AEM® Cord

Instructions For Use/Care

ENCISION®

℞ ONLY (LATEX)

ENCISION recommends placing this document in the Instructions for Use/Care Section of your AEM® Monitor Operator/Service Manual.

Device Description

AEM Cord - Reposable

The **ES4007** AEM Cord connects the AEM Laparoscopic Instrument to the AEM Monitor and electrosurgical generator, by means of the ES9005 Cord Adapter.

The cord contains, in an insulated jacket, the conductors for the active ESU current and AEM shielding and monitoring circuit.

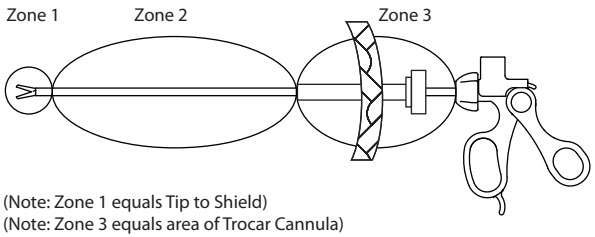
NOTE

- This product is rated to 9000 Vp-p. Limit electrosurgical generator power setting to 80 Watts or lower (60 Watts for the Conmed Aspen Excalibur spray mode). Higher settings may result in spurious insulation failure alarms and/or insulation breakdown. See Encision AEM Monitor Operator/Service Manual for list of compatible electrosurgical generators.
- This instrument has been validated for 25 typical cycles (including sterilization and use). The actual number of uses may vary depending on usage conditions. Discard if any End of Life Indicators are present.
- This product is supplied non-sterile and must be sterilized prior to use.

Use with Monopolar Electrosurgery

AEM instruments, in conjunction with an AEM Monitor properly connected to the electrosurgical generator (ESU), continuously monitor and dynamically manage "stray energy" (insulation failure and capacitive coupling) in zones 2 & 3, which are likely out of the surgeon's field of view.

AEM shielding does not cover zone 1, which the surgeon should keep in view during instrument activation. As in all applications, "misapplied" electrosurgical energy remains the responsibility of the attending surgeon.



(Note: Zone 1 equals Tip to Shield)
(Note: Zone 3 equals area of Trocar Cannula)

Laparoscopic procedures should be performed only by surgeons having adequate training and familiarity with laparoscopic techniques and who are also knowledgeable about anatomy and pathology as well as the complications, hazards, risks and benefits of the procedure.

Indications/Intended Use

These AEM instruments incorporate the use of AEM technology and are intended for use in delivering monopolar electrosurgical energy during laparoscopic procedures only.

AEM instruments are intended for use with the AEM Monitoring System and electrosurgical generators having compatibility with the AEM Monitor.

Contraindications

These instruments are not intended for use when laparoscopic electrosurgical techniques are contraindicated.

Instructions For Use

Prior to Use

Thoroughly read these instructions and the instructions in the AEM Monitor Operator/Service Manual.

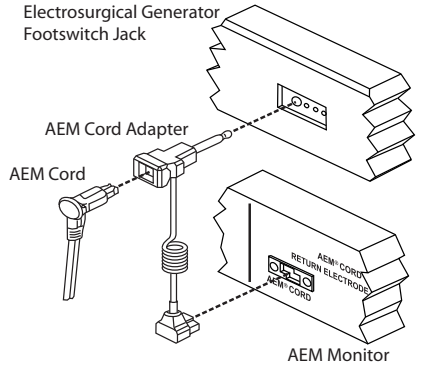
Reusable components are supplied non-sterile. Refer to Reprocessing Instructions prior to use.

Visually inspect cord for any potential issues. See End of Life Indicators.

AEM System Setup

See laminated Setup Sheet (00701) when using the ES9005 series AEM Cord Adapter and (02678) when using the ES9015 Universal Adapter.

Connect one end of the cord to the laparoscopic instrument. Connect the other end of the cord to the ES9005 Cord Adapter, which connects the electrosurgical generator and the AEM Monitor together for use with the cord. Electrically inspect cord for potential issues. See End of Life Indicators.



CAUTION

- Always fully connect AEM cord to instrument and adapter. Partial connections may cause arcing, which will damage the product.

WARNING

- Pulling or tugging cords can result in breaking of internal conductors, causing intermittent alarms or sparking and burning of insulation during use. The AEM Monitor is not designed to detect or prevent an arc in the event of a broken active wire.
- Damage to connector body and/or insulation may result in shock or fire hazard.
- Keep electrical connections dry while in use to prevent potential conduction of HF current to the user.
- Damaged external insulation AND incorrect setup of the AEM Monitor may result in a risk of unintended patient burn, shock or fire hazard. Do not use product having damaged insulation.

CAUTION

- Good operating room practice suggests that connections of accessories to electrosurgical generators be made only while the generator is OFF or on Standby.
- Use these instruments only in conditions that assure adequate visualization to minimize risk of misapplied electrosurgical energy.
- Keep ESU power setting as low as possible for the intended purpose to minimize unintended burns.
- Damaged internal insulation of the cord and/or instrument, or loss of shield continuity, may cause ESU return pad alarms triggered by the AEM Monitor's Fault Indicators. For maximum patient safety, discontinue use of the instrument if this occurs.
- A singular AEM instrument must be the sole conductor of energy to tissue. Do not conduct energy by touching an AEM instrument to a second instrument contacting tissue. The second device will not be protected from capacitive coupling and insulation failure.
- Keep electrosurgical instruments away from the patient and operative field when not in use. Accidental activation can result in unintended injury to the patient.
- See electrosurgical generator manual and AEM Monitor Operator/Service Manual for precautions concerning the general application of electrosurgical equipment.

Disassembly/Disposal

Always disconnect cord by pulling on connector body. Replace cord if intermittent alarms are experienced during use or set up.

Reprocessing Instructions

After use, the instrument must be cleaned and sterilized before reuse.

This product has been validated for 10^{-6} sterility assurance level when reprocessed in accordance with these cleaning and sterilization instructions.

CAUTION

- Treat a used instrument as a potential biohazard until cleaning and sterilization has been completed. Microscopic residues may remain after cleaning.
- Do not use bleach (sodium hypochlorite) based products during cleaning. Bleach is extremely corrosive to metals and can negatively affect the electrosurgical instruments. Refer to your cleaning products Material Safety Data Sheet (MSDS) to ensure that they are not corrosive or harmful to various metals (including stainless steel, gold, etc).
- Certain cleaning chemicals may negatively affect metals, such as the gold connectors. Refer to your cleaning products Material Safety Data Sheet (MSDS) to ensure that they are not corrosive or harmful to various metals (including stainless steel, gold, etc).

NOTE

- Used instruments are considered medical waste. Dispose of in accordance with local regulations.

Cleaning

Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated washer/disinfector system may be used as a follow-up to manual cleaning, but is not required.

NOTE

- The use of fully distilled or demineralized water is preferred for cleaning and rinsing.
- Visually inspect cord per instructions under End of Life Indicators.

Manual Cleaning	
Step	Description
1	Immerse all components in KLENZYME® or equivalent blood dissolving enzymatic solution (prepared per manufacturer's instructions) for at least 5 minutes and gently agitate. (Soak longer if proteinaceous material is present.)
2	Remove the device from the enzyme solution and rinse thoroughly under running tap water (minimum of 3 minutes).
3	Immerse all components in MANU-KLENZ® or equivalent detergent solution (prepared per manufacturer's instructions) and clean all surfaces with a soft bristle brush.
4	The contact area may be cleaned with a 5mm brush.
5	Remove the device from the detergent solution and rinse thoroughly under running distilled or demineralized water (minimum of 3 minutes).

Combination Manual/Automated Cleaning	
Step	Description
1	Follow Manual Cleaning steps 1 – 5.
2	Use of a sonicator or ultrasonic cleaner at 35-45 kHz can support manual cleaning of devices. Cycle time 5 minutes maximum. Do not exceed water temperatures above 50°C (122°F).
3	Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/ disinfector cleaning cycle. See Table listing typical cycles.

Typical Automated Washer/Disinfector Cycle for Surgical Instruments	
Step	Description
1	Prewash with cold tap water for 1-10 minutes.
2	Enzyme spray with hot tap water for 1-15 minutes.
3	Rinse with hot or cold water for at least 20 seconds.
4	Detergent wash with hot tap water for 1-20 minutes.
5	Hot water rinse for at least 20 seconds.
6	Thermal rinse (80°C to 98°C / 176°F to 208°F) for 1-5 minutes. Lubricant may be added during this cycle.
7	Hot air dry (use low temperature setting) for 0-10 minutes.

NOTE

- The washer/disinfector manufacturer's instructions should be strictly adhered to.

Sterilization

Monitoring sterility using Geobacillus stearothermophilus spore strips is recommended.

NOTE

- Do not exceed temperatures of 135°C / 275°F. Performance to specification has not been verified above this temperature. Damage to the product may occur.
- Validation of sterilization cycles other than steam autoclave is the responsibility of the end user.

Step	Description
1	Allow the instrument to dry thoroughly prior to sterilization.
2	Steam Sterilization (use one of the methods listed below):
	Prevac (2 layers of Sterile Wrap or Unwrapped) Temperature: 132°C / 270°F minimum Duration: 4 minutes minimum
	Gravity Steam (2 layers of Sterile Wrap) Temperature: 121°C / 250°F minimum Duration: 60 minutes minimum.
	Gravity Steam (FLASH/Unwrapped)* Temperature: 132°C / 270°F minimum Duration: 10 minutes minimum * Flash Sterilization is not recommended, except in emergency situations.

CAUTION

- Cold Soak Sterilization is not recommended. Testing results indicate that cold soak sterilization (Glutaraldehyde) is not adequate for this product. Manufacturer's recommended cycle times DO NOT always provide a 10^{-6} sterility assurance level.
- Gas Plasma (Hydrogen Peroxide) Sterilization is not recommended for ENCISION Instruments. Instruments with long, narrow lumens may pose a challenge for this type of sterilization.

Product Life

This product has been tested and shown to remain safe and effective for up to 25 uses under typical use and reprocessing conditions.

The life of this surgical instrument is largely dependent on the care and handling at the point of use / cleaning / sterilization. For optimal instrument life, protect it from contact / impact with other instruments during decontamination and sterilization.

Encision recommends the user track cable usage to determine the expected lifetime based on the institution's use, replacement rate and failure rate for the AEM Cord. The cord may be used up to 25 sterilization and reuse cycles. Discard after 25 uses or evidence of End of Life Indicators. The number of uses may be reduced by improper handling, and "prevac" or "flash" sterilization methods.

End of Life Indicators

The cords may be used until a cord exhibits any of the following end of life indicators.

Visually inspect and electrically test prior to use. Discontinue use if any of the following are evident:

- Intermittent electrical performance.
- Cord: Damaged insulation (i.e. Cracks, nicks, abrasions, holes, tears, kinks, bulges, burns or melted areas). Pay special attention to cord/connector interface. Manually flex the cable near the connector ends. Increased flexibility may indicate a conductor wire break, even without obvious insulation damage.
- Connector: Bent, broken, loose or missing components, or corroded contacts. Damaged active contact (center post) insulation (i.e. cracks, nicks, abrasions, holes, tears, burns or melted areas).
- Electrical Inspection: Shield Contact Continuity – Connect the cord to an AEM Monitor and to an AEM instrument of any type. Verify the AEM Cord indicator turns off as the cord is connected and remains off as the cord is flexed near its plugs. If there is any illumination of the indicator after the cord is fully connected, remove the cord from service.

Express Warranty

ENCISION hereby warrants to Buyer that products purchased hereunder shall be free from defects in materials and workmanship under normal use and service, as specified in these Instructions for Use/Care, for the period of six months from date of purchase, or upon reaching an end of life indicator (including Maximum Number of Uses), whichever occurs first. Any evidence of unauthorized modification or repair of this device will void the warranty.

See AEM Monitor Operator/Service Manual for details of Limitations, Disclaimer, and Exclusions.

Return of Used Product

If for any reason this product must be returned to ENCISION, a returned goods authorization is required prior to shipping. Appropriate return instructions may be obtained from ENCISION.

Product

ENCISION reserves the right to amend, modify or to change any product, to introduce new products, to withdraw products and otherwise vary product specifications at any time without notice.

Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician.
	Consult Instructions for Use
LATEX	Latex Free

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CE 1275

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