CE APTIS
Putting Ideas in Motion

Warning - Clean Non-Sterile

PRODUCT INSERT
RECOMMENDATIONS FOR INSTRUMENT CARE, CLEANING, AND STEAM/MOIST HEAT STERILIZATION

CAUTION
Federal (United States) law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION
Specialty instrumentation is designed to aid the surgeon in installation, assembly, and/or removal of a surgical device. The surgical techniques for implantation of the device describe the proper application of specialty instrumentation and should be read and understood by the surgeon prior to use. These instructions are not applicable to air or electrically powered equipment. However, they are applicable to functional attachments (e.g. reamers and drill bits) that are connected to powered equipment for use.

MATERIALS:

ASTM F 138 Stainless Steel F 316 L	ASTM A 564 Stainless Steel 17-4Ph
ASTM A 276 Stainless Steel 440C	Aluminum
Ultem™ or Radel™ Plastic	

WARNINGS
Instruments which are not sterile must be sterilized prior to each use. New, used, repaired, refurbished, borrowed, or consigned instruments should be examined, cleaned, and sterilized according to written recommendations prior to use in a health care organization.

Examination should include all moving parts, drive ends, tips, box locks, ratchets, screws, and cutting edges for evidence of defects and wear to ensure proper working order.

Inspecting the instrument verifies that the instrument has no obvious defects and has not sustained damage during shipping.

The most common cause of instrument damage or breakage is misuse. Specialty instrumentation should never be used for tasks it was not specifically designed to perform. Misuse of an instrument may result in damage to the instrument, unsuccessful assembly of a surgical construct, or trauma to the patient or operating room personnel.

If not handled properly, instruments with cutting edges or sharp corners may compromise sterility by tearing surgical gloves.

If an instrument tip becomes bent, chipped, or otherwise damaged the instrument should be replaced or repaired before further use. Attempts to straighten bends are not advised as the metallurgical integrity of the metal may be compromised in the process, and the instrument may subsequently break during use.

LIMITED WARRANTY
Aptis Medical, LLC warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse, or improper handling of the product subsequent to receipt by the purchaser. Aptis Medical, LLC does not warrant the outcome of the surgical procedure.

INSTRUMENT CARE
New instruments are packaged clean, not sterile and should be assumed to be contaminated. All instruments must be cleaned and sterilized before each use.

For your safety, be familiar with the procedures for handling contaminated materials at your facility before following these instructions.

Clean instruments as soon as possible after use and avoid allowing soiled instruments to dry. Instruments should be wiped as needed with sterile surgical sponges moistened with sterile water during the procedure, to remove gross soil. Contaminated instruments must be contained during transport and should be transported in a timely manner to a location designed for decontamination.

Blood and body fluids can cause pitting of instruments and, if left to dry, can be difficult to remove. Blood, body fluids, and saline, are highly corrosive. Corrosion, rusting, and pitting occur when saline, blood, and debris are allowed to dry in or on surgical instruments. Instruments should be rinsed with water because of the corrosive nature of blood, body fluids, and saline. If blood and body fluids are not removed, they can prevent adequate sterilization, which could be an avenue for transmission of other potentially infectious materials. Dried blood and debris can be difficult, if not impossible, to remove from all surfaces during the decontamination process; therefore, subsequent disinfection or sterilization may not be achieved. Immerse or use damp towels or sponges saturated with deionized or distilled water to keep soiled instruments moist prior to cleaning. Cannulated instruments (instruments with lumens) should be irrigated with sterile water, as needed, throughout the surgical procedure to help remove residue.

Instrument lumens can become obstructed with organic material. Irrigating these instruments with sterile water helps remove residue. Instrument lumens should be irrigated with sterile water, as needed, throughout the surgical procedure.

Avoid using extreme detergent concentration levels. Warm or hot water (300°F/149°C maximum) may aid in cleaning. Ultrasonic cleaning is recommended for instruments with lumens, internal surfaces or crevices, which may be hard to clean manually.

Neutral pH cleaners (pH 6.0-8.0) are recommended for longer life of the instruments. If acidic or alkaline solutions are used, follow the manufacturer's recommendations for neutralizing the pH by rinsing with water or neutralizing agent. Highly alkaline or acidic cleaners (used in some mechanical washers) are not recommended as they will reduce the life of the instruments and may affect instrument performance. Avoid prolonged exposure to acidic or alkaline solutions and solutions containing chlorides, bromides or iodine.

Use of water soluble lubricants is recommended for instruments with moving parts or those intended to be assembled intraoperatively to another instrument.

Check instruments thoroughly for damage. Do not use damaged instruments as they may compromise the surgical outcome. Replace damaged instruments before next use.

CLEANING INSTRUCTIONS
Before sterilization, rinse each instrument thoroughly under running tap water until all visible soil is removed. Prepare a room temperature tap water and mild detergent (such as Enzol®) solution bath prepared following the detergent manufacturer's recommendations, fully immerse the instruments and allow to soak for a minimum of 20 minutes. Thoroughly clean and scrub each instrument manually with a clean, soft-bristled brush or soft cloth in a mild detergent (such as Enzol®) bath prepared to the detergent manufacturer's recommendations to ensure removal of any visible soil/proteinaceous material, paying particular attention to crevices and other hard to reach areas. Clean instrument lumens internally with a pipe cleaner or equivalent brush, pass completely end to end through the lumen. Flush lumens and holes thoroughly and rinse lumens with a syringe and PURW (purified water). Rinse each instrument thoroughly using purified water for a minimum of 3 minutes.

..Prepare a mild detergent (such as Enzol®) and tap water ultrasonic cleaner bath and fully immerse and ultrasonically clean the instruments for 10 minutes. After sonication rinse all instruments thoroughly for a minimum of 3 minutes. Repeat cleaning all lumens and holes after sonication using a syringe and PURW.

Thoroughly inspect each instrument for visible soil/proteinaceous material following sonication and rinsing. Dry each instrument using a soft clean cloth.

Thoroughly clean and visually inspect the tray and each instrument for cleanliness including internal surfaces and crevices. The tray and instruments should be re-cleaned and washed and re-inspected if not visually clean and there are any signs of foreign matter or residue.

Use of mechanical washers has not been evaluated by the manufacturer. Qualification of specific wash cycles and equipment should be completed by the user.

STERILIZATION
This sterilization recommendation describes steam/moist heat sterilization methods. The following sterilization cycles have been shown to produce a sterility assurance level of 10^{-6} when parts have been cleaned to the instructions above. Other similar steam cycles and cleaning procedures may be used but have not been evaluated. Sterilization qualification was performed using specific equipment and procedures. Use of cycles, equipment and procedures other than those listed should be qualified by the user. Do not exceed 300°F/149°C. Do not stack trays during sterilization or load above 25 lbs.
*Note: Instrument cases do not provide a sterile barrier and must be used in conjunction with an FDA cleared, intact steam sterilization compatible wrap to maintain sterility.

RECOMMENDED STEAM STERILIZATION PARAMETERS

Cycle Type	Minimum Temperature	Minimum Exposure Time	Minimum Dry Time	Note
Prevacuum Steam Sterilization	134° C	3 minutes	40 minutes	1,2
Prevacuum Steam Sterilization	132° C	4 minutes	60 minutes	3
Immediate Use Prevacuum Steam Sterilization	132° C	3 minutes	Not applicable	2,3,4

Note: Wrapped gravity steam sterilization is no longer recommended due to the extended processing time required.
[1] Sterilization parameters not for use in the United States
[2] Minimum validated time to achieve a 10^{-6} sterility assurance level (SAL)
[3] Minimum validated temperature to achieve a 10^{-6} sterility assurance level (SAL)
[4] Flash (immediate-use) steam sterilization by exposure at 132°C should only be used as an emergency procedure.

For further information on the above cleaning and sterilization recommendations please contact:

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