Camber Spine Technologies

SPIRA®-C Integrated Fixation System

NON-STERILE PRODUCT

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The SPIRA®-C Integrated Fixation System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one or two levels from the C2-C3 disc to the C7-T1 disc. The system is comprised of a Titanium Alloy (Ti-6Al-4V ELI) interbody cage and bone screws or anchors. When bone screws are used, the SPIRA®-C Integrated Fixation System is a stand-alone interbody fusion device. The SPIRA®-C interbody can also be used with anchors which requires supplemental fixation.

The SPIRA®-C Integrated Fixation System cages are provided in 7 degrees of lordosis, 6-12mm heights, 14-20mm widths and 13-16mm depths. The titanium alloy interbody cage also comes preassembled with a titanium alloy, built-in rotary locking mechanism. The bone screws used with this device are provided in self-drilling and self-tapping options and are manufactured from medical grade titanium alloy. The bone screws are provided in 3.5mm and 4.0mm diameters and 12-18mm lengths, in variable angle and fixed angle trajectories, along with self-drilling and self-tapping screw tip geometry. The anchors are manufactured using titanium alloy and come in sizes of 12-18mm lengths, corresponding to the screws. This device must be used with autogenous bone graft or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. The SPIRA®-C Integrated Fixation System has spiral supports to allow for a hollow chamber to permit packing with autogenous bone 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.

MATERIALS

The Camber Spine Technologies SPIRA®-C Integrated Fixation System implants are additively manufactured from Titanium Alloy TI-6AL-4V (Grade 23) per ASTM F3001-14, in addition with bone screws and bone anchors are made of wrought titanium, TI-6AL-4V per ASTM F136.

INDICATIONS FOR USE

The SPIRA®-C Integrated Fixation System is intended for use as a cervical intervertebral fusion system indicated for use at one or two contiguous levels in the cervical spine (C2-T1), in skeletally mature patients who have had six weeks of non-operative treatment for the following: degenerative disc disease (DDD, defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), cervical spondylotic myelopathy, trauma (such as fracture or dislocation), spinal stenosis, deformities or curvatures (such as scoliosis, kyphosis, or lordosis), pseudarthrosis, and failed previous fusion. The device is intended for use with autogenous or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

When used with screws, SPIRA®-C Integrated Fixation System are standalone interbody fusion devices intended for use at one or two contiguous levels in the cervical spine (C2-T1). When used with anchors, SPIRA®-C Integrated Fixation System is intended for use at one level of the cervical spine with additional supplemental fixation such as posterior cervical screw fixation.

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. Camber Spine Technologies SPIRA®-C Integrated Fixation System components are contraindicated in the following patient situations:

1. When there is active systemic infection, local infection at the site of surgery, or when the patient has demonstrated an allergy or foreign body sensitivity to any of the implant materials.
2. Severe osteoporosis may prevent adequate fixation and may lead to the collapse of the vertebral bodies around this or any other orthopedic implant.
3. Conditions that place great stress on the implant or the interface with the endplates of the vertebral bodies such as severe obesity may lead to collapse of the vertebral bodies around the device and are relative contraindications. The treating surgeon must weigh the benefits versus risks of using the device in order to decide what is in the best interest of the patient.
4. Presence of fracture or tumor of the vertebral body.
5. Use of the device is relatively contraindicated in patients who may be at a higher risk for implant or fusion failure due to activity, mental capacity, illicit drug abuse, alcoholism, mental illness, occupation or lifestyle which may interfere with postoperative restrictions and which may place undue stresses on the implant during bone healing.
6. Prior fusion at the level(s) to be treated.
7. 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 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 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 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 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

Intraoperative:

1. The implantation of the Camber Spine Technologies SPIRA-C Integrated™ Fixation System should be performed only by experienced spinal surgeons 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 surgeon 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 instruments must be thoroughly cleaned and sterilized before use.
4. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

Postoperative:

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 removal of supplemental fixation after healing should be determined. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: 1) Corrosion, with localized tissue reaction or pain; 2) Migration of implant position resulting in injury; 3) Risk of additional injury from postoperative trauma; 4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; 5) Pain, discomfort, or abnormal sensations due to the presence of the device, 6) Possible increased risk of infection; and 7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture. If, for example, the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.
4. 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.

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:

- 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.
- Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
- Spinal cord impingement or damage.
- Fracture of bony structures.
- Reflex sympathetic dystrophy.
- Degenerative changes or instability in segments adjacent to fused levels.
- 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, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage) gastrointestinal, urological and/or reproductive system compromise (including sterility, impotency and/or loss of consortium).
- Pain or discomfort.
- Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of

the vertebra).
- 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.

MAGNETIC RESONANCE

The SPIRA®-C Integrated Fixation System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of SPIRA®-C Integrated Fixation 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) 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	43ºC tap water (Set point)	Enzymatic detergent per washer instructions
Rinse 1	01:00	Warm tap water	N/A
Pure Water Rinse	01:00	43ºC DI water	N/A
Dry TIme	10:00	90ºC	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 recommends the following parameters:

Method	Steam	Steam
Cycle	Gravity Displacement (Wrapped)	Pre-vacuum (Wrapped)
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.

SINGLE USE ONLY ②

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 Rd,
King of Prussia, PA 19406 Phone:
(484) 427-7060