Semi-Rigid Ureteroscope

Operation and Maintenance Manual
Warnings

Please read this manual and follow its instructions carefully. The words warning, caution, and note carry special meanings and should be carefully reviewed:

WARNING  The personal safety of the patient or physician may be involved. Disregarding this information could result in injury to the patient or physician.

Caution Special service procedures or precautions must be followed to avoid damaging the instrument.

Note Special information to make maintenance easier or important information more clear.

An exclamation mark within a triangle is intended to alert the user to the presence of important operating and maintenance instructions in the literature accompanying the product.

A lightning bolt within a triangle is intended to warn of the presence of hazardous voltage. Refer all service to authorized personnel.

WARNING  To avoid potential serious injury to the user and patient or damage to this device, the user must:

1. Read this operating manual thoroughly and be familiar with its contents prior to assembling or using this product.
2. Be a qualified physician, having complete knowledge of the use of this equipment.
3. Keep the distal tip of the probe, laser fiber, or other surgical instruments in the field of view at all times during the procedure.
4. Pay close attention to the care, cleaning, disinfection, and sterilization instructions in this manual. A deviation may cause damage to the product and harm to patients.
5. Clean and disinfect the unit before placing it in the carrying case. The carrying case cannot be cleaned or disinfected, so placing a contaminated product in the case may present an infection control risk. Sterilize the product again prior to use.
6. Never reuse a disposable port seal valve. Disposable port seal valves are intended for single use only and will compromise sterility if reused.
7. Port seal valve must be used when irrigation is on, or back flow fluid from working channel could cause contamination.
8. When several pieces of electrical medical equipment are used together, leakage current may be additive. Lower leakage currents may be achieved by using only CF applied parts.
9. To minimize the risk of patient infection, the Semi-Rigid Ureteroscope must be cleaned and sterilized prior to the first use and every subsequent use. See the “Cleaning and Maintenance” section for details.

10. Before all surgical procedures and sterilization processes, inspect the Semi-Rigid Ureteroscope for damage. Do not use any damaged Ureteroscope in a surgical procedure.

11. This manual does not provide information specific to each instrument that may be used. Read and understand all user instructions associated with each instrument prior to use.

12. Clean the ureteroscope immediately after the surgical procedure or blood and mucus may dry in the working channels and become difficult to remove, compromising the future sterility of the ureteroscope.

13. Allow semi-rigid ureteroscope to immerse in enzymatic solution for a set period of time while cleaning or infection may result.

14. Use only instruments that provide sufficient patient isolation. Instruments cannot depend on the ureteroscope to provide patient isolation.

15. Using Cidex OPA for disinfection is not recommended for the Stryker Semi-Rigid Ureteroscope. Please contact the solution manufacturer for specific product information and contraindications.

16. Never look directly at the light emitted from the endoscopic light source, light guide, or ureteroscope. Damage to the eye may result.

17. Use only non-conductive light guides in conjunction with this product or user and/or patient injury may occur.

18. Never leave the ureteroscope unattended while attached to a high-intensity light source. Heat from the light source may ignite drapes or similar materials if left unattended.

19. Do not sterilize the Semi-Rigid Ureteroscope using methods other than those described in this manual. Infection or device damage may result.

20. The surface temperature of the Semi-Rigid Ureteroscope may exceed 41°C due to the heat produced by the illumination source used. Handle the heated ureteroscope carefully as it can cause injury such as burns, permanent tissue damage or coagulation. Prior to disconnecting light guides or light guide connectors, turn off the illumination source and allow the ureteroscope to cool.

The warranty is void if any of these warnings are disregarded.

WARNING Federal law (United States of America) restricts this device to use by or on order of a physician.
Stryker Endoscopy reserves the right to make improvements in the product(s) described herein. Product(s), therefore, may not agree in detail to the published design or specifications. All specifications are subject to change without notice. Please contact the local Stryker Endoscopy distributor listed in the Other Service section or call your local Stryker Endoscopy sales representative or agent for information on changes and new products.

**Cautions**

1. Carefully unpack the unit and check if any damage occurred during shipment. If damage is detected, please refer to the Service and Claims section in this manual.

2. Test this equipment before every medical procedure. This product was fully tested at the factory before shipment. Inspect all surfaces of the ureteroscope, ensuring there are no rough surfaces, sharp edges, or protrusions.

3. Use only in conjunction with other Type BF or CF rated medical electrical equipment listed and approved to IEC 60601-1 or equivalent standard. Applied part isolation and patient leakage current is dependent on the proper isolation provided by these devices.

4. Never attempt repairs or adjustments to this product. See the ‘Service and Claims’ section of this manual for further information.

5. To prevent damage to the ureteroscope, always treat the Semi-Rigid Ureteroscope with care. Do not drop the ureteroscope or crush, cut, or severely bend the Semi-Rigid outer tube.

6. Scope and accessories must be disposed of according to local laws and hospital practices.

7. When using semi-rigid instruments, advance the instrument into the working channel slowly and carefully. If the instrument encounters any resistance, withdraw the instrument several millimeters and then resume introduction.

**Indications for Use**

The Stryker Semi-Rigid Ureteroscope is indicated for use during minimally invasive urological surgical procedures accessed through natural body orifices, and is intended for, but not limited to, transurethral examination of the urinary tract. It is also intended for the performance of various diagnostic and therapeutic procedures (utilizing additional accessories).
Product Description

Figure 1 shows the components of the Semi-Rigid Ureteroscope.

1. Semi-Rigid Outer tube: contains the working channel, light, and image fibers
2. Large Working Channel: for introducing flexible instruments or irrigation
3. Small Working Channel: for inserting flexible instruments or irrigation
4. Light Post: for attaching a light cable
5. Eyepiece: for viewing the image

Setting up the Semi-Rigid Ureteroscope

1. Ensure the ureteroscope is clean and sterile. For cleaning and sterilization instructions, see the “Cleaning and Maintenance” section of this manual.
2. Attach the ureteroscope to a coupler.
   Note If the ureteroscope will be used without a camera or coupler, use eyepiece for viewing the procedural site.
3. Attach a light cable to the ureteroscope.
   • Connect a cable adapter to the light post (a).
   • Attach a light cable to the cable adapter
WARNING Never reuse an instrument port seal valve. Instrument port seal valves are intended for single use only and will compromise sterility if reused.

4. Connect irrigation tubing to the ureteroscope (if necessary). (See Figure 3).
   • Attach irrigation tubing to either of the working channels.
   • If desired, attach a port seal valve to the other working channel (channel not used for irrigation).

Figure 3: Attaching the irrigation tubing

Note Stryker couplers, light-fiber cables, light-fiber cable adapters, and various Semi-Rigid Ureteroscope accessories are available for purchase through Stryker Endoscopy. Refer to the individual product manuals for further product information.

WARNING When several pieces of electrical medical equipment are used together, leakage current may be additive. Lower leakage currents may be achieved by using only CF applied parts.

5. Connect the ureteroscope to a camera.
   • Adjust coupler to achieve sharp and clear image.
   • Pointing the ureteroscope towards a white 4x4 gauze, white balance the camera.

Note Refer to camera user manual for operating instructions.

Operating the Semi-Rigid Ureteroscope

WARNING To minimize the risk of patient infection, the Semi-Rigid Ureteroscope must be cleaned and sterilized prior to the first use and every subsequent use. See the “Cleaning and Maintenance” section for details.

WARNING Before all surgical procedures and sterilization processes, inspect the Semi-Rigid Ureteroscope for damage. Do not use any damaged Ureteroscope in a surgical procedure.
Caution  To prevent damage to the ureteroscope, always treat the Semi-Rigid Ureteroscope with care. Do not drop the ureteroscope or crush or severely bend the Semi-Rigid outer tube.

**Inspecting the Scope Before the Procedure**

**WARNING** Always inspect the ureteroscope before a procedure. Never use the Semi-Rigid ureteroscope if it has nicks, burrs, or sharp edges.

1. Inspect the entire surface of the semi-rigid outer tube for nicks, burrs, and other irregularities.
2. Inspect the working channel for obstruction by inserting a cleaning brush into the channel during the cleaning procedure.
3. Inspect the optics.
   - Clean all lens surfaces with lens cleaner (P/N 503-888-004).
   - Focus the ureteroscope on an object 8mm away. The honeycomb fiber pattern should be crisp and clear.

**Using Instruments in the Working Channels**

**WARNING** This manual does not provide information specific to each instrument that may be used. Read and understand all user instructions associated with each instrument prior to use. Using instruments incorrectly may result in user or patient injury.

**WARNING** Clean the ureteroscope immediately after the surgical procedure. Blood and mucus may dry in the working channel and become difficult to remove, compromising the future sterility of the ureteroscope.

**WARNING** Use only instruments that provide sufficient patient isolation. Instruments cannot depend on the ureteroscope to provide patient isolation, and patient safety may be compromised.

**WARNING** Port seal valve (P/N 503-888-001) is a single use device. Do not reuse device or it could compromise sterility.

The working channels accommodate various medical instruments, enabling the surgeon to access the procedural site through the ureteroscope itself.

1. If irrigation will be used with the ureteroscope, a port seal valve may be attached to the working channel that is not being used for irrigation. Turn the port seal valve counter clockwise to open the valve.
2. Insert the instrument into the working channel carefully and slowly, beginning at the port entry (see Figure 4). Pass the instrument through the port seal valve (if used) to access the working channel.

3. When the instrument is inserted several millimeters into the port seal valve, tighten the valve by turning the port seal valve clockwise to prevent irrigation leaks.

4. Advance the instrument its full length and begin using instrument.
   - Grasp the instrument close to the port entry and advance it into the channel using short, repeated movements.

**Caution**  
Advance the instrument into the working channel slowly and carefully. If the instrument encounters any resistance, withdraw the instrument several millimeters and then resume introduction.

![Figure 4: Introducing instruments into the working channel](image)

**Cleaning and Maintenance**

**Cleaning the Scope**

**WARNING**  
Clean, disinfect, and sterilize the ureteroscope before initial and every subsequent use or infection may result.

**WARNING**  
Clean the ureteroscope immediately after the surgical procedure or blood and mucus may dry in the working channel and become difficult to remove, compromising the future sterility of the ureteroscope.
WARNING  Allow Semi-Rigid Ureteroscope to soak in enzymatic solution for a set period of time or infection may result.

Figure 5: Cleaning the irrigation port and working channel with the cleaning brush

1. Prepare Cleaning Solution  
   a. Dilute the enzymatic cleaning agent in warm water (38-49 ºC). Read the instructions supplied with the agent carefully. 
   b. Stir the mixture to homogenize the solution.

2. Prepare for Soak  
   a. Handle the ureteroscope with care. 
   b. Remove all accessories from the ureteroscope (stopcocks, port seal valves, etc.). 
   c. Remove heavy or large debris using single use absorbent paper wipes soaked in appropriate cleaning solution.

3. Soak  
   a. Soak ureteroscope for at least 5 minutes. 
   b. Using a syringe, aspirate and squirt the cleaning solution several times in hard to reach areas (working channels). 
   c. Repeat aspiration and squirt at least twice.

4. Clean  
   a. Remove debris using the suitable cleaning tool. 
   b. The following cleaning tools may be used: 
      - Soft polishing brush on surface of the ureteroscope. 
      - Hard (nylon) bristle brush. 
      - Syringe for solution injection into hard to reach parts. 
      - Brush with fine stiff bristles. 
      - Supple polishing brush 
   c. Insert brush in one end of the device. Move back and forth twice. (See Figure 5). 
   d. Wipe exterior of device with a cloth soaked in enzymatic solution. 

Note  Repeat cleaning at least once.
5. Rinse
   a. Rinse the ureteroscope in running potable water for one minute until it is no longer slippery to touch.
   b. Use syringe to deliver rinse water to the port of the ureteroscope.
   c. Inspect the ureteroscope for remaining debris, in particular hard to reach areas (working channels).
   d. Repeat Steps 3 and 4 for residual debris removal at least once and as many times as necessary.

6. Dry
   a. Dry ureteroscope with soft, clean lint-free towel or equivalent until ureteroscope has no visible moisture.
   b. Use a syringe to flush air through the device to remove remaining water. Medical compressed air may be used to dry the ureteroscope.

   Note  Repeat if necessary.

**Disinfecting the Scope with Glutaraldehyde Solution**

**WARNING**  Using Cidex OPA for disinfection is not recommended for the Stryker Semi-Rigid Ureteroscope. Please contact the solution manufacturer for specific product information and contraindications.

   Note  Disinfection is not to be used in lieu of sterilization.

1. Prepare Disinfection Solution
   a. Glutaraldehyde disinfection solution may be used in accordance with manufacturer's instructions.

2. Soak in Disinfection Solution
   a. Glutaraldehyde disinfection solution may be used in accordance with manufacturer's instructions.

3. Dry
   a. Ureteroscope must be dried prior to the next step.
   b. Dry ureteroscope with soft, clean lint-free towel or equivalent until ureteroscope has no visible moisture.
   c. Medical compressed air may be used to dry the ureteroscope.
   d. Repeat if necessary.
Post-Cleaning Inspection

1. Before preparing for sterilization, all medical devices should be cleaned.
2. Generally, an un-magnified visual inspection using good light condition is sufficient.
3. All parts should be checked for visible soil and/or corrosion. Particular attention should be paid to:
   - Mating surfaces
   - Working channel entrances/exits
   - Recessed features

Sterilizing the Ureteroscope

**WARNING** Do not sterilize the Semi-Rigid Ureteroscope using methods other than those described in this manual. Infection or device damage may result.

Autoclave Steam Sterilization

**Note** Use Stryker Sterilization Tray (P/N 233-032-890) for Autoclave Steam Sterilization.

1. Clean
   a. Before sterilization, clean ureteroscope as indicated in the ‘Cleaning’ section.
   b. Ureteroscope must be dried prior to the next step.

2. Wrap
   a. If ureteroscope is to be stored, double wrap in blue muslin paper or a tyvek pouch.
   b. If ureteroscope is sterilized in a sterilization tray, wrap the tray.
   c. Please refer to "NOTE: Flash Sterilization" for unwrapped method.

3. Autoclave Parameter
   a. The following autoclave parameters are the minimum time and temperature parameters for sterilization:

<table>
<thead>
<tr>
<th>Chamber Configuration</th>
<th>Flash (Pre-Vac)</th>
<th>Gravity</th>
<th>Pre-Vacuum</th>
<th>Gravity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chamber Temperature</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>132°C (270°F)</td>
<td>121°C (250°F)</td>
<td>132°C</td>
<td>132°C (270°F)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sterilization Time</th>
<th>4 minutes</th>
<th>30 minutes</th>
<th>4 minutes</th>
<th>15 minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry Time</td>
<td></td>
<td>20 minutes</td>
<td>20 minutes</td>
<td>60 minutes</td>
</tr>
<tr>
<td>Product Configuration</td>
<td>Unwrapped</td>
<td>Double Wrapped</td>
<td>Double Wrapped</td>
<td>Double Wrapped</td>
</tr>
</tbody>
</table>
b. The ureteroscope has been validated up to 18 minutes at 137°C.

**Flash Sterilization**

1. Flash sterilization is not recommended for high frequency use. Repeated Flash Sterilization will affect the lifetime of your ureteroscope.
2. During flash sterilization, the ureteroscope is unwrapped and immediately air dried or quenched after the steam sterilization cycle.

**Ethylene Oxide (EtO) Sterilization**

**Note** Use Stryker Sterilization Tray (P/N 233-032-890) for Ethylene-Oxide Sterilization.

1. Clean
   a. Before sterilization, clean ureteroscope as indication in the ‘Cleaning’ section.
   b. Ureteroscope must be dried prior to the next step.
2. Wrap
   a. If ureteroscope is to be stored, double wrap in blue muslin paper or a tyvek pouch.
   b. If ureteroscope is sterilized in a sterilization tray, wrap the tray.
3. EtO Parameters
   a. The following parameters are the minimum time and temperature parameters for sterilization:

<table>
<thead>
<tr>
<th>Ethylene oxide (EtO)</th>
<th>Preconditioning</th>
<th>Sterilization</th>
<th>Aeration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temperature</strong></td>
<td>55°C (131°F)</td>
<td>55°C (131°F)</td>
<td>55 ± 4°C (131 ± 7°F)</td>
</tr>
<tr>
<td><strong>Relative Humidity</strong></td>
<td>70%</td>
<td>70%</td>
<td>-</td>
</tr>
<tr>
<td><strong>Vacuum Set Points</strong></td>
<td>1.30 psia</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>EtO Concentration</strong></td>
<td>-</td>
<td>725 mg/L</td>
<td>-</td>
</tr>
<tr>
<td><strong>Time</strong></td>
<td>30 minutes</td>
<td>60 minutes</td>
<td>12 hours</td>
</tr>
</tbody>
</table>
Steris System 1

STERIS® Sterilization

WARNING  To ensure the sterility of the ureteroscope, follow the sterilization setup for the flexible ureteroscope from STERIS® Corporation, or infection may result.

1. Clean
   a. Before sterilization, clean ureteroscope as indicated in the ‘Cleaning’ section.
   b. Ureteroscope must be dried prior to the next step.

2. Quick Connect (QC1671)
   a. Attach STERIS Quick Connect to each of the working channel ports.
   b. Contact Steris at 1-800-8STERIS for details.

3. Run Steris System 1
   a. Run standard Steris System 1 cycle as indicated in manufacturer instructions.

Technical Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total length</td>
<td>561mm or 461mm</td>
</tr>
<tr>
<td>Working length</td>
<td>330mm or 430mm</td>
</tr>
<tr>
<td>Distal/Proximal Size</td>
<td>6.9 Fr / 10.5 Fr</td>
</tr>
<tr>
<td>Working channel diameters</td>
<td>0.82mm / 2.5Fr, 1.12mm / 3.4 Fr</td>
</tr>
<tr>
<td>Field of view in air</td>
<td>80°</td>
</tr>
<tr>
<td>Field of view in water</td>
<td>60°</td>
</tr>
<tr>
<td>Direction of view</td>
<td>7.5°</td>
</tr>
<tr>
<td>Weight</td>
<td>175g</td>
</tr>
<tr>
<td>Transport and Storage Limits</td>
<td>Relative Humidity:10% ~ 80%</td>
</tr>
<tr>
<td>Temperature</td>
<td>-35°C ~ 65°C</td>
</tr>
</tbody>
</table>
**Part Listing**

<table>
<thead>
<tr>
<th>Part List</th>
<th>Part Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRU-6 Semi-Rigid Ureteroscope</td>
<td>502-880-330</td>
</tr>
<tr>
<td>SRU-6X Semi-Rigid Ureteroscope</td>
<td>502-880-430</td>
</tr>
<tr>
<td>Disposable Port Seal Valve</td>
<td>503-888-001</td>
</tr>
<tr>
<td>Flexible Cleaning Brush, large</td>
<td>504-999-001</td>
</tr>
<tr>
<td>Flexible Cleaning Brush, small</td>
<td>504-999-002</td>
</tr>
<tr>
<td>Lens Cleaner</td>
<td>503-888-004</td>
</tr>
<tr>
<td>SRU-6/6X Tray</td>
<td>233-032-890</td>
</tr>
</tbody>
</table>

**Warranty Statement**

Stryker Corporation warrants all semi-rigid ureteroscope optics and associated components to the original purchaser for a period of 90 days from the date of purchase to be free from defects in material and workmanship. This warranty extends to all purchases and is limited to the repair or replacement of the product without charge when returned to:

Stryker Endoscopy  
5900 Optical Court  
San Jose, CA 95138  
USA

Stryker cannot accept responsibility for returns or replacements which have not been authorized.

This warranty does not cover damages caused by misuse or failure to follow procedures outlined in this manual or as demonstrated by Stryker Corporation Representatives.

This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

This warranty applies only to the original purchaser of Stryker Endoscopy products purchased directly from Stryker Endoscopy, USA, or from a Stryker Endoscopy authorized agent. The warranty cannot be transferred or assigned by the original purchaser.

Fiberoptic cables and light sources are covered under a separate warranty.
This warranty does not cover damages caused by misuse or by failure to follow the procedures outlined in this manual or demonstrated by Stryker Endoscopy representatives.

There are no other expressed warranties.

**Service and Claims**

Do not attempt to service this product yourself. If service is needed either during or after the warranty period:

1. Contact Stryker Endoscopy at 1-800-624-4422, or phone your local Stryker Endoscopy sales representative.
2. Clean and sterilize all parts that will be returned for service. Follow the instructions provided in this manual.
3. Package all the components carefully in the original shipping container to maintain warranty after purchase.
4. Ship the product pre-paid and insured to:

   Stryker Endoscopy Customer Service  
   Attention: Repair Department  
   5900 Optical Court  
   San Jose, CA 95138  
   USA

For international service locations, refer to the Stryker website at the following URL: www.stryker.com

The product described in this manual is continually being reviewed, and improvements may be made without notice.

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