Disposable Sheath

EN Instructions For Use/Care

REF ES0150A, ES0150-45

ENCISION
AEM® SAFETY – PERFORMANCE – VALUE

STERILE R LATEX ℞ ONLY

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

Device Description

Disposable Sheath – For Single Use Only

The Disposable Sheaths are designed for use with the AEM® Handle Assemblies with Scissors Inserts.

Principle of Operation

The sheath allows the surgeon to control the amount of exposed electrosurgically active metal. This device can also reduce the risk of accidental puncture of tissue during insertion through the trocar. It is not designed for use with graspers.

The Disposable Sheath is designed for insertion through a standard 5.5mm surgical cannula. Size the cannula to the outer diameter of the instrument shaft.

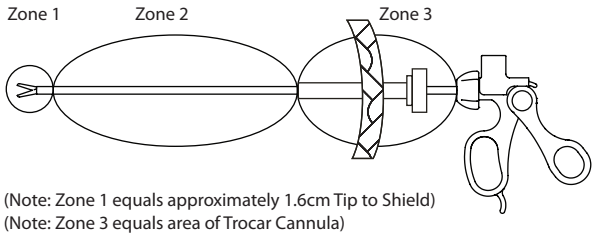
NOTE

- 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 Operation/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" (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.

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

The Disposable Sheath may be trimmed to a desired length prior to use.

AEM System Setup

See laminated Setup Sheet (00701) when using the ES9005 series AEM Cord Adapter and (02678) when using the ES9015 Universal Adapter.

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.

Assembly Instructions

NOTE

- Install the sheath onto the Handle *after* the scissors have been inserted into the Handle assembly. To insert scissors into the handle assembly, refer to the Instructions for Use/Care for AEM Instruments and Inserts.

1. Remove the sheath from the sterile pouch.
2. Grasp the sheath by the hub only. Avoid bending the sheath tube.
3. Insert the instrument tip into the hub. Keep the sheath tube parallel to the shaft of the Handle assembly during installation.
4. Carefully slide the sheath onto the shaft of the instrument.

During Use

During the procedure, adjust the position of the sheath to control metal exposure at the scissors tip.

Monitor the distal end of the sheath tube during use for splitting, cracking, melting or other deterioration that may affect the insulating qualities of the sheath. Replace the sheath when the distal end is unable to provide the desired protection.

Disassembly/Disposal

1. Hold the Handle assembly and slide the sheath off the shaft.
2. Discard the sheath.

NOTE

- Always remove sheath before sterilizing the instrument.
- 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:

- Any damage to sheath tube
- 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, or one (1) use, whichever occurs first.

Any evidence of repair, modification, or resterilization 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 (Expiration Date)	2607
LOT	Batch Code or Lot Code	2492
REF	Catalog Number/Reference	2493
STERILE R	Medical Device that has been sterilized using irradiation	2502
	DO NOT USE if package is damaged or opened	2606
	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**
EC REP	Authorized Representative in the European Community	ISO 15223 5.1.2 EN980 5.13
CE 0197	CE Mark	Medical Device Directive 93/42/EEC
LATEX	Not made with natural rubber latex	ISO 15223 5.4.5 with negation symbol Annex B.2
Rx ONLY	Prescription Only	21 CFR PART 801

Made in USA

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CE 0197

EC REP **Authorized Representative**
(according to MDD93/42/EEC)
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Printed in USA

Tijdens gebruik

Stel tijdens de ingreep de positie van de schede zo in dat het blootliggende metaal bij de punt van de schaar wordt gecontroleerd.

Monitor het distale uiteinde van de buis van de schede tijdens gebruik op scheuren, breuk, smelten of andere achteruitgang die de isolerende kwaliteit van het materiaal kan beïnvloeden. Vervang de schede wanneer het distale uiteinde niet de gewenste bescherming kan bieden.

Demontage/afvoer

1. Houd de samengestelde handgreep of elektrode vast en schuif de schede van de schacht af.
2. Voer de schede af.

OPMERKING

- Verwijder de schede altijd vóór sterilisatie van het instrument.
- Gebruikte instrumenten worden beschouwd als medisch afval. Afvoeren in overeenstemming met plaatselijke regelgeving.

Indicatoren einde gebruiksduur

Staak het gebruik indien één van de volgende zaken blijkt:

- Enige beschadiging van de buis van de schede
- Na eenmalig gebruik van product.

Opnieuw verwerken

Dit product is bedoeld voor eenmalig gebruik en mag niet opnieuw verwerkt of gesteriliseerd worden. Opnieuw steriliseren kan de integriteit van het instrument aantasten, wat kan leiden tot storing.

Uitdrukkelijke garantie

ENCISION garandeert hierbij aan Koper dat hieronder aangeschafte producten vrij zullen zijn van defecten in materialen en vakmanschap bij normaal gebruik en onderhoud, zoals gespecificeerd in deze instructies voor gebruik/onderhoud, tot de op het label aangegeven uiterste gebruiksdatum of na eenmalig (1) gebruik, welke van de twee zich eerder voordoet.

Enig bewijs van reparatie, aanpassing of opnieuw steriliseren van dit product zal deze garantie doen vervallen.

Raadpleeg de bedienings-/onderhoudshandleiding van de AEM Monitor voor informatie over beperkingen, disclaimer en uitsluitingen.

Retourneren van gebruikte producten

Als dit product om enige reden geretourneerd moet worden naar ENCISION is voor verzending een retourautorisatie goederen (returned goods authorization) nodig. Er kunnen bij ENCISION passende instructies voor retournering worden verkregen.

Product

ENCISION behoudt zich het recht voor om op enig moment en zonder voorgaande kennisgeving producten aan te vullen, te modificeren of te veranderen, nieuwe producten te introduceren, producten terug te trekken en anderszins te variëren met productspecificaties.

SYMBOOL	BETEKENIS	ISO 7000 REF NR.
	Fabrikant	3082
	Houdbaarheidsdatum (vervaldatum)	2607
	Partijcode of artikelcode	2492
	Catalogusnummer/referentie	2493
	Medisch instrument dat middels straling is gesteriliseerd	2502
	Niet gebruiken indien de verpakking geopend of beschadigd is.	2606
	Medisch instrument bedoeld voor eenmalig gebruik of voor gebruik bij één patiënt tijdens één procedure	1051
	Raadpleeg de gebruiksaanwijzing	1641

SYMBOOL	BETEKENIS	REFERENTIE
	Geautoriseerde VERTEGENWOORDIGER IN DE EUROPESE GEMEENSCHAP	ISO 15223, 5.1.2 EN 980, 5.13
	CE-markering	Richtlijn inzake medische hulpmiddelen 93/42/EEG
	Bevat geen natuurlijk rubber, geen natuurlijk rubber aanwezig	EN ISO 15223 5.4.5, met minteken bijlage B.2
	Alleen op voorschrift	21 CFR onderdeel 801,109

Vervaardigd in de V.S.

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Gedrukt in de VS