STANSION MATRIX INSTRUCTIONS – FOR – USE

Indications For Use
The STANSION MATRIX is indicated for use in the thoracolumbar spine (*i.e.,* T1 to L5) to replace a portion of a diseased vertebral body that is resected or excised for the treatment of tumors, where the defect is contained within a single vertebral body, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The device is also indicated for treating fractures of the thoracic and lumbar spine. The STANSION MATRIX 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 of time. The device is intended for use with supplemental rigid posterior pedicle screw fixation.

Description Of Device
The STANSION MATRIX implants are designed to allow for a maximum volume of bone ingrowth. This growth of new bone through the implant is intended to provide long term structural support to the surrounding elements, thus rendering the implant static. At the front and rear ends of the implant are attachment sites to accommodate an insertion tool. The top and bottom of the implant has a series of indentations to assist in site fixation.

Product Configuration
The STANSION MATRIX implant is provided in nonsterile sealed packaging. The device should be cleaned and sterilized prior to use. The STANSION MATRIX is provided in 7 sizes to allow the surgeon a variety of options when determining the appropriate size for the procedure.

Instructions For Use
Caution: The STANSION MATRIX should only be implanted by surgeons who have previous experience in the use of such implants and the required specialized spinal surgery techniques.

Contraindications
Contraindications include, but are not limited to, any medical or surgical condition which would inhibit the potential benefit of spinal implant surgery such as: systemic infections that are either localized or spinally uncontained; morbid obesity; signs of local inflammation; fever or leukocytosis; metal sensitivity/allergies to the implant materials; elevation of white blood count; magnified deformations of the localized anatomy due to congenital irregularities, joint disease, significantly advanced osteoporosis or osteopenia, incidents of significant bone loss or compromised bone stock; any case not needing a bone graft; any case where there exists significant tissue loss or compromised coverage from said tissues; any case not described within the Indications For Use; any situation where the patient is unwilling to cooperate with the Postoperative Instructions, pregnancy, drug or alcohol abuse.

Warnings
Surgeons should be aware of the following information before utilizing metallic surgical implants:
1. Selecting the correct size, shape and design of an implant is extremely important. Selecting the proper implant can increase the potential for surgical and healing success.
2. The size of the human spine, the associated internal shapes or existing anatomical abnormalities, may present limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
3. The surgeon must confirm that all necessary implants and instruments are present prior to surgery. The device must be handled and stored with care and protected from damage. They should be carefully unpacked and inspected for damage prior to use.
4. For any nonsterile devices, all implants and instruments must be cleaned and sterilized prior to surgery.
5. The mixing of dissimilar metals has shown to accelerate the corrosion process. Stainless steel and titanium implants must not be used together.
6. The STANSION MATRIX implant should never be reused under any circumstances.
7. Proper patient selection, implant choice, and patient postoperative education and subsequent compliance will significantly affect the surgical outcome.

Cleaning
Implants must be clean and free of bio-contaminates prior to sterilization. Implants must be cleaned and inspected by hospital personnel trained in contaminant removal. Clean by immersion and/or hand washing in a warm neutral aqueous cleaning solution. Soak or ultrasonic clean soiled products for a minimum of 10 minutes. Scrub threads and hard to reach areas with a small brush. Rinse for several minutes using a flush of de-ionized or distilled water. Dry and inspect implants for dryness prior to sterilization**.**

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Precautions

Preoperative:

1. Only patients meeting the criteria described in the **Indications For Use** should be selected.
2. Any patient defined to have those conditions and/or predisposals addressed in the aforementioned **Contraindications** should be avoided.
3. The implants should not be scratched or damaged during handling and storage. Likewise all instruments should be kept in proper working order.
4. A sufficient amount of implants should be made available at the time of the surgery to address the predetermined size to be utilized; as should a full selection of other sizes for any unforeseen changes that may occur intraoperatively.
5. The surgeon should be familiar with all implants chosen for each case and should personally assemble any devices to be used in conjunction with said implants.
6. All implants and instruments should be provided for each case clean and ready for sterilization.

Intraoperative:

1. Surgeons should carefully follow any instruction manuals.
2. Damage to nerves may occur and result in the loss of neurological function. Care should be taken at all times to protect the spinal cord and associated nerve roots.
3. The structural integrity of a metallic implant can be compromised by scratches or notches. Care should be taken to avoid these problems.
4. Bone graft must be placed in the area to be fused and the graft must be in contact with viable bone.

Postoperative:

1. Detailed instructions on the use, limitations and proper postoperative compliance of the implant should be given to each patient.
2. The patient should be warned about the possible risks to effective bone healing caused from, but not limited to, the following situations: excessive inappropriate bending, non-prescribed weight bearing, exposure to mechanical vibrations and consumption of alcohol and smoking.
3. If it is determined that a nonunion has occurred at the implant site, an immediate reoperation should be considered to address the problem. Failure to address a well fixed implant can result in excessive stress upon the implant possibly leading to fracture or displacement of the implant.
4. All implants retrieved in a surgical revision should be properly disposed of and never reimplanted in any other surgical procedure.

Complications

Possible adverse effects include, but are not limited to, deformation, migration, loosening, or fracture of the implants or instruments; loss of fixation; sensitivity to a metallic foreign body, including possible tumor formation; skin break down from inadequate tissue coverage over the operative sight, which may result in wound complications; nonunion or delayed union; infection; nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage; pain or discomfort; bone loss due to absorption or stress shielding, or bone fracture at, above or below the level of surgery; hemorrhage of blood vessels and/or hematomas; bursitis and/or other types of inflammatory conditions; deep venous thrombosis, thrombophlebitis and/or pulmonary embolus; adverse effects due to wear debris; malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height; inability to resume activities of normal daily living; reoperation or death.

Sterilization

The STANSION MATRIX implants are provided nonsterile. Prior to use, nonsterile implants must be cleaned and sterilized. The STANSION MATRIX implant must be sterilized in a properly functioning and calibrated steam sterilizer. The following sterilization cycle should be used:

Method:	Steam
Cycle:	Prevacuum
Temperature:	132°C/270°F
Exposure time:	4 min

Caution

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

SpineWorks
2802 Florida Street
Huntington Beach, CA
92648
Tel: (714) 969-9100
Fax: (714) 374-5100
PN 10029 Rev9

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