Component Familiarization

Components of the trocar sleeve. (Figure 1)
1 Spring cap
2 Color coding
3 Sheath tube
4 Sealing cap
5 Main part with seal
6 Housing
7 Cock plug
8 Stopcock with Luer Lock connection

Figure 1: Trocar sleeve with stainless steel, smooth sleeve.
Note: Trocar sleeve is available with different sheath tubes.

Catalog Numbers: All products covered by these instructions for use are listed in the appendix.

Caution: The instrument may only be used by qualified medical and technical specialist personnel. Federal (USA) law restricts this device to sale by or on the order of a physician or hospital.

Explanations of Symbols

WARNING: Indicates a danger which can result in death or serious injury if not avoided.
IMPORTANT: Indicates measures in order to prevent damage to property.
Refer to the BD Symbols Glossary for symbol definitions not listed above at www.bd.com/symbols-glossary.

General References/Precautionary Measures
Use this product only for the purposes described in these instructions. A non-sterile product must be prepared appropriately before first use and before each reuse. All products should be stored in a dry place and should not be exposed to extreme temperatures.

Possible Complications
• Infection
• Injury

Safety Instructions
Risk of Infection
• Prepare the instrument before use.
• Prepare before returning to the dealer.

Risk of Injury
• The instrument may only be used by qualified medical and technical specialist personnel.
• Only use original accessories.
• Do not use damaged instruments and do not repair.
• Remove from the packaging with care.
• Do not touch the sharp edges and tips.
• Do not place the instrument on the patient.

Assembly Instructions of Trocar Sleeve
1. Fit the seal and sealing cap. (Figure 2)

Figure 2
2. Screw the main part into the housing. (Figure 3)

![Figure 3](image1)

3. Screw on the sheath tube.
4. Insert the cock plug into the stopcock so that the pin is positioned in the intended space.
5. Screw the spring cap onto the cock plug. (Figure 4)

![Figure 4](image2)

Assembly Instructions of Incision Pick

Caution: Risk of cuts.
1. Carefully insert the tip. (Figure 5)

![Figure 5](image3)

2. Tighten the union nut. (Figure 6)

![Figure 6](image4)

Disassembly Instructions of Trocar Sleeve

1. Remove the sealing cap.
2. Remove the main part. (Figure 7)

![Figure 7](image5)
3. Remove the seal from the main part. (Figure 8)

4. Unscrew the sheath tube.
5. Unscrew the spring cap and cock plug. (Figure 9)

Disassembly Instructions of Incision Pick
1. Loosen and remove the nut. (Figure 10)

Caution: Risk of cuts!
2. Remove the tip carefully. (Figure 11)

Accessories and Spare Parts
The following parts can be ordered individually:
- Incision pick replacement blades
- Trocar sleeve bodies
- Obturators
- Sleeves
- Sealing caps
- Silicone valves
- Spring caps
- Stopcock valves

Indications For Use
The trocar sleeve is designed for use in minimally invasive surgery and, in particular, laparoscopy. It enables access to the operation site.
The incision pick is designed for use in minimally invasive surgery and, in particular, laparoscopy and arthroscopy.

Intended Use
The incision pick is a reusable surgically invasive device for temporary use. The instrument serves to create a body orifice at the surgical site.

Product Description
The trocar sleeve enables access to the site of the operation and allows various instruments to be inserted into the patient’s body. It features a cone-shaped seal which reduces gas loss upon removing the instrument.
The incision pick can be used to pierce the abdominal wall to enable access via a trocar sleeve.
Contraindications
This instrument is not designed for use on the central nervous and
circulatory systems.

Combination with Other Products/Instruments
Only use accessories with a technical design tailored to the instrument.

Instructions for Use
Before using the instrument, read and follow the Instructions for Use.
Keep in a place where they can be easily seen for reference at a later
date. The instruments should always be examined for correct assembly
and function, surface damage, tears, and bent or worn parts. Damaged
or defective instruments or individual parts may no longer be used.

The following procedure is recommended for the cleaning and
preparation of laparoscopic access devices.

Procedure: Automated or Manual Cleaning Process

Products:
Trocar Sleeves
Incision Picks
Introducer Sleeve

Limitations on Reprocessing
End of life is determined by wear and damage due to use. For additional
guidance, see the Inspection section of these instructions.

For all metal sheath tubes, the useful life of this product is \( \leq 1,000 \) cycles or \( \leq 2 \) years.

For all housing, the useful life of this product is \( \leq 400 \) cycles or
\( \leq 2 \) years.

For all puncture trocars, the useful life of this product is \( \leq 1,000 \) cycles
or \( \leq 5 \) years.

Cleaning – General Instructions

- All devices must be cleaned in the disassembled configuration.
- Note that disassembly should not involve the use of any mechanical
tooling (i.e. screwdriver, pliers, etc.).
- All ports shall remain in the fully open position.
- Devices may be cleaned by following either the Manual or Automatic
Cleaning Instructions.
- In the case of manual cleaning, the individual parts of the instruments
must be soaked in an active cleaning and disinfection solution.
- Observe the instructions of the disinfectant manufacturer. All surfaces,
including those of internal cavities, lumens and openings, must come into
contact with the solution.
- “Drinking water” refers to water which meets the specifications for Utility
Water listed in AAMI TIR34.
- “Treated water” refers to water which meets the specifications for Critical
Water listed in AAMI TIR34, and is extensively treated (for example by
deonization, distillation, or reverse osmosis) to ensure that
microorganisms and the inorganic and organic material are removed from
the water.

WARNING: Risk of infection due to insufficient reprocessing.
- Remove protective caps (if relevant).

IMPORTANT: Avoid damaging product.
- Do not use abrasive brushes or scourers.
- Only use the cleaning agents which are listed in the individual sections.
- With plastic instruments, avoid contact with hydrogen peroxide (H₂O₂).

WARNING: Risk of infection due to insufficient reprocessing.
- Special reprocessing requirements must be observed if there is a
suspection of prions and Creutzfeldt-Jakob disease.

Transportation
Store and transport the device safely to the cleaning area to avoid any
damage and contamination to the environment.

Pre-Processing Instructions

- To prevent surgical residue from drying on, initiate decontamination and
pre-cleaning directly after surgery.
- Rinse the instrument, remove coarse dirt and rinse out the cavities with
cold water.

Note: If it is not possible to rinse with cold water, the instrument must
be wrapped in a moist cloth to prevent any residues from drying on.

Tip: Remove caked-on tissue residues with a plastic brush.
- Immerse the instrument in a cold water bath with 0.8% cleaning solution
for at least 5 minutes.
- Brush the instrument under cold water until all visible signs of soiling
have been removed.
- Dismantle the instrument and open stop cock.
Warning: Risk of infection and pyrogenicity from residues if unsuitable cleaning agents are used.

- Do not use fixing agents.
- Do not rinse with hot water.

**Important:** Avoid damaging the product.

- Do not use abrasive brushes or scourers.
- Only use the cleaning agents which are listed in this section.
- Use disinfectant with corrosion protection.

### Manual Cleaning: Enzymatic/Neutral pH Detergent

1. Ensure all pre-processing and disassembly instructions are followed prior to cleaning.
2. Place the instrument in cold drinking water for at least 10 minutes.
3. Brush the instrument under cold drinking water until all visible signs of soiling have been removed.
4. Rinse out cavities, drill holes and threads with a cleaning gun with cold drinking water for at least 20 seconds at 3-5 bar.
5. Clean the components in an ultrasonic bath with 0.8% cleaning agent at 40-45°C (104-113°F), 35 kHz for 10-15 minutes.
6. Turn and move the components several times during cleaning in the ultrasonic bath.
7. Rinse out cavities, drill holes and threads with a cleaning gun with cold drinking water for at least 20 seconds at 3-5 bar.
8. Immerse the instrument in deionized water and rinse through the cavities several times with deionized water.

**Note:** Also clean the inner chambers of the instrument below water using a clean brush.

9. Dry on the inside and outside for at least 10 minutes at 50-100°C (122-212°F) and/or blow through with sterile compressed air.
10. Disinfect with a pH 10.5 disinfectant for at least 10 minutes.

### Automatic Cleaning: Enzymatic/Neutral pH Detergent

1. Ensure all pre-processing and disassembly instructions are followed prior to cleaning.
2. Immerse the instrument in an ultrasonic bath at 40-45°C (104-113°F), 35-45 kHz for 10-15 minutes. Turn and move the components several times during cleaning.
3. Clean all components using the automatic cleaning parameters below.
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 the cleaning procedure until the device is thoroughly clean.

<table>
<thead>
<tr>
<th>PHASE</th>
<th>MINIMUM RECIRCULATION TIME</th>
<th>WATER TEMPERATURE</th>
<th>DETERGENT TYPE AND CONCENTRATION (IF APPLICABLE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Wash</td>
<td>1 Minute</td>
<td>Cold Drinking Water 1°C - 25°C (33°F - 77°F)</td>
<td>N/A</td>
</tr>
<tr>
<td>Pre-Wash</td>
<td>3 Minutes</td>
<td>Cold Drinking Water 1°C - 25°C (33°F - 77°F)</td>
<td>N/A</td>
</tr>
</tbody>
</table>
| Wash        | 5 Minutes                 | 45°C (113°F)      | Detergent: pH-neutral/enzymatic
Concentration: Per the detergent manufacturer’s recommendations |
| Rinse       | 3 Minutes                 | Hot Treated Water 43°C - 82°C (110°F - 179°F) | N/A                                             |
| Rinse       | 2 Minutes                 | Hot Treated Water 43°C - 82°C (110°F - 179°F) | N/A                                             |
| Automatic Disinfection | Completely desalinated water, the thermal disinfection is carried out at temperatures >65°C and corresponding application time according to the A0 concept. DIN EN ISO 15883 (e.g. A0 3000 = 90°C and 5 minutes application time). The operator is responsible for the implemented A0 value. **Note:** 95°C is the maximum temperature to be utilized during this step. |
Automated Cleaning: Alkaline Detergents

1. Ensure all pre-processing and disassembly instructions are followed prior to cleaning.
2. Immerse the instrument in an ultrasonic bath at 40-45°C (104-113°F), 35-45 kHz for 10-15 minutes. Turn and move the components several times during cleaning.
3. Clean all components using the automatic cleaning parameters below:

<table>
<thead>
<tr>
<th>PHASE</th>
<th>MINIMUM RECIRCULATION TIME</th>
<th>WATER TEMPERATURE</th>
<th>DETERGENT TYPE AND CONCENTRATION (IF APPLICABLE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Wash</td>
<td>1 Minute</td>
<td>Cold Drinking Water</td>
<td>N/A</td>
</tr>
<tr>
<td>Pre-Wash</td>
<td>3 Minutes</td>
<td>Cold Drinking Water</td>
<td>N/A</td>
</tr>
<tr>
<td>Wash</td>
<td>5 Minutes</td>
<td>55°C (131°F)</td>
<td>Detergent: Alkaline</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Concentration: Per the detergent manufacturer’s recommendations</td>
</tr>
<tr>
<td>Neutralization</td>
<td>3 Minutes</td>
<td>Hot Treated Water</td>
<td>N/A</td>
</tr>
<tr>
<td>Rinse</td>
<td>2 Minutes</td>
<td>Hot Treated Water</td>
<td>N/A</td>
</tr>
<tr>
<td>Automatic Disinfection</td>
<td>Completely desalinated water, the thermal disinfection is carried out at temperatures &gt;65°C and corresponding application time according to the A0 concept, DIN EN ISO 15883 (e.g. A0 3000 = 90°C and 5 minutes application time). The operator is responsible for the implemented A0 value. Note: 95°C is the maximum temperature to be utilized during this step.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Drying
Automated Drying: Dry the outer surfaces of the instruments in the drying cycle of your washer-disinfector for 15-25 minutes at 90-110°C (194-230°F). Remove the product immediately at the end of the cycle. If necessary, also blow through the product with sterile compressed air until it is completely dry. If needed, additional manual drying can be performed using a lint-free towel.

Inspection
Proper care and handling is essential for satisfactory performance of any surgical device. The previously listed cautions should be taken to ensure long and trouble-free service. All devices must be examined for full functionality prior to and after use. Moving parts of the device should be easily operable. Inspect devices for broken, cracked, discolored, or tarnished surfaces. Inspect for hindered movement of hinges, loose components, and chipped or worn parts. Inspect insulation for breaks or damage. If any of these conditions appear, do not use the device. Return devices to an authorized V. Mueller representative for repair or replacement.

When disposing of or returning devices, products may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and all applicable local, state, federal, or country laws and regulations.

The right care of instruments will lengthen their service life and should therefore be carried out after every cleaning process.

**WARNING:** Risk of injury from faulty or damaged components
- Do not use damaged instruments and do not repair.
- Check to ensure they are clean and, if necessary, repeat cleaning.
- Check for damage (e.g., sharp edges, rough surfaces).
- Replace brittle and cracked seals (if relevant).
- Lubricate moving parts (e.g., joints, rotating stop cocks) with medical oil.
- Remove any excess oil.
- Assemble instruments (if possible) and check to ensure they are in perfect working order.

Packaging
The instrument must be packed appropriately prior to sterilization to ensure that the sterile barrier remains intact after removal from the sterilizer. Package the instrument to comply with ISO 11607 and EN 888.

Sterilization
General Instructions
**IMPORTANT:** Avoid damaging product.
- Observe the device’s maximum load.
WARNING: Risk of infection due to insufficient reprocessing.

- Special reprocessing requirements must be observed if there is a suspicion of prions and Creutzfeldt-Jakob disease.
- Sterilization is performed with the instrument assembled.
- Open stop cocks and place in sterilization device so that the components are not touching each other and the steam can circulate freely.

**Sterilization and Packaging for US Market**

**Packaging**

Use FDA-cleared sterilization wrap or sterilization container.

- Use in accordance with packaging manufacturer's sterilization instructions while being sure to protect jaws and cutting edges from damage.
- Device configuration must meet the requirements of the packaging system.
- Sterilization wrap material must be cleared for the applicable sterilization modality by your country's regulatory body.
- When utilizing a sterilization container, refer to container IFU for additional reprocessing instructions.

**Prevacuum Steam Sterilization Parameters**

- Sterilization Configuration: Wrapped (2-layer 1-ply or 1-layer 2-ply) or containerized
- Temperature: 132°C (270°F)
- Exposure Time: 4 minutes
- Minimum Dry Time: 30 minutes

**Sterilization and Packaging for Outside United States Market**

**Packaging**

Wrap the instruments in the appropriate sterilization wrap according to ISO 11607 and EN 868 and facility guidelines.

- Sterilization Configuration: Wrapped (2-layer 1-ply or 1-layer 2-ply) or containerized

**Prevacuum Steam Sterilization Parameters**

- Minimum Preconditioning Pulses: 3
- Temperature: 134°C (273°F) - 137°C (278°F) at 3 bar, 44psi
- Exposure Time: 4 minutes
- Minimum Dry Time: 30 minutes

**Note:** France and Switzerland require sterilization for at least 18 minutes.

**Storage**

To avoid reducing durability and forfeiting any resistance to bacteria, the following storage conditions must be observed:

- Store the sterile device in a clean, dust-free and dry sterile container.
- Protect from direct light.
- Store the sterile container in a clean and dry environment with controlled humidity at room temperature.
- Do not store the sterile container in the vicinity of aggressive substances (e.g., alcohols, acids, bases, solvents and disinfectants).

**Note:** Also observe your internal storage standards for sterile devices.

**Disposal**

Environmentally sound disposal enables valuable raw materials to be recycled.

Dispose of the product in an environmentally friendly manner in accordance with the valid hospital guidelines.

**Additional Instructions**

Any deviation from the validated parameters must be validated by the user. It is the duty of the user to ensure that user facility cleaning and sterilization procedures, resources, materials, equipment and personnel are adequate and capable of achieving the required results. State-of-the-art and national legal guidelines require these procedures, resources, materials, equipment and personnel qualifications to be properly and regularly validated and maintained.
To learn more about US sterilization practices and what is required of manufacturers and end users, visit:
- www.aami.org
- www.aorn.org
- www.iso.org

Further EU References for the Cleaning, Disinfection and Sterilization of Medical Devices
- Internet: http://www.a-k-i.org
- Hygienic requirements for the preparation of medical devices - recommendation of the commission for hospital hygiene and infection prevention of the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) regarding the "hygiene requirements for the preparation of medical devices." 6

Warranty
All Snowden-Pencer instruments are protected by a full service 1 year warranty and lifetime warranty against manufacturer defects. Damage caused to the instrument by overstress, mechanical shock, improper processing, or repair by a party other than Snowden-Pencer is not covered. Repair, alteration or modification of any product by persons other than Snowden-Pencer, or products subjected to misuse or abuse will result in immediate loss of warranty. If Snowden-Pencer instruments are damaged by accident or when used for a purpose other than originally intended, a repair charge will apply.

Repair Service

⚠️ WARNING: Risk of injury from improper repairs.
- Only allow repairs to be performed by the manufacturer or by persons authorized by the manufacturer.

⚠️ WARNING: Risk of infection from non-sterile instruments.
- Reprocess the instrument before returning it to the dealer.

All instrument repairs must be returned to an authorized Snowden-Pencer representative, to the address below or to an authorized representative for international repairs. If the repair is covered under warranty, it will be repaired or replaced at no charge when requested in writing. A nominal service charge will be made for repaired instruments outside the warranty.

Note: All instruments being returned for maintenance, repair, etc. must be cleaned and sterilized per these instructions prior to shipment. Send the instrument back to the dealer in a reprocessed state and in its original packaging.

Contact Information:
BD Customer Service
800-323-9088
For email inquiries: Customer_Support@BD.com
www.bd.com
For customers outside of the USA, please contact your local distributor.

Appendix
All product codes covered by this instruction for use are listed in the following tables.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>IP20</th>
<th>IP10</th>
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