AEM® Burn Protection System Cable

EN Instructions For Use/Care

REF ES6107+

ENCISION
AEM® SAFETY – PERFORMANCE – VALUE

STERILE R | LATEX | Rx ONLY | MD

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

Device Description

Disposable Cord—For Single Use Only

The **ES6107+** Disposable AEM Cord connects the AEM Laparoscopic Instrument to the AEM Monitoring System.

The cord is classified for continuous operation.

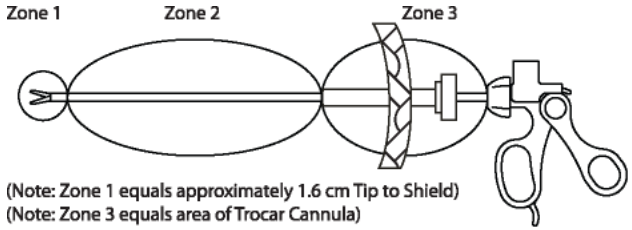
CAUTION

- This product is rated to 9000 Vp-p. Limit electrosurgical generator power setting to 80 Watts or lower . 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 supplied sterile and is not intended for use more than one time. No attempt should be made to reprocess this 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" (intraoperative 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 approximately 1.6 cm 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.

The Disposable Sheath is supplied sterile. Inspect the package and product for damage prior to use.

The Disposable Sheath may be trimmed to a desired length prior to use.

AEM System Setup/Assembly Instructions

CAUTION

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

For setup of the AEM Monitoring System, see the AEM Monitor instructions for use.

1. Connect the "Burn Protection" end of the AEM Cord to the laparoscopic instrument.
2. ***When using the EM200 AEM Monitor***, connect the other end of the AEM Cord to the monitor's pigtail cord.
3. ***When using the EM2 Series AEM Monitor***, connect the other end of the AEM Cord to the ES9005 Cord Adapter (connected to the electrosurgical generator and the monitor). If the ES9015 Universal Adapter is installed on the monitor, connect the other end of the AEM Cord to the Universal Adapter.

CAUTION

- 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.

4. ***When using the EM3 Series AEM Monitor***, connect the other end of the AEM Cord directly to the monitor

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.
- 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.
- Do not activate the ESU if the monitor's green Ready light is off. No Ready light means there is a setup error or equipment malfunction.
- 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.

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

NOTE

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

End of Life Indicators

Discontinue use if any of the following are evident:

- Any damage to sheath tube
- After one use of product.

Reprocessing

WARNING

- This product is intended for single use and shall not be reprocessed or resterilized. Resterilization may compromise the integrity of the device, which may result in malfunction.

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 Instruction for Use/Care, until the labeled USE BY date, or one (1) use, whichever occurs first.

Any evidence of repair or modification 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

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.

GLOSSARY OF SYMBOLS		
SYMBOL	**MEANING**	**ISO 7000 REF NO.**
	Manufacturer	3082
	Use By Date	2607
	Batch Code or Lot Code	2492
	Catalog Number/Reference	2493
	Single sterile barrier system	3707
	Sterilized Using Irradiation	2502
	DO NOT USE if package is damaged or opened	2606
	Medical Device is intended for one use, or for use on a single patient during a single procedure	1051
	Consult Instructions for Use	1641
	Temperature Limits	0632
	Humidity Limitation	2620
	CAUTION—Read Instructions for use for further detail	0434B

GLOSSARY OF SYMBOLS		
SYMBOL	**MEANING**	**REFERENCE**
	Not made with natural rubber latex	ISO 15223-1 5.4.5 with negation symbol Annex B.2
	Prescription Only	21 CFR Part 801
	Medical Device	ISO 15223-1 5.7.7

Made in Mexico

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