STRAUSS DIAMOND
INSTRUMENTS

INSTRUCTIONS FOR USE FOR STERILE AND NON-STERILE-DIAMOND COATED DENTAL BURS, TUNGSTEN CARBIDE DENTAL BURS AND DENTAL DISCS

SCOPE

These Instructions For Use (IFU) provide general instructions for MDT's rotary devices and specific reprocessing instructions that are applicable to the cleaning and steam sterilization of the multi-use Diamond Dental Burs/Discs and Tungsten Carbide (from herein after "TC") burs prior to initial use, and there after every subsequent re-use. The multi-use Diamond Dental Burs/Discs and TC burs are supplied mechanically clean, but NOT sterile.

MDT Diamond Dental Burs are manufactured from stainless steel coated with Diamond.
Tungsten Carbide Burs – are manufactured from a single piece of TC or from a TC tip brazed onto a surgical grade stainless-steel stem.
Diamond coated dental discs are manufactured from stainless steel coated with diamond particles on the working part.
The Diamond Burs/Discs and TC dental burs are part of MDT's Dental Rotary instruments portfolio available to its customers including diamond coated burs, TC dental burs, discs and dental polishers.

The rotary instrument can be supplied as Single use Sterile using Gamma Irradiation or non-sterile for multi-use as follow:

	NON STERILE Multi-Use*	STERILE R Single Use
Diamond burs	+	+
Tungsten-Carbide burs	+	+
Diamond Discs	+	-

* Following reprocessing instructions

DENTAL ROTARY INSTRUMENT INDICATION FOR USE

These rotary instruments 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 instrument is intended for laboratory and dental applications in clinics and hospitals both chair side and within the dental oral orifice.

INTENDED USERS

Professional use - Dental Rotary Instruments 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 AND WARNINGS

- For the use of MDT Diamond burs, TC bur or Diamond discs is contraindicated on any patient with known allergy to Nickel.
- The use of Tungsten Carbide burs in patients with known sensitivity to cobalt is not recommended; In these cases, the use of alternative devices should be considered.

PRODUCTS IN COMBINATION WITH MDT'S DENTAL BURS/DISCS:

The diamond and TC dental burs/discs are compatible with any approved medical device handpiece that can be operated with FG, RA or HP bur shanks. MDT's rotary instruments can be supplied in any of the following shanks:

MDT Rotary Instrument	FG	RA	HP
Diamond burs	+	+	+
Tungsten-Carbide burs	+	+	+
Diamond discs	-	+	+

Maintain handpieces in good working conditions 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.

STORAGE (PRE-USE):

Store in a dry and clean environment at ambient temperature.

The bur pattern selected will be chosen to cut a specific material in a specific application.
The following table gives guidance and provides **recommended RPM** for the user.

For FG diamond burs:

Instrument head diameter 1/10 mm	Maximum permissible speed (RPM)	Recommended operational speed (RPM)
007 - 010	450,000	100,000 - 220,000
011 - 014	450,000	70,000 - 220,000
015 - 018	450,000	55,000 - 160,000
019 - 023	300,000	40,000 - 120,000
024- 027	160,000	35,000 - 110,000
028 - 031	140,000	30,000 - 95,000
032 - 040	120,000	25,000 - 75,000
041 - 054	95,000	15,000 - 60,000
055 - 070	60,000	12,000 - 40,000
071 - 100	45,000	10,000 - 20,000

For HP burs and HP diamond discs, the following table applies:

Process	Gross reduction	Contouring	Finishing	Polishing
Standard color Code	blue	green	yellow	white
Speed, rpm	7,000-10,000	7,000-10,000	2,000-3,000	2,000-3,000

For Tungsten-Carbide burs, the recommendations are listed below:

Application	TC Bur Type	Material	Size (mm)	MDT's ID Number	Recommended operational speed (RPM)
Cavity preparation	Standard	Enamel/Dentine	010-023	FG.TC0002-0008 / 0057 / 0556-0557	<450,000
Removal of fillings	Standard	Amalgam/Composite	010-018	FG.TC0330-0331	60,000-120,000
Excavation	Standard	Enamel/Dentine	010-023	FG.TC0002-0008 / 0035	<2,000
Finishing margins	Finishing	Enamel	010-016	FG.TC0057	10,000-20,000
Finishing restorations	Finishing	Amalgam	012-023	FG.TC0245	18,000-30,000
Finishing restorations	Finishing	Composite	012-023	FG.TC 557 / 057	10,000-20,000
Finishing restorations	Finishing	Glass ionomer	012-023	FG.TC 557 / 057	10,000-20,000
Crown & bridge finishing	Finishing	C&B polymer	010-016	FG.TC 557 / 057	40,000-80,000
C&B metal trimming	Standard	Metals	018-027	FG.TC1157-1158 / 1557-1558	<30,000
Prosthetic polymer trimming	Standard	Polymer	018-027	FG.TC 1157 / 1158 / 330	<20,000

CLINICAL PRECAUTIONS AND WARNINGS:

Read carefully:

a) The device is to be used as per the following instructions by physician or licensed practitioner.
b) Carefully read package labels to ensure appropriate 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.
c) Failure to follow this IFU may cause the following: possible damage to the tooth/restoration, injury to the patient or user, or possible aspiration or swallowing of the instrument.
d) Clean and sterilize the instruments 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.
e) Always wear gloves when handling contaminated instruments.
f) Sterile devices' pouch must be opened right next to use. The pouch should be kept until the end of treatment in order to allow proper identification.
g) Protect patient's eyes and vulnerable tissues when using these instruments.
h) Clinicians should wear eye protection and facemask when using these instruments.
i) Surgical masks shall be worn to avoid inhalation of aerosol and/or dust generated during the procedure.
j) Ensure the instrument is fully seated and gripped in the handpiece collet to. Failure to follow these instructions may cause possible damage to the tooth, injury to the patient or user, or possible aspiration or swallowing of the instrument.
k) Prior to use inspect the instrument for rust, broken and/or damaged flutes, discard any potentially defective burs/discs. Do not use worn- out or dull instruments.
l) Do not apply excessive pressure on the instrument as this could cause undesirable heat and/or may cause the device to fail.
m) Move the device continuously when in use to avoid localized heating and/or damage to the instrument. Undesirable heat generation can cause patient discomfort, tooth or tissue necrosis, or patient burns.
n) Avoid removing the instrument at too sharp angle to avoid leverage and breakage which could cause patient or user injury.
o) Never force an instrument into a handpiece as this could cause damage to the handpiece collet which could result in procedural delays.
p) Do not exceed the maximum speeds as shown on the label as this may generate undesirable heat or lack of application.
q) Pediatric Diamonds Burs should be used with mini handpiece intended for use with short shank burs and normal burs up to 20 mm in length.

The dental instrument pattern and shape shall be selected by physician discretions and will be chosen according to the needed application.

REPROCESSING INSTRUCTIONS FOR DIAMOND DENTAL BURS/DISCS AND TC BURS (MULTI-USE)

SCOPE

The reprocessing instructions detailed below apply only to reusable burs/discs. Burs shall be reprocessed upon initial use and prior to being reused.

LIMITATIONS OF RE-USE

Reprocessing will have little effect on MDT's dental burs/discs. The end of bur/disc's life is determined by wear and damage in use and the burs 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 dental instruments 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 burs/discs immersed in disinfectants that have a fixative action (such as aldehyde-based products) unless the burs/discs have been thoroughly cleaned first.

WARNINGS

Used instrument 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 burs are also considered as biohazard and need to be discarded as bio-hazard waste unless reprocessing procedures has been done according to the instructions.

PREPARATION FOR CLEANING	There are no special requirements for pre-cleaning 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 burs/TC/Discs shall be used and the manufacturer's instructions followed. Due to limited reproducibility of manual cleaning, automated cleaning and steam sterilization are the preferred processes for the cleaning stage.
MANUAL CLEANING, DRYING AND INSPECTION PROCEDURE	If manual cleaning is implemented, the instruments should be cleaned in a sink reserved for this purpose. Pre-clean under running water with a brush directly after use, particularly at the difficult to access points (grooves, bristles, holes, rough surfaces). 1) Rinse the instrument under running cold water at least 1 minute. 2) Soak in a 0.1-0.3% enzymatic neutral cleaning or cleaning/disinfecting detergent labeled for use on dental rotary instruments or other types of reusable medical instruments, following the agent manufacturer's instructions. Soak for at least 2 minutes. 3) Then, keeping them immersed, brush thoroughly away from the body in a slow controlled way to avoid spreading contaminants by spraying or splashing during the brushing process. 4) In all cases soft nylon brush is recommended in order to avoid possible device damage. 5) Take the instruments out of the bath and rinse them under warm running water for at least 2 minutes and until visibly clean. 6) After cleaning, inspect the cleanliness of the instruments with the aid of magnifying glass, to ensure that all contamination has been removed. Repeat the cleaning process if necessary. 7) Dry the instruments using a non-shedding wipe or clean compressed air. 8) Inspect the instruments, with the aid of magnifying glass if necessary for any signs of damage and/or deterioration such as corrosion. Pay particular attention to the flute, teeth and shanks for any chips/cracks, chatter marks, distortion, and general wear & tear. Any instrument found in condition which causes concern, must be discarded. Note: Surface contamination on the instruments must be removed prior to automatic reprocessing.
AUTOMATED CLEANING	PRE-CLEANING – 1) Prepare a 0.1-0.3% neutral/mild pH enzymatic detergent, according to manufacturer's instructions. 2) Rinse the instruments under running tap water for at least one (1) min. 3) Soak instruments immediately into detergent solution, for at least two (2) minutes. 4) Scrub under running water with soft nylon brush to remove any remaining blood or debris for at least one (1) minute (for discs- one minute for each side). 5) Place the instruments on a clean cloth to avoid any contact between them during the next cleaning procedure. AUTOMATED CLEANING PROCEDURE

Place the instruments 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 neutral 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).

Note: For the purpose of MDT instruments automated reprocessing validation, a Miele PROFFESIONAL washer (model PG8593) and the cleaning agent Power Zyme (Deconex) were used.
Other equivalent reprocessing cleaning agents can be used upon local validation by the user.
Any cleaning and disinfecting agents used must be compatible with dental burs/discs; otherwise, accelerated corrosion or other damage may occur.
The washer disinfector and the cleaning agent manufacturers' instructions must be followed.

POST AUTOMATED CLEANING PROCEDURE –

1) Remove the instruments at the end of the washer program.
2) Check that the instruments are dry, if necessary, dry with medical grade compressed air.
3) Visually inspect the burs for cleanliness.
   If contamination is still visible, reclean the instruments again manually.
4) Subsequently, the recleaned instruments must be reprocessed again automatically before sterilization.
5) All instruments must be inspected visually for cleanliness, integrity, and functionality, if necessary, by using an illuminated magnifying glass.
6) All instruments are to be checked for damage and wear. Damaged medical devices may no longer be used and must be sorted out.

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STERILIZATION - USING STEAM

SCOPE

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

<table>
<tr><td>PACKAGING FOR STERILIZATION</td><td>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.</td></tr>
<tr><td>STERILIZATION</td><td>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).

<table><tr><td>Cycle duration minutes minimum (Min.)</td><td>Cycle temperature (°C)</td><td>Drying time (Min.)</td></tr><tr><td>4</td><td>134 °C</td><td>15</td></tr></table>
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.</td></tr>
<tr><td>STORAGE</td><td>The device should be stored in the sterilization pouch until required. Storage should be in dry, clean conditions and at ambient temperature.</td></tr>
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VALIDATION OF CLEANING AND STEAM STERILIZATION

The above detailed processes have been validated as being capable of preparing MDT's dental burs and discs 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.

DISPOSAL

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