NEO CAGE SYSTEM ™

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CE 1250

Important Information on the NEO CAGE SYSTEM™

PURPOSE
This device is a titanium alloy Ti6Al4V interbody fusion device intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant's material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations

DESCRIPTION
The NEO Cage System™ comprises a variety of sizes of titanium alloy (Ti-6Al-4V ELI) cages as well as instruments. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with bone graft material. They are all delivered sterile and ready to use.

The cage system consists of cages which differ in length and height. The system includes the relevant instruments which are disposable and delivered sterile. All the system components are made of materials compliant with current ISO and/or ASTM standards. The cages are delivered individually pre-packed in a protection sleeve. The size and form of the devices is adjusted to the morphology of the body and the operation technique.

Implants and instruments of the NEO Cage System™ are single use device and 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 Cage System™ are for single use. The instruments of the NEO Cage System™ are for single use as well and fully disposable. It is forbidden to reuse or to try to re-sterilize any part of the NEO Cage System™ as certain technical characteristics of the system are not compatible with it. The reuse of any part of the system may lead to a risk for the patient.

An attempt to reprocess, clean, sterilize and or disinfect the system 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 instruments need to be decontaminated and disposed according to local laws and regulations regarding infectious waste.

INDICATIONS U.S.A. AND CANADA
Neo Cage System™ is an intervertebral body fusion device intended to be used with autogenous bone graft to facilitate interbody fusion and to be used with supplemental spinal fixation systems that have been cleared for the use in the lumbosacral spine. The cage is to be implanted in open surgery via a posterior or transforaminal approach.

The indication for use is Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have grade 1 Spondylolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- This device is not intended for cervical spine use.
- Infection local to the operative site
- Signs of local inflammation
- An overweight or obese patient can produce loads on the spinal system, which can lead to failure of the fixation of the device or to failure of the device itself.
- Pregnancy
- Open wounds
- Any mental or neuromuscular disorder, which would create an unacceptable risk of fixation failure or complications in postoperative care
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Patients with a known hereditary or acquired bone friability or calcification problem
- Suspected or documented allergy or intolerance to the materials used
- Any case not described in the indications
- Any condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Spondylolisthesis unable to be reduced to Grade 1
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any case that requires the mixing of metals from two different components or systems
- Any patient having inadequate tissue coverage over the operative
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance
- Prior fusion at the level to be treated
- Any neuromuscular deficit, which places an unsafe load level on the device during the healing period

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

Adverse effects may occur when the device is used either with or without associated instrumentation.

The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:

- Implant migration
- Breakage of the device(s)
- Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring
- Pressure on the surrounding tissues or organs
- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Bone fracture or stress shielding at, above, or below the level of surgery
- Non-union (or pseudoarthrosis)
- Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain
- Neurovascular compromise including paralysis, temporary or permanent retrograde ejaculation in males, or other types of serious injury
- Cerebral spinal fluid leakage.
- Hemorrhage of blood vessels and/or hematomas
- Discitis, arachnoiditis, and/or other types of inflammation
- Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus
- Bone graft donor site complication

- Inability to resume activities of normal daily living
- Early or late loosening or movement of the device(s)
- 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
- 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
- Loss of or increase in spinal mobility or function
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.)
- Change in mental status
- Cessation of any potential growth of the operated portion of the spine
- Death

WARNING

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. Use of this product without bone graft or in cases that do not develop a union will not be successful.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.

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

PRECAUTIONS

The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and correct selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and the compliance of the patient will greatly affect the results. The physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fusion device. Patients who smoke have been shown to have a reduced incidence of bone fusion. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol/drug abuse patients and those with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

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. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the human anatomy. Unless great care is taken in patient selection, placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage or loosening of the device before the fusion process is complete, which may result in further injury or the need to remove the device prematurely.

PREOPERATIVE

- Only patients that meet the criteria described in the indications section should be selected.
- Patient conditions and/or predispositions 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.
- The size of device for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those 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 Cage 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

- The instructions in the Neo Cage System™ surgical technique should be carefully followed.
- 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.
- To ensure proper fusion below and around the location of the fusion, autogenous bone graft must be used.
- Utilize an imaging system to facilitate surgery.

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. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity, or sudden jolts or shock to the spine.
- The patient should be advised not to smoke or consume excess alcohol during the period of the bone fusion process.
- The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and/or break, the devices should be revised and/or removed immediately before serious injury occurs.
- Neo Cage System™ implants are interbody devices and are intended to stabilize the operative area during the fusion process.
- 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 Cage System™ components must not be reused under any circumstances.
- Non-clinical testing and MRI simulations were performed to evaluate the entire family of the Neo Cage System™. Non-clinical testing demonstrated that the entire family of the Neo Cage System™ is MR Conditional. A patient with an implant from this family can be scanned safely in an MR system under the following conditions:

    - Static magnetic field of 1.5-Tesla and 3-Tesla, only
    - Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
    - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning in the Normal Operating Mode
    - Under the scan conditions defined, the Neo Cage System™ is expected to produce a maximum temperature rise of 1.1°C after 15-minutes of continuous scanning.

  In non-clinical testing, the image artifact caused by the Neo Cage System™ extends approximately 10-mm from this device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

REVISION

If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the Neo Cage**™** is not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should take into consideration such factors as:

- The risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.

PACKAGING

Sterile components of the NEO Cage 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.

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.). 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

	Do not use if package is damaged	CE 1250	The device complies with EuropeanDirectiveMDD93/42/EEC
Rxonly	CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a licensed healthcare practitioner	STERILE R	Sterilized using irradiation
	Consult instructions for use		Use by date
	Do not re-use	REF	Catalogue number
LOT	Batch code		MR Conditional
	Manufacturer		Caution / Warning
	Temperature limit		Keep dry