IFU / STERILIZATION INSTRUCTIONS

INTENDED USES OF STEVENSON DENTAL SOLUTIONS INSTRUMENTS

The Stevenson Dental Solutions Composite Mastery Instrument Kit components are intended to place and shape composite inside the oral cavity, prior to light polymerization.

The Stevenson Dental Solutions RGS 1-2 and 3-4 instruments are intended to measure preparations parameters inside and outside the oral cavity.

The Stevenson Dental Solutions Impression Trays are intended to carry elastomeric dental materials into the oral cavity for the purpose of making impressions.

The Stevenson Dental Solutions Rubber Dam Clamps are intended to affix to teeth in preparation to retain rubber dam and retract tissues inside the oral cavity.

The Stevenson Dental Solutions Rubber Dam Clamp Forceps are intended to carry rubber dam clamps into the oral cavity.

The Stevenson Dental Solutions Rubber Dam Clamp Frame is intended to hold rubber dam material outside of the oral cavity, however, near the mouth.

The Stevenson Dental Solutions Rubber Dam Clamp Punch is intended to punch holes into rubber dam material prior to application in the oral cavity.

The Stevenson Dental Solutions Rubber Rainbow Well is intended to hold dental materials for dispensing in the oral cavity. The Rainbow Well is not intended for intraoral use. This product should be treated as any operation room surface, and not subjected to the sterilization process.

Intended User
For use by a dentist, dental assistant, dental hygienist, or dental surgeon. Any surgical procedures should be performed by licensed healthcare professionals trained and familiar with surgical techniques. This instruction for use alone does not provide sufficient background for direct use of the Device.

Patient Target Group
Person receiving treatment as part of a dental or surgical procedure.

CONTRADICTIONS

- Surgical & Dental Instruments should not be used for anything other than their intended use.

- Instruments should not be used with patients that have allergies to the specific materials used including stainless steel, titanium nitride and tungsten carbide.

MAINTENANCE AND REPAIR

Always inspect instruments before use. Edges should be free of nicks and have a continuous smooth edge. Moveable parts should have smooth movement without excessive play. Locking mechanisms should fasten securely and close easily.
The products should be visually inspected for mechanical damage (breakage, deformation, corrosion, etc.) and fault-free operation. Products that are damaged or are not fully functional may never be used in patients. They must be sent off for repair. Stevenson Dental Solutions instruments should only be repaired by an authorized service agent only. Please see the Stevenson Dental Solutions website for details on repairing instruments (www.stevensondentalsolutions.com)
All products are guaranteed to be free from defects in material and workmanship at the time of shipping. All our products are designed and manufactured to meet and exceed the highest quality standards. We cannot accept liability for failure of products which have been modified in any way from their originals.

PRECAUTIONS AND WARNINGS

- Devices shall be used in accordance with these instructions for use. Read all sections of this insert prior to use. Improper use of this device may cause serious injury. In addition, improper care and maintenance of the device may render the device non-sterile prior to patient use and cause a serious injury to the patient or health care provider.
- Inappropriate use of instruments may result in patient injury, damaged or broken.
- Proper cleaning, handling, sterilization, and standard routine maintenance (such as sharpening, lubrication if applicable) will ensure that the instruments perform as intended and will extend their useful
- Delicate surgical/dental instruments require special handling to prevent damaging the tips. Use caution during cleaning and
- We do not recommend cold sterilizations or solutions containing Benzyl Ammonium Chloride, which will deteriorate or discolor the instruments.
- Do not expose instruments to phenols.
- Before use, inspect the instruments for possible damage, wear or non-functioning Carefully inspect the critical, inaccessible areas, joints, and all movable parts.
- Damaged or defective instruments should not be used.
- Improper cleaning may lead to inadequate sterilization. Failure to completely dry instruments during autoclaving may leave moisture and cause discoloration and oxidation.

The use of hydrogen peroxide or other oxidizing agents will damage the surface of the instruments. Periodic testing, cleaning, and calibration of the autoclave equipment is recommended to ensure the unit remains in proper working order.

- Instruments are supplied non-sterile and must be cleaned and sterilized before the first use and before each subsequent use. It is important that instruments be well cleaned before the sterilization process.

DIRECTIONS FOR USE

Proper surgical procedures and restorative techniques are the responsibility of the dental professional. Each clinician must evaluate the appropriateness of the procedure used based on personal dental training and experience as applied to the patient case.
Stevenson Dental Solutions instruments may be sterilized in any conventional manner and are guaranteed to be capable of all high-level sterilization procedures.

CLEANING & MAINTENANCE

DECONTAMINATION:
MANUAL

1. A) Immediately after use

Directly after use, rinse instruments under warm (hot) running water. Rinsing should remove most of the blood, body fluids, and tissue.

1. B) Ultrasonic Cleaning and rinsing

- To avoid blood and other proteins from sticking to instrument surfaces, an enzymatic cleaner bath (soaking) should be used on all instruments. After soaking for a minimum of 10 minutes, rinse all instruments in running tap water.
- Immerse instruments completely in any approved disinfectant for another 10 minutes or more, then rinse again.
- Never expose stainless steel instruments to bleach or other chemicals for the purpose of disinfection. Exposure to bleach will result in severe pitting of your instruments and will void all manufacturer's guarantees.

Ultrasonic

Follow the recommendations of the ultrasonic manufacturer regarding cycle times, detergents, proper placement of the instrument tray, and conditioning (degassing) of the cleaning solutions, etc. Use an ultrasonic cleaner to remove soil from hard-to-reach surfaces such as grooves, crevices, lumens, instruments with moving parts, etc., after gross soil has been removed. Open or disassemble instruments as appropriate. Place instruments in a mesh bottom stainless steel instrument tray. The Composite Mastery instrument s may be left in the steel cassette during this process. Place the tray into the ultrasonic cleaner. Flush air out of lumens and fill them with the ultrasonic cleaning solution (under the solution level in the chamber) for effective removal of soil from that inner surface by the ultrasonic activity.

1. C) Final rinse with “treated water”

Softened or deionized water should be used for the final rinse to better remove detergents etc. Softening water removes calcium and magnesium ions that cause water to be hard. Iron ions may also be removed by this treatment. Deionization removes ionized salts and particles from the water. Excessively hard water can spot or stain instruments and excessive chlorine in water can cause pitting of the instrument. Deionized water is preferred for the final rinse.

1. D) Decontaminate clean instruments

Once instruments have been cleaned, they must be rendered safe for handling, inspection and assembly. They may be steam-sterilized without a wrapper or disinfected following the instructions from the instrument, sterilizer, and disinfectant manufacturers.

1. E) Visual inspection and instrument set assembly

Visually inspect the instrument for cleanliness and to ensure all parts are in proper working order, as the set is assembled. Inspection is a vital part of proper care and maintenance. Instruments in need of repair will not perform accurately in surgery and breakage is likely to occur. Do not use damaged instruments. Worn ratchets, loose box locks, and misaligned jaws can be repaired at a fraction of the cost of new instruments.
Contact your local representative or visit our website for information regarding our instrument repair program.

1. F) Lubricate Instruments

The use of an instrument lubricant, that is compatible with the method of sterilization to be used, is recommended before instruments are sterilized. Be certain that the instrument lubricant is diluted and maintained properly, according to the manufacturer’s instructions. This type of lubricant is referred to as “instrument milk” and is usually applied by spraying into the box locks and moving parts or by dipping the opened instruments into a solution. Lubricants that are too concentrated or too heavily applied will result in slippery instruments that will also be mistaken as wet after sterilization.

1. G) Drying Instruments

Before instruments are wrapped for sterilization or storage, they must thoroughly dry. If a set of instruments is wet when wrapped for sterilization it is likely to come out of the sterilizer wet. “Wet Packs” are not suitable for use after sterilization because they may be easily contaminated when handled. In addition, remaining moisture, particularly in box locks and hinges may result in corrosion that will weaken the instrument and lead to breakage during use. Prepare instrument sets for sterilization using a wrapper, pouch, or rigid sterilization container that is appropriate for the method of sterilization to be used. The Association for the Advancement of Medical Instrumentation (AAMI) and individual sterilizer manufacturers provide guidance for the proper preparation of surgical instrument trays for sterilization. Some sterilizer manufacturers can also provide information regarding wet pack problem-solving. See also, “Sterilization for the Healthcare Facility, 2nd Edition”, Reichert, M.; Young J., “Wet Pack Problem Solving”, Lee, S. (Frederick, MD: Aspen, 1997).

MECHANICAL DECONTAMINATION

General surgical instrumentation may be processed in a washer sterilizer or washer decontaminator/disinfector. Some of these processes include an enzyme application phase and a lubrication phase that is designed into the cycle. Follow the manufacturer's specifications when using automatic washer sterilizers or washer decontaminators/disinfectors. They usually require the use of a low foaming, free rinsing detergent with a neutral pH (7.0). A high-foaming detergent may clean effectively but will often leave residual deposits on the instruments and do harm to mechanical washers.

Automated washer sterilizers and washer decontaminator/disinfectors usually have adjustable wash and rinse times. Some washers enable the user to customize extra cycles to process heavily soiled surgical instruments more effectively. Check with a Technical Service representative for questions regarding processing delicate, complex, and/or multipart instruments by this method.

TERMINAL STERILIZATION

After following the decontamination recommendations, reusable instruments are ready for sterilization. Independent laboratory testing, conducted according to the F.D.A. (21CFR PART 58) and Good Laboratory Practice Regulations (G.L.P.), has validated steam sterilization as an effective process for reusable instruments. See also, AAMI Standards and Recommended Practices, "Steam Sterilization and Sterility Assurance in Health Care Facilities, " ANSI/AAMI ST46:2002; "Flash Sterilization Steam Sterilization of Patient Care Items for Immediate Use.". ANSI/AAMI ST37: 3ED. AAMI standards recommend that the sterilizer manufacturer's written instructions for cycle parameters should also be followed. Steam sterilization of lumened instruments requires that they be flushed with sterile water just prior to wrapping and sterilization. The water generates steam within the lumen to move air out. Air is the greatest enemy to steam sterilization, preventing steam contact if not eliminated. Medical device manufacturer's exposure times to sterilization temperature may need to be longer than the minimum indicated by the sterilizer manufacturer but never shorter.

Sterilizer	Exposure Temperature	Exposure Time	Minimum Time
Pre-Vacuum (wrapped)	121°C (250°F) 132°C (270°F) 134°C (273°F)	20 minutes 4 minutes 3 minutes	20 minutes 20 minutes 15 minutes
Pre-Vacuum (unwrapped)	132°C (270°F)	4 minutes	
Gravity Steam (unwrapped)	132°C (270°F)	18 minutes	