




## NeoDiamond® Non-Sterile, Diamond Strips 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.

### 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.**

### CONTRAINDICATIONS TO USE

- a) Use of NeoDiamond® IPR Strips is contraindicated on any patient who is allergic to any of the product components including nickel.
- b) Do not reuse. 
- c) Do **NOT** use the product if the package is opened or damaged. 
- d) Do **NOT** use a NeoDiamond® IPR Strip if it is damaged.
- e) NeoDiamond® IPR Strips are for Single-Patient-Use only and should be used exclusively in a dental setting.
- f) 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 WARNINGS

- 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.
  - a. Surgical masks must be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
- e) Failure to properly remove the accumulated debris may cause the device to break causing user harm.
- f) 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.

### CLEANING AND STERILIZATION INSTRUCTIONS FOR DIAMOND DENTAL STRIPS

These instructions are applicable to all NeoDiamond® IPR Strips before initial use. The strips are provided mechanically clean but are non-sterile. Therefore, NeoDiamond® IPR Strips should be cleaned and sterilized before first use.

### WARNINGS



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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.

Do not use cold sterilizing methods for the sterilization of NeoDiamond® IPR Strips. These agents often contain strong oxidizing chemicals that may attack the substrate that bonds the diamond particles to the steel blanks.

<b>Preparation for Cleaning</b>	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.
<b>Manual Cleaning Procedure</b>	<p>The strips should be cleaned in a sink reserved for the purpose.</p> <ol style="list-style-type: none"> <li>1. Prepare a fresh bath of neutral-pH cleaning solution following the manufacturer’s directions. Immerse the device and soak for at least ten (10) minutes.</li> <li>2. After soaking, and keeping it immersed, brush thoroughly away from the body using the neutral cleaning agent for at least one (1) minute. Use wire brushes with caution as brass particles may result in galvanic corrosion, which may cause discoloration of stainless steel.</li> <li>3. Thoroughly rinse the device under running warm water for at least one (1) minute and until visibly clean.</li> <li>4. Dry the device using a non-shedding wipe or clean compressed air.</li> <li>5. Inspect the strips, with the aid of magnification if necessary and discard any damaged or corroded instruments</li> </ol>
<b>Ultrasonic Cleaning Procedure</b>	<p><b>Pre-Cleaning</b></p> <ol style="list-style-type: none"> <li>1. Prepare a fresh pH-neutral cleaning solution following the manufacturer’s instructions for correct concentration, exposure time, water temperature and quality.</li> <li>2. Place the device in a sonication unit ensuring the device is completely submerged and sonicate for at least fifteen (15) minutes.</li> <li>3. Perform a final thorough rinse of the device under running warm tap water for at least one (1) minute.</li> <li>4. Visually inspect to confirm the removal of gross debris from perforations, crevices and other hard to reach areas.</li> <li>5. Repeat the cycle if needed until visibly clean.</li> <li>6. Dry the device using a non-shedding wipe or clean compressed air.</li> </ol> <p><b>Inspection Testing</b></p> <p>Visually inspect the device for damage/wear that would prevent proper operation.</p> <ol style="list-style-type: none"> <li>1. Do not use if the NeoDiamond® IPR Strip is dull, chipped, broken, missing diamond particles, or is damaged in any manner.</li> <li>2. Do not use if Diamond Strip exhibits signs of corrosion or damage.</li> </ol>

#### STEAM STERILIZATION

<b>Packaging for Sterilization</b>	<p>If using an autoclave with a pre-vacuum cycle, pack the strips in appropriate instrument trays or pouches validated for steam sterilization.</p> <p>If using an autoclave without a pre-vacuum cycle, the strips should not be packed or wrapped but should be contained in appropriate stands with perforated lids.</p>
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	<p><b>NOTE:</b> Local legislation for sterilization may require that instruments are wrapped in pouches for processing in either type of autoclave.</p>								
<b>Sterilization</b>	<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 in an autoclave without a pre-vacuum cycle (gravity displacement type) for a holding time of three (3) minutes minimum and six (6) minutes maximum at a temperature of 134°C and drying time of thirty (30) minutes.</p> <p>The holding time is the minimum time for which the minimum temperature is sustained.</p> <ol style="list-style-type: none"> <li>1) Place the packaged products in the sterilization chamber.</li> <li>2) Start the program.</li> </ol> <table border="1" style="width: 100%; border-collapse: collapse; margin: 10px 0;"> <thead> <tr> <th style="text-align: center;">Cycle duration minutes minimum (Min.)</th> <th style="text-align: center;">Cycle duration minutes maximum (Min.)</th> <th style="text-align: center;">Cycle temperature (°C)</th> <th style="text-align: center;">Drying time (Min.)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">3</td> <td style="text-align: center;">6</td> <td style="text-align: center;">134°C</td> <td style="text-align: center;">30</td> </tr> </tbody> </table> <ol style="list-style-type: none"> <li>3) Remove the strips at the end of the program and allow to cool down.</li> <li>4) Check the packaging for possible damage and screening effects.</li> <li>5) Faulted packaging must be inspected as being non-sterile. The instruments must be repacked and re-sterilized.</li> </ol> <p><b>NOTE:</b> Local infection control practice may recommend a different combination of holding time and temperature.</p>	Cycle duration minutes minimum (Min.)	Cycle duration minutes maximum (Min.)	Cycle temperature (°C)	Drying time (Min.)	3	6	134°C	30
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<b>Storage</b>	<ul style="list-style-type: none"> <li>The strips should be stored in the sterilization container (stand or pouch) until required.</li> <li>Containers or pouches must be dried before opening to avoid recontamination of the contents with water.</li> <li>Storage should be in dry, clean conditions and at ambient temperature</li> </ul>								

#### 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.		Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
<span style="border: 1px solid black; padding: 2px;">LOT</span>	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.

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	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.
	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.		Date of Manufacture	Symbol for date of manufacture.
	Medical Device	Indicates device is designed and intended for medical use.		Keep Dry	Indicates a medical device that needs to be protected from moisture.
	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.		Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.

#### CONTACT INFORMATION



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