

Instructions for Use – Retractor Blades –

Page 1 of 2

This device is part of a group of manually operated, minimally invasive surgical instruments. These reusable instruments are **packaged non-sterile** and are steam sterilizable.

INDICATIONS

Sontec retractor blades are manually operated instruments designed to perform specific functions such as providing access and exposure for a variety of surgical procedures.

CONTRAINDICATIONS

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



Warnings/Precautions



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



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 or three years, whichever comes first.

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.

Example Sontec retractor blade devices:



WARNING: Do not flash sterilize (IUSS – Immediate Use Sterilization in Surgical Settings) 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, screws etc. Instruments that show any sign of damage or corrosion should be repaired or replaced prior to further 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's 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.**

Continued on next page...

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Page 2 of 2

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.

The 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 protections and observe applicable safety procedures when handling, cleaning, and sterilizing surgical instruments.

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

Disinfecting – Immerse instruments in a suitable disinfectant approved for use on surgical instruments following the manufacturers 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.

Sterilization – The most common method of sterilization is by autoclaving following the manufacturer's instructions. Some facilities use ethylene oxide gas sterilization which is not recommended, but if used, great care must be exercised with this hazardous chemical and the 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.

Industry Recommended Minimum Parameters for Wrapped Steam Sterilization:

- a) Pre-vacuum Type; 134°C (273°F); 3bar (28.5psi); 18 min exposure; 30+ min dry time.
- b) Gravity Displacement: 121°C (250°F); 30-60min exposure; 45+ min dry time.
- c) Load size, atmospheric, and other conditions may alter specifications. If stricter specifications are required by the user then those specifications should be used.
- d) Instruments should be open and/or disassembled and carefully prepared in accordance with the sterilization equipment manufacturer's guidelines.
- e) Equipment and procedures used for sterilization should be in compliance with ANSI/AAMI ST79, AST-MF1744, and ISO 17665. www.a-k-i.org
- f) 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.

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.