AEM® Suction and Irrigation Electrodes and Adapters

EN Instructions For Use/Care

REF ES3770 Series Electrodes
REF ES3700 and ES3800 Series Adapters

ENCISION
AEM® SAFETY – PERFORMANCE – VALUE

LATEX Rx ONLY NON STERILE MD

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

Device Description

Suction-Irrigation Electrodes

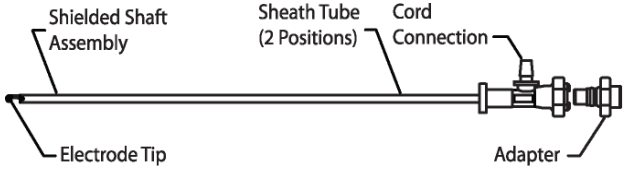
The **ES3770 series** Suction Irrigation Electrode (SIE) is a reusable instrument designed to fit commonly used 5.5mm trocar cannulas. Various tip styles are available.

The **ES3700 series** and **ES3800 series** Adapters (sold separately) allow the SIE to connect to a variety of suction irrigation trumpet valves. When using a Stryker® trumpet valve, an adapter is not required.

- The **ES3700 series** Permanent Adapter (amber color) is designed to be permanently attached to the SIE and, once assembled to the instrument, should not be removed. Reprocess the instrument and adapter assembled together
- The **ES3800 series** Removable Adapter (black color) may be removed from the SIE. The instrument and adapter may be reprocessed disassembled or assembled.

Principle of Operation

The **ES3770 series** Suction Irrigation Electrode combines AEM technology with suction and irrigation of fluids during laparoscopic electrosurgery. The Sheath Tube is an integral part of the SIE and must be used at all times. When the sheath is in the extended position it facilitates suction and irrigation. When the sheath is retracted the electrode tip is exposed, allowing application of energy to the electrode tip.



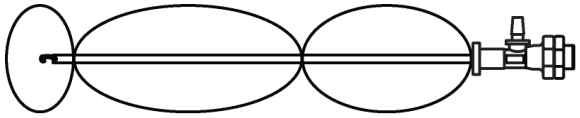
CAUTION

- 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.
- 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" (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 1.5cm 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.

Disposable inserts and sheaths are supplied sterile.

Inspect the instrument for proper assembly and function. See End of Life Indicators. Hipot testing is not required before use.

AEM System Setup

See your AEM monitor IFU for information on System Setup.

While connecting the AEM Cord, do not touch the shield connector and the patient simultaneously. In fault conditions, leakage current in excess of limits may be present.

WARNING

- Explosion Hazard. Do not use electrosurgery in the presence of flammable solutions (e.g., alcohol) or in an oxygen rich environment.
- 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.
- 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.

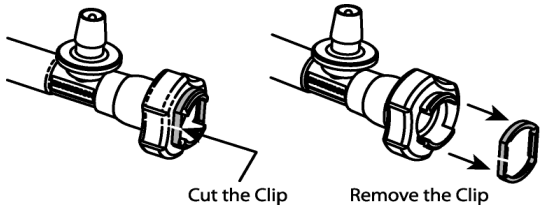
CAUTION

- 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.
- Any modification of the instrument (including bending of the tip) may cause permanent product damage such as breakage, or reduce the life of the instrument.
- 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.

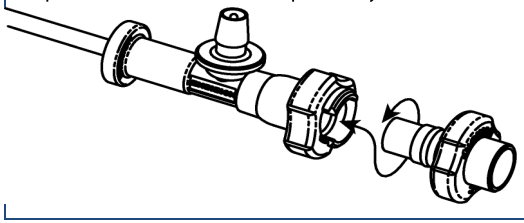
Assembly Instructions

ES3700 series Permanent Adapter (amber color)

1. Remove the amber colored clip from the SIE instrument. To make removal of the clip easier, cut the clip on one side.

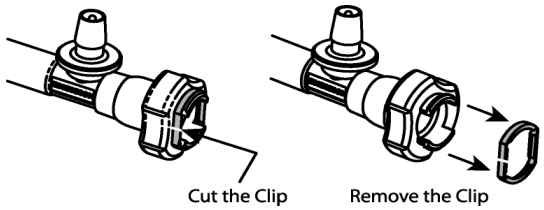


2. Insert and twist the adapter into the SIE instrument until there is no gap between the instrument and adapter. Proper assembly of the adapter to instrument is accompanied by an audible click.



ES3700 series Permanent Adapter (amber color)

1. Leave the amber colored clip in its original position on the SIE instrument.



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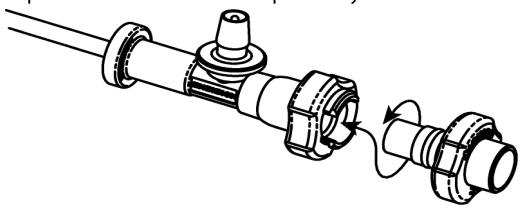


During Use

WARNING

- Extend the sheath tube over the electrode tip prior to insertion into or removal from the trocar cannula. The extended sheath position is important in preventing patient injury or instrument damage.
- Pull the sheath tube back prior to activation of the device to prevent unintended electrical energy from arcing through the aspiration holes of the sheath.
- Always use the electrode with the sheath in place. Use without the sheath may allow arc from shaft in Zone 1 to tissue in an unintended location.
- The active electrode should not be activated until it is in close proximity to tissue. This minimizes risk of contacting unintended tissue.
- Activating the electrosurgical unit simultaneously with the suction/irrigation function may alter the path of the electrical energy away from target tissues.

CAUTION

- Any modification of the instrument (including bending of the tip) may cause permanent product damage such as breakage, or reduce the life of the instrument.

Disassembly

ES3700 series Permanent Adapter (amber color)

CAUTION

When using an **ES3700 series** Permanent Adapter, do not disassemble the adapter and SIE instrument for reprocessing. Product damage will result if the instrument and adapter are disassembled.

ES3800 series Removable Adapter (black color)

Twist the adapter and pull away from the SIE instrument.

Reprocessing Instructions

After use, the instrument must be disassembled, cleaned, lubricated 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.
- Stainless Steel is rust-resistant, not rust-proof. Instruments should be kept dry when not in use.
- 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).
- Use of some detergent solutions may leave a surfactant residue on the gold connector surface, depending on the strength of the solution and how thoroughly the residues are rinsed off. This may result in intermittent cord alarms. The residue may be removed by use of an alcohol-soaked swab, rotated completely around the external gold connector surfaces.
- 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).
- Do not use metal brushes, or brushes larger than the recommended sizes. Instrument damage will occur.
- Do not use a scratch pad or other abrasive cleaner to clean the Electrode tip, Shaft, or Sheath Tube. Instrument damage will occur.

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.

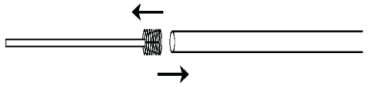
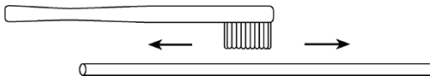
CAUTION

- When using an **ES3700 series** Permanent Adapter (amber color), do not disassemble the adapter and SIE instrument for reprocessing. Product damage will result if the instrument and adapter are disassembled.

NOTE

- The use of fully distilled or demineralized water is preferred for cleaning and rinsing.

Manual Cleaning

Step	Description
1	Remove the Sheath Tube from the SIE instrument. When using an **ES3800 series** Removable Adapter (black color), the adapter may be removed from the instrument prior to cleaning and sterilization.
2	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.)
3	Remove the components from the enzyme solution and rinse thoroughly under running tap water (minimum of 3 minutes).
4	Immerse all components in MANU-KLENZ® or equivalent detergent solution (prepared per manufacturer's instructions) and clean all surfaces with a soft bristle brush, including any hard to reach areas.
5	**Electrode and Adapter**: Using a 2mm (1/16") long-handled soft-bristle brush, clean the inner lumens using complete strokes while immersed. Push the brush all the way through the lumens and pull it back several times for each component. For Gyrus-ACMI adapters with pin: also use a 1.8mm soft bristle brush to clean around the pin. Use the 3.2mm or 1.8mm brushes (as appropriate) to thoroughly and effectively clean the adapter lumen, including the inner lumen area around the pin. 
	Using a soft bristle brush, use a back and forth motion and brush all surfaces with particular attention paid to Cord Connector, crevices, grooves, fittings, tip, and joints. 
6	**Sheath Tube**: Using a 6mm (1/4") long-handled soft-bristle brush, clean the inner lumen using complete strokes while immersed. Push the brush all the way through the lumen and pull it back several times. Using a soft bristle brush, use a back and forth motion and brush all sheath surfaces with particular attention paid to crevices, grooves, fittings, tip, and joints. (See figure in Step 5)
7	Remove the components 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 – 7.
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/

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.
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.

CAUTION

- 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.
- 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.

NOTE

- 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	See Caution above regarding removal of detergent solution from the connector surface using an alcohol swab prior to sterilization.
3	Steam Sterilization – disassembled
	Prevac (2 layers of FDA-Cleared Sterilization Wrap or Unwrapped) Temperature: 132°C / 270°F minimum Duration: 4 minutes minimum Drying Time: 20-30 minutes 15 minute cooldown after drying
	Gravity Steam (2 layers of FDA-Cleared Sterilization Wrap) Temperature: 132°C / 270°F minimum Duration: 20 minutes minimum Dry Time: 20-30 minutes

Product Life

Product may be used until End of Life Indicators are present.

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.

The number of uses may be reduced by improper handling, and "prevac" sterilization outside of specified parameters.

Use of coagulation settings over 60 watts or use of spray coagulation will tend to shorten product life. Open circuit (non-tissue contact) activation will shorten product life.

End of Life Indicators

The **ES3770 series** electrodes may be used until an electrode 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
- Bent electrode shaft or tip affecting function of sheath or insertion into trocar
- Any insulation damage which exposes metal (AEM Shield) along the length of the instrument's shaft and/or any insulation damage in Zone 1
- Any damage to Sheath Tube.

Sheath Replacement

Sheath may be replaced if End of Life indications are detected. For replacement information, please contact the Encision Service Center (303-444-2600).

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.

US Patent Nos.: 5,769,841; 6,494,877

GLOSSARY OF SYMBOLS		
SYMBOL	**MEANING**	**ISO 7000 REF NO.**
	Manufacturer	3082
	Date of Manufacture	2497
	Batch Code or Lot Code	2492
	Catalog Number/Reference	2493
	Medical Device that has not been subjected to a sterilization process when similar or identical products are sold Sterile.	2609
	Consult Instructions for Use	1641
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 USA

Manufactured by

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