

KITS AND INSTRUMENTS CLEANING, INSPECTION, MAINTENANCE AND STEAM STERILIZATION INSTRUCTIONS

CLEANING INSTRUCTIONS FOR INSTRUMENTS AND INDIVIDUALLY PACKAGED REPLACEMENT ATTACHMENTS

- 1** Disassemble any instruments that can be disassembled according to manufacturers' instructions.
- 2** Soak instruments in enzymatic cleaning solution (mixed according to manufacturers' instructions) by completely submerging them for 20 minutes. Scrub instruments using a soft-bristled, nylon brush until all soil has been removed.
- 3** Remove the instruments from the enzymatic cleaning solution and rinse in tap water for a minimum of 3 minutes. Make sure to thoroughly flush internal holes/crevices of instruments (such as the tissue punch, drill extender, implant drivers, and disassembled core tool and ratchet torque wrench) that have difficult to reach areas.

Note: Use of a syringe or water jet will improve flushing of difficult to reach areas.

- 4** Place instruments in sonication bath (with enzymatic cleaning solution prepared according to manufacturers' instructions) making sure that they are completely submerged, and sonicate for 10 minutes.
- 5** Remove the instruments from the sonication bath, and rinse for 3 minutes making sure to thoroughly flush cleaning solution out of the holes/crevices and/or difficult to reach areas.
- 6** Remove excess moisture from the instruments with a clean, absorbent, and non-shedding wipe.

SURGICAL TRAY CLEANING INSTRUCTIONS

- 1** Rinse the tray and tray insert with tap water.
 - 2** Place the Surgical Tray and Insert in enzymatic cleaning solution (mixed according to manufacturers' instructions) and wipe off soil with a clean, absorbent, non-shedding wipe. Allow the Surgical Tray and Insert to soak in the cleaning solution for 20 minutes making sure that they are completely submerged.
 - 3** Remove the Surgical Tray and Insert from the enzymatic cleaning solution and rinse in tap water for a minimum of 3 minutes. Make sure to thoroughly flush each piece to completely remove cleaning solution residue.
 - 4** Remove excess moisture from the Surgical Tray and Insert with a clean, absorbent, and non-shedding wipe.
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KITS AND INSTRUMENTS CLEANING, INSPECTION, MAINTENANCE AND STEAM STERILIZATION INSTRUCTIONS (CONTINUED)

INSPECTION AND MAINTENANCE OF CLEANED INSTRUMENTS

1 Carefully inspect each instrument to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning process. Please note that if during inspection of instruments, you see signs of wear, damage, or unrecognizable color change, replace the instrument.

2 Re-assemble multi-part instruments and check them for proper function (LOCATOR® Core Tool and the Torque Indicating Ratchet Wrench). Reference the IFU that comes with each of these parts and subsequent sections of this document for the proper assembly process.

Please note: LOCATOR Core Tool and Torque Indicating Ratchet Wrench should be disassembled prior to steam sterilization.

STEAM STERILIZATION INSTRUCTIONS

The validation procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biological indicators, chemical indicators and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79:2006.

1 Place all instruments into the surgical tray.

2 For gravity cycle, place Surgical Kit in a 10" x 15" Autoclave Bag, and for Pre-Vacuum Cycle double wrap the kit with autoclave wrap material and secure wrap with autoclave tape.

AUTOCLAVE STERILIZATION PARAMETERS

CYCLE TYPE	PART NUMBER	DESCRIPTION	TEMPERATURE	EXPOSURE TIME	DRYING TIME
GRAVITY	7421	STANDARD SURGICAL KIT	121°C / 250°F	50 MINUTES	15 MINUTES
				OR	
	7421	STANDARD SURGICAL KIT	132°C / 270°F	15 MINUTES	30 MINUTES
	7422	PREMIUM SURGICAL KIT	121°C / 250°F	50 MINUTES	15 MINUTES
PRE-VACUUM	7421	STANDARD SURGICAL KIT	132°C / 270°F	4 MINUTES	20 MINUTES
	7422	PREMIUM SURGICAL KIT	132°C / 270°F	4 MINUTES	20 MINUTES



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