AEM enTouch® 2X Scissors Insert

EN Instructions For Use/Care

REF ES020X SERIES

ENCISION
AEM® SAFETY – PERFORMANCE – VALUE

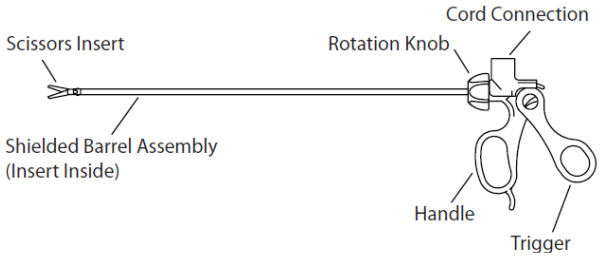
STERILE R ONLY

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

Device Description

2X Scissor Insert — ES02XX Series

The AEM enTouch® 2X Scissors Inserts are designed for use with the ES8000 / ES8200 series AEM enTouch® Handles. All scissors will fit through standard 5.5mm trocars.



Principle of Operation

The handle trigger opens and closes the scissor blades. The working tip of the instrument should always be closed when introducing or removing the instrument from the cannula.

See Encision AEM Monitor Operator/Service Manual for list of compatible electrosurgical generators, power settings and modes.

NOTE

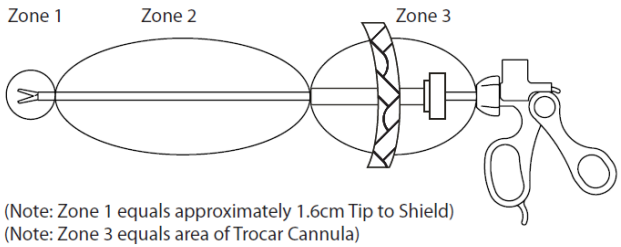
• This product is supplied sterile and is intended for one additional use. It must be sterilized prior to a second use.

• Discard after two uses or if any End of Life Indicators are present.

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 1.6cm 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 and Quick Use Guide.

The 2X Scissors Insert is supplied sterile. Inspect the package and product for damage prior to use. Refer to Reprocessing Instructions prior to second use.

Inspect the instrument for proper assembly and function. See End of Life Indicators.

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.

• Do not use product having damaged 2X Indicator.

SETUP 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.

• Keep product stored between -13 and 140° F (-25 to 60° C) and humidity 10% to 95% relative, non-condensing. Dispose of product if storage conditions are breached.

• Do not reprocess instrument if 2X Indicator is orange. This indicates the product has been previously reprocessed and should not be reprocessed again. Using the product beyond its validated service life may result in dulled blades and weakened material strength.

• See electrosurgical generator manual and AEM Monitor Operator/Service Manual for precautions concerning the general application of electrosurgical equipment.

Assembly Instructions (Handle and Insert)

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. Insert gently, making sure not to force or bend the insert.

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

2. With the scissors blades closed, rotate the insert tip clockwise to screw in the insert.

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

Disassembly/Disposal

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

NOTE

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

Reprocessing Instructions

After the first use, the AEM enTouch® 2X Scissor must be disassembled from the AEM enTouch® Handle, cleaned, lubricated and sterilized before a second use. Prior to sterilization, inspect the 2X Indicator and discard product if color is orange.

This product has been validated for 10^{-6} sterility assurance level when reprocessed in accordance with these cleaning and sterilization instructions.

REPROCESSING 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).

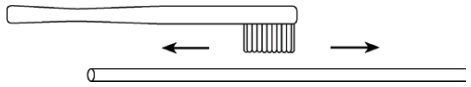
Cleaning

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	Remove the insert from the handle.
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 device 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.
5	Open the scissor blades.
6	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. 
7	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	
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/ 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 crevices, grooves, fittings, and joints. 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. Store 2X Scissors on the tray in such a way that the blades are open. Avoid contact with sharp objects.
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. 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. 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). 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. 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.	

NOTE

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

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

• Failure to lubricate may result in increased wear or binding.

Sterilization

Monitoring sterility using Geobacillus stearothermophilus spore strips is recommended.

STERILIZATION 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.

• This product is ONLY compatible with Steam Autoclave sterilization.

• Do not use Cold Soak Sterilization. Cold Soak Sterilization is not a validated sterilization method for 2X Scissor.

• Do not use Gas Plasma (Hydrogen Peroxide) Sterilization. Gas Plasma (Hydrogen Peroxide) Sterilization is not a validated sterilization method for 2X Scissor.

• 2X Indicator is NOT a verification of product sterility, nor a verification that sterilization parameters have been met.

• Dispose of product if 2X Indicator remains black after autoclave sterilization.

Steam Sterilization Options	
Allow the instrument to dry thoroughly prior to sterilization.	
Option	**Description**
Prevac **(2 layers of FDA-Cleared Sterile Wrap or Unwrapped)**	Temperature: 132-135°C / 270-275°F Duration: 4 minutes minimum Dry Time: 20-30 minutes 15 minute cooldown after drying

Product Life

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

Do not reprocess product after 2X Indicator has turned orange.

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.

End of Life Indicators

The 2X Scissor inserts may be used two times or until an insert exhibits any of the following End of Life Indicators.

Visually inspect prior to use. Discontinue use if any of the following are evident:

• Bent shaft or tip affecting insertion into handle or trocar

• Binding or impaired mechanical function

• Dulling of scissors

• Storage conditions are breached

• After two uses of product. Do not reprocess product after 2X Indicator has turned orange.

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.

GLOSSARY OF SYMBOLS		
SYMBOL	**MEANING**	**ISO 7000 REF NO.**
	Manufacturer	3082
	Use By Date	2607
	Batch Code or Lot Code	2492
	Catalog Number/Reference	2493
	Sterilized Using Irradiation	2502
	DO NOT USE if package is damaged or opened	2606
	Consult Instructions for Use	1641
	Temperature Limitation	0632
	Humidity Limitation	2620
SYMBOL	**MEANING**	**REFERENCE**
	Not made with natural rubber latex	ISO 15223 5.4.5 with negation symbol Annex B.2
	Prescription Only	21 CFR Part 801

Made in USA

Manufactured by

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