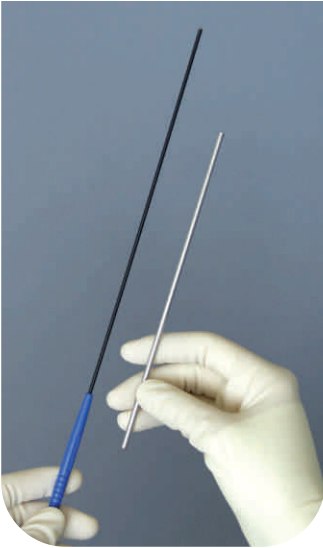


ProMap™

EMG Navigation Probe



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ProMap™

EMG Navigation Probe

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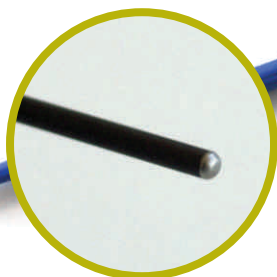
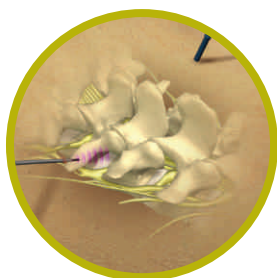
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The problem: Neural tissue cannot be observed with x-ray, making percutaneous pin and needle placement in the spine an unsettling experience.

The solution:

ProMap™

To aid surgeons in safely guiding the pins and/or needles that are so common in today's growing MIS spinal market, Spineology is offering ProMap, a one-of-a-kind EMG probe system which enables the safe delivery of sharps down to the spinal surface.



Atraumatic blunt tip
with 0.5mm exposure



Universal DIN 42 802
connector with 2m cord

Monopolar Probe

- Can be used for nerve root mapping and/or implant stimulation
- 0.5mm exposure at tip enables targeted delivery of current to map neural structures and define a clear trajectory during percutaneous pin or needle placement in spinal procedures
- Atraumatic blunt tip
- 2mm diameter provides excellent rigidity for percutaneous tissue passage
- 200mm in length
- Comes with universal DIN 42 802 connector on 2m cord; can be used with most standard monitoring systems

Exchange Tube

- Placed over Monopolar Probe during percutaneous trajectory identification
- Facilitates placement of sharps safely down to the spinal surface
- Stiffens probe for guidance through dense tissues
- 175mm in length
- 2.5mm ID makes components compatible with most spinal equipment

Patient Prep, Targeting and Equipment Set-Up

The patient is placed under anesthesia, preferably without paralytic agents or with short-acting non-fasciculating agents, and positioned. At the start of the neural mapping procedure the presence of paralytic agents will cause false-negative results. Additionally, the use of local anesthetic agents must be avoided in the area adjacent to the neural structures at risk.

Note: This probe is intended to provide EMG mapping of nerve roots only during the initial percutaneous approach to the spine. Additional modalities (SSEP, TCMEP, EEG) can be utilized simultaneously at the discretion of the user.

Have the monitoring technician place needle electrodes in the appropriate myotomes of interest for the procedure (e.g. L2 – iliopsoas and vastus lateralis, L3 – iliopsoas, vastus medialis and adductor longus, L4 – vastus lateralis, and vastus medialis, L5 - anterior tibialis, S1 gastrocnemius). Check impedances to assure they are within working levels (typically less than 5 Kohms) and that there is no discontinuity of the electric signal.

Use AP imaging that is coplanar with the vertebral endplates of the target vertebra or disc. Orient a metal pin on the skin, such that the tip is referencing the ipsilateral side of the target anatomy (**FIG. 1**). Mark the spot with a skin marker. Re-orient the pin such that the tip is referencing the desired contralateral anatomical point and mark again (**FIG. 2**). Draw a line that connects the dots and extends well lateral of each mark. This line indicates the insertion trajectory (**FIGS. 3 & 4**).

Measure the width of the spine, the distance between the dots, and transpose this dimension laterally along the line in both directions from the lateral borders of the spine. Mark the locations (**FIGS. 3 & 4**). This second set of marks indicates the approximate incision locations to begin the approach.

Note: The distance the incision is made from midline is largely dependent on patient size and the level of the pathology. The larger the patient and/or the lower the level, the further from midline the incision may need to be. (example: At lower lumbar levels in heavy patients, the incision location may need to be an additional 50% further lateral).

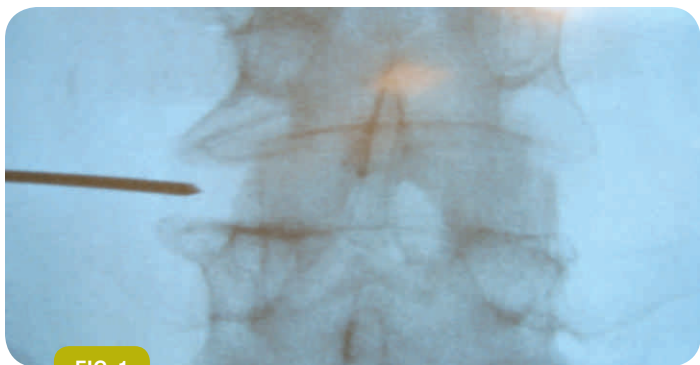


FIG. 1

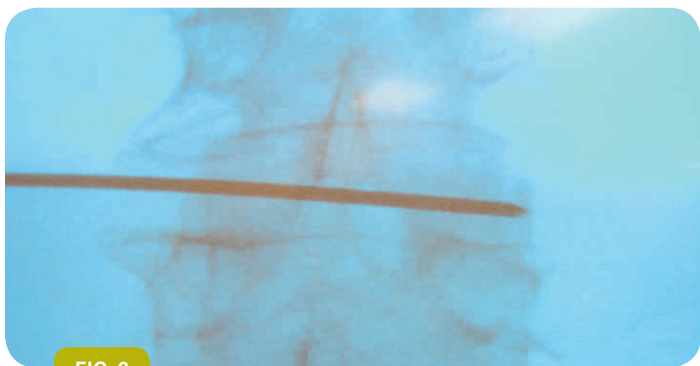


FIG. 2

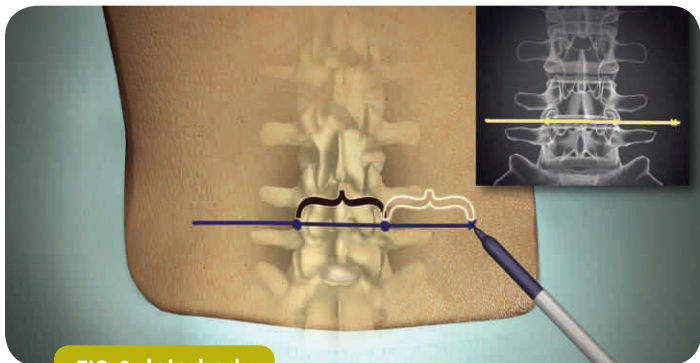


FIG. 3- Interbody



FIG. 4- Intrabody

Place a sterile return electrode (anode) in the field approximately 10cm from the target incision sites and secure it with Steri-Strips (**FIG. 5**).

Slide the ProMap Exchange Tube over the probe tip until it contacts the handle (**FIGS. 6 & 7**).

Have the monitoring technician:

- connect the ProMap probe to the cathode (-) output of the stimulator source and the return electrode to the anode (+) input
- set the stimulator to deliver a pulsed 10mA current at approximately 1-2 pulses/second
- set the Cmap sensitivity at 100 μ V (microvolts)
- configure the monitoring equipment to run both free run and triggered EMG

Note: The overall goal of the ProMap probe is to facilitate “mapping” of the nerves at a moderately high level of stimulation and titrate progressively to a lower stimulation level in the event more precise spatial localization is required.

Incise the skin at the far lateral mark desired for the approach (**FIG. 5**).

Prior to beginning navigation, touch the ProMap Probe tip to subcutaneous soft tissues so the technologist can confirm that appropriate grounding is in place and there is satisfactory current flow (**FIG. 8**).

Note: Contacting the probe on the skin is not an adequate test of current flow due to the high impedance rate of the skin compared to subcutaneous tissue.

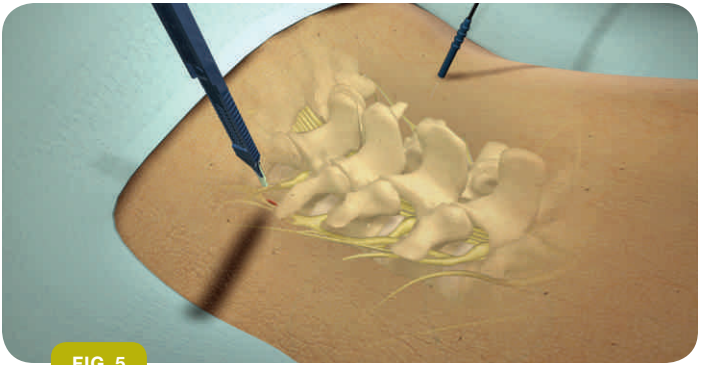


FIG. 5

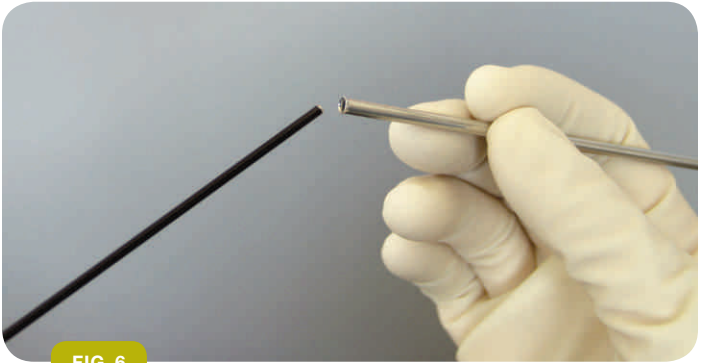


FIG. 6

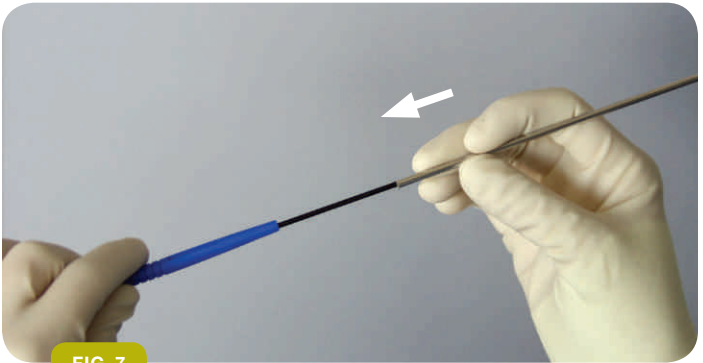


FIG. 7

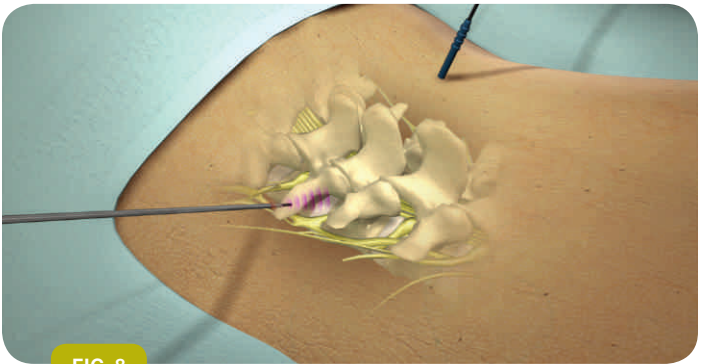


FIG. 8

Parapedicular Approach for Intravertebral Procedures

Using frequent AP imaging, insert and advance the ProMap Probe while targeting the superior lateral wall of the pedicle (**FIG. 9**). As the ProMap Probe is advanced, the electrified tip will be seeking to evoke a neural response. If at any time the technician detects a response, cease advancement and slightly retract the ProMap Probe. This is an indication that the nerve root is in, or near, the trajectory. After retraction, redirect the ProMap Probe as to provide a more medially directed trajectory. Continue advancement.

Upon trajectory change and readvancement, if a response is again evoked, titrate the ProMap Probe stimulus down in 1mA increments to improve the spatial sensitivity and continue to advance. During the identification of an assumed safe trajectory, the ProMap Probe trajectory should be altered slightly in multiple directions around the original trajectory, in order to evoke intermittent responses. This will aid in the mapping of the neural structures, while also insuring that the stimulus has not dropped below the threshold necessary to evoke a response.

When the ProMap Probe tip appears to be on the superior lateral portion of the pedicle on an AP image, use lateral imaging to inspect the location of the ProMap Probe tip. The objective is to place the tip at the superior lateral edge of the pedicle, slightly posterior to the pedicle/vertebral body junction (**FIG. 10**). If it is not at this location, retract the probe, alter the insertion angle, and re-advance the probe until it is correctly positioned and no response is evoked.

Note: If during neural mapping a stimulus level is reached at which: 1) no response can be evoked anywhere along the trajectory or 2) a continuous response is evoked along the trajectory, it is recommended that an alternate approach be considered.

If the ProMap Probe tip position was modified, use AP imaging once again to inspect the ProMap Probe tip position. If the tip still appears to be on the lateral edge of the pedicle in the AP projection, the tip is in the correct location to proceed.

Caution: If active navigation cannot identify a safe trajectory, reattempt the procedure from the contralateral side or abort.

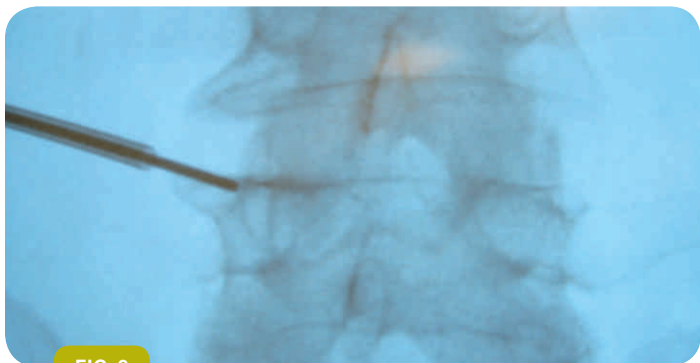


FIG. 9



FIG. 10

Transforaminal Navigation for Lumbar Intradiscal Procedures

When approaching a lumbar disc, complete the steps above for “Parapedicular Approach,” then proceed with the steps below. Initially following the Parapedicular Approach steps will simplify placement of the ProMap Probe tip in an Intradiscal Procedure by placing the tip medial to the exiting root prior to entering the inferior foramen.

With the ProMap Probe tip located on the superior lateral base of the pedicle, use AP imaging to slide the tip superiorly and medially along the base of the pedicle until the tip is located on the disc immediately superior to the coronal midpoint of the pedicle (**FIGS. 11 & 12**). Confirm the ProMap Probe tip location with lateral imagery (**FIG. 13**). The exiting nerve root occupies the superior most portion of the foramen. Making an approach to the disc through the inferior-most portion of the foramen desirable. It is not a requirement that the ProMap Probe be centered on the disc, as slight variations in trajectory will enable access into the space when desired.

During this maneuver, if a neural response is evoked, it is helpful to determine which nerve root has responded. If the exiting root has been stimulated, the ProMap Probe tip is likely too superior or lateral within the foramen. If the traversing root has been stimulated, the placement is too medial. Once it is determined which root has been stimulated, the probe is slightly retracted and repositioned further away from the offended root.

If a “no response” location cannot be identified within the foramen, titrate the ProMap Probe stimulus down in 1mA increments to improve the spatial sensitivity, while simultaneously altering the tip position slightly within the foramen. This will map the location of the neural structures, while also insuring that the stimulus has not dropped below the threshold necessary to evoke a response.

Note: If during neural mapping a stimulus level is reached at which: 1) no response can be evoked anywhere within the foramen or 2) continuous response is evoked at any level, it is recommended that an alternate approach be considered.

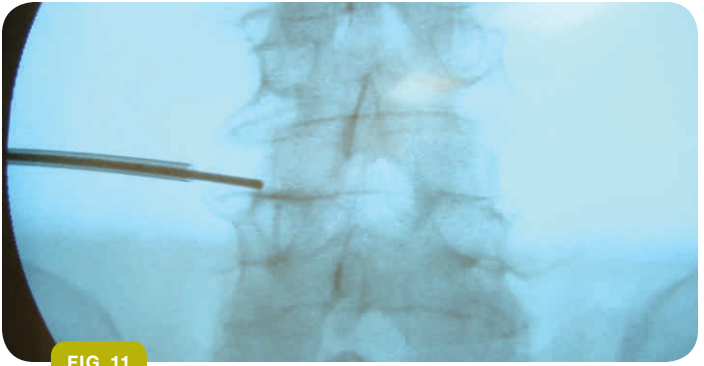


FIG. 11

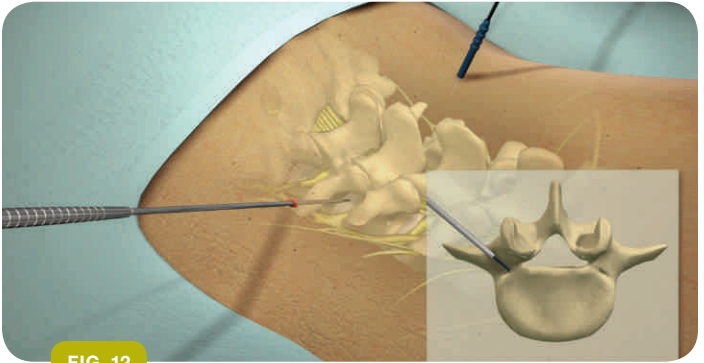


FIG. 12



FIG. 13

Once the ProMap Probe tip is observed to be on the disc, the stimulus is turned to zero. Slide the ProMap Exchange Tube down the ProMap Probe shaft to the vertebral body or disc (**FIGS. 14 & 15**). Apply slight downward pressure to hold the ProMap Exchange Tube tip against the spine and remove the ProMap Probe (**FIGS. 16 & 17**). Replace the ProMap Probe with the sharp guide pin or needle of choice. In the event a cannulated dilation system is being inserted over a guide pin, the ProMap Exchange Tube is removed after the guide pin is placed.

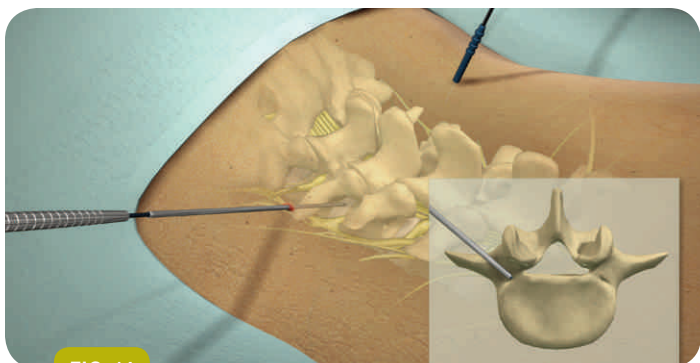


FIG. 14

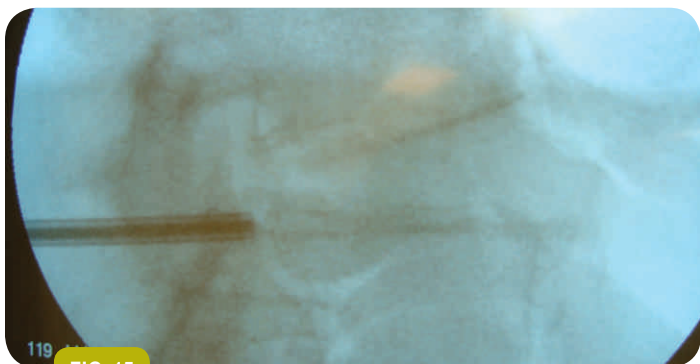


FIG. 15

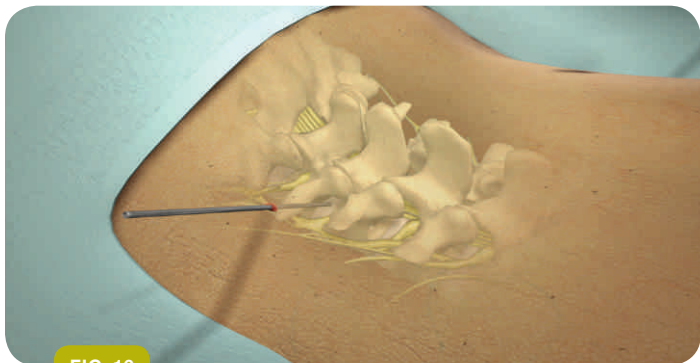


FIG. 16

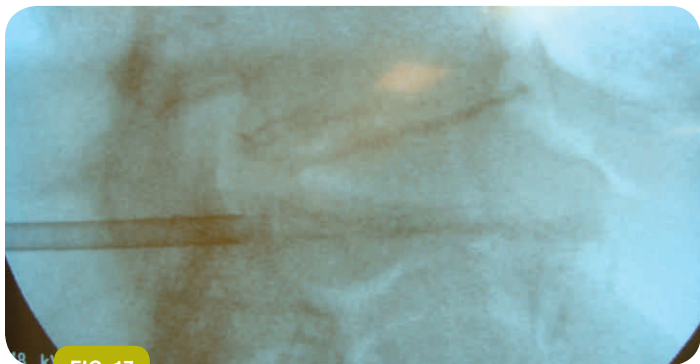


FIG. 17

This guide provides only an overview of the procedure for neuromonitoring during percutaneous access to the spine. The physician and the monitoring technician should be thoroughly familiar with the necessary modalities and equipment necessary for monitoring the balance of any procedure.

ProMap™ instruments for these procedures currently have patents pending.

Refer to package insert for labeling and cleaning and sterilization information.

The ProMap Monopolar Probe is manufactured exclusively for Magstim by Technomed Europe and distributed by Spineology Inc.



Raise your expectations.™

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