AEM® Disposable Handpiece and AEM® Disposable Electrodes

EN Instructions For Use/Care

ENCISION

STERILE R LATEX Rx ONLY

ENCISION recommends placing this document with the instructions for use for your AEM Monitor.

Device Description REF ES1300 & ES03XX Series

Disposable Handpiece - For Single Use Only

The ES1300 series AEM® Disposable Handpiece is intended to be used only with Encision's AEM Disposable Electrodes.

Disposable Electrodes - For Single Use Only

The ES03XX series AEM® Disposable Electrodes are intended to be used only with Encision's ES1300 series AEM Disposable Handle. The ES03XX series Electrodes are 5mm instruments designed to fit commonly used Trocar Cannulas. The ES03XX series are also sized for use with the Disposable Sheath.

Principle of Operation

The Handpiece provides switching for the CUT and COAG functions of the ESU. The distal yellow button is CUT. The proximal blue button is COAG.

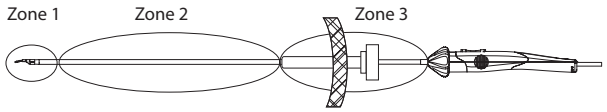
CAUTION

- 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 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" (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 2.5cm Tip to Shield)

Electrosurgical procedures should be performed only by surgeons having adequate training and familiarity with these 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

The AEM Disposable Handpiece and AEM Disposable Electrodes are electrosurgical accessories intended, by use of monopolar high-frequency electrical current from compatible electrosurgical generators, for ablation, removal, resection and coagulation of soft tissue where associated hemostasis is required in open, endoscopic and laparoscopic surgical procedures.

The devices are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

AEM instruments incorporate the use of AEM technology and 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 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 Handpiece and Disposable Electrodes are supplied sterile. Inspect the package and product for damage prior to use.

AEM System Setup

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

WARNING

- Laparoscopic surgery may result in gas embolism due to insufflation of gas into the abdomen.
- 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.
- 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.

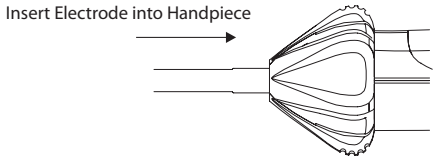
CAUTION

- Avoid buildup of eschar on the tip insulation which can provide a conductive path for HF energy when in proximity to tissue - by either:
  - Use of the Disposable Sheath (preferable), or
  - Frequent cleaning of the tip to remove eschar.
- 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.

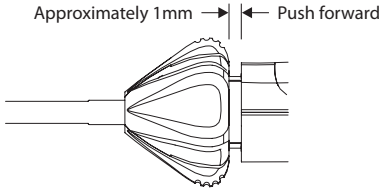
Assembly Instructions

The ES03XX series AEM Disposable Electrodes are designed to be used only with the ES1300 series AEM Disposable Handpiece.

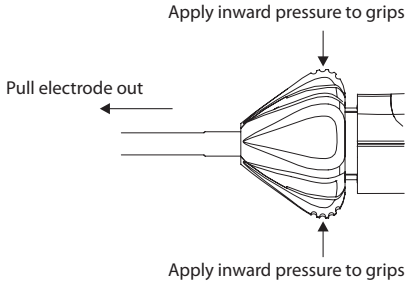
1. Grasping the rotation knob of the Disposable Electrode, insert it into the Handpiece until it snaps or clicks into place. When fully seated, the rotation knob should not rotate.



2. To rotate the tip/shaft, push the rotation knob forward approximately 1mm until it stops. This allows rotation of the electrode shaft.



3. Verify proper operation with the AEM Monitor and electrosurgical generator. The instrument should be removed from service if any malfunction occurs. Refer to "Checking the AEM Monitor" in the AEM Monitor Operator/Service Manual.
4. Use a Disposable Sheath to fully cover the tip insulation, allowing only the metal tip of the Electrode to be exposed, minimizing the possibility of eschar buildup.
5. To remove the Disposable Electrode, apply inward pressure on the rotation knob at the 2 gripping points and pull the electrode out of the Handpiece.



6. An electrode may be removed and replaced in the Handpiece as necessary during a single procedure.

End of Life Indicators

Discontinue use if any of the following are evident:

- Intermittent electrical performance
- Bent electrode shaft or tip affecting function of sheath or insertion into trocar
- Bent or damaged housing, rod or tip
- Any insulation damage which exposes metal (AEM Shield) along the length of the instrument's shaft and/or any insulation damage in Zone 1
- 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 or electrical hazard to the patient or user.

NOTE

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

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, modification, or resterilization 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.

US Patent No.: D566,836

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GLOSSARY OF SYMBOLS		
SYMBOL	**MEANING**	**ISO 7000 REF NO.**
	Manufacturer	3082
	Use by Date (Expiration Date)	2607
LOT	Batch Code or Lot Code	2492
REF	Catalog Number/Reference	2493
STERILE R	Medical Device that has been 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
	CAUTION - Read Instructions for use for further details	0434A
SYMBOL	**MEANING**	**REFERENCE**
LATEX	Does not contain or no presense of natural rubber latex	ISO 15223 5.4.5 with negation symbol Annex B.2
℞ ONLY	Prescription Only	21 CFR PART 801
	Hand Controlled	No Reference

AEM Disposable Electrodes:

Manufactured by
ENCISION Inc.
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AEM Disposable Handpiece:

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Printed in USA or Taiwan