MDT Micro Diamond Technologies Ltd.
Efficiency in your hands

Instructions for Use for MDT Diamond Coated Stainless Steel Flexible Strips

DESCRIPTION
MDT Diamond Coated Stainless Steel Flexible Strips are manufactured from stainless steel coated with Diamond.

SCOPE
The following instructions are applicable to the cleaning, disinfection and sterilization of MDT's diamond dental strips prior to initial use and after every subsequent re-use.
MDT's Diamond Coated Stainless Steel Flexible Strips are supplied mechanically clean, but NOT sterile.

INDICATIONS FOR USE
MDT Diamond dental strips are flexible and double-handed devices.
The Strips are reusable devices 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 interproximal along with interproximal enamel reduction during orthodontics.

Professional use - Dental strips are intended for dentistry and must only be used by dentists and other qualified professionals that are familiar with the use of these instruments and its reprocessing procedures based on their training and experience. Therefore, user training is not needed to ensure specified performance, safe use and reprocessing of the medical device.

PATIENT POPULATION: Patients requiring dental care.

CONTROLLED DOCUMENT

CONTRAINDICATIONS:
a. Strips contain nickel and should not be used for individuals with known allergic sensitivity to this metal as it may cause hypersensitivity.
b. Any serious incident that has occurred in conjunction to our device, must be reported to MDT (at the address listed below) and to the competent authority of the Member State in which the user/patient is established.

TRANSPORT, STORAGE AND TREATMENT OF NEW INSTRUMENTS PRIOR TO FIRST USE

a. The transportation of the dental strips should always be in its original packaging.
b. Please store all original packed instruments at a clean and dry place at room temperature.
c. The strips are not packed in sterile conditions and must be cleaned, disinfected and sterilized according to preparation instructions before use.
d. With unpacking, take care not to bend the strips.

WARNINGS AND PRECAUTIONS

a. The device is to be used in accordance with the following instructions by physician or licensed practitioner.

b. Carefully read package labels to ensure appropriate use of the device.
c. Clean and sterilize the strips supplied in a non-sterile condition in accordance with the directions below before first use and before each reuse to avoid any risk of contamination.
d. With unpacking, take care not to bend them.
e. Always wear gloves when handling contaminated instruments.
f. Eye protection must be worn to guard against ejected particles.
g. Surgical masks must be worn to avoid inhalation of any aerosol or dust generated during use.
h. 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.
i. Do not leave Diamond strips in wet conditions as this may lead to corrosion.
j. Failure to properly remove the accumulated debris may cause the device to break causing patient or user harm.
k. Always inspect the strip before use for wear, tears, rust, breaks or any other visible damage. Do not use damaged or worn-out dental strips and discard them in accordance with your local regulations. The use of damaged abrasive strips could cause procedural delays, injury to the patient or user, or aspiration or swallowing of a broken device by the patient.
l. Avoid overuse of Dental Strips as patient or user injury may result from device wear.

REPROCESSING INSTRUCTIONS FOR DIAMOND COATED STAINLESS STEEL FLEXIBLE STRIPS

Scope
The reprocessing instructions detailed below apply only to reusable Strips. Strips shall be reprocessed. Upon initial use and prior to being reused.

Limitations of Re-Use
a. Reprocessing will have little effect on MDT's Diamond Coated Stainless Steel Flexible Strips.
b. The end of strips' life is determined by wear, abrasive performance reduction and damage in use.
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

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 preferred.
2. Used strips should be considered as being 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.
3. Used strips are also considered as biohazard and need to be discarded as bio-hazard waste accordance with local regulations, unless reprocessing procedures has been done according to the instructions.
4. 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.
5. In the event of strips being returned to MDT, please ensure any contaminated and/or potentially contaminated strips have been effectively cleaned and are appropriately packaged for return.

CLEANING AND STERILIZATION INSTRUCTIONS

PREPARATION FOR CLEANING	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. Due to limited reproducibility of manual cleaning, automated cleaning followed by steam sterilization are the preferred processes for reprocessing.
PRE-USE AND RE-USE MANUAL CLEANING AND DRYING PROCEDURE	If manual cleaning is implemented, the strips should be cleaned in a sink reserved for the purpose. 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	1. This procedure should always follow the manual cleaning. 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. **NOTE:** For the purpose of MDT dental strips manual reprocessing validation, the cleaning agent Power Zyme (Deconex) was used.
PRE-CLEANING (BEFORE THE AUTOMATED PROCEDURE) AUTOMATED CLEANING PROCEDURE -	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. 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. 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).

POST AUTOMATED CLEANING PROCEDURE –	**NOTE:** MDT 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 disinfector and the cleaning agent manufacturers' instructions must be followed. For the purpose of MDT dental strips automated reprocessing validation, a Miele PROFFESIONAL washer (model PG8593) and the cleaning agent Power Zyme (Deconex) were used. 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 recleaned 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. 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	Visually inspect the device for damage/ wear that would prevent proper operation before each reuse and after each cleaning. 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 - Instructions

PACKAGING FOR STERILIZATION	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. **NOTE***: Local legislation for sterilization may require that instruments are wrapped in pouches for processing in either type of autoclave.*
STERILIZATION	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. MDT 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 ºC and drying time of 15 Min. **NOTE:** For the purpose of MDT dental strips steam sterilization validation a Yipak self-sealing sterilization pouches were used. The holding time is the minimum time for which the minimum temperature is sustained. 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).

Cycle Type	Cycle duration minutes minimum (Min.)	Cycle duration minutes maximum (Min.)	Cycle temperature (^{0}C)	Drying time (Min.)

Pre-Vacuum/Gravity Displacement	4	8	134 °C (273.2°F)	15

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.

STORAGE

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 MDT'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 **Lot number** LOT on its label.
This number must be quoted in any correspondence regarding to the product.

GLOSSARY OF SYMBOLS

REF	Catalogue number / Part Number (P/N)
LOT	Batch code/number
	Manufacturer
	Consult Instruction for use
NON STERILE	Non-Sterile Product
	Wear mask and eye protection gear while operating
RxOnly	(ref US FDA CDRH) DEVICE for professional use only
UDI	Unique Device Identifier
MD	Medical Device
	Keep Dry

	Manufacturing Date
	Importer

Contact Information

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CONTROLLED DOCUMENT

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