NEO PEDICLE SCREW SYSTEM ™

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CE 0476

Important Information on the NEO PEDICLE SCREW SYSTEM™

CAUTION: USA law restricts this device to sale by or on the order of a licensed healthcare practitioner.
Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

PURPOSE

The NEO Pedicle Screw System™ is intended to help provide immobilization, correction and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

DESCRIPTION

The NEO Pedicle Screw System™ comprises a variety of sizes of rods, screws, connectors as well as instruments. The implants are all delivered sterile and ready to use. They can be locked together into a variety of configurations which are going to be tailor-made for each individual case. The instruments are mainly delivered as single use sterile, just few are available as reusable and delivered unsterile. For sterilization and reprocessing of reusable instruments refer to the *Neo Medical Pedicle Screw System™ and Neo Medical Cage System™ Processing (cleaning, disinfection, and sterilization) of non-sterile instruments* or to the instructions for use of the specific instrument available for download on www.neo-medical.com/ifu .

The NEO Pedicle Screw System™ consists of pedicle and iliac screws which differ in length and diameter, connecting rods which differ in length and iliac, axial and parallel connectors. All the system components are made of materials compliant with current ISO and/or ASTM standards. Screw and rod are made of titanium-alloy (Ti-6AI-4vELI) and comply with ISO 5832-3 or ASTM-F136. The screws are delivered pre-mounted on a screw guide including a tissue dilator and are sterile. The 500 mm rods are also available in CoCrMo (ISO 5832-12, ASTM F1537). The rods are delivered sterile. The size and form of the devices is adjusted to the morphology of the body and the operation technique.

These implants serve as traditional pedicle screws when used without bone cement in patients. The NEO Pedicle Screw System™ contain fenestrations which allows polymethylmethacrylate (PMMA) bone cement (OSARTIS BonOs® Inject Bone Cement) to be injected into the treated site. This cement is used to augment screw fixation into the pedicle in patients whose life expectancy is of insufficient duration to permit achievement of fusion.

The system includes a removal kit which should be used for revision surgery. The procedure for use is described in the surgical technique. The T-handle option should be used in case an important torque is required to remove the set screw with the solid screw driver.

The system can be used via an open or minimally invasive posterior approach. Iliac screws, connectors and 400, 500 mm rods are intended for use only in open surgery.

Implants of the NEO Pedicle Screw System™ and single use instruments should never be reused under any circumstances. The Instruments are to be used for the implantation of the above mentioned medical devices.

LIMITED WARRANTY AND DISCLAIMER

Neo Medical's products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

SINGLE USE / DISPOSABLE MEDICAL DEVICES

The implants of the NEO Pedicle Screw System™ are for single use. The single use instruments of the NEO Pedicle Screw System™ cannot be reused under any circumstances and are fully disposable. It is forbidden to reuse or to try to re-sterilize any single use part of the NEO Pedicle Screw System™ as certain technical characteristics of the system are not compatible with it. The reuse of any single use component of the system may lead to a risk for the patient.

An attempt to reprocess, clean, sterilize and or disinfect components delivered sterile might lead to infection or toxic reaction. Furthermore, it may negatively impact the performance and characteristics of parts of the system.

After the use all single use instruments need to be disposed of according to local laws and regulations regarding infectious waste.

INDICATIONS

The NEO Pedicle Screw System™, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. The system is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, Curvatures (scoliosis, kyphosis, and/or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

When used in conjunction with BonOs® Inject Cement, the NEO Pedicle Screw System™ is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. NEO Pedicle Screws augmented with BonOs® Inject Cement are for use with 5 mm to 8 mm screw diameters at spinal levels where the structural integrity of the spine is not severely compromised.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Active infectious process or significant risk of infection (immunocompromise).
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented metal allergy or intolerance.
- Pedicular/wall defects.
- An allergy or contraindication to PMMA cement (when used for the cement-related indications).
- Any case not needing a bone graft and fusion.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Pediatric patients or where the patient still has general skeletal growth.
- Any patient unwilling to follow postoperative instructions.
- Any case not described in the indications.
- Any patient with a T-score of > -2.5 (when cement-augmentation is utilized in patients with advanced staged tumors).

ADDITIONAL CONTRAINDICATIONS
(SPECIFIC TO PATIENTS OUTSIDE SCOPE OF PMMA USAGE INDICATIONS)

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- Severe bone resorption.
- Osteomalacia
- Severe osteoporosis.

POTENTIAL ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain.
- Bursitis.
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Ileus, gastritis, bowel obstruction, loss of bowel control, or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

Serious adverse events, some with fatal outcomes, associated with the use of acrylic bone cements in the spine include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and cardiac embolism. Although the majority of these adverse events present early with the post-operative period, there have been some reports of diagnoses beyond a year or more after the procedure.

Other reported adverse events for acrylic bone cements intended for use in the spine include leakage of the bone cement beyond the site of its intended application with introduction into the vascular system resulting in embolism of the lung and/or heart or other clinical sequelae.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

ADDITIONAL POTENTIAL ADVERSE EVENTS (SPECIFIC TO PATIENTS OUTSIDE SCOPE OF PMMA USAGE INDICATIONS)

- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.

WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are: significant mechanical instability of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal tumor, failed previous fusion (pseudarthrosis) and curvatures (scoliosis, kyphosis, and/or lordosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses. In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend, or fracture as a result of exposure to every day mechanical stresses.

Do not use the cannulated screw driver in the pedicle screw instrument kit for revision surgery.

Do not use any of the NEO Pedicle Screw System™ implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another NEO MEDICAL™ document.

The following should be noted as warnings and precautions specific to the instruments used in the injection of cement:

- Always use live imaging when injecting material.
- Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events.

These risks may increase with the number of spinal levels where bone cement is used, and also with the volume of bone cement used.

The rods of the NEO Pedicle Screw System™ can be combined with the iFuse Bedrock Granite® implant system for foundational stabilization in both the SAI and Iliac trajectories. For placement of the iFuse Bedrock Granite® implant system follow the instructions for use and surgical technique provided by the manufacturer SI-BONE, Inc.

PRECAUTIONS

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. In fracture cases where the final goal is reconsolidation of vertebral body without fusion the use of bone graft is not indicated, furthermore, once fracture has healed, the threating physician might decide to remove the implants. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

MANAGING COMPLICATIONS

Best practice to avoid complications and situations potentially leading to adverse events are described in the surgical technique.

IMPLANT SELECTION

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending, or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION

For both cases where an open surgery approach or a MIS posterior approach is used, refer to the NEO Pedicle Screw System™ surgical technique. Iliac screws shall be placed via Sacral Alar Iliac (SAI) and/or Posterior Superior Iliac Spine (PSIS) approach. Any fixation involving the access of the sacral promontory is contraindicated due to high bone density and excessive torque needed for screws insertion.

NEO Pedicle Screw System™ instrumentation contains rods and implants of various diameters, which are intended to be used with device specific instruments. For the set-screw driver, always hold the assembly with the Counter Torque Handle. Tighten and use the torque limiting capability of the set-screw driver to leave the assembly at optimum fixation security. When done according the NEO Pedicle Screw System™ surgical technique, further re-tightening is not necessary and not recommended. AFTER THE SET-SCREW DRIVER TORQUE LIMITING CAPABILITY HAS BEEN USED, RE-ADJUSTMENT IS NOT POSSIBLE UNLESS THE SET-SCREW IS REMOVED AND REPLACED WITH A NEW SET-SCREW AND SET-SCREW DRIVER.

PREOPERATIVE

- Only patients that meet the criteria described in the indications section should be selected.
- Patient conditions and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.

- An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally verify that the necessary items are available before the surgery. The NEO Pedicle Screw System™ components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer.
- Additional components should be available in case of an unexpected need.

INTRAOPERATIVE

- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- Use great care to ensure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct.
- Utilize an imaging system to facilitate surgery.
- To insert a screw properly, a guide wire should first be used, followed by a sharp tap or self-tapping screw. Caution: Be careful that the guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide-wire does not advance during tapping or screw insertion. Remove the guide-wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.
- **Caution**: Do not overtap or use a screw that is either too long or too large. Overtapping, using an incorrectly sized screw, or accidentally advancing the guidewire during tap or screw insertion, may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert.
- If screws are being inserted into spinal pedicles, use as large a screw diameter as will fit into each pedicle.
- Use the Neo cement pushers and pre-fill them with the OSARTIS BonOs® Inject bone cement
- When used with bone cement, prepare in accordance with OSARTIS BonOs® Inject Bone Cement instructions for use. Refer to the OSARTIS BonOs® Inject Bone Cement, instructions for use for a complete review of all warnings and precautions. After the cement is prepared, immediately load the cement pusher per surgical technique. See techniques for guidance on suggested volumes at specific anatomical levels.
- It is recommended that a maximum of 1.8cc of cement be injected in the vertebral body for each NEO Pedicle Screw from T11 to L5 and maximum of 0.8cc of cement be used for each NEO Pedicle Screw used from T1 toT10 of the thoracic spine.

Note: the volume of cement used in Neo Medical Pedicle Screw implants should ultimately be determined by the surgeon based on the individual patient anatomy.

- Manually ensure the alignment of the screw extender with the axis of the screw thread in order to facilitate the insertion of the cement pusher in the appropriate axial position.
- Insert the cement pusher inside the screw extender and screw it down when it has reached the inside thread of the screw extender.
- Imaging systems must be used while cement is being delivered.
- Inject the cement slowly. If any extravasation is seen, stop the injection process immediately.
- Once the cement has been delivered, complete the procedure following the remaining steps outlined in the NEO Pedicle Screw System™ surgical technique.
- Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused. Use of bone graft is not indicated for fracture healing where no fusion is required.
- Before closing, all the set screws must be tightened according to the NEO Pedicle Screw System™ surgical technique.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco, utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
- The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-

union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

- As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.

The NEO Pedicle Screw System™ implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or, unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.

- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the NEO Pedicle Screw System™ components must not be reused under any circumstances.

MR Conditional

MRI Safety Information

Non-clinical testing and MRI simulations and human body model for *in vivo* modeling were performed to evaluate the entire family of the Neo Pedicle Screw System™. Non-clinical testing demonstrated that the entire family of the Neo Pedicle Screw System™ is MR Conditional. A patient with an implant from this family may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Parameter	Condition
Nominal Values of Static Magnetic Field (T)	1.5-T and 3.0-T
Maximum Spatial Field Gradient (T/m and gauss/cm)	40-T/m (4,000-gauss/cm)
Type of RF Excitation	Circularly Polarized (CP) (i.e., quadrature-driven)
Transmit RF Coil Information	There are no transmit RF coil restrictions. Accordingly, the following may be used: body transmit RF coil and all other RF coil combinations (i.e., body RF coil combined with any receive-only RF coil, transmit/receive head RF coil, transmit/receive knee RF coil, etc.)
Operating Mode of MR System	Normal Operating Mode
Maximum Whole Body Averaged SAR	2-W/kg (Normal Operating Mode)
Limits on Scan Duration	Whole body averaged SAR of 2-W/kg for 60 minutes of continuous RF exposure (i.e., per pulse sequence or back to back sequences/series without breaks)
MR Image Artifact	The presence of this implant produces an imaging artifact. Therefore, carefully select pulse sequence parameters if the implant is located in the area of interest.

NOTE: the MRI Safety Information is related only to the implants of NEO Pedicle Screw System™ used alone. The MRI Safety of the Neo Pedicle Screw System™ when used in connection with other implants has not been tested.

REVISION

The removal kit should be used for revision surgery. The procedure for use is described in the surgical technique Do not use the cannulated screw driver in the pedicle screw instrument kit for revision surgery.

PACKAGING

Sterile components of the NEO Pedicle Screw System™ are ready to use, the contents are sterile unless the package is damaged, opened, or the expiration date on the device label has passed. For non-sterile components of the NEO Pedicle Screw System™ please refer to the instruction for use for non-sterile instruments Neo Medical Pedicle Screw System™ and Neo Medical Cage System™ Processing (cleaning,

disinfection, and sterilization) of non-sterile instruments.

Caution: Packages for each of the components should be intact upon receipt. All boxes should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to the local distributor or to NEO MEDICAL S.A.

Caution: Before use the product expiration date must always be checked and not used if expired.

PRODUCT COMPLAINTS

Any health care professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the official distributor of NEO MEDICAL S.A.) and, where applicable, the local competent authority. Further, if any of the implanted spinal system component(s) ever "malfunctions" (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any NEO MEDICAL S.A. product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX, or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact NEO MEDICAL S.A.

EXPLANATION OF SYMBOLS

	Manufacturer	CE 0476	The device complies with Medical Device Regulation 2017/745
Rxonly	CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a licensed practitioner	REF	Catalogue Number
UDI	Unique Device Identification	LOT	Lot number
	Consult instructions for use	MD	Medical Device
	Do not re-use	STERILE R	Sterilized using irradiation
	Caution / Warning		Use by date
	Temperature limit		MR Conditional

	Do not use if package is damaged		Keep dry
	Date of manufacture		Double Sterile Barrier
	Contains hazardous substances (for Cobalt in CoCr rods)		