INDICATIONS FOR USE

NEXUS Spine Spacer System, a GEO Structure® is indicated for use in the thoraco-lumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The NEXUS Spine Spacer System is also indicated for treating fractures of the thoracic and lumbar spine. The NEXUS Spine Spacer System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

DESCRIPTION OF DEVICE

The NEXUS Spine Spacer System implants are designed to be highly porous to allow for maximum volume of bone ingrowth. The new bone formation through the implant is intended to provide long-term structural support to the surrounding tissue, rendering the implant inert. The large internal void of the implant is intended to facilitate the use of bone graft materials to facilitate bony ingrowth.

To facilitate placement of the implant into the defect site, an inserter plate has been incorporated into the side of the implant to accommodate the insertion instrument.

PRODUCT CONFIGURATIONS

The NEXUS Spine Spacer System is provided either sterile or nonsterile as indicated on the labeling. If the device is provided nonsterile, it should be cleaned and sterilized prior to use.

The NEXUS Spine Spacer System is provided in a wide range of sizes to allow the surgeon a variety of options when determining the appropriate size for the procedure.

INSTRUCTIONS FOR USE

Caution: The NEXUS Spine Spacer System implants should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Refer to the NEXUS Spine Spacer System Surgical Technique Manual for complete Instructions For Use.

CONTRAINDICATIONS

Contraindications include, but are not limited to,

1. infection, systemic, spinal or localized;
2. morbid obesity;
3. signs of local inflammation;
4. fever or leukocytosis;
5. metal sensitivity/allergies to the implant materials;
6. any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count;
7. grossly distorted anatomy due to congenital abnormalities;
8. 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);
9. any case not needing a bone graft and fusion or where fracture healing is not required;
10. any case requiring the mixing of metals from different components;
11. any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition;
12. any case not described in the indications;
13. any patient unwilling to cooperate with the postoperative instructions;
14. any time implant utilization would interfere with anatomical structures or expected physiological performance.
WARNINGS
In using metallic surgical implants, the surgeon should be aware of the following:
1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weightbearing.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
3. The correct handling of the implant is extremely important. Contouring of the metal devices is to be avoided.
4. For nonsterile devices, the implants and instruments must be cleaned and sterilized prior to surgery. For sterile devices, the instruments only must be cleaned and sterilized prior to surgery.
5. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together. The NEXUS Spine Spacer System should not be used with components from any other system or manufacturer.
6. As with all orthopaedic implants, the NEXUS Spine Spacer System implant should never be reused under any circumstances. Even though it appears undamaged, it may already have small defects in internal stress patterns that may lead to fatigue failure.
7. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
8. Postoperative care is important. The patient should be instructed in the limitations of his/her metallic implant and should be cautioned regarding weightbearing and body stress on the appliance prior to secure bone healing

PRECAUTIONS
Preoperative:
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindications should be avoided.
3. 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.
4. 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.
5. Because 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 Biomet NEXUS Spine Spacer System implant is not to be combined with the components from another manufacturer. Different metal types should not be used together.
6. All components and instruments provided nonsterile should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.
7. Carefully inspect all instruments prior to use. Do not use an instrument that is severely marred and/or worn, or a cutting instrument with dull edges. Note that at some point in time, instruments may wear out and should be replaced

Intraoperative:
1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in loss of neurological functions.
3. The implant surfaces should not be scratched or notched since such actions may reduce the functional strength of the construct.
4. Bone grafts must be placed in the area to be fused and the graft must be in contact with viable bone.

Postoperative:
1. The physician’s postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.
2. 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 or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of an 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.
3. To allow 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, 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.
4. 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.
5. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause 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. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the Biomet NEXUS Spine Spacer System implants should ever be reused under any circumstances.

COMPLICATIONS
Possible adverse effects include, but are not limited to,
1. bending, loosening or fracture of the implants or instruments;
2. loss of fixation;
3. sensitivity to a metallic foreign body, including possible tumor formation;
4. skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications;
5. nonunion or delayed union;
6. infection;
7. nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage;
8. gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
9. pain or discomfort;
10. bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of the vertebra);
11. hemorrhage of blood vessels and/or hematomas;
12. malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height;
13. bursitis;
14. bone graft donor site pain;
15. inability to resume activities of normal daily living;
16. reoperation
STERILIZATION

NEXUS Spine Spacer System implants are provided both sterile and nonsterile. Implants that are labeled as “sterile” are sterilized via gamma irradiation. All packaging for both sterile and nonsterile implants should be sealed and intact upon receipt. If the package or product is damaged, the implant should not be used and should be returned immediately.

Non sterile implants must be cleaned and sterilized prior to use. In addition, in the event of accidental contamination of a sterile NEXUS Spine Spacer System implant, the implant may be resterilized prior to use. The NEXUS Spine Spacer System implant must be sterilized in a properly functioning, calibrated steam sterilizer. High temperature steam sterilization should be used. All packaging materials must be removed prior to sterilization. The following sterilization cycle should be used:

- Method: Steam
- Cycle: Pre-vacuum
- Temperature: 270°F (132°C)
- Exposure Time: 8 minutes
- Drying Time: 20 minutes

CAUTION

Federal (USA) law restricts these devices to sale by or on the order of a licensed physician.

INFORMATION

For further information, please contact your local Biomet Distributor. In the United States contact Biomet Customer Service at:

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