DENTSPLY PROFESSIONAL

Addendum
INFECTION CONTROL PROCEDURES
Reprocessing Instructions

Manufacturer: DENTSPLY Professional

Device(s): Steri-Mate 360 Handpiece

WARNINGS	• All devices must be cleaned, disinfected & sterilized prior to each use. This also applies to the first use of devices supplied as non-sterile, as well as cases in which the sterile packaging has been damaged or opened. • High level disinfection by itself is not appropriate for this device. • Only use validated methods for cleaning / disinfecting and sterilizing. • Only use cleaning and disinfecting solutions tested for compatibility with the device being disinfected. Tested disinfectants are listed showing active ingredient in parentheses. ➢ Isopropyl Alcohol 70% solution in water ➢ Bleach 0.5%-0.6% solution in water (0.5% to 0.6% sodium hypochlorite) ➢ Bi-Arrest (9.5% Ortho-Phenylphenol, 9.5% Ortho-Benyzl-para-chlorophenol) ➢ Cidex OPA (55% Ortho-Phthalaldehyde) ➢ Cavicide Synergized Superquat (84.5% Isopropanol, 15.3% Ammonium Chloride) ➢ Birex SE Phenolic with detergent (7.7% O-Phenylphenol, 7.6% p-tiertiary amylphenol) ➢ Discide (63.25% Isopropyl Alcohol) ➢ Volo (41.6% Isopropyl Alcohol) ➢ Lysol IC (0.1% Alkyl Dimethyl Benzyl Ammonium Saccharinate, 79% Ethanol) • Always use a pH neutral cleaning solution (such as Sultan Healthcare ReSURGE®) / disinfecting detergent or solution. Product can be damaged by alkaline and acidic detergents. • Read cleaning detergent / disinfecting solution instructions prior to use. Do not leave product standing in detergent or solutions. • An automated method (washer / disinfector) to clean and disinfect the device is recommended. • Ensure equipment (washer / disinfector and autoclave) is regularly serviced, inspected, and the validated parameters are maintained with each cycle. • Do not allow device to exceed 279°F/137°C. • Always observe all applicable legal and hygiene regulations for practice and / or hospital. • Always wear protective gloves, glasses and a mask when handling contaminated instruments. • Remove all packaging prior to processing.
Limitations on reprocessing	• Repeated processing has minimal effect; end of life is normally determined by wear and damage due to use. See Maintenance, Inspection and Testing. • Cold liquid disinfection/sterilization, chemical vapor sterilization, and dry heat sterilization methods have not been tested or validated for efficacy and are not recommended for use.

INSTRUCTIONS	
Point of use:	• Ultrasonic inserts must be removed from the handpiece before processing. • Do not allow residue or any form of contamination to dry on device. • Remove excess soil by wiping device with a disposable wipe under running tepid (potable) water, checking for signs of visible contamination. Dry thoroughly with a disposable wipe.
Preparation for decontamination:	• Protect from damage. • Following use, device should be reprocessed as soon as is reasonably practical.

	• Device left standing wet may stain or corrode.
Automated Cleaning & Thermal Disinfection	• Use only a properly maintained, inspected, calibrated and approved washer / disinfector according to ISO 15883 displaying an effective validation (e.g. FDA certification or CE mark, accordingly). • Perform a cleaning program cycle in an automated instrument washer, with the recommended program cycle: ⇒ 2 minutes pre-wash/rinse in cold tap water ⇒ 5 minutes enzymatic wash in warm water > 43 ^{o}C ⇒ 2 minutes enzymatic neutralization in hot water at 60 ^{o}C ⇒ 2 minutes rinse in hot tap water ⇒ 10 minutes drying at 90 ^{o}C • It is recommended to use sterile or low-germ (< 10 CFU/ml) and endotoxin-free water (< 0.25 EU/ml, e.g. high purity water HPW) for the final rinse phase. • Follow cleaning detergent manufacturer's instructions, observing concentration rates and contact times. • Loading: Do not exceed 279°F/137°C when drying as part of the washer / disinfector cycle. • Unloading: Inspect for complete removal of visible soil, including holes / cannulas. If soil is still visible after processing, repeat cycle.
Cleaning: Manual	Cleaning • Follow manufacturer instructions for cleaning detergent, observing concentration rates and contact times. • Remove soil with cleaning detergent while wiping with a disposable wipe until free of visible soil. Rinsing • Remove detergent from device by placing device under running tepid (potable) water and wiping with a disposable wipe for 30 seconds. • Dry device with a disposable wipe.
Disinfection: Manual	Disinfecting • After cleaning thoroughly, wipe all device surfaces with a disposable wipe in combination with a bactericidal, virucidal, and fungicidal instrument disinfection solution (approved according to local regulations and used according to device disinfectant solution manufacturer's Instructions for Use), observing concentration rates and contact times. Rinsing • Remove disinfectant solution residue by placing the device under running tepid (potable) water, careful to follow disinfectant manufacturer's instructions. • Dry device with a disposable wipe.
Drying: Manual	Dry thoroughly with a disposable wipe.
Maintenance, Inspection and Testing:	• Inspect to ensure all visible contamination has been removed. • Check for damage and wear: corrosion, pitting, discoloration, cracking, edges should be free of nicks. • Discard damaged or corroded product. If not visibly clean, repeat the process or safely dispose of device.
Packaging	• Place product in a paper or paper/plastic steam sterilization pouch. • Ensure pack is large enough to contain the product without stressing the seals. • Product may be loaded into dedicated instrument trays or general-purpose sterilization trays.
Sterilization:	Use only validated steam vacuum autoclaves. Do not exceed 279°F/137°C. **Pre-vacuum Steam Sterilization**

	Full cycle: Bagged 132°C (270°F) for 10 minutes. **Alternate Method:** Place non-bagged instruments into the steam autoclaves and run at the listed cycles. Dry, using the drying cycle of the autoclave. Note: Instruments sterilized unbagged should be used immediately.
Storage:	To maintain sterility, instruments should remain bagged until ready for use in a dry, clean location.

Additional Information:	When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.
Manufacturer contact:	Within the United States, call DENTSPLY Professional at 1-800-989-8826. For areas outside of the United States, contact your local DENTSPLY representative.

The instructions provided have been validated by the manufacturer of the medical device as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to fully achieve the desired result. This normally requires validation and routine monitoring of the process.