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NUVASIVE NVM5 SYSTEM
INSTRUCTIONS FOR USE

For Symbols Glossary, please refer to
https://www.nuvasive.com/eifu/symbols-glossary

DESCRIPTION

The *NVM5 System* provides surgeon-driven neurophysiologic electromyography (EMG), Motor Evoked Potential (MEP), and Somatosensory Evoked Potential (SSEP) monitoring to nerve roots during spinal procedures.

Bendini is the *NVM5 Rod Bending System* used to bend rods for spinal surgery applications. The system is comprised of a camera and digitizer to register implant locations, NVM5 software to calculate bend angles between each implant and generate bend instructions, and a mechanical bender to manually bend the rod to implant specific contours.

NVM5 Guidance incorporates accelerometers attached to both the C-Arm and to the *NuVasive I-PAS needle* (accelerometers are microdevices that can measure trajectory) as well as lasers and a Reticle that together assist in aligning the *I-PAS needle* into the trajectory corresponding with the owl's eye view for pedicle cannulation.

INDICATIONS FOR USE

The *NVM5 System* is a medical device that is intended for intraoperative neurophysiologic monitoring during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. NVM5 provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG), transcranial or lumbar motor evoked potential (MEP), or somatosensory evoked potential (SSEP) responses of nerves. The System also integrates *Bendini* software used to locate spinal implant instrumentation for the placement of spinal rods.

- **XLIF (Detection)** – The XLIF (Detection) function allows the surgeon to locate and evaluate spinal nerves, and is used as a nerve avoidance tool.
- **Basic & Dynamic Screw Test** – The Screw Test functions allow the surgeon to locate and evaluate spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws.
- **Free Run EMG** – The Free Run EMG function identifies spontaneous EMG activity of spinal nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions.
- **Twitch Test (Train of Four)** – The Twitch Test Function allows the surgeon to assess moderate degrees of neuromuscular block in effect by evaluating muscle contraction following a train of four stimulation pulses.
- **MEP** – Transcranial or lumbar (i.e., conus in region of L1-L2) stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract and peripheral nerves. The MEP function provides an adjunctive method to allow the surgeon to monitor spinal cord and motor pathway integrity during procedures with a risk of surgically induced motor injury.
- **SSEP** – The SSEP function allows the surgeon to assess sensory spinal cord function in surgical procedures during which the spinal cord is at risk.
- **Remote Reader** – The Remote Reader function provides real-time remote access to the NVM5 System for a monitoring physician outside of the operating room.
- **Guidance** – The Guidance function is intended as an aid for use in either open or percutaneous pedicle cannulation procedures in the lumbar and sacral spine (L1-S1) of adult patients, and when used in conjunction with radiographic imaging and EMG, allows the surgeon to assess the angulation of system accessories relative to patient spinal anatomy for the creation of a cannulation trajectory for bone screw placement.
- **Bendini** - The Bendini Spinal Rod Bending function is used to locate spinal implant system instrumentation (screws, hooks) to determine their relative location to one another to generate bend instructions to shape a spinal rod. A surgeon is able to use those instructions and bend a rod using the Bendini Bender, a mechanical rod bender.

CONTRAINDICATIONS

The *NVM5 System* may not be effective, and is not intended for use, when neuromuscular block or epidural blocks have been used for, or in conjunction with, anesthesia. Contraindications to use of Motor Evoked Potential (MEP) monitoring include epilepsy, cortical lesions, convexity skull defects, raised intracranial pressure, cardiac disease, proconvulsant medications or anesthetics, intracranial electrodes, vascular clips or shunts, and cardiac pacemakers or other implanted biomedical devices. Otherwise unexplained intraoperative seizures and possibly arrhythmias are indications to abort MEP.

Neuromuscular Block or paralytics should not be in effect during the use of *NVM5 EMG* as they might interfere with the electromyography readings.

Do not use the *NVM5 System* in conjunction with high frequency electromagnetic diathermy devices. Failure to do so may result in patient burns at the electrode sites.

Use of MEPs is contraindicated in patients with a history of head injury, cerebral aneurysm, stroke, seizures, other neurological impairments, or patients with metal plates or fragments in their head.

Do not attempt to use this device when using paralyzing agents on the patient, as nerve surveillance may be compromised.

Do not use cutaneous electrodes for stimulation (stimulation electrodes) if the patient has a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Minimize coupling with electrosurgical equipment when setting up the *NVM5 System*. Some actions that may help reduce electrical coupling include: locate the electrosurgical patient return pad as close to the surgical site as practical; route the monopolar and bipolar electrosurgical wiring together and away from any other patient connected leads and electrodes; minimize the activation of electrosurgical instruments while they are not in patient contact; plug the electrosurgical generator equipment into a separate power outlet from any other patient-connected electrical device; and use the lowest electrosurgical power setting that achieves the surgical requirement.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; pulmonary emboli; loss of sensory and/or motor function; impotence; and permanent pain and/or deformity. Rarely, some complications may be fatal.

WARNINGS, CAUTIONS AND PRECAUTIONS

Read all instructions and understand all warnings and cautions before using the *NVM5 System* and accessories. Failure to do so may lead to serious medical consequences. Refer to the Instructions for Use accompanying other NuVasive devices before use with the *NVM5 System* to confirm proper use of these devices.

Warning:

Patients with implanted electronic devices, such as cardiac pacemakers, should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.

The MEP modality is capable of generating outputs exceeding 2mA RMS/cm² in every stimulation current (from 200 to 1500mA)/pulse (1 to 8) combination. Prolonged stimulation at outputs greater than 2mA RMS/cm² may result in skin burns.

Chronically compressed nerves, or severely compressed nerves in an acute setting, are known to be less sensitive to depolarization currents (i.e., have significantly higher depolarization current values). They are also less likely to demonstrate significant changes in their threshold depolarization current values immediately following nerve decompression. Under such circumstances, exercise caution in interpreting displayed data.

The *NVM5 System* contains no user serviceable parts inside, and servicing (other than that explicitly defined elsewhere in this manual) must be performed by the manufacturer or its authorized agent.

Do not use the *NVM5 System* in the presence of explosive gases. The device is not explosion proof.

To minimize the risk of electric shock, always connect the Patient Module cable to the Control Unit before connecting the Patient Module to the patient EMG leads. Also, always disconnect the patient EMG leads before removing the Patient Module cable from the Control Unit.

MEP scalp stimulation electrodes can deliver a high voltage shock. To avoid shock, never handle both electrodes at the same time. Confirm both electrodes are securely and properly attached to the patient before initiating any test.

MEP stimulation may introduce additional hazards to the patient through use. Examples of these hazards include: tongue or lip laceration, mandibular fracture, seizure, cardiac arrhythmia, and scalp burn.

A Red Channel may indicate a disconnected or separated electrode or poor electrode impedance. If a failed channel or channel that has been disabled is accepted, responses from this channel will not be detected during stimulation. This could lead to a false-negative result if the myotome is innervated by the spinal level under test. Free Run events on this channel will not be detected.

To avoid trans-thoracic stimulation, confirm both MEP electrodes are properly attached to the patient's scalp or abdomen before initiating any test.

To avoid bite injuries, the patient must be fitted with a bite block before initiating transcranial MEP testing.

MEP stimulation may induce violent muscle contractions throughout the patient's body. Secure physical restraints should be used, and surgical operations should be discontinued before and during MEP stimulation. Confirm the surgeon is well notified prior to any MEP testing.

Only use electrodes supplied with the *NVM5 System*. Use of other electrodes may adversely affect results.

Do not place stimulation electrodes over the patient's neck because this could cause severe muscle spasms resulting in closure of the patient's airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

Do not place stimulation electrodes across the patient's chest because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.

Do not place stimulation electrodes over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins); and

Do not place stimulation electrodes over, or in proximity to, cancerous lesions.

Electrodes should be applied only to normal, intact, clean, healthy skin.

The size, shape, and type of electrodes may affect the safety and effectiveness of electrical stimulation and recording.

Using stimulation electrodes that are too small or incorrectly applied could result in discomfort or skin burns.

Use caution if electrodes are applied over areas of skin that lack normal sensation;

Keep electrodes out of the reach of children;

Replace self-adhesive electrodes if they no longer stick firmly to the patient's skin.

The patient may experience skin irritation and burns beneath the stimulation electrodes applied to their skin; and

The patient may experience headache and other painful sensations during or following the application of electrical stimulation near their eyes and to their head and face.

Do not run any *NVM5* stimulation while *Bendini* is the active displayed screen;

Setting Free Run threshold too high may result in missed free run alert;

The *NVM5 Disposable Accessories* are single-use devices supplied ***sterile***. Sterile, single-use only products should NOT be re-sterilized. Do not use if package is opened or damaged. Do not use if the product is damaged in any way.

The *NVM5 Reusable Accessories* can be used 5 times only and are supplied ***non-sterile***. Do not use if the product is damaged in any way.

The *NVM5 Guidance Universal Clip* may ONLY be used with the *NuVasive NVM5 System, I-PAS*, and the *Guidance System*.

The *NVM5 Disposable Accessories* and *NVM5 Reusable Accessories* may ONLY be used with the *NuVasive NVM5 System*.

If system data acquisition seems inaccurate or if the software application does not initiate or malfunctions during use, and recommended steps to restore the system are not successful, abort use of the system.

The system is not suitable for use in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide.

Precaution:

The long-term effects of cutaneous electrodes for electrical stimulation and/or recording are unknown;

Improperly placed corkscrews may result in poor responses or no responses, even with high electrical current stimulus.

Proper handling, insertion and placement of electrodes is critical for monitoring. Needles should be at least 1" apart. Please follow your hospital's medical waste 'sharps' guidelines for proper disposal of needle electrodes.

Inspect all system components and packaging for damage before use. Do not use sterile components if packaging is opened or damaged. If components are visibly damaged, do not use the system.

Do not use alcohol to clean the Touch Screen on the Control Unit.

Do not allow liquids to enter the Control Unit or Patient Module, as this may result in damage or malfunction of the *NVM5 System*. Avoid dripping any fluids into any Bendini equipment. Disconnect the power and allow the system to dry if you suspect fluids may have entered any part of the System.

The *NVM5 System* is not protected against the effects of defibrillation. Do not use in conjunction with a defibrillator.

While the *NVM5 System* is designed to assist in the electromyographic location of spinal nerves in proximity to the surgical site, it is not intended to take the place of thorough knowledge of spinal anatomy and appropriate surgical technique, nor should the information provided by the system be construed as definitive indicators of nerve location. Such factors as the distance from the nerve, the position and placement of electrodes, individual muscle and/or nerve responses, the proximity and strength of sources of electrical interference, and other patient and environmental factors, may influence the operation. If, in the judgment of the clinician, this resistance is sufficient to preclude properplacement of instruments, the procedure should be suspended.

To avoid trans-thoracic stimulation, the Stimulation Anode should not be located on the chest or upper back. Place this electrode on the lower abdomen, gluteus, or upper flank.

To optimize accuracy of EMG recording, the EMG Common electrode should be located between the site of stimulation and the recording electrodes (e.g., on the flank).

The *NVM5 System* contains sensitive electronic components which may be damaged by electrostatic discharge (ESD). Normal precautions should be taken to avoid causing ESD impulses to occur directly on the EMG input electrodes. For example, it is recommended that before touching the EMG electrodes, the operator should touch the barrel of the main cable connector between the Control Unit and the Patient Module to reduce any accumulated charge on the operator.

Prior foraminal or extraforaminal surgery may leave scar tissue at the site of surgery which can result in undue resistance to instrument insertion. Exercise care in inserting instrumentation in such circumstances to prevent the application of excessive force that can damage internal structures.

The *NVM5 System* is to be used only as an adjunct to medical judgment and appropriate surgical practices. Dilator insertion and advancement should be conducted only after careful analysis of radiographic images of the operative target area. While a positive EMG detection by the *NVM5 System* can be associated with a high level of certainty that a nerve is in close proximity to the Dilator tip, the absence of such an EMG detection cannot be construed as a certain indication that no nerves are close to the Dilator tip. Do not advance Dilator probes until all available data have been considered.

Do not advance the Dilator faster than the rate of update of Detection data.

A thorough cleaning and preparation of the dermal surface prior to placement of recording electrodes is required for proper adherence and sensitivity of the electrodes. It is recommended to apply sufficient skin preparation to achieve acceptable electrode impedance. Caution should be exercised during skin preparation and electrode removal. Excessive preparation and/or sudden removal may lead to skin reaction and abrasion.

In preparing the sites for EMG Electrode placement, patient sensitivity to disinfecting and sterilizing agents (e.g., alcohol, povidine, etc.), electrode materials, and adhesive tapes and electrode backings should be considered to prevent skin reactions.

Using the provided electrode placement instructions, extreme care should be taken to confirm that the recording electrodes have been placed on the correct muscle groups, and on the correct side of the patient, before plugging the EMG Harness into the Patient Module. Failure to follow these instructions may result in the display of inadequate information necessary for data interpretation.

There may be a noticeable muscle twitch in either or both legs during the stimulation. This will subside after a few seconds. Do not attempt to restrain the legs to prevent them from twitching, as this will interfere with the EMG signals.

If the patient moves, or is moved, during the course of surgery, electrode positions may be disturbed. In such instances, electrode positions should be re-examined to confirm proper location, adequacy of contact, and security of connections. Run electrode test to affirm adequacy of EMG electrode contact.

If the intended level of surgery changes intraoperatively, EMG Recording Electrode placement may no longer be appropriate for monitoring one or more of the nerves at or near the operative site. In such an event, the EMG Recording Electrode placement should be should be altered, commensurate with change.

Movement of the patient during stimulation can cause excessive electrical “noise” and/or false EMG (noise) artifacts.

The use of electrosurgical equipment near the *NVM5 System’s* EMG Electrodes may damage the Patient Module or Control Unit.

Over-abrading can cause serious topical reaction to the patient. Always apply using the preferred patient preparation technique.

Do not touch the electrode sites with your fingers/skin as this may compromise the conductivity between the patient’s skin and electrode.

Connection of a patient to electrosurgical equipment and to the *NVM5 System* simultaneously may result in burns at the site of the electrodes and possibly damage the *NVM5 System* circuitry.

Operation of the *NVM5 System* in close proximity to shortwave or microwave therapy equipment may produce instability in the electrical stimulator output.

Do not attempt to repair the *NVM5 System*. Any malfunction which does not respond to remedies identified in this Guide (see ‘TROUBLESHOOTING’ section in the *Quick Reference Manual*) can only be addressed by manufacturer’s service. We require that the device be returned to NuVasive for any such inspection, service, or repair.

Improperly placed or bent needles increase the risk of needle breaking off in the patient.

Do not attempt to straighten bent needles because this may cause stress and weaken the needle causing it to break off in the patient.

Needles are sharp and extreme care must be taken during handling.

Do not allow liquids to enter the Stimulation Probe or Stimulation Clip, as this may result in damage or malfunction of the *NVM5 System*.

Do not use saline irrigation in the vicinity of the Stimulation Electrodes while operating the System. Saline solutions may lead to shunting of the stimulation current resulting in improper operation.

Avoid fluid contact with all cable connections.

Avoid contact between any of the *NVM5 System’s* electrical connections and any other conductive parts, including those connected to protective earth/ground.

Remain alert for audible indications of EMG-like activity as an indicator of nerve trauma. Lack of audible feedback may indicate speaker system malfunction.

The *NVM5 System* will not be able to reliably detect EMG impulses on channels degraded by noise. If an Impedance Test Error occurs, immediate attention should be directed toward correcting the problem by checking the electrode placement, securing the electrodes with tape, and eliminating any other sources of the noise. If excessive ambient noise persists or if a noise error message appears, check the position of all leads and electrodes, and position them as far away from other electronic equipment as possible. Observe the EMG signals using the free run, or evoked potentials display to determine the nature of the noise.

Poor electrode impedance may create susceptibility to electrical interference, which can adversely affect system performance.

Connection of the *NVM5 System* to unapproved equipment may result in dangerous levels of patient leakage currents. Use only approved NuVasive accessories with the *NVM5 System*. Do not use cables or accessories other than those provided with the system.

Audible alert notification of spontaneous EMG events will not be generated when the *NVM5 System* is used with the “Mute” setting activated. To receive all possible audible alerts when using the *NVM5 System*, confirm that the “Mute” setting is not activated.

Placement of recording electrodes within close proximity of one another (less than one inch) may prevent the *NVM5 System* from recording differential responses. To confirm differential responses can be recorded, position the recording electrodes at least 1 inch from each other.

Note the STERILE expiry date. Devices with elapsed STERILE expiry dates have to be considered as non-sterile and may not be used.

Caution: Federal (U.S.) law restricts this device to sale, distribution, or use by, or on the order of, a physician. Exercise caution when increasing max stimulation. Higher stimulation may result in increased patient movement, which may impact retractor position.

Do Not Implant the Instruments: Complications to the patient may include, but are not limited to:

- Nerve damage, paralysis, pain, or damage to soft tissue, visceral organ, or joints.
- Dural leak in cases of excessive load application or impingement of close vessels, nerves, and/or organs by slippage or misplacement of the instrument.
- Bony fracture, especially in the case of deformed spine or weak bone.
- Infection, if instruments are not properly cleaned and sterilized.
- Breakage of the device, which could make necessary removal difficult or sometimes impossible, with possible consequences of late infection and migration. Breakage could cause injury to the patient.
- Pain, discomfort, or abnormal sensations due to the presence of the device.

Patient Education: Preoperative instructions to the patient are essential. The patient should be made aware of the potential risks of the surgery.

Single Use/Do Not Re-Use: Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents.

MRI Safety Information: Do not use the *NVM5 System* in conjunction with, or in the presence of magnetic resonance (MR) devices. The *NVM5 System* is not compatible with the magnetic fields associated with magnetic resonance (MR) devices.

Compatibility: Do not use the *NVM5 System* with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

Pre-Operative Warnings

The methods of use of instruments are to be determined by the user’s experience and training in surgical procedures.

The instruments should be carefully examined prior to use for functionality, excessive wear, or damage. A damaged instrument should not be used as this may increase the risk of malfunction and potential patient injury.

NuVasive does not and cannot warrant the use of instruments nor any of the component parts upon which repairs have been made or attempted except as performed by NuVasive or an authorized NuVasive repair representative.

Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.

Instruments should be protected during storage and from corrosive environments.

All non-sterile parts should be cleaned and sterilized before use.

Inspect all components for damage before use.

Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

Intra-Operative Warnings

The physician should take precautions against putting undue stress on the spinal area with instruments. Any surgical technique should be carefully followed.

It is important that the surgeon exercise extreme caution when working in close proximity to vital organs, nerves, or vessels, and that the force applied to the instrumentation is not excessive, to prevent potential injury to the patient.

Over- bending, notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage.

The physical characteristics required for many instruments do not permit them to be manufactured from implantable materials. If any broken fragments of instruments remain in the body of a patient, they could cause allergic reactions or infections. If an instrument breaks in surgery and fragments go into the patient, these pieces should be removed prior to closure and should not be implanted.

Post-Operative Warnings

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Method of Use

Please refer to the *NVM5 System* Product Reference Manual (doc #9400247) for use of the entire system (software, camera, and accessories).

Refer to the Instructions for Use accompanying other NuVasive devices for proper use of these devices.

Packaging

Certain instruments are provided sterile and intended for single use only. Packages for each of the components should be intact upon receipt. Do not use if package is opened or damaged. This product should NOT be re-sterilized. Discard after use.

Certain instruments are reusable and provided nonsterile. All instruments should be carefully examined for lack of damage prior to use. Damaged packages or products should not be used and should be returned to NuVasive.

Cleaning and Decontamination

The NVM5 Control Unit and Patient Module are not intended for sterilization. If necessary, they may be cleaned with a soft towel or wipe dampened with a mild detergent and water solution according to standard hospital practices.

All non-sterile instruments must first be thoroughly cleaned using the validated methods prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896) before sterilization and introduction into a sterile surgical field. Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. The validated cleaning methods include both manual and automated cleaning. Visually inspect the instruments following performance of the cleaning instructions to confirm there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used, and should be returned to NuVasive. Contact your local representative or NuVasive directly for any additional information related to cleaning of NuVasive surgical instruments.

Sterilization

The steam sterilizable components of the *NVM5 System* are to be packaged in an FDA-cleared sterilization wrap prior to placement in an autoclave. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896).

INFORMATION

Please refer to the *NVM5 Product Reference Manual*, or please contact your local representative or NuVasive directly at +1-800-475-9131 for any information regarding the products or their uses. You may also email: info@nuvasive.com.

This Instructions for Use document is intended for the US market only. For OUS Instructions for Use, please refer to document #9402802.