INSTRUCTIONS FOR USE FOR STERILE AND NON-STERILE DENTAL POLISHERS

SCOPE

This IFU provides general instruction for MDT polishers, sterile and non-sterile, and reprocessing instructions that are applicable to the cleaning and steam sterilization of the multi-use non-sterile dental polishers prior to initial use, and there after every subsequent re-use. The dental multi-use polishers are supplied mechanically clean, but NOT sterile.

MDT's (Micro Diamond Technologies Ltd) Dental polishers consist of polyurethane polymeric matrix, pigments and abrasives. The shanks are made of stainless steel (for the non-sterile polishers) or plastic (for the sterile polishers).
The dental polishers are part of MDT's Dental Rotary instruments portfolio available to the users including diamond coated burs, TC dental burs, discs and dental polishers.
The polishers described in this IFU can be provided Sterile using Gamma Irradiation STERILE R for single use or non-sterile NON STERILE for multi-use.

MDT Polishers are available in five (5) geometries: Cup, Point, Disc, Occluflex (Daisy bud) and spiral (Daisy) which are tailored to polish varying dental restorative substrates as indicated by their name. These materials include Zirconia, Composite, Metal.
Two polishing steps are available depending on the desired outcome of polishing. We recommend using the two steps in order to reduce surface roughness and provide the highest amount of shine possible.
The polishers are designed with a color ID system to aid doctors in selecting the correct polisher.

Step 1 is a dark shade and step 2 is a light shade of that color. See the below explanation of the polisher steps.

Step 1: Silk Finish Polishers:
Designed to remove surface striations and anatomical defects.
Leaves a smooth, satin-shine surface.

Step 2: Hi-Gloss Polishers:
Designed to establish a high-gloss surface following the satin polisher.
Ideal for anterior and esthetic restorations.

DENTAL ROTARY INSTRUMENT INDICATION FOR USE

These rotary polishers are intended for a wide variety of restorative procedures including but not limited to removal of caries or old restorations, preparation of cavities for restoration, finishing of restorations, interproximal reduction (IPR), removal of crowns, orthodontic device procedure and any other dental operation. It can be used to cut, grind or polish a wide variety of dental materials, including tooth material such as enamel, dentine, as well as dental materials such as amalgam, composite, zirconia, lithium di-silicate, glass cements, polymer and ceramic veneers and various alloys.

INTENDED PURPOSE

The dental rotary polishers are intended for laboratory and dental applications in clinics and hospitals both chair side and within the dental oral orifice.

INTENDED USERS

Professional use - Dental polishers are intended for dentistry and must only be used by dentists and other qualified professionals who are familiar with use of these instruments based on their training and experience. Therefore, user training is not needed to ensure specified performance and safe use of the medical device. For laboratory applications, the use of these instruments must be by a licensed technician.

INTENDED POPULATION

All patients in need for dental care.

CONTRAINDICATIONS: If a patient is known to be allergic to any of the above components, the polishers should not be used.

All polishers have been designed and engineered for their specific application. Improper use of the product nor with the handpiece attached, can lead to tissue damage, increased wear or destruction of the polisher, as well as cause risks to the user, the patient or third parties.

In consideration of patient safety, limited extended contact to the mucosa membrane is recommended.

The polishers that are identified as single-use devices are NOT to be re-processed and/or re-sterilized and could adversely affect their performance.

PRODUCTS IN COMBINATION WITH MDT'S DENTAL POLISHERS:

MDT's polishers fit into a slow-speed, contra-angle latch dental handpiece, which provides the rotation, allowing the user to adjust or polish materials both intra-orally and chair-side i.e., composites, precious metals, non-precious alloys, lithium di-silicate, amalgam or zirconia.
Maintain handpieces in good working condition to ensure maximum effectiveness of the device. Failure to properly maintain handpieces may lead to procedural delays or injury of the patient or user, aspiration or swallowing of the device or damage to the preparation site due to vibration of a worn chuck or turbine.

PROPER USE:

a) Only turbines, handpieces and contra-angle attachments that are in perfect technical and hygienical conditions should be used, meaning that they should be well maintained and correctly cleaned. Turbines and contra-angle attachments used must ensure precise and concentric rotation.
b) The polishers are to be used as per the following instructions by physician or licensed practitioner.
c) Carefully read package labels to ensure proper use of the device. Failure to do so may cause procedural delays or patient or user injury. Before use check sterile packaging integrity for damage and tears that may impair the sterility of the product.
d) Follow package labels for optimal and maximal speed for proper use of the device.
e) Failure to follow these instructions may cause the following: preparation site damage, injury to the patient or user, or possible aspiration or swallowing of the dental Polishers
f) Clean and sterilize the polishers supplied in a non-sterile condition in accordance with the directions below before first use and before each reuse to avoid contamination risks.
g) Sterile devices' pouch must be opened right next to use. The pouch should be kept until the end of treatment.
h) Polishing paste is NOT required.
i) Instruments must be inserted as far as possible. Before applying the instruments to any surface, they must be brought to speed. check the safe connection of the polisher before using it and perform a test run.
j) If possible, polish in slightly circular movements to avoid indentations.
k) Tilting or levering is to be avoided as it leads to an increased risk of breakage.
l) The dental polishers are intended for dental applications in dental clinics and hospitals by licensed dentist.
m) Always wear Gloves when handling contaminated instruments.
n) Eye protection must be worn to protect against ejected particles.
o) Surgical mask must be worn to avoid inhalation of aerosol or dust generated.
p) Before each use, inspect the polishers for mechanical damage or excessive wear. Discard worn, deformed or non-concentric polishers.
q) Do not use after the expiry date indicated on the package of the device.

ROTATION SPEED INSTRUCTIONS:

a) Do not exceed the maximum speed. Before applying the instrument on the surface to be treated, bring it to the rotation speed needed as indicated on the label.
b) Avoid using the polisher at too high an angle in order to avoid crumble and breakage.

c) Move the polisher continuously when in use to avoid localized heating and/or damage to the polisher.

For proper rotation speed adjustments, please see the table below:

Product Type	Item Family		Grit	Recommended RPM
RA Products	Composite		M, F	3,000-10,000
	Zirconia, Alumina, Lithium Disilicate, Gold, Amalgam, Non-Precious Metals and Daisy Bud		M, F	7,000-10,000
	Universal Polishing System	Step 1: Silk Finish Polishers	M	7,000-12,000
		Step 2: Hi-Gloss Polishing	F	
	Composite Polishing System	Step 1: Silk Finish Polishers	M	3,000-10,000
		Step 2: Hi-Gloss Polishing	F	
	Zirconia & Lithium Disilicate Polishing System	Step 1: Silk Finish Polishers	M	7,000-12,000
		Step 2: Hi-Gloss Polishing	F	7,000-10,000
HP Products (Lab Polishers)	Acrylics		C, M, F	5,000-7,000
	Metals, Zirconia, Silicate Ceramics & Ceramics		C, M, F	7,000-12,000

* MAX ROTATIONAL SPEEDS FOR ALL PRODUCT IS 20,000 RPM

WATER COOLING

In order to avoid the overheating of a tooth or a restoration, sufficient water cooling must be ensured (50 ml/min). Insufficient water cooling can lead to irreversible damage to the tooth and its surrounding tissues.

PRESSURE ON THE POLISHER:

a) Do not activate excessive pressure on the polisher.
b) Excessive pressure results in more heat being produced.
c) Excessive pressure can cause early wear of the polisher.

REPROCESSING INSTRUCTIONS FOR MDT DENTAL POLISHERS

SCOPE

The reprocessing instructions detailed below apply only to reusable dental polishers. Polishers shall be reprocessed upon initial use and prior to being reused.

LIMITATIONS OF RE-USE

Reprocessing will have little effect on MDT's dental polishers. The end of reusable dental polisher life is determined by wear and damage in use and the polisher should be inspected for defects during the preliminary cleaning process.

Delay between use and reprocessing must be kept to a minimum to avoid contaminants drying, thereby making cleaning more difficult. Therefore, keep the unclean polishers immersed in the cleaning/disinfecting agent in accordance with manufacturer instructions, but in any event, do not exceed 12 hours.

Prolonged storage in disinfectant solutions may result in corrosion and should therefore be avoided.

Caution: Do not leave polishers mmersed in disinfectants that have a fixative action (such as aldehyde-based products) unless the polishers have been thoroughly cleaned first.

WARNINGS

Used polishers should be considered as being contaminated and appropriate handling precautions should be taken during reprocessing. Gloves, eye protection and a mask should be worn. Other measures may be required if there are specific infection or cross-contamination risks from the patient. Used polishers are also considered as biohazard and need to be discarded as bio-hazard waste unless reprocessing procedures has been done according to the instructions.

WARNING NOTICES

a) Observe the manufacturer's reprocessing materials information in order to ensure material compatibilities for cleaning, disinfection and sterilization.
b) The reprocessing materials exposure time and concentration specified by the manufacturer must be followed.
c) Ultrasonic bath must not exceed temperatures of 42 °C because of the possible coagulation of protein
d) Instruments that have not completely dried after cleaning and disinfection must be dried again (e.g. with medical compressed air) to avoid compromising the success of sterilization.
e) Strong acids and strong bases may oxidize the stainless-steel shank.
f) Instructions of cleaning and/or disinfecting solutions must specifically state suitable for rubber polishers or synthetics/silicones.
g) Avoid temperatures above 150 °C.
h) Instruments that have not completely dried after cleaning and disinfection must be dried again (e.g. with medical compressed air) to avoid compromising the success of sterilization.

PRE-CLEANING (FOR MANUAL AND AUTOMATED CLEANING)

a) Polishers should be cleaned in a sink reserved for the cleaning purpose.
b) Pre-clean under running water with a brush (plastic) directly after use.
c) Prepare a fresh bath of neutral-pH cleaning solution following the manufacturer's instructions for correct concentration (0.1-0.3% enzymatic cleaner solution. 0.1% was validated). Immerse the device and soak for at least ten (10) minutes.
d) After soaking, while immersed, brush thoroughly away from the body using the neutral cleaning agent for at least one (1) minute.
e) Rinse the polishers under running water for one (1) minute and brush them thoroughly with a plastic brush, particularly the difficult to access areas of the head.
f) Dry the device using a non-shedding wipe or clean compressed air.

MANUAL ULTRASONIC CLEANING

a) Clean with a suitable cleaning agent using multi-stage enzymatic cleaner.
b) Prepare a fresh pH-neutral cleaning solution following the manufacturer's instructions for correct concentration (0.1-0.3% enzymatic cleaner solution. 0.1% was validated), exposure time, water temperature and quality (at least drinking water quality) and fill into an ultrasonic bath.
c) Completely immerse the polishers in the solution.
d) Expose the products for 1 minute to the ultrasonic bath.
e) Remove the polishers from the cleaning solution and rinse them each thoroughly at least 60 seconds under running water.
f) Take the polishers out of the bath and rinse them under warm running water (approximately 30^0C) for at least two (2) minutes and until visibly clean.
g) After cleaning, inspect the cleanliness of the polishers with the aid of magnifying glass (5-10 folds), to ensure that all contaminants have been removed. Repeat the cleaning process if necessary.
h) Dry the device using a non-shedding wipe or clean compressed air.

NOTE: For the purpose of MDT dental polishers manual reprocessing validation, the cleaning agent Power Zyme (Deconex) was used. Other equivalent reprocessing cleaning agents can be used upon local validation by the user.

INSPECTION:

No residues - continue to sterilization.

Visible residues - repeat cleaning. Reject and dispose of instruments in the event of discernible defects.

AUTOMATED CLEANING AND DISINFECTING

NOTE: Coarse surface contamination on the instruments must be removed prior to automatic reprocessing (see pre-treatment).

EQUIPMENT: Cleaning and disinfection unit according to DIN EN ISO 15883-1+2 with thermal program (temperature 90 °C to 95 °C), detergent: mildly alkaline detergent (e.g. Dr. Weigert neodisher MediClean Dental).

a) Place the instruments in a suitable small parts tray or on the load carrier such that all surfaces of the instruments are cleaned and disinfected.
b) Close WD and start program, see table below for program sequence.

Prog. Step	Water	Dosage	Time	Temperature
Pre-rinse	CW		5 min	
Dosage of detergent		According to manufacturer's instructions		According to manufacturer's instructions
Clean	Fully deionized water		10 min	55^{0}C
Rinse	Fully deionized water		2 min	
Disinfect	Fully deionized water		3 min	Ao-value>3000[1] (e.g. 90^{0}C, 5 min)
Drying			15 min	Up to 120^{0}C
[1] Authorities may issue other operational regulations (disinfection performance parameters) in their area of competence.				

c) Remove the instruments at the end of the program.
d) Check that the instruments are dry and, if necessary, dry with medical compressed air.
e) Visual inspection for cleanliness is performed after removal from the WD. If contamination is still visible, reclean medical devices again manually. Subsequently, the recleaned medical devices must again be reprocessed automatically.

STERILIZATION - USING STEAM

SCOPE

These sterilization instructions applicable to polishers initially provided non-sterile and to non-sterile polishers that are being reused. No sterilization before first use is required for polishers labeled 'Sterile'.

PACKAGING FOR STERILIZATION	When using either an autoclave with a pre-vacuum cycle or gravity displacement, place the instruments in appropriate instrument trays or pack them in pouches validated for steam sterilization. ***NOTE:*** *Local legislation for sterilization may require that dental instruments are wrapped in pouches for processing in either type of autoclave.*
STERILIZATION	Follow the autoclave manufacturer's instructions to sterilize the instruments. In particular, care must be taken not to exceed the maximum recommended load for the autoclave. MDT has validated steam sterilization in an autoclave for both pre vacuum as well as in a gravity displacement type for a holding time of 4 minutes at a temperature of 134 °C and drying time of 15 Min. The holding time is the minimum time for which the minimum temperature is sustained. ***Note:*** For the purpose of MDT dental instruments, steam sterilization validation a Yipak self-sealing sterilization pouches were used. 1) Place the packaged instruments in the sterilization chamber. 2) Start the program (The validated time was four (4) minutes as a minimum, longer time is also possible). Cycle duration minutes minimum (Min.) / Cycle temperature (^{0}C) / Drying time (Min.) 4 / 134 °C / 15 3) Remove the instruments at the end of the program and allow them 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. ***NOTE:*** Instrument blocks (stand) can be used for sterilization purposes for immediate use only.
STORAGE	The device should be stored in the sterilization pouch until required. 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 polishers for reuse. It remains the responsibility of the re-processor 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.

DISPOSAL

Used polishers are considered as biohazard and need to be discarded as bio-hazard waste in accordance with local regulations.

TRACEABILITY

Each package includes Lot number 

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

CONTACTING MDT:

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.

In the event of polishers being returned to MDT, please ensure any contaminated and/or potentially contaminated polishers have been effectively reprocessed and are appropriately packaged for return.

GLOSSARY OF SYMBOLS

CE 0483	CE Compliance
XX REP	Indicate the authorized representative
MD	Medical Device
	Manufacturer
	Date of manufacture
	Expiry date ***Note****: for sterile products only*
REF	Catalogue number / Part Number (P/N)
LOT	Batch code/number
UDI	Unique Device Identifier
	Wear mask and eye protection gear while operating
STERILE R	Sterilized using irradiation ***Note****: for sterile products only*
	Do not re-use ***Note****: for sterile products only*

	Do not Re-sterilize. ***Note**: for sterile products only*
	Indicate a single sterile barrier system ***Note**: for sterile products only*
	Non-Sterile Product ***Note**: for non-sterile products only*
	Importer
	Needs to be sterilizable in a steam sterilizer ***Note**: for non-sterile products only*
	Consult Instruction for use
	Do not use if package is damaged and consult instructions for use
	Keep Dry
	Keep away from sunlight.
	Temperature limit- from 5°C to 40°C.
	Maximum speed (RPM)
RxOnly	(ref US FDA CDRH) DEVICE for professional use only

CONTACT INFORMATION:

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