INSTRUCTIONS FOR USE
Nexon System

Please read these instructions for use, the cleaning and maintenance instructions and the corresponding surgical technique guide carefully prior to use.

PRODUCT DESCRIPTION
The Nexon Lateral Cage and Nexon Screw are implants for osteosynthesis of the thoracic and lumbar spine. The cages are offered in different dimensions to accommodate individual patient anatomy.

PRODUCT MATERIAL
The Nexon Lateral Cage is made of porous structured titanium (Ti-6AL-4V) and the Nexon Lateral Screw is made of Ti-6Al-4V according to ISO 5832-3.

INTENDED USE
The Nexon System is indicated for intervertebral spinal body fusion in skeletally mature patients.

The implants are designed for use with autogenous bone graft to facilitate fusion.

The devices are to be used in patients that have had at least 6 months of non-operative treatment.

The cage offers the option to be stabilized by screws. Functionally, the screw is only intended for temporary intraoperative fixation, and it does not replace supplemental spinal fixation.

INDICATIONS
The Nexon System implants are indicated for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.

The implants shall be used at either one level or two contiguous levels in the lumbar spine, from L1/L2 to L5/S1. In addition the cage is indicated for the treatment of adult degenerative scoliosis by inducing interbody spinal fusion.

The Nexon System implants are indicated for use for thoracic interbody fusions at one level or two contiguous levels in the thoracic spine, from T4/T5 to T11/T12 and at the thoracolumbar junction (T12/L1). The implant shall be used following discectomy for the treatment of a symptomatic disc degeneration (DDD), including thoracic disc herniation (myelopathy and/or radiculopathy with or without axial pain).

CONTRAINDICATIONS
Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Prior fusion at the level(s) to be treated.

The products must be used by specifically trained personnel only.

POTENTIAL SIDE EFFECTS AND ADVERSE EVENTS
As with all major surgical procedures, there are risks, side effects and adverse events. Such complications, which may result in additional surgery, include early or late infection; damage to blood vessels, spinal cord or peripheral nerves; pulmonary embolism; loss of sensory and / or motor function; Pleural effusion, hemothorax, chylothorax, pneumothorax, subcutaneous emphysema, need for chest tube insertion, intercostal neuralgia, rib fracture, membrane injury; atelectasis; Impotence; persistent pain and / or deformation. In rare cases, complications can be fatal.

Risks related to the use of this system potentially leading to additional surgery include:

1. Bending, fracture or loosening of implant component (s)
2. loss of fixation
3. Infection
4. Reduction of bone density due to stress shielding
5. Pain, discomfort or abnormal sensations due to the presence of the device
6. Nerve damage by surgical trauma
7. Bursitis
8. Dural Leak
9. nonunion or delayed union
10. fracture of a vertebra
11. neurological, vascular or visceral injury
12. Metal sensitivity or allergic reaction to a foreign body
13. Paralysis

PATIENT INFORMATION

Preoperative instruction to the patient is essential. The patient should be aware of the limits of the implant and possible risks of the surgery. The patient should be advised to limit postoperative activity, as this may result in bending, breaking or loosening of implant components. The patient must be made aware that the implant components can break or detach due to high activity levels. During the postoperative period, it is particularly important that the physician keeps the patient informed of all treatments done. Damage to implant or the supporting fixation devices can result in loosening of components, dislocation and migration, and other complications. To ensure the earliest possible detection of such hazards equipment malfunctions must be checked regularly after surgery using suitable imaging techniques.

WARNINGS AND PRECAUTIONS

- The present device is intended for use only as indicated.
- It is strongly recommended that the Nexon System is only used by operating surgeons who are familiar with the general problems of spinal surgery and who are able to master the product-specific surgical techniques. Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.
- Only patients which meet the described criteria should be considered for surgery
- Patient's condition and / or predispositions, as directed in the contraindications mentioned above should be avoided.
- In patients with previous spinal surgery on the level(s) treated may have different clinical outcomes compared to those treated without prior surgery.
- Caution should be taken because of potential patient sensitivity to the materials. The device should not be implanted into patients with known or suspected hypersensitivity to the materials mentioned above.
- Preoperative planning (MRI, CT, X-ray, etc.) to determine patient specific and pathological factors relevant to the success of the surgery (including location and orientation of the vascular structures in the vicinity of the operating site) is highly recommended.
- Neuromonitoring may be optionally used throughout the surgery.
- Proper implant selection is a key factor for successful surgery. The physician should take into account the vertebrae to be fused, patient weight, patient activity level, other conditions of the patient, etc. when determining the implants for surgery. The size and strength of implants should correspond to the size and shape of human bones. Use caution when choosing implant size, as larger implants may not be suitable for the thoracic spine.
- Metallic internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone. These devices can break if delayed union or nonunion occurs.
- Internal fixation appliances are load sharing devices to hold the bony structures in alignment until healing occurs. If healing is delayed or does not occur, the implant may eventually bend, break or it can subside into the bony structure (where nerve compression can lead to pain). The Nexon Implants are not designed for “stand-alone” treatment.
- Nexon Screw fixation is not indicated to substitute additional spinal fixation.
- Do not use with components of other systems.
- Implantation may result in corrosion of the implant. When implanting metals and alloys in the human body, they are subject to the ever-changing environment of ions, acids and alkalis that can cause corrosion. Placing dissimilar metals in contact with each other can accelerate

the corrosion process, which in turn enhances fatigue fractures of implants. Consequently, all efforts should be made to only use similar metals in contact to each other; thus the use of Nexon devices together with materials from other supplier should be avoided.

- Before completion of the surgery it should be carefully checked that all implants are finally in place and secured. All components should be finally tightened according to the surgical technique. Implants should not be overtightened as this can potentially damage the implants.
- All implants should be used only with the correspondingly designated instrument as indicated in the surgical technique. Instruments and implants are not interchangeable between systems.
- Notching and / or scratching of implants or instrument may increase risk of breakage and should be avoided. Implants shall neither be processed mechanically nor modified in any other way. Deformation or buckling may lead to stress on the material and cause it to fail under load-bearing conditions.
- The implants should not be scratched or damaged. Implants and instruments should be protected during storage and in corrosive environments. Devices should be examined for damage prior to implantation.
- To prevent damage to the device(s) and injury to the patient instruments and implants should only be used according to the surgical technique.
- Single Use: The implants are strictly designed for single use. Do not re-use implants Due to the porous structure standard sterilization techniques might not be sufficient to ensure sterility.
- Do not use, if the package is damaged or the vacuum of the double pouch is breached.
- Do not remove the implants from the packaging until immediately before use.
- The REF. and the LOT No. of the applied implant shall be documented in the patient's records for traceability. Adhesive labels are provided in the implants packaging.
- The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/ or operating techniques, the limitations of treatment methods, or inadequate asepsis.

COMBINATION OF MEDICAL DEVICES

Unless otherwise stated, Nexon Medical devices are not to be combined with the components of other systems. Nexon Medical has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

APPLICATION

Please refer to the NEXON LATERAL CAGE SYSTEM Surgical Technique (901.000.201).

CLEANING AND DECONTAMINATION OF NEXON INSTRUMENTS

All instruments are provided non-sterile and must be sterilized before use. Please refer to the NEXON SYSTEM Instructions for Processing of Instruments and Care & Maintenance (901.000.301).

STERILE IMPLANTS

The Nexon System implants are supplied sterile. Sterilization is performed using gamma-irradiation. Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use. Prior to use, check the product expiration date and verify the integrity of the sterile packaging.

Single Use Only: The implants are strictly designed for single use only. Do not re-use implants. Do not re-sterilize opened implants. Due to the porous structure standard sterilization techniques might not be sufficient to ensure sterility.

CAUTION: Do not use, if the package is damaged or the vacuum of the double pouch is breached.

MRI SAFETY INFORMATION

The Nexon Lateral Cage Implants has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artefact in the MR environment. The safety of Nexon Lateral Cage Implants in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.

KEY TO SYMBOLS

CE 0481	„Conformité Européene“ with Number of Notified Body		Do not re-use
	Date of Manufacture		Do not use if package is damaged
	Use-by date	STERILE R	Sterilized by irradiation (R)
REF	Catalogue number		Do not resterilize
LOT	Batch Code		
	Manufacturer		All product literature is available as pdf at www.nexonmedical.ch/eifu

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