AEM® Cord Adapter

Instructions For Use/Care REF ES9005 Series Adapters

ENCISION

℞ ONLY

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

Device Description

The **ES9005 Series** AEM Cord Adapter connects the electrosurgical generator output current to the AEM Cord. It also connects the shield conductors of the AEM Cord to the AEM Monitor.

NOTE

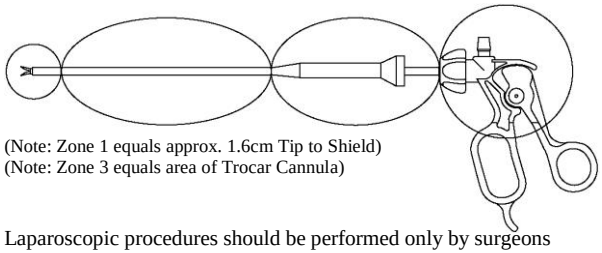
- This product is rated to 9000 Vp-p. Limit electrosurgical generator power setting to 80 Watts or lower (60 Watts for the Conmed Aspen Excalibur spray mode). Higher settings may result in spurious insulation failure alarms and/or insulation breakdown. See Encision AEM Monitor Operator/Service Manual for list of compatible electrosurgical generators.
- This product is not intended to be located in the sterile field. It is not supplied sterile. Steam sterilization will damage the device.

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.

Zone 1 Zone 2 Zone 3 Zone 4



(Note: Zone 1 equals approx. 1.6cm 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.

Inspect the instrument for proper assembly and function (see End of Life Indicators).

AEM System Setup/Assembly Instructions

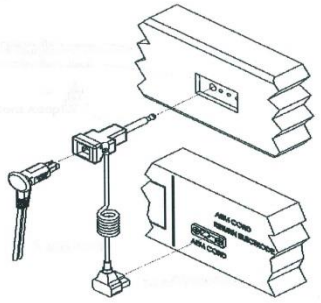
See laminated Setup Sheet (Document 00701).

Good operating room practice suggests that connections of accessories to electrosurgical generators be made only while the generator is OFF or on Standby.

Verify the patient return electrode has been properly applied to the patient.

Verify the return electrode cord is inserted into the green Inhibit Adapter from the AEM Monitor, which is connected to the patient return electrode outlet on the electrosurgical generator.

With initial hookup of the ES9005 Series AEM Cord Adapter, the Active Electrode Monitor illuminates the AEM Cord Fault Indicator. To extinguish this alarm, the AEM Cord and an AEM instrument must be connected as shown in the diagram below.



If the indicator does not extinguish, place a new AEM Cord and a new AEM instrument into the ES9005 / ES9005A AEM Cord Adapter.

Verify the AEM Cord is connected to the AEM Monitor and the AEM instrument such that contact with PATIENT or other leads is avoided.

A green Ready light on the AEM Monitor indicates all connections have been properly made.

Disassembly

Always disconnect cord by pulling on connector body.

Reprocessing Instructions

A. Manual Cleaning:

- Wipe down the exterior using a mild cleaning solution or disinfectant and a damp cloth to clean the adapter.
- Use a cotton swab to clean the internal contact of any contaminates.

B. Automatic Cleaning:

- Do not place this product in an automatic washer or immerse this product in any liquid. This will damage the device.

C. Sterilization:

- Do not sterilize. Exposure to steam sterilization or cold soak sterilization will damage the device.

CAUTION

- 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.
- Laparoscopic surgery may result in gas embolism due to insufflation of gas into the abdomen.
- 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.
- Keep electrical connections dry while in use to prevent potential conduction of HF current to the user.
- 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.
- 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.
- Pulling or tugging cord can result in breaking of internal conductors, causing intermittent alarms or sparking and burning of insulation during use. Note: 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.
- Always fully connect the cord to instrument and adapter. Partial connections may cause arcing, which will damage the product.

Product Life

The life of this surgical instrument is largely dependent on the care of handling at the point of use or cleaning, For optimal instrument life, protect it from contact / impact with other instruments during decontamination. The number of uses may be reduced by improper handling.

End of Life Indicators

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

Visual Inspection

- **Cord**: damaged insulation (i.e., cuts, cracking, brittle or rigid, permanent kinks, burnt or melted).
- **Connector**: broken or missing components, or corroded contacts.

Electrical Inspection

Verify proper operation with the Active Electrode Monitoring System and electrosurgical generator; the adapter should be removed from service if any malfunction occurs. Refer to "Checking the Active Electrode Monitoring System" in the AEM Monitor Operator/Service Manual.

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 this Instructions for Use/Care, for the period of one year from date of purchase, or upon reaching an end of life indicator, whichever occurs first.

Any evidence of repair, modification, or sterilization of this product will void this 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

We reserve 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 notification.

Symbols Glossary

Symbol	Meaning	ISO 7000 Ref No.
	Manufacturer	3082
	Batch Code or Lot Number	2492
	Date of Manufacture	2497
	Catalog Number/Reference	2493
	Consult Instructions for use	1641
Symbol	**Meaning**	**Reference**
	Does not contain or presence of natural rubber latex	EN ISO 15223 5.4.5, with negation symbol Annex B.2
	Prescription Only	21 CFR Part 801.109

Made in USA

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