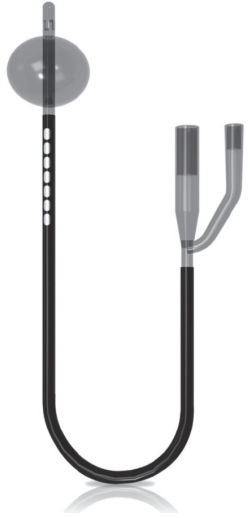
USE URETHRAL SPHINCTER ELECTRODE

Single-Use Gold Urethral Sphincter Electrode

Instructions For Use



I40-E

-Symbols used in device labeling- *Check individual device label for applicable symbols*	
Symbol	**Description**
	Sterile
	Manufacturer
	Use by date
	Do not reuse
	Do not resterilize
	Do not use if package is damaged
	Consult instructions for use
	Sterilizable in a steam sterilizer (autoclave) at temperature specified
	Catalogue number
	Batch code
	BF applied part
	Prescription only
	Medical device
	Keep away from rain
	CE Mark
	Upper limit of temperature
	Keep away from sunlight
	Non-Sterile
	Authorized representative in the European Community
	Unique Device Identifier

THIS IFU IS USED WITH THE FOLLOWING PRODUCT CODES OR CODE PRE-FIXES:		
• USE	• USE10	• USE14
• USE8	• USE12	• USE16
		• USE18

INTENDED USE

The Urethral Sphincter Electrode is intended for mucosal surface stimulation/recording from the external urinary sphincter for use in conjunction with urodynamic evaluation of the patient.

DESCRIPTION

The Urethral Sphincter Electrode is a single channel gold EMG electrode that provides monitoring of the external urethral sphincter, allowing for free running EMG and stimulation EMG. Each catheter is sterilized by ethylene oxide (EO).

CONTRAINDICATIONS

Non-reversible paralyzing agents, including anesthetic lubricants or topical sprays, may impair or reduce EMG responses rendering monitoring unreliable.

WARNINGS

- Do not use needles that have been tampered with or attempt to straighten bent needles. They may become weak and cause injury to the patient.
- Reuse or re-sterilization of single-use devices could result in patient morbidity and is an improper use of the device.
- Product is for use by a licensed physician only.
- This device does not prevent damage to nerves. The surgeon must rely on anatomical knowledge and experience to safely use this device.
- Do not suture the catheter in place.
- Do not use if sterile package has been opened or is damaged.

PRECAUTIONS

- Inspect the device for defects prior to use and discard if any defects are found.
- Do not use product if the device expiration date on the label has passed.
- Dispose of the device and packaging in accordance with hospital waste standards and federal regulations.
- Avoid injury by disposing of sharps in an appropriate biohazard container.
- Cuff pressure and volume should be monitored regularly for any significant change. Deflation or an increase in pressure due to gas diffusion requires immediate attention.
- Do not remove an inflated catheter cuff from the urethra, as this may cause injury.
- False negative responses may arise from deep anesthesia, pre-existing neuropraxia, or fluid in the surgical field. Poor electrode placement or dislodgment of electrode while moving patient can result in lack of contact between electrode and desired musculature and may also cause false negative responses.
- Avoid use of electrosurgical coagulator, ultrasonic cutting device, or other high-temperature device near the instrument as it may damage the insulated coating.
- Device has not been validated as MRI safe or compatible.
- Do not excessively bend the EMG Monitoring catheter electrodes in order to maintain electrical integrity. Check electrode integrity after insertion.
- Proper placement of the electrode recording area is critical. Review instructions for use prior to intubation.
- Maximum recommended indwelling duration for the urethral electrode is for the duration of surgery or duration of testing procedure.
- Phimosis is constriction of the prepuce (foreskin) so that it cannot be drawn back over the glans penis. This may make identifying the external urethral meatus difficult. Care should be taken when catheterizing men with phimosis to avoid trauma from forced retraction of the prepuce or by incorrect positioning of the catheter.

- Gentle finger pressure on both sides of the penis should be used when catheterizing men with a retracted penis. This pressure should encourage the penis to emerge and extend from the body to facilitate the catheterization.
- Do not use lead wires to readjust catheter.
- Removing any air from saline is standard practice.

INSTRUCTIONS FOR USE

1. Choose the appropriate urethral catheter size.
2. Reliable performance of Urethral Sphincter Electrode requires proper positioning. Please read and follow all instructions.

CAUTION: USE OF PARALYTICS IS A CONTRAINDICATION IN EMG NERVE MONITORING.

PREPARATION

1. Prior to use, test the cuff by slowly filling with a Luer tip syringe. Remove syringe from valve and check that cuff and inflation system retain air.
2. Reattach syringe and remove all air from cuff.
3. Prep the patient for insertion of the urinary catheter. Palpate the suprapubic area to detect gross distension.

INSERTION

1. A small amount of water-based lubricant may be applied to the electrode. Do not use petroleum-based lubricants.
2. Intubate using currently accepted medical techniques; insert the catheter into the urethra. For male patients, the penis should be held upright at right angle to the patient's body when the catheter is inserted.
3. Advance catheter until urethral meatus is positioned just short of the lead wire attachment at the end of the electrode.

4. Inflate the cuff with sterile water to create an effective seal and ensure that the balloon is seated against the urethral meatus on the bladder side. Check the pressure volume within the cuff regularly to ensure the seal is maintained.
5. Apply gentle outward traction on the catheter to maintain the placement of the balloon against the internal urethral meatus. This will help keep electrode stable and in contact with the relevant anatomy.

    Tips for maintaining traction & positioning: (See Figure 1)

    - Tape to patient: create gentle traction on the USE, then apply tape to secure placement/tension.
    - Without tape: The USE should hang free, allowing the weight of the catheter and tube of urometer bag to create a gentle traction.
    - Do not allow urometer bag to hang freely.
6. Note the depth of catheter by marking location on the catheter at entry point with a sterile patient marker.
7. Examine electrode impedances and free-run waveform for indications of proper electrode placement.
8. Maintain awareness of the descending catheter and electrode lead wires while navigating imaging devices around the OR table.

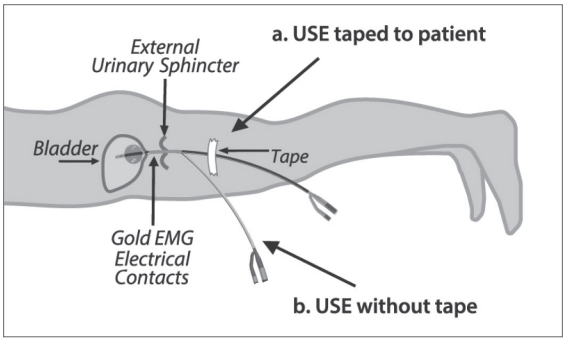


Figure 1

CONNECTING WIRES, GROUND & RETURN PLACEMENT

1. Attach red and blue electrode lead wires to the + and – terminals of the EMG recording device.
2. Apply a ground and STIM return electrode. Placement is determined by physician or monitoring personnel.

EXTRACTION

1. Extract using currently accepted medical techniques.
2. Prior to extraction, deflate the cuff completely with a Luer tip syringe.
3. If using tape, remove all tape. Pull on catheter, do not pull by the wires.

Requirements for EMG system for use with USE

Video display of free-run waveform
Video display of CMAP
Sweep of 1 to 5 seconds
Triggered sweep of 25 ms for evoked response evaluations
Vertical resolution of 200 microvolts

RECOMMENDATIONS

- Communication between the surgeon and anesthesiologist is recommended to confirm expectations for pharmacological effects on neuromuscular activity.
- Clinicians should have experience with intraoperative neurophysiologic monitoring.
- Contact Customer Service, Sales or Clinical Support for any questions concerning the care or use of this product.

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