansing and disinfecting agents used must be compatible with dental strips; Otherwise, accelerated corrosion or other damage may occur. The washer disinfectant and the cleaning agent manufacturers' instructions must be followed. For the purpose of MDT dental strips automated reprocessing validation, a Miele PROFESSIONAL washer (model PG8593) and the cleaning agent Power Zyme (Deconex) were used.</p>
<p>Post Automated Cleaning Procedure</p>	<ol style="list-style-type: none"> 1. Remove the instruments at the end of the washer program. 2. Check that the load is dry and, if necessary, dry with medical compressed air. 3. Visually inspect the strips for cleanliness. 4. If contamination is still visible, reclean the strips again manually. 5. Subsequently, the re-cleaned strips must be reprocessed again automatically before sterilization. 6. All instruments must be inspected visually for cleanliness, integrity, and functionality, if necessary, by using an illuminated magnifying glass.

**NeoDiamond®
IPR Strips (Multi-Use)
Instructions for Use**

	7. All instruments are to be checked for damage and wear. Damaged medical devices may no longer be used and must be scrapped.
Inspection Testing	<p>Visually inspect the device for damage/ wear that would prevent proper operation before each reuse and after each cleaning.</p> <ol style="list-style-type: none"> 1. Do not use if abrasive strip is dull, chipped, broken, missing diamond particles or is damaged in any manner. 2. Do not use if abrasive strip exhibits signs of corrosion or damage.

STEAM STERILIZATION

Packaging for Sterilization	<p>When using either an autoclave with a pre-vacuum cycle or gravity displacement, place the strips in appropriate instrument trays or pack them in pouches validated for steam sterilization.</p> <p>NOTE: Local legislation for sterilization may require that instruments are wrapped in pouches for processing in either type of autoclave.</p>										
Sterilization	<p>Follow the autoclave manufacturer's instructions to sterilize the strips. Care must be taken not to exceed the maximum recommended load for the autoclave.</p> <p>Microcopy has validated steam sterilization both in an autoclave without a pre-vacuum cycle (gravity displacement type) and with a pre-vacuum for a holding time of 4 minutes at a temperature of 134 °C and drying time of 15 minutes.</p> <p>NOTE: For the purpose of Microcopy dental strips steam sterilization validation a Yipak self-sealing sterilization pouches were used.</p> <p>The holding time is the minimum time for which the minimum temperature is sustained.</p> <ol style="list-style-type: none"> 1) Place the packaged products in the sterilization chamber. 2) Start the program as following (the validated time was four (4) minutes as a minimum, longer time is also possible): <table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th>Cycle Type</th> <th>Cycle duration minimum (Min.)</th> <th>Cycle duration maximum (Min.)</th> <th>Cycle temperature (°C)</th> <th>Drying time (Min.)</th> </tr> </thead> <tbody> <tr> <td>Pre-Vacuum/Gravity Displacement</td> <td>4</td> <td>8</td> <td>134°C (273.2°F)</td> <td>15</td> </tr> </tbody> </table> <ol style="list-style-type: none"> 3) Remove the strips 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. 	Cycle Type	Cycle duration minimum (Min.)	Cycle duration maximum (Min.)	Cycle temperature (°C)	Drying time (Min.)	Pre-Vacuum/Gravity Displacement	4	8	134°C (273.2°F)	15
Cycle Type	Cycle duration minimum (Min.)	Cycle duration maximum (Min.)	Cycle temperature (°C)	Drying time (Min.)							
Pre-Vacuum/Gravity Displacement	4	8	134°C (273.2°F)	15							

**NeoDiamond®
IPR Strips (Multi-Use)
Instructions for Use**

Storage	<ul style="list-style-type: none"> • The strips should be stored in the sterilization container (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 strips 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. Any deviation from these instructions should be properly evaluated for effectiveness and potential adverse results.

TRACEABILITY

Each package includes the **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.		Date of Manufacture	Symbol for date of manufacture.
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.		Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
LOT	Lot 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.
R_x	DEVICE for professional use only	(ref US FDA CDRH) Indicates device shall only be used by a trained professional.		Do not use if package is open or damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
REF	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.		Keep Dry	Indicates a medical device that needs to be protected from moisture.
MD	Medical Device	Indicates device is designed and intended for medical use.			

**NeoDiamond®
IPR Strips (Multi-Use)
Instructions for Use**

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

**REVISION HISTORY**

MCD-IFU-004 Rev. 2

Date of Issue: 30Apr2024