



Raise your expectations.™

Spineology® ProMap™ Disposable Monopolar Probe, P/N 315-0000

--- Instructions for use ---

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

USA and Canada
Rx only

Description: This device is intended for the stimulation of spinal nerve roots and must be used with a motor nerve monitor and stimulator. Follow the specific advice of the stimulator equipment when setting stimulator current; the advice given here relates to the use of the Neurosign range of nerve monitors, which have a constant current source and a rectangular pulse width of 200µs.

Return path: The stimulating probe is used in conjunction with a single needle electrode to act as the return path for the current. The electrode should be inserted close to the operative site and away from the electrocautery return plate, if fitted. The crease of the buttocks/hamstrings is suggested.

Exchange tube: Prior to use the stimulating probe is placed through an exchange tube (available separately). The exchange tube is designed so that the tip of the stimulating probe will just emerge from the tube.

The tube/probe assembly is inserted through the soft tissues and into the foramina. As the assembly is advanced, if the probe touches a nerve root, the relevant muscle will twitch, if under direct observation, or the nerve monitor will indicate that the muscle is contracting. If this occurs the assembly should be withdrawn and reinserted at a different angle until a trajectory/location is identified where no muscle contraction is seen.

Stimulator settings: It is intended that the assembly be advanced through the tissue with the stimulator set to 10mA. If a response is obtained, the physician should first attempt to redirect the assembly to a location where no muscle contraction is observed. In the event that a contraction is seen in all locales the physician will seat the probe tip against the spine in an assumed safe location (inferior lateral quadrant of foramen) and begin lowering the current in 1mA steps until a current is identified where there is no muscle contraction. While maintaining this current the physician will then map the nerve root location by altering position of the probe tip until a reaction is seen. When a reaction is seen it is an indication that the assumed safe location was clear of neural structures and the assembly is returned to that location and the procedure commenced. In the event no reaction was seen anywhere it is an indication the energy level is insufficient to penetrate the neural sheath and EMG is insufficient to enable adequate guidance past the nerve root. In this case an alternate treatment plan should be adopted.

After identification: After identifying a location void of neural structures the probe tip is seated against the spine with light pressure. The exchange tube is then advanced and held in place with gentle pressure. The probe is removed and replaced with a needle or pin and the exchange tube removed. The procedure may then continue.

Probe insulation: The probe electrode is covered in an insulating material which if damaged will degrade the performance of the probe. Take care when inserting the probe into the tube, especially for the first few centimeters. It is recommended that once inserted, the probe is not removed from the tube until stimulation is complete.

For more detailed instructions for use, contact your Spineology representative for further information.

STERILE	EO
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Handling:

1. Do not use device if individual package is damaged or seal is broken.
2. Inspect device after opening in a sterile field. Discard if device is damaged.

Note: Remove and discard the probe protection sheath on probe shaft before use.

Precautions for storage: Keep away from extreme temperature, humidity and direct sunlight.

Sterility: Sterility is guaranteed up to the expiration date unless package is open or damaged or seal is broken.

Sterilization: This product is sterilised by ethylene oxide gas and is intended for single use only. Dispose after use.

Caution:

- Only to be used by trained and skilled personnel.
- After use, safely discard in accordance with established procedures for biohazardous waste.

Warning: Careless use of any element in electrosurgical systems may cause serious burns. The use of the device with safely functioning and compatible electrosurgical generators and accessories is the user's responsibility. Read and understand all precautions and instructions before attempting to use any electrosurgical device.

Distributed by:

Manufactured Exclusively for:

Spineology 

Raise your expectations.™

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Doc. 27034-002A

Specification:

Dimensions of leaflet height x width: 15cm +/-1cm x 10cm +/-1cm

Not folded

Quality: 70 grams


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