Prestige Endoscopic Graspers
Instructions for Use

DESCRIPTION

The Prestige Endoscopic Graspers are designed to grasp soft tissue during endoscopic procedures. The graspers are designed to be used through a cannula, or port, commonly called a trocar sleeve. The graspers are delicate surgical instruments. Any use of an instrument for a task other than its intended purpose will result in a damaged or broken instrument. Surgeons and surgical staff involved in the use of this product should be fully trained in endoscopic surgery by an accredited institution prior to the use of these instruments.

Please read these Instructions for Use prior to using the product.

MATERIAL

- Stainless Steel
- Teflon Plastic
- Acetal Plastic

INDICATIONS

The Aesculap Prestige Endoscopic Graspers are indicated for general endoscopic surgery at the discretion of the practicing surgeon.

CONTRAINDICATIONS

The use of the Aesculap Prestige Endoscopic Graspers is contraindicated when, in the judgment of the physician, their use would be contrary to the best interest of the patient.

PRECAUTIONS & WARNINGS

Wear appropriate protective gloves, eyewear and clothing when handling biologically contaminated instruments. Instruments manufactured from different metals should be processed separately to avoid electrolytic action between the different metals.

If this device is/was used in a patient with, or suspected of having Creutzfeld Jakob Disease (CJD), the device cannot be reused and must be destroyed due to the inability to reprocess or sterilize to eliminate the risk of cross-contamination.

1. WARNINGS

| WARNING! | Inadvertent contact with an activated electrosurgical device may result in injury to the patient or surgeon. |
| WARNING! | Tissue graspers are intended to grasp and hold soft tissues. Using it for any other purpose can cause damage to the instrument, patient, or surgeon |
| WARNING! | Clean, sterilize, and dry product before each use to prevent cross-contamination and / or bacterial infection. |
2. CAUTIONS

| CAUTION! | • The Prestige Endoscopic Instruments are not electrical instruments. Do not perform electrical testing on the instrument or the Kynar coating may be damaged. |
| CAUTION! | • Instruments must be handled carefully during surgery and cleaning, misuse will result in damage to the instrument. |
| CAUTION! | • Use extreme care when inserting or removing endoscopic instruments through a cannula. During insertion, make sure the cannula “trap door” or trumpet valve is fully opened to allow passage of the instrument. During removal, pull the instrument straight out until it is completely clear of the cannula. Make sure the instrument does not catch on either the “trap door” or trumpet valve. Lateral pressure on the instrument when inserting or removing it may damage the shaft or the working tip. |
| CAUTION! | • Endoscopic instruments should always be opened under direct visualization. Opening an instrument inside the cannula can cause damage to the instrument and should be avoided. |
| CAUTION! | • Only manually clean the Prestige Endoscopic Grasper according to the instruction found in the CLEANING section of these Instructions for Use. Machine washing the device can lead to damage to the instrument. |

SLIDE LOCK MECHANISM

To engage the sliding lock on the Aesculap Prestige Endoscopic Graspers, close the handle and slide the trigger lock in the direction of the arrow shown in Figure 1 until you feel noticeable resistance. To release the lock, compress the handle and slide the trigger lock in the direction opposite of the arrow.

![Figure 1](image)

HOW SUPPLIED

Aesculap Prestige Endoscopic Graspers are provided non-sterile, packaged one per box. Each instrument must be sterilized before use according to the procedures described in the Sterilization section of this Instructions for Use document.

CARE AND HANDLING

The procedures outlined below should be followed to ensure safe handling of biologically contaminated surgical instruments. All instruments must be sterilized before use.
1. **PRE-CLEANING**
   
   a. Open jaws of hinged instruments for cleaning, giving special attention to joints and serrations.
   
   b. Rinse each instrument completely using deionized water to remove debris. Wash the instrument using a neutral pH instrument detergent or enzymatic instrument cleaner.
   
   c. Avoid processing instruments of different metallic composition together. Separate sharps and delicate surgical instruments.

2. **CLEANING**

   - Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood, or other body fluids. Do not exceed two hours soaking in any solution.
   
   - Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

   a. **Manual Cleaning**

   Hand wash using a low-sudsing protein dissolving detergent and either a soft nylon brush or wipe. Follow the detergent manufacturers’ directions regarding concentration, temperature, contact time and reuse.

   Use a 10 mL syringe or pulsating water jet to thoroughly flush all channels and lumens with cleaning solution to remove debris. See Figures 2 and 3.

   ![Figure 2](image1)

   ![Figure 3](image2)

   Totally immerse instruments during cleaning to prevent aerosolization. Force solution into all areas and cavities, including the flush port.
b. **Rinsing**

Rinse all instrument thoroughly with tap water, deionized, or distilled water to remove all traces of debris and cleansing agents. Make sure all internal lumens and shafts are thoroughly rinsed.

3. **DECONTAMINATION**

**Note:** The decontamination procedure does not sterilize the instruments. Refer to and process the instruments as outlined in the **STERILIZATION** section.

Select a high-level disinfection product such as the glutaraldehyde-family of disinfectant products. Follow the cleaning agent’s recommended directions regarding concentration, temperature, contact time and solution reuse.

Do not use high acid (pH 4 or lower) or high alkaline (pH 10 or higher) products for disinfection, such as bleach and bi-chloride of mercury. Use of these products may damage the instrument.

Completely immerse instruments in disinfecting solution including all lumens and shafts. Force solution into all areas and cavities, including the flush port.

Thoroughly rinse with distilled water to remove all traces of disinfection solutions. **USE STERILE WATER ON THE FINAL RINSE.**

4. **DRYING**

Instruments must be thoroughly dried and all residual moisture must be removed before they are stored. Moisture that is not removed may cause corrosion in the instrument. Use a soft, absorbent towel/cloth to dry external surfaces. Compressed air may be used to aid the drying process.

5. **INSPECTION**

**Note:** This inspection should be done just prior to sterilization. Inspect all instrument surfaces and individual parts for:

- Cleanliness of instruments, i.e. no debris, blood, tissue, etc. If not fully clean, repeat previous cleaning steps or properly dispose of the instruments.
- Breaks in instrument shaft coating
- Burrs or nicks
- Jaw misalignment or bent parts
- Jaw function: operate the instrument by normally opening and closing the handle. The jaw should move in unison with the handle action. Hold the jaws closed with one hand as shown in Figure 4, then attempt to open the handle with your other hand using normal force. The handle should not move freely with the jaws held shut.

![Figure 4](image)

**Note:** If the instrument has any of the above conditions, do not use it. It should be set aside and sent for refurbishing or repair.
6. TESTING INTEGRITY OF O-RING

Aesculap Prestige Endoscopic Graspers contain an O-ring to prevent CO₂ from escaping during an endoscopic procedure. See Figure 5 for diagram.

- Push a section of the ¼-inch internal diameter silicone tubing over the instrument jaw until the tubing is touching the black insulation on the shaft.
- Place the entire handle of the instrument in a container of clean deionized water.
- Make sure the jaw of the instrument is positioned upward.
- Attach either wall compressed air or a 100 mL syringe to the free end of the silicone tubing.
  - If using compressed air: limit the pressure to 2 psi for less than 30 seconds. (Normal insufflations pressures usually do not exceed 1 psi).
  - Alternatively, a 10 mL syringe may be used to pressurize the proper and tubing with air.
- Check the container for bubbles. If a steady stream of bubbles is observed while the air pressure is applied, the O-ring is leaking and the instrument should be returned for refurbishing or repair.

![Figure 5](image)

7. LUBRICATION

Lubrication is essential every time instruments are processed. Special attention should be given to lubrication of joints, boxlocks, and movable parts. Only lubricate dry instruments.

Do not use mineral oil, petroleum, or silicone-based products. To lubricate boxlocks and joints, use a non-silicone, water-soluble lubricant prior to sterilization such as Aesculap Instrument Oil, JG598.

Close instrument with a ratchet lock in the first ratchet position before sterilization to avoid temperature-induced stress cracks in the joints.

STERILIZATION

Aesculap does not recommend the instruments be sterilized by flash or chemical sterilization.

The recommended sterilization parameters are as follows:

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Temperature</th>
<th>STERILCONTAINER™ System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Vacuum</td>
<td>270°F</td>
<td>Variable</td>
</tr>
<tr>
<td></td>
<td>132°C</td>
<td></td>
</tr>
</tbody>
</table>

Aesculap has validated the above sterilization cycle and has the data on file. The validation was accomplished in an Aesculap Sterilcontainer cleared by the FDA in K792558 or K112671 for the sterilization and storage of these instruments. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques. Use an FDA cleared accessory to maintain sterility after processing, such as a wrap, pouch, etc.
STORAGE

Aesculap Prestige Endoscopic Graspers should be dried as well as possible before storing and must be handled with care to prevent damage. Store sterile products in sterile barrier packaging, protected from dust, in a dry, dark, room temperature-controlled area.

DISPOSAL

Dispose of the Prestige Endoscopic Graspers according to the hospital's instrument and/or biohazardous materials disposal policies.

WARRANTY

Every product bearing the Aesculap name is guaranteed to be free of defects in workmanship and materials when used normally for its intended surgical purpose. Any Aesculap product delivered from Aesculap, Inc. proving to be defective will be replaced or repaired, at Aesculap's discretion, at no charge to the customer.

These warranties shall not apply to conditions or defects resulting from, but not limited to: negligence, improper use, improper cleaning and handling, improper opening techniques, unauthorized repair work, caustic or abrasive cleaners, or items modified or customized by the customer at the customer's request.

The above warranties exclude: instrument coating or refurbishment due to normal wear and tear, and apply only to the original buyer and are in lieu of all other warranties either expressed or implied.

MAINTENANCE AND REPAIR

If your Aesculap instruments require repair or maintenance, return the instruments in the Aesculap Instrument Repair (A.I.R.) box or other sturdy box with adequate foam, bubbles, or other packaging material to protect the instruments. Send the packaged instruments to:

    ATTN: Aesculap Technical Services
    Aesculap Implant Systems, LLC.
    615 Lambert Point Dr
    Hazelwood, MO 63042
    Aesculap Repair Hotline
    Phone: (800) 214-3392
    Fax: (314) 895-4420

Instruments returned to Aesculap for repair must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

Products repaired by Aesculap are guaranteed for 90 days to be free of defects in workmanship and parts when used normally for its intended surgical purpose. Any workmanship or parts proving to be defective will be replaced or repaired, at Aesculap’s discretion, at no charge to the customer.

Contact your local Aesculap representative if you have any questions.