

NeoDiamond® Non-Sterile, Diamond Strips 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 Microcopy Diamond Strips are made of stainless steel coated with diamond particles on the working ends of the double-handed device. The Diamond Strips are provided non-sterile and can be reused, therefore read the following cleaning and sterilization instructions carefully.

Newly delivered unsterile instruments must be prepared accordingly before first use.

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

INDICATIONS

Microcopy Diamond Strips are intended to be used by dentists in dental clinics/hospitals/labs. The strip is 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, Diamond Strips may be used to finish restorations interproximally along with interproximal enamel reduction during orthodontics.

CONTRAINDICATIONS TO USE

- a) Used Diamond Strips 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 Diamond Strips 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. When unpackaging, take care not to bend the Diamond Strips.

PRECAUTIONS:

- a) The device is to be used as per the following instructions by physician or licensed practitioner.
- b) Always wear gloves when handling contaminated instruments.
- c) Clinicians should wear eye protection and facemask when using the Diamond Strips.
- d) Strips must be thoroughly cleaned and sterilized prior to the first use to prevent the risk of infection.
- e) Do not use chemical, dry heat or cold sterilization methods to sterilize Strips, as these processes have not been validated for use. Use of these processes may be corrosive to the device and could result in premature device failure
- f) Failure to properly remove the accumulated debris may cause the device to break causing user harm.
- g) Always inspect the Strip before use: Use of damaged Abrasive Strips could cause preparation site damage, procedural delays, or injury to the user.

CLEANING AND STERILIZATION INSTRUCTIONS FOR DIAMOND DENTAL STRIPS

These instructions are applicable to all Diamond Strips. They are applicable before initial use. Abrasive Strips are provided mechanically clean but are non-sterile. Therefore, Diamond Strips should be cleaned and sterilized before first use.

Limitations of Re-Use

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.

WARNINGS

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 Diamond Strips. These agents often contain strong oxidizing chemicals that may attack the substrate that bonds the diamond particles to the steel blanks.

<p>Preparation for Cleaning</p>	<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>Manual Cleaning Procedure</p>	<p>The strips should be cleaned in a sink reserved for the purpose.</p> <ol style="list-style-type: none"> 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. 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. 3. Thoroughly rinse the device under running warm water for at least one (1) minute and until visibly clean. 4. Dry the device using a non-shedding wipe or clean compressed air. 5. Inspect the strips, with the aid of magnification if necessary and discard any damaged or corroded instruments.
<p>Ultrasonic Cleaning Procedure</p>	<p>Pre-Cleaning –</p> <ol style="list-style-type: none"> 1. Prepare a fresh pH-neutral cleaning solution following the manufacturer’s instructions for correct concentration, exposure time, water temperature and quality. 2. Place the device in a sonication unit ensuring the device is completely submerged and sonicate for at least fifteen (15) minutes. 3. Perform a final thorough rinse of the device under running warm tap water for at least (1) minute. 4. Visually inspect to confirm the removal of gross debris from perforations, crevices and other hard to reach areas. 5. Repeat the cycle if needed until visibly clean. 6. Dry the device using a non-shedding wipe or clean compressed air.

	<p>Inspection Testing</p> <p>Visually inspect the device for damage/ wear that would prevent proper operation.</p> <ol style="list-style-type: none"> 1. Do not use if Diamond Strip is dull, chipped, broken, missing diamond particles, or is damaged in any manner 2. Do not use if Diamond Strip exhibits signs of corrosion or damage
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STEAM STERILIZATION

Packaging for Sterilization	<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> <p>NOTE: <i>Local legislation for sterilization may require that instruments are wrapped in pouches for processing in either type of autoclave.</i></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 in an autoclave without a pre-vacuum cycle (gravity displacement type) for a holding time of 3 minutes minimum and six minutes maximum at a temperature of 134 °C and drying time of 30 Min.</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 <table border="1" data-bbox="565 1402 1226 1602"> <thead> <tr> <th>Cycle duration minutes minimum (Min.)</th> <th>Cycle duration minutes maximum (Min.)</th> <th>Cycle temperature (°C)</th> <th>Drying time (Min.)</th> </tr> </thead> <tbody> <tr> <td>3</td> <td>6</td> <td>134 °C</td> <td>30</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. <p>NOTE: <i>Local infection control practice may recommend a different combination of holding time and temperature</i></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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Storage	<p>The strips should be stored in the sterilization container (stand or pouch) until required.</p> <p>Containers or pouches must be dried before opening to avoid recontamination of the contents with water.</p> <p>Storage should be in dry, clean conditions and at ambient temperature</p>
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Note: Local legislation may require that burs/discs will be wrapped in pouches for processing in either type of autoclave.
Sterilization Process

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

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 Number	Indicates the manufacturer's catalog number so that the medial device can be identified	LOT	Batch 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 Marking	Indicates European Conformity Mark.
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.	RxOnly	DEVICE for professional use only	(ref US FDA CDRH) Indicates device shall only be used by a trained professional.
MD	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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