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FixxSure® X-Link – Package Insert

INTENDED USE: The Innovasis *SpineWorks* brand *FixxSure X-Link* is intended to work with the Innovasis® *Excella*® *Spinal System* to provide immobilization and stabilization of spinal segments during the fusion process.
Users of these products are limited to physicians trained in orthopedic surgery. Clinical locations include hospitals and surgery sites equipped to perform spinal surgery.

INDICATIONS FOR USE:
The SpineWorks *FixxSure X-Link* is intended to work with the Innovasis® *Excella*® *Spinal System* 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 spine:

i) Severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra;
ii) Degenerative spondylolisthesis with objective evidence of neurologic impairment;
iii) Fracture;
iv) Dislocation;
v) Scoliosis;
vi) Kyphosis;
vii) Spinal tumor; and
viii) Previous failed fusion (pseudarthrosis).

The SpineWorks FixxSure Cross Link can also be used with the Talon® Pedicle Screw System.*

Contraindications for use:
Disease conditions that 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. Any entity or condition that totally precludes the possibility of fusion, i.e., cancer or kidney dialysis is a relative contraindication. Other relative contraindications include certain degenerative diseases and the patient's occupation or activity level, which may place more stress on the implants during bone healing. These include:

i) Morbid obesity;
ii) Mental illness;
iii) Alcoholism or drug abuse;
iv) Pregnancy;
v) Metal sensitivity/allergies;
vi) Severe osteopenia;
vii) Severe osteoporosis;
viii) Smoking
ix) Active infection near the surgical site; and
x) Patients unwilling or unable to follow postoperative care instructions.

MRI INFORMATION: The FixxSure Cross Link has not been evaluated for safety and compatibility in the MR environment. The FixxSure Cross Link has not been tested for heating or migration in the MR environment. The safety of the FixxSure Cross Link in the MR environment is unknown.

WARNING: The safety and effectiveness of pedicle screw systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.
FixxSure Cross Link like any other temporary internal fixation device has a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

IMPLANT SELECTION: 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.

PRECAUTIONS
GENERAL: The implantation of pedicle screw spinal systems should be performed only by experienced spinal 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. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. A surgical technique can be obtained from the local representative or SpineWorks, LLC.
Internal fixation appliances are load-sharing devices which are used to obtain 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,

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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.
Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used, if a pseudarthrosis develops, or if patients have severe or multiple preoperative curves.
PREOPERATIVE: The implant components should be handled and stored carefully and protected from damage. The Instruments and implants must be cleaned and sterilized before use. The surgeon must confirm that all necessary implants and instruments are on hand for the planned surgical construct. They should be examined for damage prior to use.
INTRAOPERATIVE: Extreme caution must be taken around the spinal cord and nerve roots, especially when inserting screws and cross connectors. Breakage, slippage or mishandling of the instruments or implant components, such as sharp edges, may cause injury to the patient or operative personnel. The Implants must be handled and contoured carefully so as to avoid notching or scratching the surface. Prior to closing the soft tissues, all screws should be tightened firmly according to the surgical technique guide. Recheck the tightness of all screws after finishing ensuring that none have loosened during the tightening or manipulation of other components.
POSTOPERATIVE: The patient must be adequately instructed as to the risks and limitations of the implant as well as postoperative care and rehabilitation, including the limitations of physical activities, which would place excessive stresses on the implant or cause delay in the healing process. The patient should be instructed in the proper use of weight-bearing or assist devices as well as the proper methods of ambulation, climbing stairs, getting into/out of bed or other daily activities while minimizing rotational and bending stresses.
The surgeon must consider the removal of the implant after healing as the implant can loosen, fracture or corrode even after fusion has occurred. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.
Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended.

POSSIBLE ADVERSE EFFECTS: Possible adverse effects of spinal surgery include, but are not limited to:

i) Bending or breaking of the instruments or implants
ii) Nerve or vascular damage due to surgical trauma
iii) Mal-alignment of anatomical structures
iv) Hemorrhage of the blood vessels and/or hematomas
v) Gastrointestinal, urological and/or reproductive system compromise (including sterility, impotency and/or loss of consortium)
vi) Skin or muscle sensitivity in patients with inadequate tissue coverage
vii) Pain, discomfort, or abnormal sensations due to presence of the device
viii) Metal sensitivity or allergic reaction to a foreign body
ix) Decrease in bone density due to stress shielding
x) Bone graft donor site pain
xi) Loss of fixation
xii) Infection
xiii) Bursitis
xiv) Non-union or delayed union
xv) Bone loss due to resorption or stress shielding, or adjacent level disc deterioration
xvi) Inability to resume normal daily living activities
xvii) Re-operation
xviii) Paralysis
xix) Death
xx) Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis
xxi) Damage to lymphatic vessels and/or lymphatic fluid exudation
xxii) Spinal cord impingement or damage
xxiii) Fracture of bony structures
xxiv) Degenerative changes or instability in segments adjacent to fused vertebral levels

MATERIAL SPECIFICATION: Implants are manufactured out of Titanium 6AL-4V ELI which complies with ASTM F-136.
SPINEWORKS expressly warrants that these devices are fabricated from material specifications. No other warranties express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.
Components of this system should not be used with components from other manufacturers not included in the Indications for Use.
Do not re-use or re-implant under any circumstances.
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 stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, cross links, etc., which come into contact with other metal objects, must be made from like or compatible metals.

CLEANING AND DECONTAMINATION: Unless just removed from an unopened SpineWorks package, all instruments and implants must be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to SpineWorks. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by deionized water rinse.
Note: certain cleaning solutions such as those containing formalin, gluteraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should NOT be used. Also, many instruments require disassembly before cleaning.
Detailed cleaning recommendations are in the Innovasis *Surgical Instrument Cleaning*, *Sterilization and Reuse* instruction LG01. A copy of this guide is available at www.spineworksusa.com or by request via telephone, fax or e-mail. Contact information appears at the heading of this document.
All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION: The Innovasis *SpineWorks* brand *FixxSure X-Link* implants are supplied NON-STERILE. The metal implants and instruments used in surgery MUST be sterilized by the hospital prior to use. FDA cleared wraps are recommended for use with the sterilization tray. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. For a 10^{-6} Sterility Assurance Level, it is recommended that the ***FixxSure X-Link*** implants be steam sterilized by the hospital using one of the two process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum (Wrapped in two layers of 1-ply cellulose based wrap, Bio-Shield®)	270°F (132° C)	4 Minutes	30 Minutes
Steam	Gravity (Wrapped in two layers of 1-ply cellulose based wrap, Bio-Shield®)	270°F (132° ±1°C)	10 Minutes	30 Minutes

It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

CAUTION: Federal Law (U.S.A.) restricts these devices to sale by or on order of a physician.