# AEM® Reusable Fixed-Tip Electrodes

EN Instructions For Use/Care

REF ES35XX SERIES

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

**Fixed-Tip Electrodes ES35XX series**

The ES3500 series Fixed-Tip Electrode is a 5mm instrument designed to fit commonly used trocar cannulas.

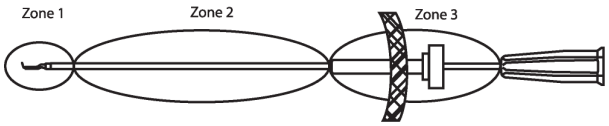
**NOTE**

- 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.
- 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 2.2cm longest 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.

**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.
- 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.

## 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).

**NOTE**

- Used instruments are considered medical waste. Once instrument reaches end of life, dispose of in accordance with local regulations.

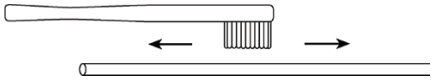
### Cleaning

Any of the three following cleaning methods may be used: Manual Cleaning, Combination Manual/Automated Cleaning, or Automated Cleaning.

**NOTE**

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

**Option 1: Manual Cleaning**

| Step | Description |
|---|---|
| 1 | 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.) |
| 2 | Remove the device from the enzyme solution and rinse thoroughly under running tap water (minimum of 3 minutes). |
| 3 | Immerse all components in MANU-KLENZ® or equivalent detergent solution (prepared per manufacturer's instructions) and clean all surfaces. |
| 4 | Using a hand held soft bristle brush, use a back and forth motion and brush all surfaces with particular attention paid to crevices, grooves, fittings, and joints.  |
| 5 | Remove the device from the detergent solution and rinse thoroughly under running distilled or demineralized water (minimum of 3 minutes). |

**Option 2: Combination Manual/Automated Cleaning**

| Step | Description |
|---|---|
| 1 | Follow Manual Cleaning steps 1 – 5. |
| 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/ disinfector cleaning cycle as described below. |

**Option 3: Automated Cleaning**

Preparation: Remove coarse debris from the instruments immediately after each use, paying particular attention to the cord connector, crevices, grooves, fittings, joints, and lumens. A soft bristle brush is recommended.

Instruments may be run through a sonicator or ultrasonic cleaner at 35-45 kHz prior to the automated washing cycle listed below. Cycle time 5 minutes maximum. Do not exceed water temperatures above 50°C (122°F).

| Step | Description |
|---|---|
| 1 | Place the product on a tray that is suitable for cleaning.<br>If the instrument has a lumen or channel connect it to the water injectors of the cleaning/disinfection machine.<br>Store any products with hinges or joints on the tray in such a way that the joints are open. |
| 2 | Prerinse for a minimum of 3 minutes with cold water. |
| 3 | Discharge. |
| 4 | Wash for a minimum of 5 minutes at 60± 5°C (140±9°F) with a 0.5% alkaline cleaning agent or an alkaline cleaning agent with a chemistry of 10.9pH.<br>Water temperatures up to 95°C (203°F) may be used, as recommended by the chemical manufacturer. |
| 5 | Discharge. |
| 6 | Neutralize as advised by the chemical manufacturer for a minimum of 3 minutes with hot water (>40°C, >104°F) and a neutralizing agent.<br>Water temperatures up to 95°C (203°F) may be used, as recommended by the chemical manufacturer. |
| 7 | Discharge. |
| 8 | Rinse for a minimum of 3 minutes with hot water (>40°C, >104°F).<br>Water temperatures up to 95°C (203°F) may be used. |
| 9 | Discharge. |
| 10 | Thermal disinfection and drying step for a minimum of 5 minutes at 90°C (194°F). Lubricant may be added during this cycle.<br>Temperature may be as high as 99°C (210°F). |

Drying: If necessary, manual drying may be carried out using a lint free cloth. Dry cavities by blowing with sterile compressed air.

### Lubrication

After cleaning all the components or as part of the automated cleaning cycle, lubricate all moving parts of the insert with water-soluble medical instrument lubrication. After lubrication, prepare the instrument for sterilization by wrapping in sterile wrap, as appropriate.

**NOTE**

- The washer/disinfector manufacturer's instructions should be strictly adhered to.

### Sterilization

Monitoring sterility using Geobacillus stearothermophilus spore strips is recommended.

**NOTE**

- 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.
- 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)<br>Temperature: 132°C / 270°F minimum<br>Duration: 4 minutes minimum<br>Drying Time: 20-30 minutes<br>15 minute cooldown after drying |
| | Gravity Steam (2 layers of FDA-Cleared Sterilization Wrap)<br>Temperature: 132°C / 270°F minimum<br>Duration: 15 minutes minimum<br>Drying Time: 15-30 minutes |

**CAUTION**

- 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.

## 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.

## End of Life Indicators

The 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

## 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

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| GLOSSARY OF SYMBOLS | | |
|---|---|---|
| **SYMBOL** | **MEANING** | **ISO 7000 REF NO.** |
| | Manufacturer | 3082 |
| | Date of Manufacture | 2497 |
| LOT | Batch Code or Lot Code | 2492 |
| REF | Catalog Number/Reference | 2493 |
| NON STERILE | 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 |
| | Caution - Read Instructions for use for further details | 0434B |
| **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 |

Made in USA

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