Nevro1™ Sacroiliac Transfixing and Fusion System
INSTRUCTIONS FOR USE

NON-STERILE PRODUCT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The Nevro1™ Sacroiliac Transfixing and Fusion System (Nevro1™) is a titanium fusion device that has a hollow chamber to permit packing with autogenous graft material to facilitate fusion. The superior and inferior surfaces of the device have a rough surface to help prevent movement of the device while fusion takes place. Additionally, the device has integrated fixation through superior and inferior transfixing anchoring plates.

These implants may be implanted via an open or MIS posterior approach. The Nevro1™ is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. The system is comprised of a Titanium Alloy (Ti-6Al-4V ELI) implant with integrated transfixing anchors.

The Nevro1™ implants are provided in 8 degrees of angle, 9, 11, 13 mm heights, 26 mm width and 23 mm depth. The titanium alloy implant also comes preassembled with integrated transfixing anchors.

MATERIALS

The Nevro1™ device body is made from a 3D printed titanium alloy Ti-6AL-4V (Grade 23) per ASTM F3001-14. The internal device components (bridge, anchor plates, deployment ram, dowel pins and retention blocking screw) are made of titanium (TAV) per ASTM F136.

INDICATIONS FOR USE

The Nevro1™ Sacroiliac Transfixing and Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

SURGICAL PROCEDURE

Please contact a customer service representative or company representative for the surgical procedure.

PATIENT SELECTION

The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome.

CONTRAINDICATIONS

Contraindications may be relative or absolute. Nevro1™ components are contraindicated in the following patient situations:

1. Deformities.
2. Tumor resection.
3. Infection local to the operative site and/or signs of local inflammation.
4. Failed previous fusion.
5. Suspected or documented allergy or intolerance to the component materials.
6. Any condition not described in the indications for use.

WARNINGS

1. Inspect implant prior to use. Do not use if implant is damaged.
2. Correct selection of the implant is extremely important. The potential for satisfactory joint fusion is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present a limitation on the size, shape and strength of the implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand the unsupported stress of a full weight bearing indefinitely.
3. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation devices are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also cause early failure. Patients should be fully informedof the risks of implant failure.
4. Mixing metals can cause corrosion. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of which can lead to fatigue fracture and the amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., which come in contact with other metal objects, therefore must be made from like or compatible metals.
5. Correct handling of the implant is extremely important. Excessive torque, when applied to long-handled insertion tools can cause splitting or fracture of the implants. When an implant is impacted or hammered into place, the broad surface of the insertion tool should be carefully seated fully against the implant. Impaction forces applied directly to a small surface of the implant could cause fracture of the implant. Split or fractured implants should be removed and replaced.
6. Proper implant selection and patient compliance with post-operative precautions will greatly affect the surgical outcome. Patients who smoke have been shown to have an increased level of non-unions. Therefore, these patients should be advised of this fact and warned of the potential consequences.

PRECAUTIONS

Procedural:

1. The implantation of the Nevro1™ should be performed only by experienced healthcare professionals with specific training in the use of this implant system as this is a technically demanding procedure presenting a risk of serious injury to the patient.
2. The healthcare professional must confirm that all necessary implants and instruments are on hand for the planned surgical procedure. The implant components should be handled and stored carefully and protected from any damage including corrosive environments. They should be carefully unpacked and inspected for any damage.
3. The implants and instruments must be cleaned and sterilized before use.
4. Based on the fatigue testing results, the healthcare professional should consider unilateral/bilateral implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
5. Implant blocking screw must completely cover the front face of the ram. Visually confirm final placement of the blocking screw after rotation to prevent the ram from backing out.

Post-Procedural:

1. The patient must be adequately instructed as to the risks and limitations of the implant as well as postoperative care and rehabilitation.
2. The patient should be instructed in the limitation of physical activities which would place excessive stresses on the implant or cause a delay of the healing process. The patient should also be instructed in the use of any required weight bearing or assist devices as well as in the proper

methods of ambulation, climbing stairs, getting in/out of bed or other daily activities while minimizing rotational and bending stresses.

3. The components of this system are designed to be used with VYRSA™ Technologies instruments and should not be used with components of any other system or manufacturer.

POSSIBLE ADVERSE EFFECTS

While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials that are placed within the body to support potential fusion of the sacroiliac joint. However, due to the many biological, mechanical, and physiochemical factors that affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.

Possible adverse effects include, but are not limited to the following:

- Bending, loosening or fracture of the implants or instruments.
- Implant material sensitivity, or allergic reaction to a foreign body (including possible tumor formation).
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma or presence of the device.
- Vascular damage could result in catastrophic or fatal bleeding.
- Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
- Fracture of bony structures.
- Reflex sympathetic dystrophy.
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which might result in skin breakdown and/or wound complications.
- Nonunion or delayed union.
- Infection.
- Nerve or vascular damage due to surgical trauma (including loss of neurological function, radiculopathy, and paralysis) gastrointestinal, urological and/or reproductive system compromise (including sterility, impotency and/or loss of consortium).
- Pain or discomfort.
- Hemorrhage of the blood vessels and/or hematomas.
- Malalignment of anatomical structures (including loss of proper spinal curvature, correction, reduction and/or height).
- Bursitis.
- Bone graft donor site pain.
- Inability to resume normal daily living activities.
- Reoperation or revision.
- Paralysis.
- Death.

Warnings and Precautions:

1. The devices should only be used by healthcare professionals who have been trained in the use of this device. Information on laboratory and clinical training, as well as additional brochures with a detailed description of proper surgical technique, may be obtained from VYRSA™ Technologies. See the Nevro1™ Surgical Technique Guide for instructions on the implant procedure.
2. Infection may occur immediately following implant fixation, fusion, or a long time afterwards due to transient bacteremia such as caused by dental treatment(s), endoscopic examination, or any other minor surgical procedure. To avoid infection at the implant fixation, or fusion site, it may be advisable to use antibiotic prophylaxis before and/or after such procedures.
3. Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fixation and/or fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.
4. If the implant has been in place for enough time for bone to have grown into the implant, removal may not be feasible.
5. Do not reuse implants; discard used, damaged, or otherwise suspect implants.
6. Single use only. Reuse of devices labeled as single use (implants, drills, tacks, trial rods, etc.) could result in injury or reoperation due to breakage or infection.
7. All implants are intended for SINGLE USE ONLY. Any used implant should be discarded. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to fatigue failure.
8. The safety, efficacy and performance of the system have been established for conditions in which the system is used as intended and when used as identified in the Indications for Use. Performance of the system has not been evaluated for use that is contrary to the intended use, indications for use or for use that is contraindicated. Failure to use the system as indicated could detrimentally affect the performance of its components.

MRI Safety Information:

The Nevro1™ has not been evaluated for safety in the MR (Magnetic Resonance) environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Nevro1™ in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

IMPLANT CARE

1. Implants can either be shipped contained within a caddy or individually packaged, non-sterile. Care should be taken when handling the implants to avoid damaging the implant.
2. If an implant was shipped individually packaged, it should be carefully transferred to its appropriate caddy for sterilization and storage. All implants will be provided non-sterile.
3. All implants must be thoroughly inspected for any debris prior to sterilization. This includes prior to initial use. Implants are single-use, and not to be reprocessed. If any biologic material is found on the implant, remove the implant from the set. This implant is not to be used. If any debris or other material is present, contact a VYRSA™ Technologies representative using the information listed at the end of this document.
4. Implants should always be contained in their appropriate caddy for sterilization.
5. Implants are identified by both catalog numbers and lot numbers, listed on the implant itself, and additionally on the packaging if received individually packaged. These numbers should be recorded when used in surgery, or when calling for a replacement. Catalog number and lot numbers provide traceability to VYRSA™ Technologies and are crucial in the event of any necessary medical device reporting.

SINGLE USE ONLY

NOTE: Implants are single-use only and not to be reprocessed.

CLEANING

MANUAL CLEANING OF INSTRUMENTS AFTER USE

1. Use utility/tap water to rinse instrument(s) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water.
2. Continue to rinse with the utility/tap water until gross debris is removed.
3. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument surfaces.
4. Mix enzymatic cleaning solution per the manufacturer›s label instructions.
5. Tube (lumen) portion of instrument(s) must be filled with cleaning solution during soak.
6. Soak in cleaning solution for a minimum of 4 minutes.
7. Mix a separate detergent bath using enzymatic cleaning solution per the manufacturer's label instructions in an ultrasonic unit.
8. Fully immerse the instrument(s), in an open position/disassembled, under the surface of the cleaning solution ensuring the cleaning solution can be reached to all instrument(s) surfaces.
9. Sonicate the instrument(s) for a minimum of 5 minutes.
10. Prepare a separate (3rd) detergent bath using enzymatic cleaning solution per the manufacturer's label instructions.
11. Fully immerse the devices into cleaning solution and using a soft-bristled or medium non-metal bristle brush, remove all visible soil and debris from the surfaces.
12. Brush difficult to reach areas such as lumens/cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
13. If all debris is not removed, repeat brushing and flushing.
14. Flush device with deionized water, or equivalent, by placing the device under the water flow for a minimum of 3x.
15. Actuate parts, if applicable 3x, under running deionized water, or equivalent.
16. Rinse lumens, tubes, or cannula under running deionized water, or equivalent, 4x.
17. Use heat or lint-free cloth to dry devices following final rinse.

AUTOMATED CLEANING FOR INSTRUMENTS AFTER USE

1. Use utility/tap water to rinse instrument(s) for a minimum of 1.5 minutes to remove gross debris. Do not use hot water.
2. Continue to rinse with the utility/tap water until gross debris is removed.
3. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument surfaces.
4. Mix enzymatic cleaning solution per the manufacturer's label instructions.
5. Tube (lumen) portion of instrument(s) must be filled with cleaning solution during soak.
6. Soak in cleaning solution for a minimum of 4 minutes.
7. Mix a separate detergent bath using enzymatic cleaning solution per the manufacturer's label instructions in an ultrasonic unit.
8. Fully immerse the instruments, in an open position/disassembled, under the surface of the cleaning solution ensuring the cleaning solution can be reached to all instrument(s) surfaces.
9. Sonicate the instruments for a minimum of 5 minutes.
10. Prepare a separate (3rd) detergent bath using enzymatic cleaning solution per the manufacturer's label instructions.
11. Fully immerse the devices into cleaning solution and using a soft-bristled or medium non-metal bristle brush, remove all visible soil and debris from the surfaces.
12. Brush difficult to reach areas such as lumens/cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
13. If all debris is not removed, repeat brushing and flushing.
14. Load the instrument(s) into the appropriate washer-disinfector.
15. Select the cycle which reflects the following parameters:

AUTOMATIC WASHER

Phase	Recirculation Time (min)	Temperature	Detergent Type & Concentration
Pre-wash 1	01:00	Cold tap water	N/A
Wash 1	05:00	43°C tap water (Set point)	Enzymatic detergent per washer instructions
Rinse 1	01:00	Warm tap water	N/A
Pure Water Rinse	01:00	43°C deionized water	N/A
Dry Time	10:00	90°C	N/A

INSPECTION

All devices must be inspected for remaining soil or cleaning solution. The cleaning steps must be repeated until the device is free from soil and cleaning solution.

STERILIZATION FOR IMPLANTS AND INSTRUMENTS

Warning: VYRSA™ Technologies does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded. Open and/or disassemble instrument(s) if applicable, so the steam can reach all instrument surfaces.

To achieve a sterility assurance level of SAL 10-6, VYRSA™ recommends the following parameters:

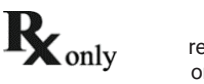
Method	**Steam**	**Steam**
Cycle	Gravity Displacement (Wrapped)	Pre-vacuum (Wrapped)
Preconditioning Pulses	N/A	4
Temperature	°132C (°270F)	°132C (°270F)
Exposure Time	15 minutes	4 minutes
Drying Time	45 minutes	45 minutes
Open Door Drying Time	15 minutes	15 minutes

Note: An FDA Cleared Wrap must be used.

* VYRSA™ Technologies has validated the above sterilization cycles and has the data on file. The validated sterilization parameters are compliant with the full cycle validation approach per ANSI/AAMI/ISO 17665-1, Annex D. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

SYMBOLS

Symbol	Definition	Reference
	Catalogue Number-Indicates the manufacturer's catalogue number to that the medical device can be identified	ISO 15223-1:2021 Symbol 5.1.6
	Batch code-Indicates the manufacturer's batch code so that the batch or log can be identified	ISO 15223-1:2021 Symbol 5.1.5
	Do not re-use-Indicates a medical device that is intended for one single use only	ISO 15223-1:2021 Symbol 5.4.2
	Non-sterile-Indicates a medical device that has not been subjected to a sterilization process	ISO 15223-1:2021 Symbol 5.2.7
	Prescription Only-Caution: Federal law restricts this device to sale by or on the order of a physician	FDA 801.15(c)(1)(i)(F)
	Consult Instructions for Use-Indicates the need for the user to consult the instructions for use	ISO 15223-1:2021 Symbol 5.4.3
	Manufacturer-Indicates the medical device manufacturer	ISO 15223-1:2021 Symbol 5.1.1
	Unique Device Identifier (UDI)-Indicates a carrier that contains unique device identifier information	ISO 15223-1:2021 Symbol 5.7.10
	Date of Manufacture-Indicates the date when the medical device was manufactured	ISO 15223-1:2021 Symbol 5.1.3

FOR FURTHER INFORMATION

If further information on this product, or the Surgical Technique Guide, is needed please contact VYRSA™ Technologies at the number listed below:

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