Packaging
Devices can be loaded into dedicated packaging systems. Sterilization wrap material must be cleared for the applicable sterilization modality by your country's regulatory body. Use in accordance with packaging manufacturer's sterilization instructions being sure to protect jaws and cutting edges from damage.

Sterilization
All devices must be processed in the completely open position (i.e. flushports, jaws, etc.) to allow sterilant contact of all surfaces.

PreVacuum Steam Sterilization Parameters
Minimum Preconditioning Puls: 3
Minimum Temperature: 132°C (270°F)
Minimum Exposition Time: 3 minutes
Minimum Dry Time: 30 minutes
Sterilization Configuration: Wrapped (2 layer 1-ply or 1 layer 2-ply)

Storage
After sterilization, devices must remain in sterilization packaging and be stored in a clean, dry environment.

Instrum ents must be completely dry and lubricated to prevent damage. Store instrum ents in areas which provide protection from extremes in temperature and humidity. Instruments are delicate and should always be stored with tip guards to prevent damage to working end of the instrum ent.

Warranty
CareFusion offers a lifetime guarantee on every surgical device bearing the Snowden-Pencer brand name (unless otherwise noted) to be free of functional defects in workmanship and materials when used normally for its intended surgical purpose. Any Snowden-Pencer device proving to be defective will be replaced or repaired at no charge. This Device carries a lifetime warranty against defects and a 1 year warranty against wear.

Repair Service
Regardless of age, if any Snowden-Pencer device needs service, return it to an authorized repair service center. For repairs outside the U.S., please contact your local distributor.

Note: All devices being returned for maintenance, repair, etc. must be cleaned and sterilized per these instructions for use prior to shipment.

Contact Information
CareFusion
1500 Waukegan Rd
McGaw Park, IL 60085 U.S.A.
800-323-9088
www.carefusion.com

For Domestic inquiries email: GMB-VMueller-Cust-Support@carefusion.com
For international inquiries email: GMB-SIT-International-Team@carefusion.com

Other Resources
To learn more about sterilization practices and what is required of manufacturers and end users, visit www.aami.org, www.aorn.org, or www.iso.org

Snowden-Pencer®
Operative Laparoscopic Instruments
Use and Operating Instructions

Catalog Numbers

Endoplus reusable laparoscopic instruments with the following configurations:

- 5mm diameter single-piece
- Lumen length up to 439.62 mm long
- 5mm diameter take-apart devices
- Lumen length up to 439.62 mm long

Suction Coagulators
- Lumen length up to 450 mm long

Probes & Knot Pushers
- Length up to 450 mm long

Indications For Use
Hand held Laparoscopic instrum ents are intended for grasping, cutting, dissecting, retracting, clamping, cauterizing, and/or suction/irrigation in conjunction with Laparoscope during laparoscopic surgery. The instrum ents are designed to be used through a portal, the opening maintained by an introducer or cannula which allows for insertion and removal of the instrum ent without damage to the surrounding soft tissue. Instruments should be used only by personnel completely familiar with their operation. Using an instrum ent improperly for a task which it was not intended, may result in a damaged or broken instrum ent.

How Supplied
Snowden-Pencer devices are packaged as non-sterile. Cleaning and sterilization must occur prior to use.

Limitations on Reprocessing
Repeated reprocessing has minimal effect on these devices. End of life is normally determined by wear and damage due to use.

Warnings
Devices shall be used in accordance with these instructions for use. Read all sections of this insert prior to use. Improper use of this device may cause serious injury. In addition, improper care and maintenance of the device may render the device non-sterile prior to patient use and cause a serious injury to the patient or health care provider.

Do not use Snowden-Pencer electrodes in the presence of combustible/explosive gases.

To reduce capacitive coupling, the electrosurgical device should only be activated when in position to deliver energy to the target tissue. Activating the electrosurgical unit simultaneously with suction/irrigation may alter the path of the energy.

Start with the lowest possible power setting on the Electrosurgical Unit and gradually increase the power to achieve proper cutting and coagulation.

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Distributed by
CareFusion
1500 Waukegan Road
McGaw Park, IL 60085 U.S.A.
If there are any variations between these instructions and either your facility’s policies and/or your cleaning/sterilization equipment manufacturer’s instructions, those variations should be brought to the attention of the appropriate responsible hospital personnel for resolution before proceeding with cleaning and sterilizing your devices.

Use of device for a task other than that for which it is intended will usually result in a damaged or broken device.

**Examples:**
1. Use of a delicate dissector as a grasper.
2. Use of a delicate scissor to cut suture.
3. Use of a dissector to remove clips.
4. Use of a 5mm grasping or dissector instead of a 10mm claw extractor forceps to remove excised tissue through cannula.

Prior to use, inspect device to ensure proper function, insulation and condition. Do not use devices if they do not satisfactorily perform their intended function or have physical damage.

Inspect insulation. Any interruptions in the coating may compromise the safety of the device. To prevent the possibility of electrical shocks or burns, do not use devices with breaks in the insulation.

Avoid mechanical shock or overstressing the devices. Close distal ends prior to insertion or removal through cannulas.

Only the cleaning and sterilization processes which are defined within these instructions for use have been validated.

Proper care and maintenance of hand held laparoscopic instruments is essential for safe and effective operation. Prior to each use, instruments should be thoroughly examined for broken or worn parts that may inhibit the function. Specifically, instruments used for electrosurgery must be checked for nicks, cracks, or exposed metal on the shaft and handle insulation. Careful inspection upon receipt and frequent inspection during use for functional integrity is recommended as a safeguard against possible injury to patient or operator. Always use caution when inserting or removing devices through cannula.

Lateral pressure on the device during removal can damage the working tip, shaft of the device and/or insulation. Be sure the tips are closed and the device is pulled straight out until completely clear of cannula to avoid catching the valve assemblies in cannulas or dislodging the cannula.

Use only neutral pH (6-8) detergent solutions.

**Rated Voltage**

The maximum recurring peak voltage for electrosurgical devices applicable to this IFU is 2kV

**Pre-processing instructions**

Initiate cleaning of device within 2 hours of use.

Transport devices via the institutions established transport procedure.

Remove excess gross soil as soon as possible after use by rinsing or wiping the device.

All devices must be processed in the completely open position (i.e. flushports, jaws, etc.) to allow solution contact of all surfaces.

**Manual Cleaning**

1. Ensure all pre-processing instructions are followed prior to cleaning.
2. Prepare the enzymatic / neutral pH detergent, utilizing tap water entailing a temperature range of 27°C to 44°C, as per vendor’s directions.
3. Place device in the open/relaxed position and completely immerse the device in the pH-neutral/enzymatic detergent solution and allow device to soak for a minimum of 5 minutes. Actuate all movable parts during the initiation of the soak time.
4. Using a soft bristled brush, remove all visible soil from the device. Actuate device while brushing, paying particular attention to hinges, crevices and other difficult to clean areas. **Note:** It is recommended that enzymatic or neutral pH detergent solution should be changed when it becomes grossly contaminated (bloody and/or turbid).
5. For lumen devices, using a soft bristled brush, entailing a brush diameter length that is equivalent to lumen diameter and length, scrub the lumen (i.e. angulated/nonangulated positions) until no visible soil is detected regarding the lumen rinsing step below.
6. For lumen devices, place the device in the open/relaxed position with the distal tip pointed down and flush the device with a minimum of 50mL of pH-neutral/enzymatic detergent solution by using the flushing port located on the handle/shaft. Repeat the flush process a minimum of 2 times (i.e. total of 3 times) ensuring all fluid exiting the lumen is clear of soil.
7. For lumen devices, if visible soil is detected during the final lumen flush, re-perform brushing and flushing of the lumen.
8. Rinse the device by completely immersing in tap water with a temperature range of 27°C to 44°C, for a minimum of 30 seconds to remove any residual detergent or debris.
9. For lumen devices, following the rinsing step above, place the device into the open/relaxed position with the distal tip pointed down and flush the device with a minimum of 50mL of tap water, entailing a temperature range of 27°C to 44°C, by using the flushing port located on the handle/shaft. Repeat the flush process a minimum of 2 times (i.e. total of 3 times).
10. Drying: dry the device with a clean, lint-free towel.
11. For lumen devices, manipulate the device to allow rinse water to drain from the lumen.
12. Visually examine each instrument for cleanliness.
13. If visible soil remains, repeat cleaning procedure.

**Automated Cleaning**

1. Device must be cleaned in the completely open and disassembled (i.e. taken-apart) configuration. Note that applicable device disassembly should not require any mechanical tooling (i.e. screwdriver, pliers etc.) unless otherwise indicated.
2. Clean the laparoscopic devices via the Automatic cleaning parameters below.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Reconciliation time (minutes)</th>
<th>Water Temperature</th>
<th>Detergent Type and Concentration (If Applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-wash 1</td>
<td>00.15</td>
<td>Cold tap water 1°C - 16°C (33°F - 60°F)</td>
<td>N/A</td>
</tr>
<tr>
<td>Enzyme Wash</td>
<td>01.00</td>
<td>Hot tap water 43°C - 82°C (110°F - 179°F)</td>
<td>Detergent: EnzolTM (pH-neutral/enzymatic detergent)</td>
</tr>
<tr>
<td>Wash 1</td>
<td>02.00</td>
<td>Tap water 43°C - 82°C (110°F - 179°F)</td>
<td>Detergent: NP+KlenzR (pH-neutral cleanser)</td>
</tr>
<tr>
<td>Rinse 1</td>
<td>00.15</td>
<td>Tap water 43°C - 82°C (110°F - 179°F)</td>
<td>N/A</td>
</tr>
<tr>
<td>Pure Rinse</td>
<td>00.10</td>
<td>Purified water 43° C – 82° C (110° F – 179° F)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

3. Manipulate the device to allow rinse water to drain from the lumen.
4. If visible moisture is present dry the instrument with a clean, lint-free towel.
5. Visually examine each instrument for cleanliness.
6. If visible soil remains, repeat cleaning procedure.

**Inspection/Maintenance**

Proper care and handling is essential for satisfactory performance of any surgical device. The steps in these instructions for use should be taken to ensure long and trouble-free service from all your surgical devices. Inspect devices before each use for broken, cracked, tamished surfaces, movement of hinges, and chipped or worn parts. Specifically, instruments used for electrosurgery must be checked for nicks, cracks, or exposed metal on the shaft and handle insulation. Careful inspection upon receipt and frequent inspection during use for functional integrity is recommended as a safeguard against possible injury to patient or operator. If any of these conditions appear, do not use the device. Return device to authorized repair service center for repair or replacement.

Before sterilizing, lubricate the device with instrument milk or a steam permeable/water soluble lubricant, following the lubricant manufacturer’s instructions. Check for smooth action of all moving parts.

Let devices drip dry for (3) minutes before packaging for sterilization.