AEM® Disposable Scissor Inserts

EN Instructions For Use/Care

REF ES01XX SERIES

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

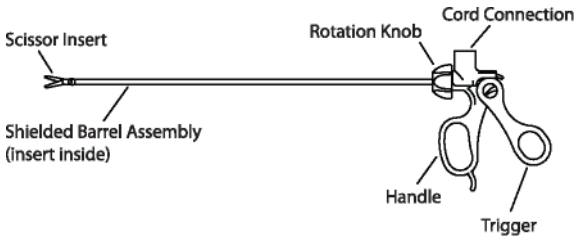
Disposable Scissors—For Single Use Only

The Scissors Inserts are designed for use with the ES8000 / ES8200 series AEM® Handle Assemblies. All scissors will fit through standard 5.5mm trocars.

Principle of Operation

The AEM Handle Assembly is sized to accept an insulating Disposable Sheath (ES0150 series) that allows the surgeon to control the amount of exposed electrosurgically active metal at the scissors.

The front and rear handles open and close the working tip (blade insert) of the instrument.



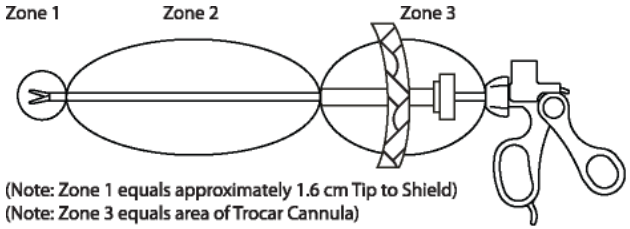
NOTE

- 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.
- See also Instructions for Use/Care for AEM Instruments, Disposable Sheath and Disposable Scissors as applicable.
- 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..

Scissors Inserts are intended for use on soft tissue only.

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 Scissors Insert is supplied sterile. Inspect the package and product for damage prior to use.

AEM System Setup

See your AEM monitor IFU for information on System Setup.

WARNING

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

Assemble the two (2) basic components.

1. Hold the instrument upside down as shown. Slide the insert (A) into the handle shaft until the trigger catches and rotates slightly upward.

DO NOT FORCE TRIGGER UP - IT WILL ROTATE AUTOMATICALLY AS INSERT ENGAGES.

2. Rotate the insert tip clockwise to screw in the insert.

DO NOT USE OPEN BLADES TO TIGHTEN SCISSORS

3. Turn the rotation knob to adjust the positioning of the insert.

During Use

The working tip (blade insert) of the instrument should always be closed when introducing or removing the instrument from the cannula or Disposable Sheath.

Scissors Inserts are intended for use on soft tissue only. Use of scissors on hard tissues or hard objects (such as staples) will cause damage to the blades or hinges of the scissors.

Disassembly/Disposal

Disassemble in reverse order from assembly. No further disassembly is recommended.

If using Disposable Sheath, see also Disposable Sheath IFU.

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:

- Binding or impaired mechanical function
- Bent or damaged housing, rod or tip
- Dulling of scissors
- After one use of product.

Reprocessing

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.

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.

Made in USA

Manufactured by

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GLOSSARY OF SYMBOLS		
SYMBOL	**MEANING**	**ISO 7000 REF NO.**
	Manufacturer	3082
	Use By Date	2607
LOT	Batch Code or Lot Code	2492
REF	Catalog Number/Reference	2493
	Single sterile barrier system	3707
STERILE R	Sterilized Using Irradiation	2502
	DO NOT USE if package is damaged or opened	2606
2	Medical Device is intended for one use, or for use on a single patient during a single procedure	1051
	Consult Instructions for Use	1641
SYMBOL	**MEANING**	**REFERENCE**
LATEX	Not made with natural rubber latex	ISO 15223-1 5.4.5 with negation symbol Annex B.2
Rx ONLY	Prescription Only	21 CFR Part 801
MD	Medical Device	ISO 15223-1 5.7.7

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