RIVA Posterior Fixation System
Product Instructions for Use
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XENIX MEDICAL
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Country of Manufacture (USA)

NON-STERILE PRODUCT and SURGICAL INTRUMENTATION
ALL **IMPLANTS** ARE INTENDED FOR ***SINGLE USE ONLY***
FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE AND USE BY, OR ON THE ORDER OF A PHYSICIAN
BEFORE USING THIS PRODUCT, READ THE FOLLOWING INSTRUCTIONS THOROUGHLY

DESCRIPTION:
The Xenix Medical RIVA Posterior Fixation System consists of medical grade Titanium Alloy (Ti-6Al-4V ELI) Implants and surgical instrumentation for implantation. Implants are provided non-sterile in a steam sterilization tray in various lengths and diameters. The reusable instrumentation is provided non-sterile in a steam sterilization instrument tray. The system consists of an assortment of implants including screw shanks, screw head assemblies, rods, set screws, connectors, and cross connectors manufactured from Ti-6Al-4V ELI titanium alloy. Rods may also be manufactured from Cobalt Chrome alloys. The system is attached to the vertebral body in the non-cervical spine.

INDICATIONS:
The Xenix Medical RIVA Posterior Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system or anterolateral fixation, in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and/or sacral spine:

- Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies).
- Spondylolisthesis
- Trauma (i.e. fracture or dislocation).
- Spinal Stenosis
- Deformities or curvatures (i.e scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Xenix Medical fenestrated screws are intended to be used with saline or radiopaque dye.

Xenix Medical RIVA Posterior Fixation System Navigation Instruments are intended to be used with the Xenix Medical RIVA Posterior Fixation System during surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic® StealthStation® S8 System, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the vertebra, can be identified relative to a CT or MRI based model, fluoroscopy images, or digitized landmarks of the anatomy.

COMPATIBILITY:
Xenix Medical is not the navigation system provider. The instruments have been tested to verify positional accuracy for use with Medtronic's StealthStation® S8 Navigation System in combination with the Medtronic® NavLock® tracker clamps and arrays. The instructions for use and the handling of third-party navigation systems, including software, are the responsibility of the hospital/surgery center and the navigation system company.

CONTRAINDICATIONS:
Contraindications include, but are not limited to:

- Deformities or anatomic variations that prevent or interfere with implant placement.
- Signs of local inflammation or active infection at treatment site.
- Suspected or documented allergy or intolerance to components and materials used during the procedure.
- Morbid obesity or patients with conditions such as mental illness, alcoholism or drug abuse may be at higher risk for implant failure.
- 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 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.
- Patients unwilling or unable to follow post-operative care instructions
- Any circumstance not listed under the heading indications

POSSIBLE ADVERSE EVENTS:
All the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

- Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy).
- Pedicle screw mispositioning, with or without neurological or vascular injury
- Proximal or distal junctional kyphosis
- Post-operative infection, wound necrosis, wound dehiscence, or peritonitis
- Local swelling, Pain, discomfort, or abnormal sensations due to presence of the implant
- Bruising
- Pedicle screw failure, such as screw or rod bending, breakage, or loosening.
- Device component failure
- Loss of fixation/stabilization
- Fracture of the vertebra
- Non-union, delayed union or mal union.
- Post-operative change in spinal curvature, loss of correction, heigh, and/or reduction.
- Infection
- Pressure on skin where inadequate tissue coverage exists over the implant, with potential extrusion through the skin
- Dural leak requiring surgical repair
- Cessation of growth of the fused portion of the spine
- Subsidence of the implant into adjacent bone
- Increased biomechanical stress on adjacent levels
- Hemorrhage
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Metal sensitivity, or allergic reaction to a foreign body, debris, corrosion products, including metalloids, staining, tumor formation and/or autoimmune disease
- Vascular injury or damage that may result in catastrophic or fatal bleeding
- Decrease in bone density due to stress shielding
- Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
- Serious complications associated with any surgery may occur. These include, but are not limited to wound complications, infection, genitourinary disorders, gastrointestinal disorders, respiratory disorders; cardiovascular disorders, including myocardial infarction (heart attack) or arrythmias; neurologic injuries resulting in weakness, paralysis, numbness, tingling, or pain; vascular (blood vessel) injuries, including hemorrhage (bleeding); thrombosis (blood clots) leading to deep venous thrombosis or pulmonary embolism; or death.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events

WARNINGS AND PRECAUTIONS:

- The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These

conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

- The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Non-Sterile Instruments: Ensure sterilization before each use. All instruments shall be handled adequately to avoid damage or injuries related to the surgical instruments provided by Xenix Medical.
- Clean Before Sterilization and Use: All instruments must first be cleaned before sterilization and introduction into a sterile surgical field.
- Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments and their capacity to perform adequately. Such products shall not be used.
- Cleaning Materials: Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments, as these practices may hinder the capacity of the instruments to perform adequately.
- Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection of placement of the implants are important considerations in the successful utilization of the system.
- Refer to the navigation system company's software and user guides for calibration and navigation guidance. Compatible third-party navigation clamps and arrays are listed in the Surgical Technique Guide for the Xenix Medical RIVA Posterior Fixation System. Ensure the hospital/surgery center has the appropriate third-party navigation instruments prior to starting the procedure
- Prior to use, carefully read and follow all instructions, including cleaning and sterilization methods.
- The selection of the proper implant size 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 patient weight, size, and patient activity level, which may have an impact on the performance of the device. Pre-operative X-rays and/or CT scan may be helpful in selecting implant size
- Patient adherence to post-operative physical activity instructions is important to support long term service life of the implant
- Inspect instruments and implants prior to use for any damage. Do not use if damaged or worn.
- The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

MRI SAFETY INFORMATION:

The Xenix Medical RIVA Posterior Fixation 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 RIVA Posterior Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. Do not perform MRI activities unless otherwise authorized.

DIRECTIONS FOR USE:

For detailed information, refer to the Xenix Medical RIVA Posterior Fixation System Surgical Technique Guide.

General Notes on the Use of Navigated Instruments:

The following section mainly covers the specific procedures for using the Xenix Medical Navigated Instruments for the Xenix Medical RIVA Posterior Fixation System. Please refer to the Surgical Technique Guide for the Xenix Medical RIVA Posterior Fixation System for the surgical steps of the procedure. Before using the Xenix Medical Navigated Instruments, please read the following information:

- Prior to navigation and frequently throughout the instrument use, check the instrument accuracy and anatomical registration accuracy after calibration and registration by positioning the instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the navigation system.
- For each change to navigated instrumentation assembly (i.e., assembly and reattachment of a new screw, tracker's adapter, clamp, array, and spherical markers), the accuracy must be re-verified.
- If accuracy is suspected, discontinue use.
- Do not rely on the stereotactic navigation system if it does not appear to be accurate or if registration of Xenix Medical Navigated Instruments fails despite troubleshooting (such as a system reset). A non-navigated technique using fluoroscopy and the appropriate Xenix Medical instruments should be utilized.
- At all times while using, make sure the navigation tracker is visible to the camera of the navigation system.
- The navigation tracker will rotate around the instrument shaft to accommodate the awls, awl tip-taps, taps, and the implant inserter. When using the instrument, please hold the tracker, so that the array markers will always be visible to the camera.
- If any parts seem loose, bent, or otherwise damaged, do not use the tracker or the Xenix Medical Navigated Instruments.

PREOPERATIVE WARNINGS:

- Only patients that meet the criteria described in the indications should be selected.
- Patient condition and/or predispositions such as those described in the contraindications should be avoided.
- Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
- All non-sterile parts should be cleaned and sterilized before use. Additional sterile components should be available in case of unexpected need.
- Devices should be inspected for damage prior to implantation.
- Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

INSTRUMENT END OF LIFE DETERMINATION:

Visually inspect the reusable instruments to determine if any instrument has reached its end of life. Xenix Medical instruments have reached end of life when:

- Instruments show signs of damage, such as bending, breakage, visible or overt signs of wear and/or any other conditions which may impact safe and effective use.
- Instruments intended for cutting or impaction into bone show signs of wear such as nicks, abrasions or dulled cutting surfaces.
- Instruments that interface with other devices (i.e., implant or instrument handle) bind or fail to hold the device securely. Instrument function should be verified prior to each use.

Do not use instruments which have reached end of life. Please return to Xenix Medical for evaluation and disposal.

INTRAOPERATIVE WARNINGS:

- Consult the Surgical Technique Guide for system specific intraoperative warnings, precautions, and recommendations.
- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological function.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- Implants and components should not be bent, reshaped, contoured, or otherwise modified.
- Use great care to ensure that the implant surfaces are not scratched or notched.
- If the construct contains screws and or connectors, prior to soft tissue closure, recheck all screws, connectors, and locking caps to ensure they are tightened. Failure to do so may cause loosening of the other components.

POSTOPERATIVE WARNINGS:

- Surgeons should advise patients regarding the risks of surgery and the importance of post-operative compliance.
- The patient should be advised to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation.
- The patient should be advised that implants may bend, break, or loosen despite restriction in activity.

- The patient should be advised to avoid mechanical vibrations that may loosen the device. The patient should be advised not to smoke or consume alcohol during recovery.

COMPLAINTS:

Immediately notify Xenix Medical or a Xenix Medical Representative by phone, fax, or email regarding complaints, malfunctions, or adverse events associated with this product. When possible, retain the product involved in the complaint and return to Xenix Medical as instructed by Xenix Medical Customer Service.

PACKAGING AND STORAGE:

Packaging 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.

Instruments and implants are provided as **NON-STERILE** and shall be cleaned and sterilized prior to each use.

ADDITIONAL NOTES:

- Implants and Instruments shall be handled with extreme care and stored in a controlled environment location that prevents extreme conditions or other eminent dangers to the integrity and fitness of the instruments.
- Implants and Instruments are provided in secure trays that contain retention positions within tray. Instruments should only be moved (transported) when using their individual trays unless authorized by Xenix Medical.
- Implants and Instruments shall be cleaned and sterilized before use.

CLEANING AND DECONTAMINATION:

Instruments and Implants of the Xenix Medical RIVA Posterior Fixation System are supplied clean and **NOT STERILE** and must be sterilized prior to use.

These instructions are provided in accordance with AAMI TIR12, AAMI TIR30, and ISO 17665 and are intended to supplement a hospital's existing instrument cleaning and disinfecting protocols. Use of these guidelines does not remove or limit the end-user's ultimate responsibility for the cleanliness and sterility of any surgical device used at their facility.

It is recommended to rinse the device components with critical water that meets specifications for AAMI TIR34 for example, DI/RO water.

Point of Use Cleaning:

Remove debris from instruments with sterile water and sponge during the procedure to prevent drying of blood and bodily fluids. Taking measures to prevent the drying of soil on the device will facilitate subsequent cleaning steps. Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment. 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. Xenix Medical instrument trays have been validated for either manual or automated cleaning procedures. It is recommended that a manual processing be performed prior to any automated cleaning to remove gross contaminants. Complex instruments such as those with lumens or hinges may require special attention.

MANUAL CLEANING STEPS

1	**Remove debris from instruments and rinse in ambient temperature tap water to remove visible soil.** **NOTE: Disassembly of instrumentation is not required**
2	Prepare enzymatic solution, such as Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner or equivalent, per manufacturer's directions and submerge device in enzyme solution. Fill all cannulations with enzymatic cleaner. Actuate the device while it is submerged and sonicate for a minimum of 15 minutes.
3	Scrub the device using an appropriately sized soft-bristled brush while fully immersed in solution. Pay special attention to brush any lumens for a minimum of 2 minutes. If needed, actuate at several locations to access all surfaces. Use of a syringe (minimum of 60 mL, 3 times) or water jet is recommended for hard-to-reach areas, rinsing until exiting water runs clear.
4	Rinse devices in warm water for a minimum of 1 minute.
5	Prepare cleaning solution, such as Prolystica® 2X Concentrate Alkaline Detergent, per manufacturer's recommendations and submerge and actuate devices in cleaning solution and sonicate for a minimum of 10 minutes.
6	Thoroughly rinse devices with DI/RO water to remove all detergent residues for a minimum of 2 minutes. All cannulations must be fully flushed until rinse water runs clear.
7	Visually inspect each instrument for contamination. If there is any visual soil, repeat cleaning steps until the instruments are visibly clean.
8	Dry devices with a clean, lint free cloth and/or allow to air dry.

AUTOMATED CLEANING STEPS

1	**Rinse devices in ambient temperature tap water to remove visible soil. Complex instruments, such as those with lumens and hinges require special attention during cleaning. Actuate devices where appropriate. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe with ambient temperature tap water where debris could become trapped.** **NOTE: Disassembly of instrumentation is not required**
2	Prepare enzymatic solution, such as Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner or equivalent, per manufacturer's recommendations and submerge devices in enzyme solution. Fill all cannulations with enzymatic cleaner and soak for a minimum of 15 minutes.
Place devices into a Washer/Disinfector and process through a surgical instrument cycle as follows:	
3	Enzyme wash using cleaner such as Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner or equivalent, per manufacturer's recommendations, using hot tap water (66°C/150°F minimum) for a minimum of 4 minutes.
4	Detergent wash using detergent such as Prolystica® 2X Concentrate Alkaline Detergent or equivalent, per manufacturer's recommendations, using hot tap water (66°C/150°F minimum) for a minimum of 2 minutes.
5	Rinse with hot DI/RO water (66°C/150°F minimum) for a minimum of 2 minutes.
6	Dry using hot air (115°C/239°F minimum) for a minimum of 12 minutes.
7	Visually inspect each instrument for contamination. If there is any visual soil, repeat cleaning steps until the instruments are visibly clean.

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, components and instruments are to be sterilized by the hospital prior to surgery.

Implants and Instruments are provided **NON-STERILE** and must be cleaned and sterilized before use. Non-sterile implants and instruments should be autoclaved in accordance with the sterilization parameters previously validated by *ANSI/AAMI/ISO 17665-1: 2013. Sterilization of health care products-Moist Heat-Part1Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices and ANSI-AAMI ST79:2010- Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* These parameters were validated to sterility assurance level ***(SAL) of 10 $^{-6}$.***

Using the Xenix Medical Instrument Tray, Steam Sterilize prior to use according to the following parameters:

Method	Steam
Cycle Type	Pre-vacuum
Temperature	270°F (132°C)
Exposure Time	4 minutes
Minimum Drying Time	30 minutes
Configuration	Double wrapped using an FDA cleared wrap

GRAPHIC SYMBOLS:



Catalog Number



Lot Number/Batch Code


Manufacturer


Do not 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