

INDICATIONS FOR USE

- Use the SGS® instrument to place and cure composite for Class I-V preparations.
- Use the SGS® instrument with any non-flowable composite material.
- Use the SGS® instrument with any matrix system.

RECOMMENDED PROCEDURE

- After the prep is completed and/or the matrix system is in place, place the composite into the prep box. If the box is wide from mesial to distal, form the composite material into a box shape against the mesial or distal areas first. If the box is narrow, layer the composite material from mesial to distal.
- Place the SGS® instrument on top of the composite and condense. **WARNING:** Do not condense more than half a millimeter. Too much pressure against the composite will create a mushroom effect and undercuts will be created.
- Once the composite is in place, angle instrument against composite, apply slight condensation and photo-cure with the instrument in place with an appropriate dental curing light.
- Complete subsequent composite layers accordingly until occlusal layer/anatomy is completed.

CONTRAINDICATIONS

- Instrument should not be used for anything other than its intended use.
- Do not use the SGS® instrument to place silver or gold metal alloy materials.
- The SGS® instrument is not intended for use with flowable composite.
- Do not use corroded, damaged, or worn out instruments.

WARNINGS AND PRECAUTIONS

- The instrument is to be used only by a dentist or other licensed dental practitioner.
- Instruments must be thoroughly cleaned and steam sterilized prior to first use and each subsequent reuse.
- Maintain instruments in good working condition to ensure maximum effectiveness of the device.
- Before use, inspect the instruments for possible damage. Damaged or defective instruments should not be used or processed.
- Wear appropriate gloves, eyewear and clothing when handling biologically contaminated instruments.
- **Sterilize instruments in a cassette to avoid tip breakage.** Cassettes are not intended to store or maintain sterility of the instrument.
- Do not use chemical or dry heat to sterilize Sapphire Technology instruments. These processes have not been validated for sterilization.
- **Delicate dental instruments require special handling to prevent damaging the tips. Use caution during cleaning and sterilization. Do not apply excessive pressure on the tip. This could cause the tip to break.**
- Clean and sterilize new (non-sterile) instruments in accordance with the below validated procedures prior to first use and subsequent use.

DECONTAMINATION AND STERILIZATION PROCEDURES

- Personnel should follow accepted guidelines as recommended in ANSI/AAMI ST79 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities and ISO 17664-Sterilization of medical devices: Information to be provided by the manufacturer for the processing of resterilizable medical devices.
- Instruction for reprocessing reusable instruments is provided according to ISO 17664.
- The “Decontamination Procedure Care and Handling” does not sterilize the instruments.
- Refer to and process the instruments as outlined the MANUAL CLEANING OR STEAM STERILIZATION PROCEDURE sections.

DECONTAMINATION PROCEDURE CARE AND HANDLING

1. CLEANING PRECAUTIONS

- To prevent formation of biofilm, cleaning should occur as soon as possible after instrumentation is used.
- When appropriate, disassemble instruments prior to cleaning and sterilization.
- Do not use steel wool, wire brushes, or abrasive detergents to remove soil as these will damage the instrument and lead to corrosion. Use a soft brush instead.
- Carefully protect the instrument tips throughout the entire cleaning and sterilization process.

2. PRECLEANING

- Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments.
- Remove gross contaminants with steady stream of lukewarm/cool water (below 110°F/43°C). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions. Avoid processing instruments of different metallic composition altogether.
- **Rinse instruments thoroughly** under warm distilled or demineralized water for thirty (30) seconds.

MANUAL CLEANING PROCEDURE

After following decontamination recommendations reusable instruments are ready for sterilization.

- Submerge device in an Enzymatic Detergent solution and soak for ten (10) minutes. This step softens and loosens much of the soil that may have dried on the instrument between the time it was used and the time cleaning has started. The duration of the soak depends upon how much soil is on the instruments and how long the soil has been allowed to dry.
- While submerge, gently brush all surfaces with a nylon bristled brush for thirty (30) seconds. The use of enzyme detergents is preferred as they help to break up organic soil more readily and rapidly than do conventional detergents. Note: Brushing should be done under the surface of the water to minimize aerosols and with brush strokes away from the body to avoid exposure to spray from the brush.
- Rinse instrument under running water for three (3) minutes. If difficult-to-remove soil remains, another enzyme soak followed by brushing and rinsing should be done.
- Instruments must be thoroughly dried and all residual moisture must be removed before they are stored.
- Use a soft, non-linting wipe to dry external surfaces.
- Allow instrument to completely dry.

STEAM STERILIZATION PROCEDURE

After following decontamination recommendations reusable instruments are ready for sterilization.

- Refer to ANSI/AAMI ST 79.
- AAMI standards recommend that sterilizer manufacturer's written instructions for cycle parameters should also be followed. Medical device manufacturer's exposure times to sterilization temperature may need to be longer than minimum indicated by sterilizer manufacturer, but must never be shorter. It is the responsibility of the user to establish whether sterilizer meets these minimum recommendations.
- Instruments may be packaged in rigid containers, or packaging cleared for use in sterilizations. Packaging should ensure sterility of instruments until opened for use at the sterile field and permit removal of contents without contamination.

SGS® Composite Instrument Instructions for Use Sheet

- Recommended steam sterilization parameters to achieve Sterility Assurance Level (SAL) of 10⁻⁶ are shown on table:

Gravity-Displacement Steam	Temperature	Exposure Time	Dry Time
Pouched cassette container Perforated unstacked	250°F(121°C)	45 Minutes	20 minutes
High Vacuum Steam (Pre-vacuum)	Temperature	Exposure Time	Dry Time
Wrapped cassette container Perforated unstacked	270°F(132°C)	4 Minutes Minimum	20 minutes

RETURNED GOODS POLICY

Products must be returned in unopened packages with manufacturer’s seals intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Determination of a product defect will be made by Sapphire Technology. Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

REPAIRS AND MAINTENANCE

Improper, ineffective and insufficient maintenance can reduce the life of an instrument and will invalidate the instrument’s warranty.

Should instruments require repair or maintenance, contact Sapphire Technology for return authorization and address. Instruments returned to Sapphire Technology for repair must have a statement testifying that each instrument has been thoroughly cleaned and sterilized. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

PRODUCT INFORMATION DISCLOSURE

SAPPHIRE TECHNOLOGY AND ITS SUBSIDIARIES (“SAPPHIRE TECHNOLOGY”) AND MANUFACTURER EXCLUDE ALL WARRANTIES, EXCEPT SAPPHIRE TECHNOLOGY’S APPLICABLE STANDARD WARRANTY WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NEITHER SAPPHIRE TECHNOLOGY NOR MANUFACTURER SHALL BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. NEITHER SAPPHIRE TECHNOLOGY NOR MANUFACTURER ASSUME NOR AUTHORIZE ANY PERSON TO ASSUME FOR THEM ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.