

## Instructions for Use - Thoracoscopic Instruments

### Please read carefully before you start using the instruments!

The following instructions must be followed to assure the functionality and safety of these instruments.

### First Use of New Instruments

All instruments distributed by Sontec Instruments, Inc. will be delivered non-sterile, unless otherwise labeled. Sterilize before use.

### Sterilization

All instruments that come with these instructions can be autoclaved. Instruments with plastic parts cannot be sterilized by exposure to plasma, gamma radiation, or hot air. It would destroy the plastic.

- Time: 25 minutes max

Gravity steam (wrapped) / 132° C / 270° F / 15 minutes

Prevac (wrapped) / 132° C / 270° F / 4 minutes

Gravity steam (unwrapped/ flash) / 132° C / 270° F / 10 minutes

**Notice: Cold Soak Sterilization is not recommended.**

Testing results indicate that cold soak sterilization is not adequate for this product. Manufacturer's recommended cycle times DO NOT always provide a 105 sterility assurance level.

### Safety Control and Inspection

Before each use instruments should be visually inspected for scratched, broken or malfunctioning parts. Above all, check the critical parts of the instrument: Tips, cutting edges, and ratchets.

### Cleaning and Care of the Instruments

Instruments should be washed and disinfected immediately after use. Special attention should be given to critical parts such as ratchets, cutting edges, slits and other difficult to reach areas. (See ultrasonic cleaning discussed below.)

Instruments that can be taken apart must be cleaned while dismantled.

Instruments should be dried immediately after washing and rinsing.

After every washing and before sterilization, instruments must be treated with oil that is appropriate and physiologically neutral.

### Ultrasound Cleaning

Ultrasonic cleaning is preferable to mechanical cleaning. This is especially true for the sensitive instruments used for endoscopies.

- Instruments must be completely immersed in cleaning solution.
- Instruments must be cleaned for at least 3 minutes at a frequency of 35 KHz.
- Instruments can be rinsed either mechanically or by hand. Rinsing must be thorough and with desalinated water if possible.

With minimally invasive instruments, one must be sure to clean the moveable jaw tips sufficiently in the ultrasonic bath. During cleaning, the jaws should be opened and closed repeatedly. Unless this is done immediately after the operation, residues can form in the front part of the jaws and prevent seals from functioning properly.

Follow the manufacturer's instructions for the ultrasonic unit.

### Handling

Always handle surgical instruments with care. Take measures to protect instruments against damage during transport, cleaning, sterilization and storage. Do not allow instruments to come into contact with corrosive substances such as acids or caustic cleaning detergents, which could lead to rust formation. Such damage could make instruments useless.

**Warning: Please read manufacturer's instructions for all detergents and disinfectants.**

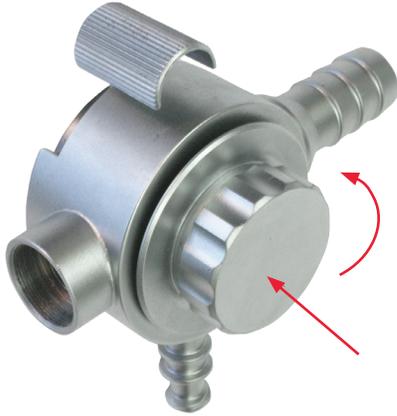
### Storage

Instruments should be stored dry and not in metal containers (with the exception of refined steel and aluminum containers). Direct exposure to sunlight is to be avoided.

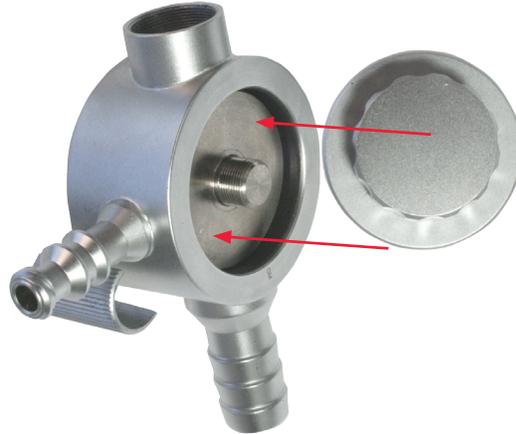
**Lack of proper handling, proper use and routine care of instruments obtained by Sontec Instruments voids all warranty claims.**

## Suction- Irrigation Valve Disassembly

Step 1: Press cap inward while turning counter-clockwise to unscrew.



Step 2: Using your thumbs, firmly push inside of valve to release.

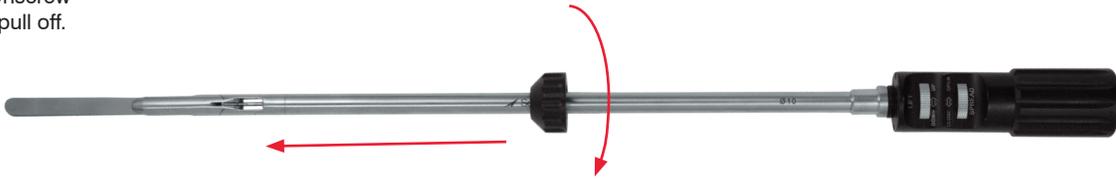


Reassembly: Reassembly is opposite of the disassembly. Make sure that the notch lines up with the notch on the valve.



## Fan Retractor Disassembly

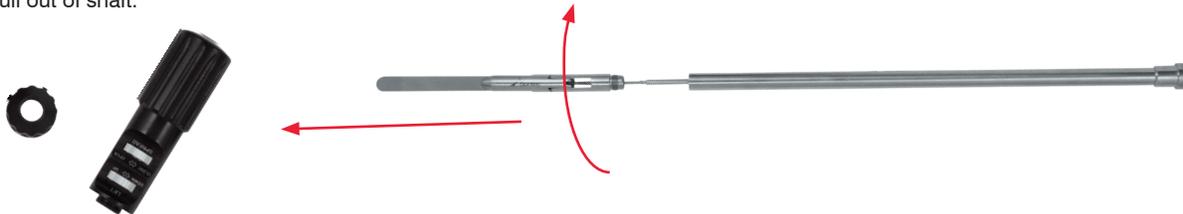
Step 1: Unscrew cap and pull off.



Step 2: Turn top dial counter clockwise and pull off shaft.



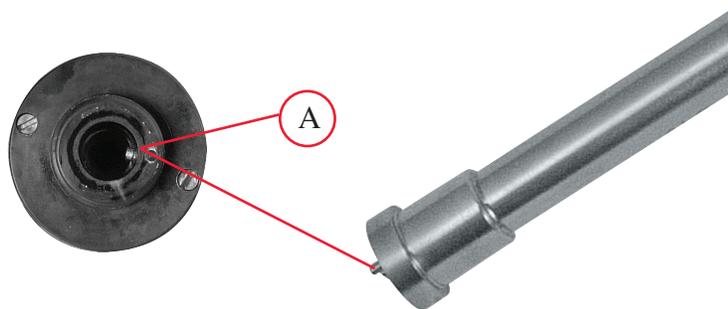
Step 3: Turn top piece clockwise to pull out of shaft.



Step 4: All instrument parts can be hand cleaned with a soft brush. Instrument parts must be fully immersed in order to not damage any coating. Jointed part must be opened. Take special care to rinse hollow spaces.



Step 5: Reassembly is opposite of the disassembly. Make sure that notch A lines up with the bottom notch on shaft.



Step 6: Reverse order to reassemble. \* On Step 2 top dial turns opposite direction

To avoid coagulation of proteins, the rinse water temperature must be below 45 degrees C. Fan Retractor must be cleaned carefully with a soft brush and taken apart. Three way tap must be taken apart for

cleaning also. Lift edge of cap, slide off, then push valve out. Re-assembles the same way in reverse. Use proper amount of cleaning solutions as per instructions of manufacturer. Ultrasound Cleaning is preferred to

mechanical cleaning, especially for sensitive laparoscopic instruments. All instruments are autoclavable including electric cables and flexible trocars.

## Fan Retractor Disassembly For the Sontec Deluxe 5mm Fan

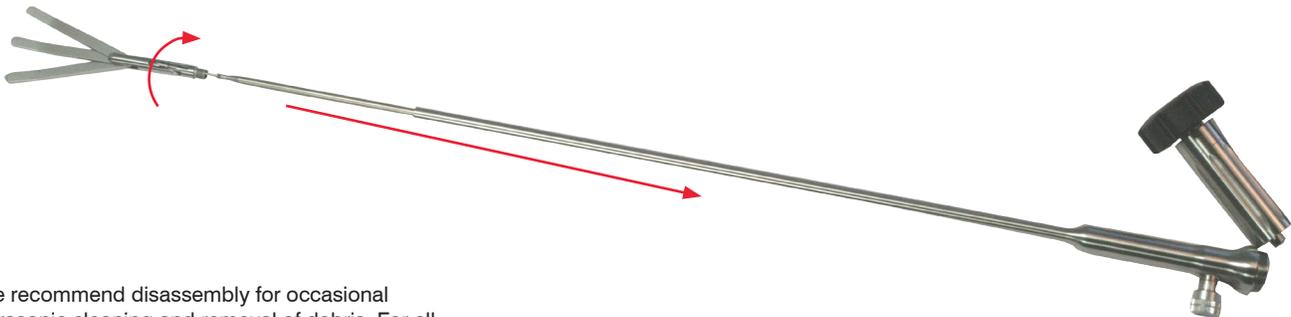
Step 1: Unscrew handle. Gently push fan blades forward with finger.



Step 2: After unscrewing, Carefully disconnect handle from ball joint by tilting handle down, and set handle aside.



Step 3: Push fan blades down grasp fan below blades and gently twist counter-clockwise to unscrew shaft. Remove shaft from assembly.



We recommend disassembly for occasional ultrasonic cleaning and removal of debris. For all other cleaning, use flush valve.



Reassembly: Reassembly is opposite of disassembly. • Inset the shaft into the assembly and screw on clockwise. • Gently tilt fan tip up with finger. • Insert ball into ball joint in handle. • push tip of fan down and screw on handle. • check fan to make sure ball joint is connected and is operating correctly.

## Important Directions for Thoracoscopic Trocars

### Thoracoscopic Flextrocar Cleaning Instructions

- Disassemble the trocar into its three parts: 1) titanium head, 2) obturator, 3) flexible tube.
- Place parts into ultrasound bath for cleaning (manufacturer strongly recommends ultrasound cleaning).
  - Instrument parts must be completely immersed in cleaning fluid during the cleaning procedure.
  - The cleaning time should be at least 3 minutes at a frequency of 35 KHz.
  - Use only distilled/desalinated water for rinsing, whether manual or ultrasonic.



1. Titanium head



2. Obturator



3. Flexible tube



Flexible tubing may shrink during autoclaving. It can be returned to exact size using the appropriate size stretch pin (10.5mm or 7mm), pictured here.

**When cleaning mechanically, please take care that rinse water temperature does not exceed 113 degrees Fahrenheit (45 degrees Celsius) to avoid coagulation of any proteins that may still adhere to the instrument.**

**Before autoclaving, all three parts must be cleaned, either mechanically or manually.**

- When cleaning manually, use a soft cleaning brush.
- Use enzymatic cleaners to release blood, proteins, etc.
- After cleaning and rinsing, all parts must be thoroughly dried.

### Sterilization

- Reassemble parts before sterilizing. The trocar must remain complete with obturator inserted.
- All trocar parts can be sterilized in a steam autoclave only.
- Gamma, hot air, and plasma sterilization methods cannot be used as these methods could cause damage to the trocar.

- Pressure: 2 bar max
- Time: 25 minutes max

Gravity steam (wrapped): 132° C/ 270° F/ 15 minutes

Prevac (wrapped): 132° C/ 270° F/ 4 minutes

Gravity Steam (unwrapped/ Flash): 132° C/ 270° F/ 10 minutes

**Notice: Cold Soak Sterilization is not recommended.**

Testing results indicate that cold soak sterilization is not adequate for this product. Manufacturer's recommended cycle times DO NOT always provide a 105 sterility assurance level.

If not reassembled before sterilizing and you need to assemble under sterile conditions in the operating room:

- If the diameter of the flexible sleeve is smaller than the outer diameter of the obturator, we recommend that you use the correct size stretching tool (sterilized).
- Take hold of the obturator head with middle, index finger, and thumb.
- Tip must be in upward position.
- Take the titanium trocar head at the thread and turn it to attach.
- Insert obturator through the titanium trocar head.
- Take up the flexible plastic sleeve at the blunt tip end and use the blunt obturator to position the sleeve at the head of the fixation screw.
- Turn until all parts are screwed tightly together.

## Directions for Use of Thoracoscopic HF Electrodes and Instruments

### 1. General Information

- Please read directions before using this instrument.
- MICTEC HF-instruments function with the following HF units:

Erbe: Erbotom ACC430/450, ACC 410, ACC450T, ACC450Z, ACC 451; Endoscopy; T 50 B, T130, T175E; ICC350, ICC 300, ICC 200

Martin: ME 50, 80, 200, 400, MIC, 60, 70, Elektrotom; 80B, 80, 200, 390, 400

Berchtold: Elektrotom 80, 80B, 200, 390, 400, 505, 540

Valley Lab: Force 1, 2, 10, 20, 30, 40, 40S, 10A, 20A, 30A, 40A, 40AS

Olumpus: UES, UES-2, UES-10, PSD-2, PSD-3, PSD-10

Aesculap: GN 350, 60; GK 170, 450, 455, 20, 50, 55

Further units on demand.

- Following HF cables are approved for MICTEC HF instruments:

- Monopolar HF cable, 4 m long, 4 mm connection plug for Erbe T-series/Wolf/Stroz art.no.26944-01

- Monopolar HF cable, 4 m long, 5 mm connection plug for Erbe ACC, ICC art.no 26944-02

- Monopolar HF cable, 4 m long for Valley Lab art. no.26944-03

- Monopolar HF cable, 4 m long for Martin/Berchtold/Aesculap units art.no.26944-33

### 2. Sterilization

- New instruments must be washed, rinsed, dried, inspected, and sterilized before using, as described below.

#### 2.1 Steam Sterilization

- Before sterilizing, individual components must be cleaned following the instructions under point 5 below.
- All components can be steam sterilized under the following conditions:

Regular sterilization: Pressure: max 2 bar. Time: 25 min.

Flash sterilization (for faster turnaround):

Pressure: max 2.5 bar

Time: 10 min. with 134<sup>o</sup> C

**Warning! Follow the manufacturer's instructions for the steam sterilizer!**

#### 2.2 Gas Sterilization (ETO)

- Before sterilizing, individual components must be cleaned following the instructions under point 5 below.
- All components can be sterilized with gas.

**Warning! Follow the manufacturer's instructions for the gas sterilizer!**

#### 2.3 Disinfection

- Before sterilizing, individual components must to be cleaned following the instructions under point 5 below.
- All components can be immersed in disinfectant solutions that have been approved by the disinfectant manufacturer for endoscopic instruments.

**Warning! Follow the manufacturer's instructions for the sterilizer!**

### 3. Inspect before every operational use!

#### 3.1 Inspection of the Insulation

- Inspect instrument carefully for damage to plastic coating on hooks, scissors, suction irrigation tubes.

**Any instrument found to be damaged must be removed from service and returned for repair or replacement.**

#### 3.2 Function Tests

Check:

- Is the instrument functional?
- Can the valve be opened and closed?
- Is the valve complete?
- Is the piston oiled and sealed?

**Warning! If any irregularity is found during the inspection, the defect must be corrected before using the instrument.**

### 4. Directions for Use

#### 4.1 Attaching to Suction/Irrigation Unit

- Connect the silicon suction tube to the longitudinally directed tube connector as in illustration on page 43.
- Connect the silicon irrigation tube to the transverse directed tube connector as in illustration on page 43.

Be sure to use the appropriate tube diameter to prevent the tube from slipping off connector.

### 5. Care and Cleaning of Individual Components

#### 5.1 Cleaning Instrument Parts

Mechanical cleaning:

- All parts can be cleaned by machine.
- Parts must be placed in machine so that coating is not damaged.
- Be sure all hollow spaces are also washed and rinsed.
- Water temperature must not go above 45<sup>o</sup> C to avoid protein coagulation and sticking to valve.
- Follow instructions given by manufacturer for proper amount of detergent.

**Warning! MICTEC® 3-Way Valves must be taken apart for cleaning. All tubes must be removed from the valve!**

Ultrasound cleaning:

Ultrasonic cleaning is preferable to mechanical cleaning. This is especially true for the sensitive instruments used for endoscopies.

- Instruments must be completely immersed in cleaning solution.
- Instruments must be cleaned for at least 3 minutes at a frequency of 35 KHz.
- Instruments can be rinsed either mechanically or by hand, but rinsing must be thorough and with desalinated water if possible.

**Follow the manufacturer's instructions for the ultrasonic unit.**

#### 5.2 Care of Valve

After cleaning and drying, all moveable parts such as the rotation

---

## Directions for Use of Thoracoscopic HF Electrodes and Instruments

---

adaptor and joints must be treated with an appropriate paraffin oil based preservative.

**Warning! The rotation adapter and sliding surface of the piston must be greased with our special care lubricant. (Art. No. 26905-00)**

### 6. Assembly and Inspection

The valve is to be put back together and tested in the same way as described in 3.2.

### 7. Maintenance

Should any serious damage to the coating appear on any part of the valve, please send the valve to us for repair.

### 8. Tips for Avoiding Mistakes

- Be sure that the power paths between neutral electrode and MICTEC HF instruments are as short as possible.
- The power path must not cross through the body and absolutely never across the thorax.
- The HF cable and the HF instrument must not be allowed to lay directly on the patient's skin, as this could lead to burns caused by capacitive currents.
- The HF cable must not be allowed to coil or lay in a coil as this could result in dangerous inductive currents.
- Completely insulate the patient from any contact with any other conductive surfaces.
- Ground the operation table!
- Avoid skin-to-skin contacts on arms and legs of the patient; for example, by wrapping in dry gauze.
- Switch on HF power only when the HF instrument is in contact with the tissue that is to be coagulated.
- The tissue to be coagulated must not be in touch with any part of other tissue surfaces, since it could lead to unwanted coagulations.
- Cord or band shaped tissue parts may be coagulated only at the thinnest part.
- The coagulating HF instrument tip must be at least 10 mm from other surgical instruments.
- When using gas (for example, insufflation gas), make sure that only non-inflammable gas is used, otherwise explosions and oxygen burns could result.
- The size of the neutral electrode must be appropriate for the power of the HF used, as it could lead to burns on the wrong place.

### 9. Interactions with Other Apparatuses

**When using electrocardiograms (ECG) the following points must be observed:**

- Connect neutral ECG cable to the neutral HF electrode.
- The distance between active HF electrode and ECG electrodes must be at least 150 mm.
- Do not use ECG needle electrodes.
- All ECG electrodes must have HF choke or protective circuitry.

**Cardiac Pacemaker:**

- Cardiac pacemakers could be damaged by HF power.
- Before using please consult a cardiologist.
- Never make ambulant operations on patients with cardiac pacemakers.

## Directions for Use of Thoracoscopic 3-Way Tap

### 1. General Information

- Please read these directions carefully before using the instrument.
- New instruments must be washed, rinsed, dried, inspected, and sterilized before using, as described below.

### 2. Sterilization

#### 2.1 Steam Sterilization

- Before sterilizing, individual components are to be cleaned following the instructions under point 5.3 below.
- All components can be steam sterilized under following conditions:

Pressure: 2 bar max

Time: 25 minutes max

Gravity steam (wrapped) / 132° C / 270° F / 15 minutes

Prevac (wrapped) / 132° C / 270° F / 4 minutes

Gravity Steam (unwrapped/ Flash) / 132° C / 270° F / 10 minutes

**Notice: Cold Soak Sterilization is not recommended.**

Testing results indicate that cold soak sterilization is not adequate for this product. Manufacturer's recommended cycle times DO NOT always provide a 105 sterility assurance level.

**Warning! Follow the manufacturer's instructions for the sterilizer!**

#### 2.2 Gas Sterilization (ETO)

- Before sterilizing, individual components are to be cleaned following the instructions under point 5 below.
- All components can be sterilized with gas.

**Warning! Follow the manufacturer's instructions for the sterilizer!**

#### 2.3 Disinfecting

- Before sterilizing, individual components are to be cleaned following the instructions under point 5.3 below.
- All components can be immersed in disinfectant solutions that have been approved by the disinfectant manufacturer for endoscopic instruments.

**Warning! Follow the manufacturer's instructions for the sterilizer!**

### 3. Inspect Before Each Use!

#### 3.1 Inspect Chrome Plating

- Inspect instrument carefully for damage to chrome plating.

**Remove any instrument found to be damaged.**

#### 3.2 Function Tests

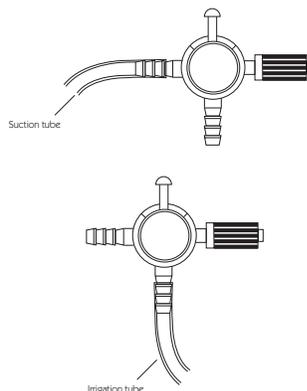
Check:

- Is the instrument functional?
- Can the valve be opened and closed?
- Is the valve complete?
- Is the piston oiled and sealed?

**Warning! If any irregularity is found during the inspection, the defect must be corrected before using the instrument.**

### 4. Directions for Use

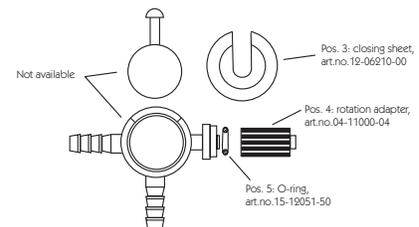
#### 4.1 Attaching to Suction/Irrigation Unit



- Connect the silicone tube to the longitudinally directed tube connector as in illustration.
- Connect the silicone tube to the transverse directed tube connector as in illustration.
- Be sure to use the appropriate tube diameter to prevent the tube from slipping off connector.

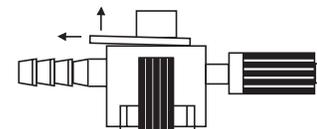
### 5. Care and Cleaning of Individual Components

#### 5.1 Components

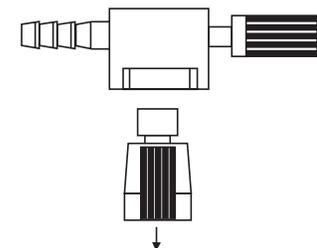


#### 5.2 Dismantling the Instrument

- Hold the valve body, lift the closing plate and slide it to the side.



- Then push the piston out of the body of the valve using your thumb.



#### 5.3 Cleaning Instrument Parts

MICTEC 3-Way Valves must be taken apart for cleaning, as described under point 5.2 above. All tubes must be removed from the valve!

Machine washing:

- All parts can be cleaned in a machine.
- Parts must be placed in machine so that coating is not damaged.
- Be sure all hollow spaces are also washed and rinsed.
- Water temperature must not go above 45°C to avoid protein coagulation and sticking to the valve.
- Follow instructions given by manufacturer for proper amount of detergent.
- Follow manufacturer's instructions for use of machine.

Ultrasound cleaning:

The ultrasound cleaning is preferred to mechanical cleaning. This is especially true for the sensitive instruments used for endoscopies.

- Instruments must be completely immersed in cleaning solution.
- Instruments must be cleaned for at least 3 minutes at a frequency of 35 KHz.
- Instruments can be rinsed either mechanically or by hand, but rinsing must be thorough and with desalinated water if possible.
- Follow the manufacturer's instructions for the ultrasonic unit.
- After cleaning, instrument parts must be clean to visual inspection and must be sufficiently dried.

## 5.4 Care of Valve

After cleaning and drying, all movable parts such as the rotation adapter and joints must be treated with an appropriate preservation based on paraffin oil.

**Warning! The rotation adapter and sliding surface of the piston must be greased with our special care lubricant. (Art. No. 26905-00)**

## 5.5 Assembly

The valve is to be put back together by reversing the order of operations as described in point 5.2.

Then test the valve in the same way as described in 3.1 and 3.2.

## 6. Maintenance

Should any serious damage to the coating appear on any part of the valve, please send the valve to us for repair.