



Camber Spine Technologies
ORTHROS™ Posterior Stabilization System
ORTHROS™ MIS Posterior Stabilization System

NON-STERILE PRODUCT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The ORTHROS™ Posterior Stabilization System consists of a variety of shapes and sizes of rods, monoaxial screws, polyaxial screws, locking caps, locking set screws, and associated manual surgical instruments. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws are intended for posterior and anterior use. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps and locking set screws are used to connect screws to the rod. All implants, including rods, are composed of titanium alloy, as specified in ASTM F136.

MATERIALS

All implants are manufactured out of titanium alloy, specifically TAV, per ASTM F136.

INDICATIONS FOR USE

ORTHROS™ Posterior Stabilization System

The ORTHROS™ Posterior Stabilization System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/ilium spine (T1-S1/ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

In addition, the ORTHROS™ Posterior Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

ORTHROS™ MIS Posterior Stabilization System

The ORTHROS™ MIS Posterior Stabilization System, when used in a posterior percutaneous approach is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/ilium spine (T1-S1/ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), spinal tumor, and failed previous fusion (pseudarthrosis).

In addition, the ORTHROS™ MIS Posterior Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

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.

Patents: <https://www.cambermedtech.com/patents>

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. Camber Spine Technologies ORTHROS™ Posterior Stabilization System components are contraindicated in the following patient situations:

1. When there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated an allergy or foreign body sensitivity to any of the implant material;
2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopedic implant;
3. Conditions that may place excessive stresses on the bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patients;
4. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bone healing and may be at a higher risk for implant failure.

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 anterior column support 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 appliances 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 informed of 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 implants 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. 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, 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 instruments or 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 nonunions. Therefore, these patients should be advised of this fact and warned of the potential consequences.

PRECAUTIONS

1. The implantation of the ORTHROS™ Posterior Stabilization System is a technically demanding procedure that presents a risk of serious injury to the patient. Accordingly, such a procedure should be performed only by experienced spinal surgeons with specific training in the use of this system. The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant procedure, and the surgeon must be thoroughly knowledgeable of the mechanical and metallurgical limitations of the implant components.
2. Based on fatigue testing results, when using the ORTHROS™ Posterior Stabilization System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.
3. The components of this system are designed to be used with Camber Spine Technologies instruments and should not be used with components of any other system or manufacturer.
4. Instructions for the patient's postoperative care, and the patient's ability and willingness to follow such instructions are extremely important for successful bone healing. In addition to the instructions described previously, please instruct the patient on the limitations of the implant, and to limit and restrict physical activities, especially lifting and twisting motions and sports-related activities. Please inform the patient that an implant is not as strong as normal healthy bone, and that the implant could loosen, bend, and/or break if excessive demands are placed on the implant, especially in the absence of complete bone mass fusion. Please inform the patient that improper activities may cause the implant to become displaced or damaged and may cause the implant to migrate and damage nerves or blood vessels.
5. Because vascular and neurological structures are located near the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage during and after the implantation procedure. Serious or fatal hemorrhage may occur if (i) the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage or migration of implants or (ii) pulsatile erosion of the vessels occurs due to the placement of the implants adjacent to the vessels.
6. Contouring and shaping of implants should only be done with proper equipment. Care must be taken to avoid any notching, scratching, or reverse bending of the implant component or other operation that may produce defects in surface finish and internal stresses which may become a potential site for eventual breakage of the implant.

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 spine. 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:

- Infection, early or late.
- Metal sensitivity or allergic reaction to the implant.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Bending or fracture of implant.
- Loosening of the implant.
- Screw back out, possibly leading to the implant loosening and/or further surgical procedures for device removal.
- Nonunion, delayed union.
- Decrease in bone density due to stress shielding.

- Bursitis.
- Nerve damage due to surgical trauma or presence of the device.
- Neurological difficulties, such as, bowel and/or bladder dysfunction, impotence, retrograde ejaculation and paresthesia.
- Spinal cord impingement or damage.
- Paralysis.
- Degenerative changes or instability in segments adjacent to fused vertebral levels.
- Dural tears.
- Fracture of bony structures.
- Further surgery, for instance for dural repair, a chronic CSF leak or fistula, and meningitis.
- Lymphatic vessels damage and/or lymphatic fluid exudation.
- Vascular damage due to surgical trauma or presence of the device (NOTE: Vascular damage could result in catastrophic or fatal bleeding. Positioning implants adjacent to large arteries or veins may result in erosion of these vessels and cause catastrophic bleeding in the last postoperative period.
- Death

MRI SAFETY INFORMATION

The Camber Spine Technologies ORTHROS™ Posterior Stabilization System has not been evaluated for safety and compatibility in the MR (Magnetic Resonance) environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of ORTHROS™ Posterior Stabilization System 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. If any biologic material remains in the rough surface of the implant after sterilization, remove the implant from the set. Clean and sterilize the implant again. If any debris or other material is still present, contact a Camber Spine 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 Camber Spine Technologies and are crucial in the event of any necessary medical device reporting.

INSTRUMENT CARE

Surgical instruments are provided by Camber Spine Technologies and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experience extensive use or excessive force are more susceptible to fracture depending on the operative precaution, number of procedures and disposal attention. Instruments must be examined for wear or damage prior to surgery and after sterilization.

CLEANING

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

MANUAL CLEANING OF REUSABLE INSTRUMENTS

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. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument(s) surfaces.
12. 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.
13. Brush difficult to reach areas such as lumens/cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
14. If all debris is not removed, repeat brushing and flushing.
15. Flush device with DI water, or equivalent, by placing the device under the water flow for a minimum of 3x.
16. Actuate parts, if applicable 3x, under running DI water, or equivalent.
17. Rinse lumens, tubes, or cannula under running DI water, or equivalent, 4x.
18. 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. Open, disassemble and/or flush instrument(s) if applicable, so cleaning solution can reach all instrument surfaces.
12. 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.

13. Brush difficult to reach areas such as lumens/cannula, hidden surfaces, and actuate device, if applicable, 4x (back and forth=1x).
14. If all debris is not removed, repeat brushing and flushing.
15. Load the instrument(s)/implant(s) into the appropriate washer-disinfector.
16. 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 DI 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: Camber Spine 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.

To achieve a sterility assurance level of SAL 10⁻⁶, Camber Spine Technologies recommends the following parameters:

Method	Steam	Steam
Cycle	Gravity Displacement (Wrapped)	Pre-vacuum (Wrapped)
Preconditioning Pulses	N/A	4
Temperature	132°C (270°F)	132°C (270°F)
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.

*Camber Spine 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.

ORTHROS™ Posterior Stabilization System and ORTHROS™ MIS Posterior Stabilization Implants are Single Use Only ②

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

All implants and instruments should be visually checked to ensure that there are no signs of damage prior to use. Examine for evidence of corrosion, pitting, and cracks. Damaged products must not be used and should be returned to Camber Spine Technologies for replacement.

FOR FURTHER INFORMATION

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

Manufactured for:
Camber Spine Technologies
501 Allendale Road,
King of Prussia, PA 19406
Phone: (484) 420-7060