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

Device Description

Disposable Suction Irrigation Electrodes, Handset and Suction Tubes – Single Use Only

The ES1700 AEM® Disposable Suction Irrigation Handset is intended to be used only with Encision’s ES077X series AEM Disposable Suction Irrigation Electrodes and ES078X series Disposable Suction Tubes. The electrodes and tubes are designed to fit commonly used 5.5mm trocar cannulas. Various electrode tip styles are available.

Principle of Operation

The ES077X series Electrodes combine AEM technology with suction and irrigation of fluids during electrosurgical procedures. The sheath is an integral part of the electrode and must be used at all times. The sheath may be locked in the extended position, covering the electrode tip. When the sheath is in the retracted position, the electrode tip is exposed allowing application of energy to the tip. Suction and irrigation are operable in either sheath position. The electrode tip may be rotated to provide a user preferred orientation between the tip and the handset. The sheath position or electrode tip rotation may be adjusted with one finger operation of the rotation knob.

The ES1700 Handset provides controls for suction and irrigation. The red button is suction and the blue button is irrigation. A control lever provides constant suction. The handset also provides switching for the CUT and COAG functions of the Electrosurgical Unit (ESU). The yellow button is CUT and the blue button is COAG.

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.

Disassembly Instructions.

• 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.
• Keep 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. These instruments have not been shown to be effective for tubal sterilization procedures, and should not be used for these procedures.

Instructions For Use

Prior to Use

Thoroughly read these instructions and the AEM Monitor instructions for use. The Disposable Suction Irrigation Electrodes, Handset and Suction Tubes are supplied sterile. Inspect the package and product for damage prior to use.

AEM Monitoring System Setup

For setup of the AEM Monitoring System, see the AEM Monitor instructions for use. If using the Encision EM2 Series Monitor, see the Encision ES9015 Universal Adapter instructions for use and the laminated Troubleshooting Guide (02678) for correcting error conditions.

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

Encision’s Disposable Suction Irrigation Electrodes, Handset and Suction Tubes are sterile, single-patient-use electrosurgical accessories having applications in general endoscopy and laparoscopy such as cholecystectomy and are intended to deliver electrosurgical current for cutting and coagulation of tissue and suction/irrigation functions to the surgical site. The devices are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

CAUTION

• This product is supplied sterile and is not intended for use more than one time. No attempt should be made to reprocess this device.

AEM® Disposable Suction Irrigation Electrodes, Handset, and Suction Tubes
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.

**WARNING**

- Do not place the suction tube in close proximity to an activated electrosurgical device. The suction tube has a non-insulated shaft and may conduct electrosurgical energy from the device to the patient.
- 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 instructions for use for precautions concerning the general application of electrosurgical equipment.

**CAUTION**

- 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.
- 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.
- Damage to cord insulation, internal instrument insulation or loss of shield continuity may cause setup alarms or insulation failure alarms at the AEM Monitor.

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**Assembly / Disassembly Instructions – Suction Irrigation Electrode to Handset**

The ES073X series AEM Disposable Irrigation Electrodes are designed to be used only with the ES1700 AEM Disposable Suction Irrigation Handset.

1. To insert the electrode into the handset, grasp the rotation knob of the electrode and push it onto the handset until it snaps into place.
2. To remove the electrode from the handset, first activate suction to clear fluid from the electrode tube. Then apply inward pressure on the two release tabs of the locking knob and pull away from the handset.

**Handset Connections**

1. Connect suction and irrigation tubing to the handset.
   A high-flow, regulated suction source and a gravity fed infusion bag or pressurized irrigation source (such as an inflatable pressure infusion bag, mechanical pump or other source approved for laparoscopic use) are recommended.

**CAUTION**

- The handset suction/irrigation fluid path is rated to a maximum pressure of 700 mm Hg. Connecting the suction or irrigation tubing to a pressure source that exceeds 700 mm Hg may result in internal fluid leakage and damage to the handset.

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**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.

**During Use**

Electrodes and suction tubes may be removed and replaced in the handset as necessary during a single procedure.

The cord of the Suction Irrigation Handset is insulated to protect against effects of discharge from a cardiac defibrillator device.

**WARNING**

- Inserting the electrode tip into the trocar cannula with the sheath in a retracted position may cause patient injury or instrument damage.
- Always keep the end of the sheath and the sheath aspiration holes in view during instrument activation. Electrosurgical energy may emit through the end of the sheath or the aspiration holes when near tissue and may cause injury.
- Activating the device using the cut or coag buttons while the sheath is in the extended position may result in unintended electrical energy arcing through the aspiration holes of the sheath and may cause patient injury.
- 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.
- When using a scratch pad, wire brush or other abrasive means to clean the electrode tip, use care not to damage adjacent tips.
- Damage electrical insulation may allow electrosurgical energy to emit from an unintended region of the device.

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**A. Extending the Electrode Sheath**

To extend and lock the sheath, slide and rotate the knob to position the release tab at the end of the short slot. The sheath locks into the extended position as it snaps in place.
AEM® Disposable Suction Irrigation Electrodes, Handset, and Suction Tubes
Instructions For Use/Care

**WARNING**
- Extend the sheath over the electrode tip and lock in place prior to insertion into or removal from the trocar cannula. The extended and locked sheath position is important in preventing patient injury or instrument damage.

**B. Retracting the Electrode Sheath**
To retract the sheath, slide and rotate the knob to position the release tab at the end of the long slot. The sheath snaps into the fully retracted position.

**WARNING**
- Retract the sheath prior to activation of the device to prevent unintended electrical energy from arcing through the aspiration holes of the sheath.

**C. Rotating the Electrode Tip**
To rotate the electrode tip, turn the rotation knob.

**D. Using Constant Suction**
To activate constant suction:
1. Depress the red suction button.
2. Rotate the handset suction control lever.
   Full counterclockwise rotation of the lever opens the suction pathway. This function is available when using either the electrode with sheath or the suction tube.

**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 suction tube
- Damaged handset housing
- Fluid leaking from handset or connection point of handset to electrode/suction tube
- Any insulation damage which exposes metal (AEM Shield) along the length of the instrument’s shaft or sheath and/or any insulation damage in Zone 1
- Any insulation damage to the cord
- 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 instructions for use 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.

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**RX ONLY**
Federal (USA) law restricts this device to sale by or on the order of a physician.
- Do Not Reuse
- Consult Instructions for Use
- Latex Free
- Do not use if the product sterilization barrier or its packaging is compromised.
- Type CF applied part
- Locked Position, Electrode Sheath
- Unlocked Position, Electrode Sheath
- Temperature Limitation
- Humidity Limitation, non-condensing

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