PROMETHEAN RESTORATIVE™ INC.
333 Perry Street, Suite 210
Castle Rock, CO 80104
USA

INSTRUCTIONS FOR USE

Rx ONLY

Before Using Product, Read the Following Information.

Info-PR@prometheanrestorative.com
prometheanrestorative.com
1 (720) 512-5947

DYNAMIS® IMPLANT SYSTEM

ENGLISH EN

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

DESCRIPTION: The DYNAMIS® Implant System is a minimally invasive sacroiliac joint fusion implant that is intended for implantation across the joint space (i.e., the implant transfixes the SI joint). The DYNAMIS® Implant System consists of threaded, fenestrated, cannulated, 3D-printed implants and associated instruments. Implants are constructed from medical grade titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The implants are fully threaded with a lag design.

To accommodate varying patient anatomy, the DYNAMIS® Implants are available in multiple diameters and length offerings. The DYNAMIS® Implants consist of a cannulated central threaded body. The implants, available in various lengths and diameters, allow for packing of autograft and allograft materials. Using the designated instrument system, two or more implants should be inserted across the SI Joint to apply a compressive force across the joint and to provide stabilization and fusion. The DYNAMIS® Implants are single use devices that are provided sterile.

DYNAMIS® TRU-NANO screws: The surfaces of the DYNAMIS® TRU-NANO Screws incorporate a micro- and nano-roughened surface that demonstrates the requirements for nanotechnology. The surface of the screws have been deliberately manipulated to produce nanoscale dimensions which exhibit specific properties. These screws are electrochemically treated to possess a controlled nanotopography composed of nanotube arrays having a pore size diameter between 30-97 nanometers. Calcium and phosphate are incorporated into the nanotube surface.

INTENDED USE: The DYNAMIS® Implant System is indicated for sacroiliac joint fusion for: Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis. Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. The DYNAMIS® Implant System is also indicated for fracture fixation of the pelvis, including acute, non-acute and nontraumatic fractures.

INTENDED USER: Surgical procedures should be performed only by people having adequate training and familiarity with surgical techniques. Consult medical literature relative to techniques, complications, and hazards prior to performing any surgical procedure. Before using this product, all instructions regarding its safety features must be read carefully.

CONTRAINDICATIONS: Contraindications include, but are not limited to: infection, local to the operative site, signs of local inflammation, fever or leukocytosis, morbid obesity, pregnancy, mental illness, alcoholism, drug abuse, heavy smoking, cancer, diabetes, any medical or surgical condition, which would preclude the potential benefit of surgery, suspected or documented metal allergy or intolerance, any case requiring the mixing of metals from different components, any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition, any case not described in the Indications, any patient unwilling to cooperate with the post-operative instructions. Deformities or anatomic variations that prevent or interfere with implant placement. Bone tumor involving the site of operation. Compromised vascularity that would inhibit adequate blood supply to the operative site.

POTENTIAL ADVERSE EVENTS: Potential adverse events include, but are not limited to:

- Potential adverse events include fracture of components, reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively. Potential risks also include those associated with any surgery resulting in neurological, vascular, cardiovascular, respiratory, gastrointestinal, or reproductive compromise, or death. Additional surgery may be necessary to correct some of these anticipated adverse events. Additional risks may include reactions to anesthesia, hemorrhage, bone, muscle, or tissue damage, hematoma or seroma, injury to pelvic structures, infection, peritonitis, wound dehiscence, pulmonary or systemic embolism, thrombosis, death, bruising, local swelling, and radiation exposure.

WARNINGS AND PRECAUTIONS: These warnings do not include all adverse effects that can occur with surgery in general but are important considerations to general surgical risks and should be explained to the patient prior to surgery.

1. Women of childbearing age should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fusion. If pregnancy occurs the woman should review delivery options with her obstetrician.
2. Patients with previous SI Joint fusion on the treated side may have different clinical outcomes.
3. Correct selection of the implant is important to minimize risks of symptomatic malposition, inadequate fracture fixation, inadequate stabilization of the SI joint, or over advancement of the implant.
4. These implants have not been studied in patients with osteopenia or osteoporosis.
5. Patient factors such as size and weight may make the implants more difficult to implant.
6. Implants are for single-use only, an explanted implant should never be re-implanted.
7. For optimum results careful preoperative diagnosis and planning, meticulous surgical technique and extended post-operative care by experienced surgeons are essential.
8. Prior to use, the surgeon should be specifically trained in the use of this system and the associated instrumentation to facilitate correct selection and use of the instruments.
9. An active, debilitated, or uncooperative patient who cannot properly restrict activities may be at particular risk during post-operative rehabilitation for migration, loosening, or fracture of the implant.
10. Potential risks identified with the use of this device system which may require additional surgery include device component failure, neurological, vascular, or visceral injury, failure to achieve SI fusion, fracture of ilium or sacrum, non-union or delayed union,

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decrease in bone density due to stress shielding, and potential difficulty in delivering a fetus vaginally due to device related restriction of SI joint stretching.

11. Cutting, bending, scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the system and should be avoided where possible. These in turn may cause cracks and or internal stresses that are not obvious to the eye and may lead to fracture of the components or the need for re-operation or removal of the implant(s).
12. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis which can cause corrosion. Putting dissimilar metal (e.g., titanium and stainless steel) in contact with each other can accelerate the corrosion process which in turn may enhance fatigue fractures of implants. Thus, every effort should be made to use compatible metals and alloys.
13. Special protection of instruments during storage is recommended when exposed to corrosive environments such as moisture, salt, air, etc.

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warnings and Precautions should be avoided.
3. Use care in handling and storage of the implants and instruments. Prior to surgery components should be inspected for any evidence of damage or corrosion.
4. An adequate inventory of implants and instruments should be available at the time of the surgery.
5. All non-sterile components should be cleaned and sterilized before use.
6. Before the initial procedure we recommend that the surgeon critically review all available information and consult with other surgeons that have experience with the device.

INTRAOPERATIVE:

- Care should be taken when using the implants and instruments to avoid neurological damage.

POSTOPERATIVE:

- Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing.

MANUAL CLEANING: Reusable devices are supplied non-sterile and must be thoroughly cleaned prior to sterilization.

Point of Use:

1. It is recommended that instruments should be reprocessed as soon as reasonably practical following use.
2. Reprocessing begins at the point of use, which includes initial cleaning measures to prevent drying of the soil and contaminants in and on the device.
3. Do not use saline or chlorinated solutions in order to prevent corrosion of the instruments.

Presoaking:

1. Keep instruments moist and do not allow blood and/or body fluids to dry on the instruments.
2. Soak and/or rinse heavily soiled instruments prior to cleaning to loosen any dried soil or debris. Use a neutral pH (7-9) enzymatic soak or detergent.
3. Follow the manufacturer's instructions for proper use and preparation of the enzymatic cleaner. Use the recommended exposure time, temperature, water quality, and concentration.
4. Use cold tap water to rinse the instruments.

Disassembly and Articulation:

1. Disassemble instruments, if possible, prior to cleaning. Refer to the Surgical Technique Guide for instructions.
2. Open any articulating instruments, if possible.

Cleaning:

1. Unless specifically labeled as STERILE, reusable devices are supplied non-sterile and must be thoroughly cleaned prior to sterilization.
2. The most important step in decontamination is thorough cleaning and rinsing of each device.
3. Lumens/Cannulas should be brushed using appropriately sized brushes using a twisting action. Brushes should be tight fitting.
4. Instruments with multiple components should be articulated to allow cleaning solution to enter and debris to be removed from crevices.
5. Rinse the soiled instruments under cold tap water for a minimum of two minutes. Use a soft bristle brush to remove gross soil and debris.
6. Soak the instrument in a neutral pH (between 7-9) enzymatic cleaner or detergent solution in cold to warm tap water for a minimum of ten minutes.
7. Follow the manufacturer's instructions for proper use and preparation of the enzymatic cleaner. Use the recommended exposure time, temperature, water quality, and concentration.
8. Rinse the device in cold tap water for a minimum of two minutes. Use appropriate cleaning techniques to flush lumens, channels, and other hard to reach areas.
9. Manually clean the instrument for a minimum of five minutes in a newly prepared neutral pH enzymatic cleaner or detergent with a temperature >40°C. Use a soft bristled brush to remove soil and debris. Actuate joints, handles, and other movable instrument features to expose all areas to the solution. Clean the instruments under water to prevent aerosolization of contaminants.
10. Rinse the instrument thoroughly with warm Deionized or purified water with a temperature >40°C for a minimum of two minutes. Use a soft bristled brush to remove soil and debris. Actuate joints, handles, and other movable instrument features to expose all areas to the solution.
11. Visually inspect the instrument and repeat cleaning steps until no visible soil remains on the instrument.
12. Perform a final rinse using cold deionized or purified water for a minimum of two minutes.
13. Dry the device using a clean, soft, lint free cloth or clean compressed air.

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DISCLAIMER: It is the responsibility of the reprocessor to ensure reprocessing is performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This requires validation and routine monitoring of the process. Any deviation by the reprocessor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.

MAINTENANCE: Apply lubricant only on the connecting elements (locking mechanism) and moving parts. Discard damaged, worn or non-functional devices.

LIMITATIONS ON REPROCESSING: Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.

PACKAGING: Implants are provided Sterile; do not re-sterilize. Components labeled as STERILE were sterilized by Gamma radiation. Packages for each of the components should be intact upon receipt. Do not use implants after the expiration date. Do not use if package is damaged. If the tamper proof seals or sterile packaging appear to be compromised or damaged, return the package and its contents to Promethean Restorative™ Inc.

Components labeled as NON-STERILE must be thoroughly cleaned prior to sterilization. All sets should be carefully checked for completeness and all components should be carefully checked for damage prior to use. Do not use if damaged.

The non-sterile instruments are provided in a modular case specifically intended to contain and organize the system's components. The system's instruments are organized into trays within each modular case for easy retrieval during surgery. These trays also provide protection to the system components during shipping. Additionally, individual instruments are provided in sealed poly bags with individual product labels. Unless otherwise noted, these poly bags are provided non-sterile.

STERILIZATION: When using an FDA cleared wrap to ensure that the device is sterile prior to use. The system should be sterilized by the hospital using the recommended cycle:

Autoclave Cycle:	Prevacuum
Pulses:	4
Temperature:	270°F (132°C)
Time:	4 minutes
Drying Time:	30 minutes

INSTRUCTIONS FOR USE: For complete instructions refer to the appropriate surgical technique provided by your local sales representative.

MRI COMPATIBILITY: The DYNAMIS® Implant 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 this system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

COMPLAINTS: Any adverse event or issue with any device, should be reported to the manufacturer Promethean Restorative™ Inc at Complaints-PR@prometheanrestorative.com.

WARRANTY: All products are guaranteed to be free from defects in material and workmanship at the time of shipping. Promethean Restorative™ Inc instruments are reusable and meet AAMI standards for sterilization. All our products are designed and manufactured to meet the highest quality standards. We cannot accept liability for failure of products which have been modified in any way from their original design.

Symbol Key	
	Manufacturer
Rx ONLY	Federal Law (USA) restricts these devices to sale by or on the order of a physician.
LOT	Batch Code
REF	Catalog Number
	Do not re-sterilize
	Do not re-use
	Consult instructions for use
	Caution
NON STERILE	Device is provided Non-Sterile; Device must be sterilized prior to use
US	Country of Manufacture
MD	The device is a Medical Device
STERILE R	Sterilized using Irradiation
	Use by Date
	Do not use if package is damaged