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Recommendations for the Care and Handling of Synvasive Surgical Instruments and Instrument Cases

DESCRIPTION AND MATERIALS

Synvasive instruments and instrument cases are generally composed of aluminum, stainless steel, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The instrument cases are perforated to allow steam to penetrate these various materials and components. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing a cleaning, sterilization and drying cycle that has been validated by the user for the equipment and procedures employed at the user facility.

Note: Instrument cases do not provide a sterile barrier and must be used in conjunction with a sterilization wrap to maintain sterility.

DISCLAIMER

Synvasive instrument cases are intended to contain and protect instruments in addition to facilitating the sterilization process by allowing steam penetration and drying. A certified independent laboratory has verified Synvasive instrument cases are suitable for the specific sterilization methods and cycles tested and documented below. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is suitable for use in sterile processing and sterility maintenance in a particular health care facility. Testing should be conducted in the health care facility to assure that conditions essential to sterilization can be achieved. Synvasive does not accept responsibility or liability arising from a lack of cleanliness or sterility of any medical devices supplied by Synvasive being cleaned and sterilized by the end user.

CLEANING AND DECONTAMINATION

1. **Removal of Gross Contamination-** Manual cleaning – Instruments opened on the sterile field require decontamination. Although automated methods are preferred, instruments may be washed manually in a manner that protects personnel who are handling the instruments. Personal protective attire should be worn by personnel when cleaning and decontaminating instruments. Instruments should be kept free of gross soil during surgical procedures. The effectiveness of decontamination processes depends on prior removal of gross soil as it may be impaired by dried or coagulated protein. Keep instruments moist until they are cleaned and decontaminated. Presoaking in lukewarm water/detergent solutions (at temperatures below 43 ^{o}C (110 ^{o}F)) will prevent coagulation and thus assist in the removal of protein substances. When presoaking instruments, personnel should refer to the solution manufacturer's instructions for the correct dilution, temperature, and soak time. Instruments should be thoroughly rinsed after presoaking. Gross soil should be removed while instruments are submerged under warm water with appropriate detergents. Care should be taken to avoid splashing and generating aerosols by holding instruments below the surface of the water in a sink into which water is running and draining out continuously. Brushes and other cleaning implements should be disinfected or sterilized daily. Abrasive cleaning compounds and implements should not be used. Operatives should wear protective gloves and goggles, and care should be taken to avoid penetrating or cutting injuries. Particular attention should be taken to remove all debris from obscure holes in the instruments.
2. **Disassembly:** Currently our surgical instruments are simply constructed and do not require disassembly.
3. **Washing/Disinfecting:** We recommend that the instruments be decontaminated using an automatic washer disinfection unit utilizing thermal disinfection. This should preferably be of the ultrasonic type. A washer /decontaminator may be used with a single chamber for rinsing, cleaning, and drying or may use multiple chambers (one for each phase of the cycle). These phases may include an initial cool water rinse to remove protein debris; a wash with detergent; an ultrasonic cleaning, a hot water rinse; and a drying cycle. Sequencing and number of stages may vary among manufacturers.
   Note: Compatible detergents and rinse aids may be used as recommended by the manufacturer of the washer-disinfection unit, but these should be of neutral or near neutral pH. Excessively acidic or alkaline solutions may corrode aluminum instruments or instrument cases. See ANSI/AAMI ST35 for additional guidelines on cleaning and decontamination.

PREPARATION AND ASSEMBLY

After cleaning/disinfecting, the instruments should be placed in their proper locations in the instrument cases.

CARE AND HANDLING OF INSTRUMENTS

1. **General -** Surgical instruments and instrument cases are susceptible to damage from prolonged use and through misuse or rough handling. Care must be taken to avoid compromising their exacting performance.
   To minimize damage, the following should be done:
   i. Inspect the instrument case and instruments for damage upon receipt and after each use and cleaning. Incompletely cleaned instruments should be re-cleaned and those that need repair set aside for repair service or return to Synvasive.
   ii. Only use an instrument for its intended purpose.

2. **General Cleaning.** Clean instruments as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place groups of instruments in a covered container with appropriate detergent or enzymatic solution to delay drying. Wash all instruments whether or not they were used or were inadvertently contacted with blood or saline solution.

3. **Ultrasonic Cleaners** can be used with hot water per manufacturer's recommended temperature and specially formulated detergents. Follow manufacturer's recommendations for proper cleaning solution formulated specifically for ultrasonic cleaners. Be aware that loading patterns, instrument cassettes, water temperature, and other external factors may change the effectiveness of the equipment.

4. **Washer-Decontamination Equipment** will wash and decontaminate instruments. Complete removal of soil from crevices and serrations depends on instrument construction, exposure time, pressure of delivered solution, and pH of the detergent solution, and thus may require prior brushing. Be familiar with equipment manufacturers' use and operation instructions. Be aware that loading, detergent, water temperature, and other external factors may change the effectiveness of the equipment. See ANSI/AAMI ST35 for additional guidelines on cleaning and decontamination.

RESPONSIBILITIES OF THE USER

General: Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material is suitable for use in sterile processing and sterility maintenance.

Sterility: Users should conduct testing in the health care facility to assure that the conditions essential to sterilization can be achieved and that specific configuration of the container contents is acceptable for the sterilization process and for the requirements at the point of use. ANSI/AAMI ST33: 1996 Guidelines for the Selection and Use of Reusable Rigid Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities covers the selection and use of reusable rigid sterilization container systems. Guidelines are provided for cleaning and decontamination, preparation and assembly, sterilizer loading and unloading, matching the container system to the appropriate sterilization cycle, quality assurance, sterile storage, transport, and aseptic use.

WARNINGS AND PRECAUTIONS

When handling sharp instruments use extreme caution to avoid injury: consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.

Unless otherwise indicated, instrument sets are NOT Sterile and must be sterilized prior to use.

Instruments should NOT be flash-autoclaved inside the instrument case. Flash-autoclaving of individual instruments should be avoided.

Unwrapped instrument cases DO NOT maintain sterility.

Surgical instruments may be autoclaved using a full cycle. Instruments that have been used in a surgical environment should be thoroughly cleaned prior to autoclaving. Use of ANSI/AAMI ST46:2002 is recommended. Flash autoclaving should be avoided, whenever possible. Instruments should never be flash autoclaved in an instrument case.

STORAGE AND SHELF LIFE

Instrument cases that have been processed and wrapped to maintain sterility should be stored in a manner to avoid extremes in temperature and moisture. Care must be exercised in handling of wrapped cases to prevent damage to the sterile barrier. The health care facility should establish a shelf life for wrapped instrument cases, based upon the type of sterile wrap used and the recommendations of the sterile wrap manufacturer. The user must be aware that maintenance of sterility is event-related and that the probability of occurrence of a contaminating event increases over time and with handling, whether woven or non-woven materials, pouches, or container systems are used as the packaging method.

STERILIZATION

Instrument sets supplied by Synvasive have been thoroughly cleaned prior to shipment. Unless otherwise indicated, these sets are NOT STERILE and must be sterilized prior to use. INSTRUMENTS SHOULD NOT BE FLASH-AUTOCLAVED INSIDE THE INSTRUMENT CASE.

Synvasive instruments can be steam autoclaved and repeated autoclaving will not adversely affect them, unless otherwise indicated in the labeling. If you have any problems when using our instruments or instrument cases, please contact our Global Customer Service Center at 916-939-3913 between the hours of 7:30 and 4:00pm Pacific Standard Time (California) or via
E-mail to customerservice@synvasive.com .

Unless supplied sterile, instruments must be sterilized prior to surgical use. Following is a recommended minimum cycle for steam sterilization that has been validated by Synvasive under laboratory conditions. Individual users must validate the cleaning and autoclaving procedures used on-site, including the on-site validation of the recommended minimum cycle parameters described below.

PRE-VACUUMED STERILIZER

270º - 275º F (132º - 135º C) - Wrapped
8 minutes exposure time - 30 minutes drying time
Since Synvasive is not familiar with individual hospital handling procedures, cleaning methods, and bioburden levels, Synvasive will not assume the responsibility for sterilization of product by a hospital even though the general above guidelines are followed.

Comments regarding Synvasive devices or instruments can be directed to Attn: Quality & Regulatory Affaires, Synvasive Technology, Inc., 4925 Robert J. Mathews Pkwy., El Dorado Hills, CA. 95762 USA, FAX: (916) 939-3919.

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