AESCULAP ELECTROSURGICAL COAGULATING FORCEPS AND CORDS
Instructions for Use

PRODUCT DESCRIPTION

Electrosurgical Bipolar Forceps
Aesculap’s bipolar forceps are available with two different styles of connections
1. flat prong (GK prefix material number)
2. round pin (US prefix material number)
Aesculap’s bipolar forceps are available in a variety of sizes and styles, and with or without irrigation and insulation and are compatible to Aesculap and other USA manufactured Bipolar Generator Units

Electrosurgical Bipolar Cords
Aesculap US349SP – Disposable Dual Bipolar Cord (no irrigation) is compatible with the following:
1. All Aesculap flat prong, non-irrigating bipolar forceps
2. All Aesculap and most USA manufacturer’s round pin, non-irrigating forceps
3. Aesculap and most USA manufactured Bipolar Generator Units

Aesculap GK200 – Reusable Bipolar Cord (no irrigation) is compatible with the following:
1. All Aesculap flat prong, non-irrigating bipolar forceps
2. Aesculap and most USA manufactured Bipolar Generator Units

Aesculap US351 – Reusable Bipolar Cord (no irrigation) is compatible with the following:
1. All Aesculap and most USA manufacturer’s round pin, non-irrigating forceps
2. Aesculap and most USA manufactured Bipolar Generator Units

Aesculap US352 – Disposable Bipolar Irrigation Cord is compatible with the following:
1. All Aesculap flat prong, irrigating bipolar forceps
2. All Aesculap and most USA manufacturer’s round pin, irrigating bipolar forceps
3. Aesculap and most USA manufactured Irrigation Units

Aesculap US353 – Disposable Bipolar Irrigation Cord is compatible with the following:
1. All Aesculap and other USA manufacturer’s round pin, irrigating bipolar forceps
2. Aesculap and most USA manufactured Irrigation Units

Aesculap US355 – Disposable Bipolar Irrigation Cord is compatible with the following:
1. All Aesculap flat prong, irrigating bipolar forceps
2. All Aesculap and most USA manufacturer’s round pin, irrigating bipolar forceps
3. Codman Irrigation Unit 1000 Only

Aesculap US356 – Disposable Bipolar Irrigation Cord is compatible with the following:
1. All Aesculap and most USA manufacturer’s round pin, irrigating bipolar forceps
2. Codman Irrigation Unit 1000 Only

Aesculap GK210 – Reusable Bipolar Cord (no irrigation) is compatible with the following:
1. All Aesculap GK style with round pin, non-irrigating bipolar forceps
2. Aesculap and most USA manufactured Bipolar Generator Units

Aesculap US400 – Reusable Bipolar Cord (no irrigation) and
Aesculap GK215 – Reusable Bipolar Cord (no irrigation) are compatible with the following:
1. Aesculap bipolar forceps GK560R and GK580R
2. Aesculap and most USA manufactured Bipolar Generator Units

Electrosurgical Monopolar Cables
Aesculap GK245 Reusable Monopolar Cable, 4 mm, 12 feet
Aesculap GK246 Reusable Monopolar Cable, with large Pin, 12 feet
Aesculap US354 Reusable Monopolar Cable, with large pin, 12 feet

INDICATIONS FOR USE
Aesculap's electrosurgical coagulating forceps are intended for use in cauterizing tissue during surgical procedures. Aesculap's electrosurgical cords are designed to bring electric power from the electrosurgical generator to the electrosurgical instrument. The use of bipolar forceps or cords for tasks other than those for which they are indicated will usually result in damaged or broken instruments. Surgeons and surgical staff involved in the use of this product should be fully trained in use of electrosurgical devices prior to use. Please read these instructions prior to use.
CONTRAINDICATIONS
The use of electrosurgical instruments is contraindicated when, in the judgment of the physician, their use would be contrary to the best interest of the patient.

ELECTROSURGERY PRECAUTIONS
Refer to your electrosurgical system operator’s manual for proper use and set-up. Ensure that all manufacturer’s precautions have been observed. The inspection, handling and use of electrosurgical devices is the responsibility of the user.

Warnings:
1. Uninsulated forceps are intended only for use in low power electrosurgical procedures. The insulated forceps may be used for all electrosurgical procedures.
2. Do not perform electrosurgery in the presence of flammable anesthetics or other flammable gases, near flammable fluids or objects, or in the presence of oxidizing agents, as fire could result.
3. When using instruments in electrosurgery, keep the voltage/power as low as possible to achieve the desired effect. The user should only activate the device when it is in contact with the target tissue or is in a position to deliver energy to target tissue by fulguration.
4. Place active electrodes in a non-conductive dedicated instrument holder or in a clean, dry, non-conductive area away from the patient when not in use. Inadvertent contact with the patient may result in burns. Contact with drapes may cause a fire.

PREPARATION AND USE
1. Attach an electrosurgical cord to the connector end of the forceps until the cord receptacle sleeve connects securely against the connector cup on the forceps. (When using an irrigation forceps connect tubing to back end of the forceps, use luer adapter if necessary)
2. Connect the end of the cord to the electrosurgical coagulation unit. (When using an irrigation forceps connect tubing to generator and prime it according to generators manual.)
3. Connect accessories to electrosurgical generators only while the system is “off”. Failure to observe this precaution or handling of these connections while the system is activated may result in injury or electrical shock to the patient or operating room personnel.

HOW SUPPLIED
1. Disposable Electrosurgical Cords are sterile and designed for single use only. DO NOT RESTERILIZE.
2. Reusable Electrosurgical Cords and Electrosurgical Forceps are provided non-sterile and must be cleaned and sterilized prior to use according to the directions outlined below.

CARE AND HANDLING
The procedures outlined below should be followed to ensure safe handling of biologically contaminated instruments.

PRE-CLEANING
1. Keep forceps moist and do not allow blood and/or body fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.
2. Using a steady stream of lukewarm/cool water, rinse each forceps thoroughly to remove gross debris.

CLEANING
Forforceps
1. Hand wash using a low-sudsing, neutral pH (pH 7-9), protein dissolving detergent. Follow manufacturers' directions regarding concentration, temperature, and contact time.
2. Totally immerse instruments during cleaning to prevent aerosolization. Do not exceed two hours soaking in ANY solution.
3. Do not soak forceps in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids.
4. Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents. Use of anything other than high quality brushes designed for instrument cleaning may result in damage to the instrument.
5. Flush irrigation channels with demineralised water, use stylus to remove clogs if necessary.

Reusable Cords
6. Gross organic contaminates should be removed with a damp cloth or soft bristle brush and gentle cleaning detergent. Excess detergent may be wiped off with a clean, damp cloth.
7. Cords should never be immersed in cleaning or rinsing solutions, or placed in an ultrasonic cleaning device. Rinse and dry the cords before sterilization.
8. Proceed to “Testing/Preparation for Sterilization” Section.

DECONTAMINATION / DISINFECTION
1. Select a high-level disinfectant. 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.

RINSING / DRYING
1. Thoroughly rinse forceps with distilled water to remove all traces of disinfecting solution. USE STERILE WATER ON THE FINAL RINSE.
2. Instrument must be thoroughly dried to remove residual moisture before they are stored.
3. Use a soft, absorbent towel/cloth to dry external surfaces.
4. Use compressed air or a 70% alcohol rinse to aid the drying process.

TESTING / PREPARATION FOR STERILIZATION
1. WARNING: Use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.
2. Instruments should be inspected and prepared for sterilization following the disinfection process.
3. Visually inspect the instruments and cords. Check for nicks, misalignment, burrs or bent tips. Examine insulated instruments and cords for integrity; observe for cuts, gouges or any exposed metal.
4. Mechanically test the working parts to verify that each instrument functions correctly.
5. Wrap each pair of forceps separately or place in a container to prevent the forceps from contacting each other or other instruments.
1. Sterilization of electrosurgical forceps and reusable cords may be accomplished by steam or ethylene oxide (EtO) gas.

2. Aesculap does not recommend the electrosurgical forceps or cords be sterilized by “Flash” or Chemical Sterilization.

3. Surgical instruments may also be placed within an Aesculap rigid sterilization container (STERILCONTAINER™) for processing under generally accepted hospital in-use conditions.

4. The stylus for irrigation forceps should not be placed in the forceps but can be autoclaved separately.

The recommended sterilization parameters are as follows:

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Temp.:</th>
<th>Min. Ex. Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Wrapped</td>
<td>In a STERILCONTAINER™ System</td>
</tr>
<tr>
<td>PRE-VACUUM</td>
<td>270°-275°F</td>
<td>4 minutes</td>
</tr>
<tr>
<td>GRAVITY</td>
<td>250°-254°F</td>
<td>15 minutes</td>
</tr>
<tr>
<td></td>
<td>270°-275°F</td>
<td>10 minutes</td>
</tr>
<tr>
<td>ETHYLENE OXIDE (EtO)</td>
<td>125°-130°F</td>
<td>105 minutes with 12%EO-88% FREON;</td>
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</tbody>
</table>

STORAGE

1. Aesculap’s electrosurgical forceps must be completely dry before storing and must be handled with care to prevent damage. Take precautions to prevent tip breakage.

2. Instruments should be stored in areas which provide protection from extremes of temperature and humidity.

3. Store forceps in sterilization trays or the plastic shipping tube to prevent damage to the instrument.

WARRANTY

1. Aesculap Electrosurgical Coagulating Forceps and Cords are guaranteed to be free of functional defects in workmanship and materials when used normally for their intended surgical purpose and life. Care must be taken in the use and reprocessing of this product.

2. Any Aesculap brand instrument delivery from Aesculap, Inc. proving to be defective will be replaced or repaired, at Aesculap’s discretion, at no charge.

3. Repair of the product may be necessary after repeated use, or if damage occurs in handling or reprocessing. Contact Aesculap, Inc., Repair Services.

MAINTENANCE AND REPAIR

1. Repair of the instruments by parties other than Aesculap will void the warranty.

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

3. Send your bipolar instruments for repair to:
   Aesculap, Inc.
   615 Lambert Pointe Drive
   Hazelwood, MO 63042
   Attn.: REPAIR SERVICES
   or call the Repair Hotline at 1-800-214-3392

4. 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.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.