Sontec

Sontec Instruments

INSTRUCTIONS FOR USE

This device is an assemblage of manually operated minimally invasive surgical instruments that are accessories for endoscopic procedures consisting of Clamps, Forceps, Knot Tiers, Needle Holders, Knot Pushers, Scissors and Suction Tips. These reusable devices are packaged non-sterile and are steam sterilizable.

INDICATIONS

Sontec Instruments are manually operated instruments designed to perform specific functions such as aspirating, clamping, cutting, dissecting, draining, grasping, ligating, probing, or suturing during open, mini-open, or endoscopic surgical procedures such as thoracoscopy and laparoscopy.

CONTRAINDICATION

These instruments should not be used for anything other than their intended use.

Warnings/Precautions

℞ Only

CAUTION: US Federal Law restricts these devices to sale by or on the order of a physician and device is intended for use only or under direction of trained surgeons.

NON STERILE **CAUTION:** These reusable devices are packaged non-sterile and are steam sterilizable

CAUTION: Normal repeated use has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

CAUTION: Use of this instrument for any purpose, or in any manner other than those described here may cause instrument damage or failure which could result in serious patient injury or death. If needed, all metal products or fragments thereof can be located by means of an X-Ray.

CAUTION: The World Health Organization recommends the longest exposure times when there is concern regarding HIV, TSE, CJD, etc. contamination. It is the user's responsibility to determine what contamination exists and what procedure is appropriate to ensure proper sterilization.

WARNING: Do not flash sterilize these instruments. The instruments have not been designed for flash sterilization. Discard instruments after suspected Creutzfeld-Jakob Disease (CJD) exposure – these instruments have not been designed to withstand the chemical and thermal exposures recommended to eradicate prions.

Every surgical instrument must be properly inspected, cleaned, lubricated and sterilized before the initial use and all subsequent uses. Carefully examine each surgical instrument for proper function and damage of any sort prior to and after each use. It is extremely important to check all working parts including blades, locks, points, stops, ratchets, screws, etc. Instruments that show any sign of damage or corrosion should be repaired or replaced prior to further use.

Instruments may only be used for their intended purpose in their respective surgical specialties by properly trained and qualified personnel. The surgeon (qualified user) shall be responsible for the proper instrument selection for each application, for obtaining the appropriate training for use, for insuring the proper care and sterilization, and for their operative use.

Sontec Instruments, Inc. does not have any control over the ultimate use of the surgical instruments and therefore, cannot accept any responsibility or liability for any damages caused by inappropriate application and use or by inappropriate sterilization and maintenance of the instruments.

Materials Used: Sontec Instruments are manufactured using either high quality stainless steel, titanium (including titanium alloys), or aluminum unless otherwise stated. These metals are durable and will last for years if properly used and maintained. It is the user's responsibility to ensure continuous and proper care of the surgical instruments in addition to proper preparation, cleaning, and sterilization.

Stainless Steel: Stainless steel provides excellent, but not complete protection from rust and corrosion. The main enemies of stainless steel are organic materials not removed immediately after use, chloride ions, common salts and other contaminants contained in tap water. The use of proper cleaners, disinfectants and distilled water cannot be overemphasized.

Titanium – Titanium and titanium alloys are used to make light weight instruments. These instruments can be handled and treated like stainless steel instruments. Titanium instruments are often anodized blue for color identification.

Aluminum – Aluminum is also used to make light weight instruments. However, only neutral, non-alkaline cleaners and fully de-mineralized water may be used with aluminum instruments.

Tungsten Carbide – Chemical/cold sterilization should never be used for instruments with tungsten carbide inserts/edges. The solutions used are harmful to tungsten carbide.

Phenolic Handles – Instruments with phenolic handles may be cared for in the same manner as the metal used for the instrument.

Cleaning and Sterilizing Guidelines: Sontec Instruments, Inc. has no control over the conditions or contaminants the user will subject the instruments to, therefore, it is the ultimate responsibility of the user to determine what cleaning and sterilizing methods and additional steps might be needed to properly remove all known and

unknown organisms or contaminants. In all circumstances the user should closely follow the recommendations provided by the manufacturers of the cleaning/sterilizing products and equipment used. Following are the essential steps that Sontec Instruments, Inc. recommends.

First and Foremost – Never allow organic materials or other contaminants to dry or get encrusted on the instrument.

Important – Always process dissimilar metals separately including different grades of the same metals. Do not allow instruments to stand while touching each other.

Always – Wear appropriate safety protection and observe applicable safety procedures when handling, cleaning, and sterilizing surgical instruments.

Pre-cleaning/Holding – Thoroughly rinse instruments with warm water immediately after use. If not possible to start cleaning process immediately after use, apply a neutral pH enzymatic solution for holding following the manufacturer's instructions, and then rinse thoroughly before continuing disinfecting and cleaning. Sontec recommends Ruhof'.

Disinfecting – Immerse instruments in a suitable disinfectant approved for use on surgical instruments following the manufacturer's instructions. Rinse instruments thoroughly after disinfecting.

Cleaning – Instruments must be thoroughly cleaned before sterilization and have all organic materials, stains, rust, corrosion, and other contaminants completely removed. Regardless of the cleaning method used, stubborn particles will need to be removed manually by soaking in a suitable enzymatic cleaner following the manufacturer's instructions and then brushing with a Whisk'R Brush'. All instruments should be cleaned in the open and/or disassembled position. Most rust, pitting, stains, and corrosion can be removed using a suitable surgical instrument rust and stain remover following the manufacturer's instructions. Black coated and color anodized components may be negatively affected if aggressive cleaning mediums or appliances (e.g. extreme acidic/alkaline, abrasives) are used. A pH neutral cleaner, which may or may not contain enzymes, (such as pH neutral cleaner Prepzyme or enzymatic cleaner Endozime manufactured by Ruhof) is recommended. Exposure to chlorides or hydrogen peroxide may negatively affect the coating or colorization of components. Ultrasonic or automatic washer using suitable instrument cleaners and following the manufacturer's instructions is preferred over manual cleaning alone. In all instances care should be taken to always use clean, fresh solutions and finish by thoroughly rinsing the instruments. Instruments should be completely dry before storage.

Manual Cleaning Instructions:

- Rinse and/or flush under warm flowing tap water to remove visible debris for a minimum of 30 seconds.
- Ultrasonically clean using a detergent solution prepared according to the manufacturer's Instructions for a minimum of 10 minutes.
- Completely Immerse the Instruments in a detergent solution prepared according to the manufacturer's instructions.
- Scrub all instruments with an appropriately sized soft nylon bristle brush for a minimum of one minute, paying particular attention to crevices and hard to clean areas.
- Scrub cannulations with an appropriately sized soft nylon bristle brush for a minimum of 30 seconds.
- Flush cannulations at least three times with a syringe (50 ml.).
- Rinse with flowing purified (deionized) water for a minimum of 30 seconds.
- Dry the instruments using absorbent, low-lint wipes to remove excess water. Automated Cleaning Instructions:
- Use only washer/dIsinfector machines that have been validated in accordance with ISO 15883.
- Perform pre-cleaning to remove gross contaminants as follows:
  - Submerge and soak in a pH neutral detergent solution prepared according to the manufacturer's instructions for a minimum of 1 minute.
  - Flush any cannulations that may be present.
  - While still submerged, remove visible soil by scrubbing with an appropriately sized soft nylon bristle brush d. Rinse with flowing purified (deionized) water for a minimum of 30 seconds.
  - Load instruments into washer/disinfector in accordance with the manufacturer's instructions.
  - Arrange Instruments with curved surfaces and cannulations facing downward to prevent pooling of water.
- Operate the washer/disinfector cycle according to the manufacturer's Instructions. a. Recommended minimal washer/disinfector parameters:
  - Heated Wash at 140F° (60°C) for 2 minutes
  - Heated Tap Water Rinse at 140°F (60°C) for 20 seconds
  - Heated purified Water Rinse at 180°F (82°C) for 1 minute
  - Forced Air Drying at 240° F (116°C) for 9 minutes

  Note: Automated cleaning is not suitable for instruments with long lumens, ball joints, or stainless steel cables (e.g. suction tubes and surgical arms). Such instruments should undergo a manual cleaning prior to sterilization.
- Manual cleaning instructions for articulating arms and flex arms:
  - Turn tightening knob counter-clockwise to loosen the internal cable to enable movement of the surgical arm beads to allow fluid to flow between each link prior to placing arm in autoclave.
  - Place surgical arm into autoclave with enzymatic cleaner prepared using the minimum concentration recommended by tile detergent manufacturer and warm tap water with a temperature ranging from 25°C to 35'C for a minimum of 10 minutes.
  - Completely submerge surgical arm in enzymatic cleaner prepared using warm tap water (25*C to 35°C) for manual cleaning with appropriately-sized soft nylon bristle brush for a minimum for 2 minutes
  - Rinse surgical arm for up to 1 minute with flowing deionized water.
  - Manually dry surgical arm using clean, absorbent, low-lint wipes to remove excess water. Surgical arm Inspection before use:
  - Inspect entire assembly for damage.
  - Hold arm assembly at column and tighten central tightening knob clockwise.
  - Check to make sure that arm is rigid at all three joints.
  - Insert column into rail clamp, tighten column tightening lever and make sure that it holds securely.

Lubrication – Thoroughly lubricate all working parts and joints of instruments prior to inspection and sterilization with a lubricant suitable for use on surgical instruments that will withstand the temperature used during sterilization. For instruments with moving parts, lubricate joints with a steam-permeable, water soluble instrument lubricant prior to sterilization. Some lubricants and rust inhibitors may be used during the cleaning process. Sontec recommends Ruhof'.

Sterilization – The most common method of sterilization is by autoclaving following the autoclave manufacturer's instructions.

Some facilities use ethylene oxide gas sterilization, not recommended, but, if used, great care must be exercised with this hazardous chemical and manufacturer's instructions followed closely. Cold sterilization is not recommended because of the risk of potential damage to the instruments resulting from the lengthy chemical action required.
Instruments should be sterilized in the open or unlocked position utilizing FDA-cleared Sterilization Pouches only.

- Instruments made of different alloys should be cleaned and sterilized separately.
- Instruments should be sterilized by standard cycles using steam with established procedures.

Industry Recommended Minimum Parameters for Wrapped Steam Sterilization:

A) Pre-vacuum Type; 134°C (273°F); 3bar (28.5psi); 5-18min exposure; 30+min dry time

B) Gravity Displacement; 121°C (250°F); 30-60min ex-posture; 45+min dry time

(Note: Contact your steam autoclave manufacturer to confirm appropriate temperatures and sterilization times.)

Store: Instruments should be stored In a clean dry area with tip protectors. Please examine instrument prior to use for functionality and damage. Dispose of at end of life in accordance with national regulations and approved hospital practices for surgical instrumentation disposal & Warning/Precautions:

Load size, atmospheric, and other conditions may alter specifications. If stricter specifications are required by the user, then those specifications should be used.

Instruments should be open and/or disassembled and carefully prepared for sterilization following the sterilization equipment manufacturer's guidelines. Equipment and procedures used for sterilization should be in compliance with ANSI/AAMI ST79, AST-MF1744 and ISO 17665, www.a-k-i.org.

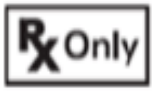
It is the user's responsibility to validate the sterilization process used.

Storage: Instruments should be stored individually or in a protective tray with partitions in a clean, dry location. Use Sontec Tip Covers to protect sharp tips.
Marking: Medi-Mark' Tape or Sontec Sheet Tape may be used to color code instruments. Use caution when applying so as to not stretch tape or place in a location that inhibits the operation of the instrument.

Symbols used on labeling

Packaged Non Sterile

Caution! See Warnings and Precautions



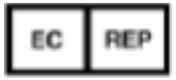
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

Consult Instructions for Use

Handling & Storage only between 1° C to 35°C

Handling & Storage only in dry location

Product complies with requirements of directive 93/42/EEC for medical devices



European Authorized Representative

Manufacturer

Reference Number

Lot Number

Manufacture Date

Quantity

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