NEUROMONITORING KIT

Triggered EMG for lateral approach
Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
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Intraoperative neuromonitoring refers to the graphical and acoustic representation as well as the documentation of neurophysiological activity of one or several nerves. An electric stimulation, at a motor peripheral nerve, leads to the formation of action potentials and thus to a contraction of the innervated muscle.

Triggered electromyography (t-EMG) is the form of neuromonitoring where an external stimulus (neuromonitoring probe) is used to generate an action potential, the recording of which in a specific muscle (recording electrodes) identifies the nerve stimulated.

t-EMG helps the surgeon in localizing relevant neural structures. By using t-EMG during the lateral approach, the operating time, incision size and tissue dissection can be reduced significantly (Arnold 2012).

The Neuromonitoring Kit is specially designed to support triggered EMG for the lateral approach.

- The monopolar tip allows for stimulation in the surgical field
- Isolated shaft along stimulation probe allows stimulation solely at the tip.
- The stimulation probe is compatible with lateral eccentric Synthes dilators for lateral approach.
- Sterile packed components.
T-EMG FOR LATERAL APPROACH

During the lateral approach to the spine with a blunt dissection through the psoas muscle, iatrogenic injuries of the nerve roots, the lumbar plexus and/or individual nerves are most likely to occur.

Neural injury during this surgery can be caused by compression, stretch, transection and ischemia of nervous structures as well as operative hematoma in the psoas.

Using t-EMG during transpsoatic approaches supports the surgeon in the detection of motoric neural structures and in doing so, allows the surgeon to adjust his/her approach to potentially reduce the occurrence of nerve damage.
The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability – Alignment – Biology – Function.1,2

**Stability**
Stabilization to achieve a specific therapeutic outcome

**Alignment**
Balancing the spine in three dimensions

**Biology**
Etiology, pathogenesis, neural protection, and tissue healing

**Function**
Preservations and restoration of function to prevent disability

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1 Aebi et al (1998)
2 Aebi et al (2007)
INDICATIONS AND CONTRAINDICATIONS

The Neuromonitoring Kit is intended for use in intraoperative spinal procedures for patient connected intraoperative neuromonitoring where an appropriate neuromonitoring machine is also used. The Neuromonitoring Kit allows for triggered EMG stimulation and subsequent recording of the stimulus from the muscle whose nerve was initially stimulated.

For use of the Neuromonitoring Kit in conjunction with surgical systems and the EMG neuromonitoring machine refer to the associated product information for details on their use, precautions, warnings and side effects.

**Indications**
The Neuromonitoring Kit is indicated for intraoperative use during lateral approach surgeries utilizing the Synthes lateral product family where the patient’s peripheral motor neural structures are at risk of damage due to manipulation. Please refer to the indications of the associated system used.

**Contraindications**
- Patients with pre-existing nerve damage in the vicinity of or below the area of treatment
- Patients with illnesses or conditions resulting in reduced nerve conduction
- In surgeries where paralyzing anesthetic agents are being used
- In surgeries involving direct stimulation of the central nervous system
- Contraindications associated with respective system(s)
Before the surgery is scheduled with intraoperative neuromonitoring (IONM), the patient needs to be examined on neurological and physiological conditions. If nerve impingement or even permanent nerve injury is already present prior to surgery an induced action potential may be inhibited during surgery. This may lead to adverse events for the patient if the signal is not recorded during surgery.

**Note:** Consider other surgery approaches to avoid any complications if the above situation is presented.

### Instruments

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<th>Code</th>
<th>Description</th>
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<tr>
<td>03.662.029</td>
<td>Handle for Neuromonitoring Stimulation Probe</td>
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<tr>
<td>03.662.027S</td>
<td>Neuromonitoring Stimulation Probe</td>
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<tr>
<td>03.662.028S</td>
<td>Electrode Kit for Neuromonitoring</td>
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**Precaution:** Only motoric nerves can be detected with triggered EMG. Special attention needs to be paid to sensoric nerves e.g. part of N. genitofemoralis which occurs from nerve roots L1 and L2 and runs obliquely through the psoas muscle. It exits the m. psoas major anteriorly approximately at disc level L2/3.

**Warning:** Do not use any muscle relaxant anesthetics.
Prepare the needed amount of probes and electrodes:

The Neuromonitoring Stimulation Probe contains one stimulation probe with cable and one reference electrode. The Electrode Kit for Neuromonitoring contains four paired electrodes and a ground electrode. One pack is sufficient to monitor four muscles. If more muscles need to be monitored, prepare more electrodes (for instance another Electrode Kit for Neuromonitoring).

One stimulation probe is sufficient to map nerves in the psoas. If the nerves around the dilators need to be checked in parallel, a second probe might be helpful.

Have all imaging equipment available for visualization of instrumentation during the procedure.
NEUROMONITORING PREPARATION

1

Patient positioning

Place the patient in a lateral decubitus position with the iliac crest positioned over the table breaking point and with the preferred side (left or right) facing upwards. A bolster placed underneath the hip, to aid in opening the space between the twelfth rib and iliac crest, is recommended. It is also recommended to flex the table, to aid in opening the space between the twelfth rib and iliac crest.

Flex the upper leg to relax the psoas muscle. Ensure that the rotational alignment is correct. Secure the patient to the table.

Note: For lateral access to the lumbar spine a breakable table is recommended.

Precaution: Prevent undue pressure points when positioning and securing the patient.
2

Electrode placement

Instrument

| 03.662.028S | Electrode Kit for Neuromonitoring |

Unpack the sterile packed electrodes and remove the protection cap on the electrode needles. The muscles monitored depend on the target operating disc level and access side (left side access, muscles on left side to be monitored).

An overview list of the disc levels and the corresponding muscles is shown in the table below¹.

<table>
<thead>
<tr>
<th>Operating Level</th>
<th>Innervated muscles</th>
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<tr>
<td>L2 – L3</td>
<td>m. sartorius; (m. vastus lateralis; m. vastus medialis; m. rectus femoris)</td>
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<tr>
<td>L3 – L4</td>
<td>m. vastus lateralis; m. vastus medialis; m. rectus femoris</td>
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<tr>
<td>L4 – L5</td>
<td>m. rectus femoris; m. vastus lateralis; m. vastus medialis; m. tibialis anterior; (m. semitendinosus)</td>
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¹ Gonzalez 2009, Vogel 2011
For recording, one pair of needle electrodes (black and red plugs) is placed in one of the muscles monitored (1). The two needles of the pair are placed proximal and distal in the same muscle 2–4 cm apart. Repeat this procedure for however many muscles need to be monitored.

The set-up is completed with a ground electrode (green) which is placed in the subcutaneous tissue close to the hip (2).

If more than four muscles need to be monitored use an additional electrode kit for neuromonitoring.

**Note:** Use standard aseptic techniques for electrode placement which includes disinfection of the patient’s skin prior needle electrode placement.

**Note:** After placing them, the needle electrodes should be fixed and secured with tape.

**Precaution:** After placement, always confirm that the electrodes are placed correctly in the muscle (depth and position). Refer to IONM machine manufacturer’s manual for further instructions.
3

Connect electrodes to IONM machine

The placed electrodes are connected to the corresponding input of the IONM system.

Refer to the manufacturer’s manual for detailed instructions.

The electrodes can be attached to DIN 42802 connections on neuromonitoring machines with basic capability of t-EMG monitoring.

**Precaution:** The electrodes may only be connected to devices, which are conforming to medical device directive 93/42 EEC.

Before use make sure that the electrode can be connected with the device for intended application.
4 Electrode check

When all required electrodes are placed, refer to the manufacturer’s manual to check electrodes and choose the correct program on the IONM system.

5 Sterile draping of patient

Cover the patient in sterile cloth and perform a lateral and anterior-posterior fluoroscopic check to locate the correct level to operate.
6
Installing stimulation probe

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To assemble the stimulation probe with the handle, screw the red cable into the handle (1) and gently push the probe into the handle until it is finally seated (arrow on probe indicates correct side) (2).

The reference electrode (black) is placed close to or even in the surgical field and secured with sterile tape. Make sure it will not interfere with subsequent instruments used during the surgery.

Connect the reference electrode (black) and the cable of the sterile stimulation probe (red) to the IONM system’s output.

Refer to the manufacturer’s manual for detailed instructions.
Lateral approach

Introduce the stimulation probe into the surgical site avoiding any surrounding structures/instruments. After reaching the psoas muscle, triggered EMG is used to localize neural structures running through and around the muscle.

In general, a response with a threshold below 5 mA means direct contact with a nerve in the psoas, whereas 5 mA–10 mA indicates a close vicinity to a nerve (see Uribe 2010 and Tohmeh 2011).

Start your stimulation with 10 mA.

Before penetrating the psoas muscle with the stimulation probe, map the surface of the muscle to find the area of highest threshold, which resides over the disc level of interest.

If the approach chosen is satisfactory, slowly insert the probe through the muscle while stimulating. During any or all of these manipulations, a warning shows if there is a triggered EMG response at which point appropriate intervention should be taken.

Note: If the stimulation current evokes a muscle reaction, a nerve is situated near the stimulation probe. The lower the stimulation current at which a muscle reaction is recorded, the closer the nerve is.

Precaution: Upon insertion of the probe in the surgical site, take care not to damage any of the anatomical structures exposed during the approach.
If there is no response from the muscle at stimulation thresholds of above 10 mA, the probe can be advanced into the psoas muscle under lateral and AP fluoroscopy confirming probe placement over the appropriate disc space. Dissect the muscle bluntly with the stimulation probe until it reaches the disc space and anchor it there. Always check for neural structures on the way to the disc space.

**Precautions:**
- Do not push the stimulation probe through the muscle in one step.
- Do not overstimulate the nerves with more than 25mA as this might lead to oversaturation during surgery and temporary numbness of the nerves after surgery.
- Do not stimulate against conductive instruments.

Check the position of the probe by lateral and AP fluoroscopy.

After bluntly dissecting through the psoas, the surgeon may monitor the circumference of the approach with a second probe to detect nerves in proximity.
2
Interpreting the signals

Refer to the manufacturer’s manual for instructions on how to read the monitored signals (i.e. curves on display).

3
Proceed with lateral fusion procedure

Once the probe is securely inserted in the vertebral disc start separating the posas muscle by using the eccentric dilators. First remove the handle from the stimulation probe, then proceed with the next steps to keep the access open and perform the necessary procedure.

Refer to the respective Surgical Technique for details (036.000.266).
INSTRUMENTS

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03.662.028S  Electrode Kit for Neuromonitoring

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