panaSIa SI Fusion System

wenzel spine

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LBL-0106 Rev C

System Contents:
- Sterile Implants – Single Use Only
- Non-Sterile Instruments - Reusable

Caution: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DESCRIPTION and INTENDED USE:

The Wenzel Spine panaSIa SI Fusion System is implanted into the SI joint space via a posterior approach.

The panaSIa device is a threaded, expandable SI Fusion Device with an interior sliding wedge and a proximal end cap. The device is generally frustoconical in shape, designed to stabilize the SI joint by piercing the adjacent cortical bone when expanded. The panaSIa SI Fusion Device has large fenestrations to allow for uninterrupted graft contact across the SI joint space.

INDICATIONS FOR USE:
The Wenzel Spine panaSIa SI Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

CONTRAINDICATIONS:
1. Acute or chronic infection of the SI joint
2. Deformity, post traumatic or developmental, which will not accept the device
3. Inadequate bone density, osteoporosis or osteomalacia, which may cause an inability to hold the device
4. Compromised metabolic or nutritional status that will impair postoperative healing
5. Inadequate skin or soft tissue coverage
6. Primary sacroiliac instability, ligamentous laxity or inadequacy
7. Inadequate bone surface area to accept a bone grafting procedure
8. Inadequate ability to visualize with proper imaging equipment/bone landmarks
9. Inadequate surgical training and experience with the technique by surgeon or staff
10. Inadequate or inappropriate bone graft to accomplish the grafting/arthrodesis procedure successfully
11. Incomplete set of the necessary instruments, including proper guide pins and tools for the distracting, alignment, drilling, preparation and implantation steps
12. Very small or very large habitus outside the range for available surgical tools and implants
13. Surgical conditions that preclude the possible benefits of sacroiliac surgery (e.g. severe damage to bony structures at the implant site, or severely deformed anatomy due to anomalies)
14. Medical conditions that could be an obstacle to successful implantation (e.g. obesity, mental illness, pregnancy, pediatric cases, poor general health, lack of cooperation on the part of the patient, unstable psychosocial circumstance
15. Inadequate physical proximity to medical care for evaluation, re-evaluation and support/ revision of the procedure
16. Pelvic pain or instability due to neoplasia, primary or metastatic cases not included in the indications
17. Cases not included in the indications
18. Hypersensitivity or allergy to Titanium: Ti-6Al-4V, Grade 5, ELI

MATERIALS:
The panaSIa SI Fusion Devices are manufactured from Titanium Alloy (Ti6Al4V ELI per ASTM F136). Surgical instruments provided with the panaSIa implants are manufactured from stainless steel (per ASTMs A276, A564, F899 or equivalent), aluminum (per ASTM B211-12 or equivalent), or polymeric materials.

CLEANING of INSTRUMENTS:
During the surgical procedure the instruments should be kept as free of bioburden as possible by wiping all surfaces with a moistened sponge and placing them in a basin filled with sterile water. Avoid saline as it causes corrosion and deterioration of the instrument surfaces. Any instruments which were assembled during the procedure should be disassembled. Do not disassemble any instruments with multiple, permanently attached components. At the conclusion of the procedure, universal precautions should be implemented to clean and re-sterilize all instruments. The cleaning method must prevent cross contamination, damage to the instruments, and injury to the worker. Avoid the use of metallic brushes and scouring pads. Cleaning instructions have been validated on the worst-case instrument.

The recommended validated procedure for thoroughly cleaning the instruments is as follows:

Step	Solution	Time (Min)	Temperature	Instruction
1	Hospital Grade Detergent and Water	10	Warm, as delivered from the available hot water tap	Immerse and soak for required time, then scrub all surfaces, including fine features and hard to reach areas, with soft bristle brush. Inspect for visible soil on all surfaces.
2	Hospital Grade Detergent and Water	As Required	Warm, as delivered from the available hot water tap	Ultrasonic if required to remove visible soil not removed in Step 1.
3	Water	As Required	Ambient	Rinse thoroughly immediately after Step 1 or 2.
4	Air	As Required	Ambient	Allow to air dry in clean area, to speed drying, place in clean oven at temperature not to exceed 50˚C.

Preparation and Assembly: After thorough cleaning and drying, visually inspect all instruments. Check for misalignment, burrs, and bent or fractured tips. Return all instruments to the instrument case and secure them in their appropriate brackets, as depicted on the bottom of the case.

INSPECTION
1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your Wenzel Spine representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Wenzel Spine representative for a replacement.

STERILIZATION:
The panaSIa SI Fusion Device is provided sterile packaged with a five (5) year shelf-life. A 25kGy sterilization dose that resulted in a SAL of 10-6 was validated using VDmax25 per AAMI TIR 27, ISO 11737-1 and ISO 11737-2.

The five (5) year shelf-life was validated in accordance with ASTM F1980 - 07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

The surgical instruments provided for use with the panaSIa Fusion Devices are provided non-sterile.

Wenzel Spine instruments and instrument cases are generally composed of aluminum, stainless steel, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing the cleaning, sterilization, and drying cycle that has been validated and listed below. Instrument cases do not provide a sterile barrier and must be used in conjunction with sterilization wrap to maintain sterility.

The following moist heat sterilization that resulted in a SAL of 10-6 was validated for use:
Method: Moist Heat
Cycle: Pre-Vacuum
Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Dry Time: 30 minutes
Wrap: 2 times utilizing FDA cleared wrap

The moist heat sterilization cycle above was validated for use with the panaSIa surgical instruments in accordance with AAMI TIR No. 12-1994, ISO 17664:2004 and ANSI/AAMI ST79:2006.

Instruments should be positioned to allow steam to come into contact with all surfaces. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled.

Should the original sterile implant package be inadvertently opened or compromised before implantation, the metallic devices may be resterilized prior to use following the guidelines listed below.

The following moist heat sterilization that resulted in a SAL of 10-6 was validated for use with the panaSIa implants
Method: Moist Heat
Cycle: Gravity Displacement
Temperature: 270°F (132°C)
Exposure Time: 9 minutes
Dry Time: 30 minutes
Wrap: 2 times utilizing FDA cleared wrap

This 9 minute exposure at 270°F sterilization cycle is not considered by the United States Food and Drug Administration (US FDA) to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery.

POSTOPERATIVE MOBILIZATION:
The surgeon should advise the patient to restrict bending, lifting, and twisting for six weeks after surgery. The surgeon may advise the patient to limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

WARNINGS:
Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general but are important considerations particular to SI fusion devices. General surgical risks should be explained to the patient prior to surgery.

PATIENT SELECTION:
In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

1. A patient may have multiple pain generators. Careful review of the clinical record, including radiographic studies and applicable diagnostic tests, should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.
2. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to loosening or failure of the implant.
3. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause loosening or failure of the implant.
4. Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
5. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
6. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

PRECAUTIONS
1. THE IMPLANTATION OF SI JOINT FUSION DEVICES SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT. Based on fatigue testing results, when using the panaSIa SI Fusion Device, the physician/surgeon should consider patient weight, patient activity level, other patient conditions, etc., which may have an impact on the performance of the device.
2. DO NOT USE IN UNEXPANDED OR PARTIALLY EXPANDED STATE. This device is not intended for use in the unexpanded or partially expanded state.
3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
4. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
5. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is non-compliant with post-operative guidance is particularly at risk during the early postoperative period.
6. MRI Safety Information. The panaSIa devices have 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 the panaSIa devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

RISKS
1. Adverse reaction to anesthesia
2. Bruising
3. Hemorrhage
4. Hematoma or seroma
5. Bending or fracture of implant.
6. Loosening or migration of the implant
7. Allergic reaction to a foreign body
8. Local swelling
9. Infection
10. Pain, discomfort, or abnormal sensations due to the presence of the device
11. Vascular and/or nerve damage due to surgical trauma or presence of the device
12. Paralysis
13. Death

LIMITED WARRANTY:
Wenzel Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Wenzel Spine for current information.

For product information, questions pertaining to sales and service, or to request a surgical technique manual, please contact your local sales representative or Wenzel Spine customer service.

To report a product event or product feedback, please contact Wenzel Spine Quality at productcomplaints@wenzelspine.com.

Key to the symbols on the labeling:

	Single use - do not reuse
	Use By Date
	Caution, Consult Documents
	Keep Dry
REF	Catalogue Number
LOT	Lot number
STERILE R	Sterility symbol: R: gamma rad. min.25 kGy
	Not to be used in case package is damaged
	Manufacturer
Qty.	Quantity of items in package
NON STERILE	Sterility Symbol: Non-sterile
Rx only	Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.
	Consult Instructions for Use