

## Instructions for Use for – MDT Diamond Dental Strips

### Description

MDT Diamond Dental Strips are manufactured from stainless steel coated with Diamond

The strips are provided as non-sterile . The devices are pre-sterilized using steam sterilization.

### Intended Use

MDT Dental Strips are double-handed devices.

The Strip intended for manual use in multiple dental treatments. Designed to pre-polish, contour, finish polish and high shine polish interproximal areas of composite restorations and/ or used in interproximal reduction of enamel. Some are used to finish restorations interproximally along with interproximal enamel reduction during orthodontics.

### Contraindications for the use of MDT Diamond Strips

- a) Strips contain nickel and should not be used for individuals with known allergic sensitivity to this metal as it may cause hypersensitivity.
- b) Used Strips shall be considered as contaminated after use and as such, appropriate precautions shall be taken during disposal.
- c) In the event of a used strip being returned to MDT, please ensure any contaminated and/or potentially contaminated strip have been effectively cleaned, and is appropriately packaged for return.

### Transport, storage and treatment of new instruments prior to first use

There are no particular conditions necessary for transport.

- a) Please store all original packed instruments at a clean and dry place at room temperature.
- b) The Strips are not packaged in sterile condition and must be cleaned, disinfected and sterilized according to preparation instructions before use.
- c) With unpacking, take care not to bend them.

### Warnings and 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) Strips must be thoroughly cleaned and sterilized prior to the first use to prevent the risk of infection.
- d) 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
- e) Failure to properly remove the accumulated debris may cause the device to break causing patient or user harm.
- f) Always inspect the Strip before use:

Use damaged Abrasive Strips could cause preparation site damage, 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 Abrasive Strips made from stainless steel. They are applicable before initial use. Abrasive Strips are provided mechanically clean, but are not sterile. Therefore, Abrasive Strips should be cleaned and sterilized before first use.

#### Warnings

1. 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.
2. Do not use cold sterilizing methods for the sterilization of Diamond-Coated 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.</li> </ol> <p>Use wire brushes with caution as brass particles may result in galvanic corrosion, which may cause discoloration of stainless steel.</p> <ol style="list-style-type: none"> <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>	<b>PRE-CLEANING –</b>

	<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 (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 Abrasive strip is dull, chipped, broken, missing diamond particles or is damaged in any manner</li> <li>2. Do not use if Abrasive strip exhibits signs of corrosion or damage</li> </ol>
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## STERILIZATION - USING STEAM

<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> <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. In particular, care must be taken not to exceed the maximum recommended load for the autoclave.</p> <p>MDT 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"> <li>1) Place the packaged products in the sterilization chamber</li> <li>2) Start the programme</li> </ol>

	<table border="1"> <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> <tr> <td>3</td> <td>6</td> <td>134 °C</td> <td>30</td> </tr> </table>	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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	<p>3) Remove the strips at the end of the programme and allow to cool down</p> <p>4) check the packaging for possible damage and screening effects</p> <p>5) Faulted packaging must be inspected as being non-sterile. The instruments must be repacked and re-sterilized.</p> <p>NOTE: Local infection control practice may recommend a different combination of holding time and temperature</p>								
<b>STORAGE</b>	<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>								

#### TRACEABILITY

Each package includes **Lot number** LOT on its label.

This number must be quoted in any correspondence regarding to the product.

#### GLOSSARY OF SYMBOLS

	Catalogue number / Part Number (P/N)
	Batch code/number
	Manufacturer
	Consult Instruction for use
	Non-Sterile Product
	(ref US FDA CDRH) DEVICE for professional use only

### Contact Information

 <p>Manufacturer</p>	<p>MDT, Micro Diamond Technologies Ltd. Ha'amal 2St., Afula 1857107, Israel Phone: +972-4-6094422 Fax: +972-4-6597812 Email: <a href="mailto:info@mdtdental.com">info@mdtdental.com</a> Web: <a href="http://www.mdtdental.com">www.mdtdental.com</a></p>
 <p>European Community Authorized Representative</p>	<p><b>OBELIS S.A</b> BD. GÉNÉRAL WAHIS 53 1030 BRUSSELS, BELGIUM TEL: + (32) 2. 732.59.54 FAX: +(32) 2.732.60.03 E-MAIL: MAIL@OBELIS.NET</p>

