neoWave™ C

Product Instructions for Use

All Rights Reserved
Confidential

Xenix Medical
149 W. Michigan Street
Orlando, FL 32806

STERILE PRODUCT and NON-STERILE SURGICAL INSTRUMENTATION

BEFORE USING THIS PRODUCT, READ THE FOLLOWING THOROUGHLY.

Important Information on the neoWave C porous titanium interbody cage

Description:
The neoWave C porous titanium interbody fusion device is used to maintain disc space distraction in skeletally mature patients requiring an intervertebral body fusion. It is designed to be used in conjunction with supplemental spinal fixation instrumentation. The implant is available in a range of footprints and heights to suit the patient's pathology and anatomical conditions of the patient. The implant contains interconnected porosity and allow for radiological evaluation. The implants include large central, vertical graft windows, and smaller interconnected graft pathways, which may be packed with bone graft material prior to implantation.

The neoWave C porous titanium interbody fusion devices are additively manufactured from Titanium6Al-4V per ASTM F-3001. To achieve the best results, unless otherwise specifically described in another neoWave C document, do not use cervical components in conjunction with components from any other system or manufacturer. neoWave C warrants that these devices are fabricated from the foregoing material specification. No other warranties expressed or implied, are made.

Devices incorporate Xenix Medical's proprietary NANOACTIV™ micro and nano-roughened surface designed to improve fixation to adjacent bone. The Xenix Medical implant surfaces have been engineered with surface features at a nanometer (10^{-9}) level, which have demonstrated the ability to elicit an endogenous cellular and biochemical response as represented by mineralization in human mesenchymal stem cells *in vitro*. The implant surface demonstrates elements to be considered a nanotechnology as outlined in the FDA nanotechnology guidance document. *In vitro* results may not be representative of clinical performance. Note: Supporting Study Data will be provided upon request.

Caution:
Federal law (USA) restricts this device to sale and use by, or on the order of a physician.

All implants are intended for single use only. The neoWave C porous titanium interbody cage must not be reused under any circumstances. The NeoWave C porous titanium interbody cage is not a stand-alone device and must be utilized in conjunction with supplemental anterior cervical plate fixation. These instructions for use are designed to assist in use of the neoWave C porous titanium interbody cage and are not a reference for surgical techniques.

Indications:
The neoWave C Porous Titanium Cage is intended for use in skeletally mature patients with cervical degenerative disc disease (DDD) at one level or two contiguous levels from C2 to T1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received six (6) weeks of prior non-operative treatment prior to treatment with the device. The devices must be used with supplemental fixation and must be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion.

Contraindications:
- Acute or chronic infectious diseases of any etiology and localization
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Metal/polymer sensitivity/allergies to the implant materials
- Mental illness, alcoholism, drug abuse
- Medical or surgical conditions, which would preclude the potential, benefit of spinal implant surgery.
- Grossly distorted anatomy due to congenital abnormalities
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any condition that totally precludes the possibility of fusion, e.g., cancer, kidney dialysis.
- Any case not described in the Indications.
- Any patient unwilling to cooperate with the post-operative instructions.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance, or if the patient has grossly distorted anatomy caused by congenital abnormalities.
- Symptomatic cardiac disease.
- Systemic or terminal illness.
- Prior fusion at the level to be treated.

These contraindications can be absolute or relative and must be taken into account by the physician when making surgical decisions. The list above is not exhaustive.

Possible Adverse Events:
A listing of possible adverse events includes, but is not limited to:
- Bending or fracture of implant.
- Loosening of the implant.
- Implant material sensitivity, or allergic reaction to a foreign body.
- Infection, early or late.
- Decrease in bone density due to stress shielding.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Tissue damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Dural tears.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Change in mental status.
- Non-union (or pseudarthrosis). Delayed union. Mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of spinal mobility or function.
- Inability to perform the activities of daily living.
- Paralysis.
- Death.

Note: Re-operation or revision may be necessary to correct some of these anticipated adverse events.

Warnings and Precautions:
The neoWave C porous titanium interbody cage is intended to be used to augment the development of a spinal fusion by providing temporary stabilization while a solid fusion mass forms. This device is not intended to be the sole means of spinal support. The use of autogenous bone graft must be part of the spinal fusion procedure in which the neoWave C porous titanium interbody cage is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, loosening, disassembly and/or breakage of the device will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the neoWave C porous titanium interbody cage 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 and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery.

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

Never use a STERILE implant if the packaging is damaged. Never use a STERILE implant that is past its expiration date.

PHYSICIAN NOTE: *Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.*

CAUTION: *The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.*

CAUTION: *The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. The physician should always consider a variety of patient conditions including but not limited to the levels of implantation, patient weight, and patient activity level, which may have an impact on the performance of the intervertebral body fusion device.*

MRI Safety Information:

The Xenix Medical neoWave C porous titanium interbody system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Xenix Medical neoWave C porous titanium interbody system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury**.**

neoWave™ C is and NANOACTIV™ are registered trademarks of Xenix Medical

CAUTION: *FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.*

Implant Selection:
The choice of proper size, shape, and design of the implant for each patient is crucial to the success of the surgery. 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 fatigue and consequent breakage 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. The surgeon is responsible for this choice, which is specific to each patient. Overweight patients may be responsible for additional stresses and strains on the device, which can speed up fatigue and/or lead to deformation or failure of the implants. The surgeon must be thoroughly trained with the surgical procedure, instrumentation and implant characteristics prior to performing surgery. The use of dissimilar materials (e.g., titanium and stainless steel) should not be used together because of the risk of galvanic corrosion.

Preoperative:
- Only patients that meet the criteria described in the indications 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 especially from corrosive environments.
- The type of construct to be assembled 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.
- The surgeon must ensure that all necessary implants and instruments are available and on hand prior to surgery.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The neoWave™ C porous titanium interbody cage components are not to be combined with the components from another manufacturer.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.
- All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to all surgeries.
- A surgical technique manual may be obtained from Xenix Medical or any of its representatives.

Intraoperative:
- Any instruction manual should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.
- Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.
- Before closing the soft tissues, all of the devices should be securely seated.
- Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.

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 risk of fatigue and/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, demented or otherwise unable to use crutches or other such weight supporting devices. 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 device should not be exposed to mechanical vibrations 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 or consume alcohol during the bone graft healing process.
- The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. 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 eventual 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. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of initial implant removal.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved neoWave C implantable devices should ever be reused under any circumstances.

Packaging and Storage:
Packages for each of the components should be intact upon receipt. All sets and components should be carefully checked for completeness and lack of damage prior to use. Damaged packages or products should not be used, and should be returned immediately to Xenix Medical.

The implants are delivered in sterile packages; these must be intact at the time of receipt. The implants are provided STERILE and are individually packed in protective packaging that is labeled according to its contents.
- Do not remove the STERILE implant from the packaging until immediately before use.
- The STERILE implant should be stored in ambient temperature in a secure location.

Both inner and outer packaging of STERILE implants, including seals, should be thoroughly inspected prior to implantation.

Cleaning and Decontamination:
Instruments of the neoWave C porous titanium interbody cage are supplied clean and NON-STERILE and must be sterilized prior to use.

Cleaning:
All instruments must first be cleaned before sterilization and introduction into a sterile surgical field.

Precleaning:
Remove debris from instruments with sterile water and sponge during the procedure to prevent drying of blood and bodily fluids. Blood and bodily fluids are highly corrosive and can produce stains that are difficult to remove.

Cleaning:
All instruments must first be thoroughly cleaned before sterilization and introduction into a sterile surgical field.

Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment.

Prepare an enzymatic cleaning solution per manufacturer's specifications. Separate dissimilar metal instruments and disassemble all instruments. Fully immerse and soak all instruments in enzymatic cleaner for 15 minutes. Fill all cannulations with enzymatic cleaner. Use a small soft-bristle brush to remove visible soil from all surfaces of the instrument while fully immersed in the solution paying special attention to remove soil from hinges, jaws, tips, box locks, and ratchets. Agitate the instruments in the solution while scrubbing. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. Actuate any movable parts to loosen any trapped soil. Rinse instruments under warm (38-49°C) running water until all evidence of detergent is removed. Place the instrument into a bath containing warm (38-49°C) water. Agitate the instruments by hand for at least three minutes. All cannulations must be fully flushed until rinse water runs clear. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Prepare an enzymatic cleaning solution to the manufacturer's specifications using distilled water. Ultrasonicate devices for 10 minutes, ensuring the devices are completely submerged. Rinse instruments under warm running water for at least one minute or until all evidence of detergent is removed. All cannulations must be fully flushed until rinse water runs clear. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Dry with clean lint-free cloth and/or allow to air dry.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The instruments should be inspected and checked to make certain they are functioning properly. Visually inspect all devices for any evidence of deterioration, corrosion, and/or discoloration and if found, the instrument should be replaced.

Sterilization:
The implants are clearly labeled STERILE and are provided clean and sterile. These devices are sterilized with gamma sterilization with a Verification Dose (10^{-6} SAL) 6.6 kGy (range of 5.9 to 7.3 kGy) validated by AAMI/ANSI/ISO 11137 – method VDmax[25].

The implants should never be cleaned or otherwise reprocessed and 9)should be discarded if they becomes soiled. Verify the expiration data and return or discard any expired devices.

For NON-STERILE instrumentation, moist heat sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline ST79:2006 according to the following validated cycle parameters:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Prevacuum	270°F(132°C)	4 minutes	60 minutes

Wrap tray with a towel placed between tray and FDA cleared wrap.

The Sterility Assurance Level (SAL) is 1 x 10^{-6}, via the indicated methods. No claims of pyrogenicity are made.

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Always immediately re-sterilize all instruments used in surgery. This process must be performed before handling or returning to Xenix Medical.

It is the end user's responsibility to use only sterilizers and sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications.

Product Complaints:

Any Health Care Professional who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify Xenix Medical or its representative. Further, if any of the implanted neoWave C porous titanium interbody cage component(s) ever malfunctions, Xenix Medical or its representative must be notified immediately.

If any Xenix Medical product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or Xenix Medical must be notified immediately by telephone, fax or in writing.

For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help Xenix Medical understand the cause of the complaint.
If further information is needed or required, please contact:

Xenix Medical
149 W. Michigan Street
Orlando, FL 32806

Phone: 888-594-6433

neoWave™ C ™ and NANOACTIV™ are registered trademarks of Xenix Medical

XENIX

PN M010 Rev. E (08/2025)

GRAPHIC SYMBOLS:



Catalog Number



Lot Number/Batch Code


Manufacturer


Use by Date



Sterilized using Irradiation


Do not use if package is damaged

E- 
Consult electronic Instructions for use
www.xenixmedical.com



Non-sterile


Single Use Only; Do not re-use


Caution



Federal Law (USA) restricts this device to
sale by or on the order of a physician

neoWave[tm] C [is] and NANOACTIV[TM] are registered trademarks of Xenix Medical