

IMPORTANT INFORMATION



BACFIX® Stainless Steel SPINAL FIXATION SYSTEM

Please read before use.

NON-STERILE IMPLANTS

SINGLE USE ONLY



5301 Riata Park Court, Bldg. F
Austin, TX 78727
U.S.A.

Phone: 512-918-2700
Fax: 512-918-2784

www.spinalconcepts.com

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

PURPOSE:

The Spinal Concepts, Inc. BacFix® Stainless Steel (ss) Spinal Fixation System is designed to aid in the surgical correction of several types of spinal conditions. This system is intended only to provide stabilization during the development of a solid fusion with a bone graft. These implants are intended to be removed after the development of a solid fusion mass.

DESCRIPTION:

The BacFix ss Spinal Fixation System consists of longitudinal members (spinal rods), spinal anchor components, hooks and screws, locking connectors (wedge and nut) sized to fit the spinal rods; and a transverse

connector assembly (link), also in various lengths. Hooks and screws may be placed at any position along the spinal rods and are secured with a three point shear clamp (wedge and nut). The open face of the wedge may be snapped over the spinal rod. Thus the component and wedge may be preassembled outside the wound, eliminating the need to attach the nut within the surgical opening and the need to pre-plan the position of each eyebolt on the spinal rod. Furthermore, an anchor component may be added to (or removed from) the construct at any time during the procedure.

Refer to the BacFix® ss Surgical Technique for instructions for implantation.

MATERIALS:

All implant components are manufactured of either ASTM F-138 (316LS) or ASTM F-1314 (22Cr-13Ni-5Mn) implant quality stainless steels. These materials are not compatible with titanium or MP35N®. Specifications are controlled for optimization of metallurgical properties and corrosion resistance, and are based on the strength and rigidity requirements of the individual component. Thus to achieve the best results, do not use any of the BacFix™ components with the components from any other system or company unless otherwise stated in this document. As with other orthopaedic implants, none of the BacFix components should be reused or reimplanted under any circumstances.

INDICATIONS:

The SCI BacFix Spinal Fixation System consists of a combination of components which include rods, hooks, locking wedges, screws, and transverse connectors which are indicated to provide temporary stability of the thoracic, thoracolumbar, or lumbar spine (T1 to S1).

When intended for pedicle screw fixation, implants are 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 the thoracic, lumbar and sacral spine: Degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). Levels of pedicle screw attachment for these indications range from T1 to the sacrum.

In addition, when intended for pedicle screw fixation, implants are intended for treatment of severe spondylolisthesis (grades 3 and 4) of the vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of implants after attainment of solid fusion. The levels of screw fixation for these indications range from L3 to the sacrum.

When intended for non-pedicle, posterior screw fixation of the non-cervical spine, the indications are:

- Idiopathic scoliosis.
- Neuromuscular scoliosis/kyphoscoliosis with associated paralysis or spasticity.
- Scoliosis with deficient posterior elements such as that resulting from laminectomy or myelomeningocele.
- Spinal fractures (acute reduction or late deformity).
- Degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Neoplastic disease.
- Spondylolisthesis.
- Spinal Stenosis.
- Failed previous fusion.

After solid fusion occurs, these devices serve no functional purpose and should be removed. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

The use of posterior spinal instrumentation in children has been reported in the literature. BacFix® ss may be used for non-pedicle posterior use in this patient group.

CONTRAINDICATIONS:

1. Disease conditions which have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices.
2. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
3. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other posterior spinal instrumentation system.
4. Any entity or conditions that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis or osteopenia, are relative contraindications. Other relative contraindications include obesity, pregnancy, certain degenerative disease, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant. See also the WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS sections of this insert.

STERILIZATION:

All implants and instruments are supplied clean and non-sterile and must be sterilized prior to use. The following sterilization cycle has been laboratory validated:

Method:	Steam
Cycle:	Vacuum
Temperature:	270°F (132°C)
Exposure Time:	25min

Routine monitoring per AORN recommended practices for in-hospital sterilization should be followed.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately re-sterilize all implants and instruments used in surgery.

POSTOPERATIVE MOBILIZATION:

Careful patient handling for two to four months post-operatively is very important while the fusion mass matures and becomes able to share load with the implant.

Until X-rays confirm maturation of the fusion mass, external mobilization (such as bracing or casting) is recommended.

Instructions to the patient to reduce stress on the implant are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

In younger patients, once the fusion mass has healed, the implants may be removed to allow the fused bone to return to a better state of load transfer. This is, as with all patient care, left to the discretion of the operating surgeon.

WARNINGS, PRECAUTIONS, AND ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

Following are specific warnings, precautions, and adverse effects which should be understood by the surgeon and explained to the patients. These warnings do not include all adverse effects which can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

WARNINGS:

1. In the U.S.A., this product has labeling limitations.
2. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These

conditions are significant mechanical instability secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions is unknown.

3. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines. Potential risks identified with the use of this device system, which may require additional surgery, include:

- a. Device component fracture.
- b. Loss of fixation.
- c. Non-union.
- d. Fracture of the vertebra.
- e. Neurological injury.
- f. Vascular or visceral injury

4. **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.**

The potential for satisfactory fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

5. **IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NON-UNION.**

Internal fixation appliances are load sharing devices which 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 metal fatigue. The degree or 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 contribute to early failure. Patients should be fully informed of the risks of implant failure.

6. **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, accelerates the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with other metal objects, must be made from like or compatible metals.

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

- a) The patient's weight. An overweight or obese patient can produce loads on the device which can lead to failure of the appliance and the operation.
- b) The patient's occupation or activity. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the device.
- c) A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
- d) Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary relief.

- e) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- f) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.

PRECAUTIONS

1. **THE IMPLANTATION OF PEDICLE SCREW SPINAL SYSTEMS SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF THIS PEDICLE SCREW SPINAL SYSTEM BECAUSE THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.**
2. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted metal implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
3. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Contouring of the metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease fatigue life and may cause failure.
4. **REMOVAL OF THE IMPLANT AFTER HEALING.** Metallic implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.
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 limitations of the implant and that physical activity and full weight bearing have been implicated in bending or fracture. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

POSSIBLE ADVERSE EFFECTS

1. Non-union, delayed union.
2. Bending or fracture of implant. Fraying, kinking loosening, bending or breakage of any or all of the cable implant components.
3. Loosening of the implant.
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Loss of proper spinal curvature, correction height and/or reduction.
9. Cable cutting through soft osteoporotic, osteogenic or cancellous bone.
10. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
11. Bursitis.
12. Dural leak.
13. Paralysis.

14. Death.

15. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

LIMITED WARRANTY. Spinal Concepts 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.

MANUFACTURED BY:

Spinal Concepts, Inc.
5301 Riata Park Court
Bldg F
Austin, Texas 78727
Tel: (512) 918-2700
Fax: (512) 918-2784

For product information or questions pertaining to sales and service, please contact the national distributor in your area or the manufacturer.

Catalog #899-0002-LB Rev. E per DCR 2005

©2003 Spinal Concepts