# SOLACE™ Sacroiliac Fixation System

**Product Instructions for Use**

**All Rights Reserved**

**XENIX MEDICAL**
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**Country of Manufacture (USA)**

**STERILE PRODUCT and NON-STERILE 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 SOLACE Sacroiliac Fixation System consists of 3D printed medical grade Titanium Alloy Implants (Ti-6Al-4V ELI per ASTM F-3001) and surgical instrumentation for implantation. Implants are provided sterile in various lengths and diameters. The reusable instrumentation is provided non-sterile in a steam sterilization instrument tray.

## INDICATIONS:

The SOLACE Sacroiliac Fixation System is intended for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including degenerative sacroiliitis and sacroiliac joint disruptions
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion

The SOLACE Sacroiliac Fixation System is also indicated for fracture fixation of acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

The SOLACE Sacroiliac Fixation System Navigation Instruments are intended to be used with the SOLACE Sacroiliac 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 pelvis or vertebra, can be identified relative to a CT or MRI based model, fluoroscopy images, or digitized landmarks of the anatomy.

**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.**

## 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:

- Deformities or anatomic variations that prevent or interfere with implant placement.
- Tumor of sacral or iliac bone.
- 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.
- Medical or surgical conditions which would preclude the potential benefit of sacroiliac surgery.
- 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.

**POSSIBLE ADVERSE EVENTS:** As with other surgical procedures for sacroiliac joint fusion and/or pelvic fracture fixation use and/or misuse of this system include, but are not limited to the following:

- Post-operative infection, wound necrosis, wound dehiscence, or peritonitis
- Local swelling, Pain, discomfort, or abnormal sensations due to presence of the implant
- Bruising
- Migration, loosening, or fracture of the implant requiring surgical intervention.
- Loss of fixation/stabilization
- Non-union, delayed union or mal-union.
- 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.
- 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
- Potential difficulty in delivering fetus vaginally due to device-related restriction of SI joint stretching
- Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
- Death

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

## WARNINGS:

- 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.
- Women with the potential for childbearing should be cautioned that vaginal delivery of a fetus may not be advisable after fusion of the SI joint. If a pregnancy is possible or occurs, women should review delivery options with her physician.
- 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 SOLACE Sacroiliac Fixation System. Ensure the hospital/surgery center has the appropriate third-party navigation instruments prior to starting the procedure.

**PRECAUTIONS:**

- 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.
- Do not use implants if packaging has been opened or damaged.
- Inspect instruments and implants prior to use for any damage. Do not use if damaged or worn.

**MRI SAFETY INFORMATION:**

The Xenix Medical SOLACE™ Sacroiliac Fixation System Implant 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 SOLACE Sacroiliac Fixation System Implants 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 SOLACE Sacroiliac 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 SOLACE Sacroiliac Fixation System. Please refer to the Surgical Technique Guide for the Xenix Medical SOLACE Sacroiliac 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 (IMPLANT):**

- 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. Units 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 SOLACE Sacroiliac Fixation System implants are not to be combined with the components from another manufacturer.
- All 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.

**PREOPERATIVE (INSTRUMENTS):**

- The surgeon using these instruments should have full understanding of the surgical technique and the instrument's application. This includes functions and limitations of each instrument.
- All instruments should be inspected prior to use to ensure that there is no potential damage, unacceptable wear, or non-functioning components.
- All instruments should be handled with care and stored in a manner that ensures the prevention of scratches, damage, corrosion, loss or other.

**Instrument End of Life Determination:**

Visually inspect the reusable instruments to determine if the instruments have 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 (drill, tap, spiked guide, pin) 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 (IMPLANT):**

- At all times, extreme caution should be used around the spinal cord and nerve roots.
- Damage to nerves may 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.
- Before closing the soft tissues, all 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 (IMPLANT):**

- 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 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 movement.
- 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.
- 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 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.

**POSTOPERATIVE (INSTRUMENTS):**

- Postoperative operations should include an inventory count of the instruments before changing locations.
- This includes the logistical movement from OR (Operating Room) to decontamination and sterilization areas.
- Ensure that the set, or instrument, or assembly of instruments, is complete and accounted for.
- In case of damage, communicate immediately if any of the units of unit components has been damaged or is no longer fit to continue to be use as part of the set.
- Note any additional information regarding change of instruments after preoperative operations.
- NOTE: Disassembly of instrumentation is not required for cleaning.

**PACKAGING & 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.
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. Instruments are provided as **NON-STERILE** and shall be clean and sterilized prior to each use.

**ADDITIONAL NOTES:**

- 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.
- 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.
- 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.
- Instruments shall be cleaned and sterilized before use.

**CLEANING AND DECONTAMINATION:**

Instruments of the SOLACE™ Sacroiliac 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.<br>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.<br>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:**

Implants are clearly labeled **STERILE** and are provided clean and sterile. These devices are sterilized using gamma irradiation processes validated by AAMI/ANSI/ISO 11137-2-Method VDmax[25].

Instruments are provided **NON-STERILE** and must be cleaned and sterilized before use. Non-sterile 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-Part1Requierments 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 | Cycle Type | Temperature | Exposure Time | Dry Time | Configuration |
|---|---|---|---|---|---|
| Steam | Pre-Vacuum | 270°F (132°C) | 4 minutes | 30 Minutes | Double wrapped using an FDA cleared wrap |

**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