ASTRA SPINE SYSTEM
INSTRUCTIONS FOR USE

CAUTION: USA law restricts this device to sale by or on the order of physician.

IMPORTANT NOTE TO OPERATING SURGEON

ASTRA Spine System implants, like any other temporary internal fixation devices, have 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.

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 pseudo-arthrosis develops, or if patients have severe or multiple preoperative curves.

The surgeon may remove these implants after bone fusion occurs. 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.

DESCRIPTION

The ASTRA Spine System consists of longitudinal, lordosed, contoured, and revision rods, pedicle screws (monoaxial, polyaxial, and uniplanar), cannulated pedicle screws (monoaxial, polyaxial and uniplanar), hooks, lateral iliac connectors, rod-to-rod connectors and transverse (cross) connectors.

The ASTRA Spine System components are available in titanium alloy conforming to ASTM F136 specifications. Rods are also available in Cobalt Chromium alloy conforming to ASTM F1537 specifications.

INDICATIONS

The ASTRA Spine 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 the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudo-arthrosis).

The ASTRA Spine System is also a sacral/iliac screw fixation system of the non-cervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudo-arthrosis).

When used in a percutaneous, posterior approach with AVANT Spine MIS instrumentation, the ASTRA Spine System is intended for non-cervical pedicle fixation for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudo-arthrosis, and failed previous fusion in skeletally mature patients . Levels of fixation are for the thoracic, lumbar and sacral spine.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ASTRA Spine System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the ASTRA Spine System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Only legally marketed, and locally approved sterilization barriers (e.g. wraps, pouches or rigid containers) should be used for packaging terminally sterilized devices, in compliance to the manufacturer's instructions. Care should be taken to protect implants, and pointed and sharp instruments from contact with other objects that may damage the surface. Damaged packages or products should not be used, and should be returned to SpineCraft.

CLEANING AND DECONTAMINATION:

Unless just removed from an unopened SpineCraft package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to SpineCraft. 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 a deionized water rinse.

NOTE: Certain cleaning solutions such as those containing formalin, glutaraldehyde, 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. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device. Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all products must be sterilized prior to use.

INSPECTION

- SpineCraft implants should be inspected after processing, prior to sterilization.
- Any implant with corrosion, discoloration, excessive scratches, cracks, wear, residue or debris should be discarded.

STERILIZATION

Implants and instruments of the ASTRA Spine System are supplied clean and not sterile. All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Instructions for cleaning and sterilization of ASTRA instruments can be found in SpineCraft publication # RG-0032-1 and can be obtained by contacting the company. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the steam pre-vacuum process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	30 Minutes

Blue Wrap: The wrap should be FDA cleared for the proposed cycle specifications.

Or

Reusable Rigid Sterilization Containers:

Testing has demonstrated the ASTRA Spine System, when processed in Aesculap JN443 and JK445 rigid containers (with corresponding JK490 lid and Aesculap single use filters US751 or US994), can be sterilized to a 10-6 sterility assurance level (SAL) in a pre-vacuum steam sterilization cycle when processed using the required sterilization cycle.

Ensure that the supplied reusable rigid sterilization container is in proper working order prior to sterilization.

Aesculap rigid containers JN443 and JK445 have been validated ONLY with Aesculap single use filters US751 or US994. For more information on the use of the Rigid Sterilization Containers please consult the Instructions for Use of the Manufacturer (https://www.aesculapusa.com/products/instructions-for-use).

THE STERILIZATION PARAMETERS PROVIDED IN THIS INSTRUCTIONS FOR USE SUPERCEDE THOSE LISTED IN THE AESCULAP INSTRUCTIONS FOR USE. ALL OTHER USAGE, CARE AND MAINTENANCE INSTRUCTIONS SPECIFIED IN AESCULAP DOCUMENTATION REMAIN APPLICABLE.
Monitor every load with a PCD containing a BI and a Class 5 integrating indicator.

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.

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

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 US FDA for the selected sterilization cycle.

STORAGE

Sterilized products should be stored in a dry, clean environment, protected from direct sunlight, pests, and extremes of temperature and humidity.

Refer to sterilization wrap or rigid container manufacturers IFU for limits on sterile product storage time and storage requirements for temperature and humidity.

USAGE

WARNING: 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 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 neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudo-arthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

PRECAUTION: 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. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device.

Refer to the individual system surgical technique manuals for additional important information.

SpineCraft Spinal Systems components should not be used with components from other manufacturers.

During the surgical procedure, the rods may be cut to size and shaped to provide correction and maintain proper anatomic lordotic and kyphotic alignment.

After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer or to 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.

These devices are not intended or expected to be the only mechanism for support of the spine. Regardless of the etiology of the spinal pathology, for which implantation of these devices was chosen, it is the expectation and requirement that a spinal fusion or arthrodesis be planned and obtained. Without solid biological support provided by spinal fusion, the devices cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure.

The implanting surgeon should consider carefully the size and type of implants most suitable for the patient's age, size and weight.

The ASTRA Spine System has not been evaluated for safety and compatibility in the MR environment. The ASTRA Spine System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the ASTRA Spine System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PREOPERATIVE PLANNING AND POSTOPERATIVE CARE:

Preoperative planning provides essential information regarding the appropriate implant and likely combinations of components.

Since mechanical parts are involved, the surgeon should be familiar with the various components before using ASTRA Spine System and should personally verify that all required implants sizes and necessary instruments are present before the surgery begins.

POSTOPERATIVE:

- The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.
- Detailed instructions on the use and limitations of the device should be given to the patient. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.
- The patient should be advised not to smoke or consume excess alcohol, during period of the bone fusion process.
- The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and / or break, the devices should be revised and / or removed immediately before serious injury occurs.
- ASTRA Spine System implants are internal fixation devices and are intended to stabilize the operative area during the fusion process.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

- POSTOPERATIVE MOBILIZATION: Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended.
- Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

CONTRAINDICATIONS

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.

Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.

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 spinal instrumentation system.

Any condition not described in the Indications for Use.

Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

Use of this type of surgical implant surgery in children or pediatric patients presents particular risks because of bone growth or physical movement. Subsequent re-intervention may be required.
Infants with a known hereditary or acquired bone friability or calcification problem, or those with a very short life expectancy, should not be considered for this type of surgery.
See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES section of this insert.

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

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that 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. **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.

2. **IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.** 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, 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.

3. **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 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, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metals.

4. **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 that 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 that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

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 remedy.

E. **Foreign body sensitivity**. The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

F. **Smoking.** Patients who smoke have been observed to experience higher rates of pseudo-arthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

PRECAUTIONS

1. **SURGEON TRAINING AND EXPERIENCE.** The implantation of pedicle screw fixation systems should be performed only by experienced spinal surgeons with specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon.

2. **DEVICE FIXATION.** Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by SPINECRAFT. In the interests of patient safety, it is therefore recommended that SPINECRAFT implants are not used with devices from any other source. Never, under any circumstances, reuse an ASTRA Spine System implant.

3. **SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Reusing an implant can potentially cause cross contamination. It is advised to utilize new implant of current design.

4. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT**. Contouring of 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 the fatigue life and may cause failure.

5. **CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING**. If the device is not removed after 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 refracture. If 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.

6. **ADEQUATELY INSTRUCT THE PATIENT**. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

7. **CORRECT PLACEMENT OF ANTERIOR SPINAL IMPLANT.** Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of this product. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants or if pulsatile erosion of the vessels occurs because of close apposition of the implants.

8. **IMPLANTS FATIGUE**. 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.

9. **PREVIOUS SPINAL SURGERY.** Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

POSSIBLE ADVERSE EFFECTS

1. Bending or fracture of implant.
2. Early or late loosening or movement of the implant.
3. Implant migration
4. Metal sensitivity or allergic reaction to a foreign body.
5. Infection, early or late.
6. Nonunion, delayed union.
7. Decrease in bone density due to stress shielding.
8. Pain, discomfort, or abnormal sensations due to the presence of the device.
9. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation in males, paraesthesia, or other types of serious injury.
10. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring.
11. Pressure on the surrounding tissues or organs.
12. Loss of proper spinal curvature, correction, height, and/or reduction.
13. Bursitis.
14. Paralysis temporary or permanent
15. 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.
16. Vascular 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 erode these vessels and cause catastrophic bleeding in the late postoperative period.
17. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
18. Damage to lymphatic vessels and/or lymphatic fluid exudation.
19. Spinal cord impingement or damage.
20. Non-union (or pseudoarthrosis)
21. Degenerative changes or instability in segments adjacent to fused vertebral levels.
22. Fracture of bony structures or stress shielding at, above, or below the level of surgery.
23. Discitis, arachnoiditis, and/or other types of inflammation.
24. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus.
25. Spinal epidural hematoma.
26. Inability to resume activities of normal daily living.
27. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.

28. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
29. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
30. Loss of or increase in spinal mobility or function.
31. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
32. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
33. Change in mental status.
34. Cessation of any potential growth of the operated portion of the spine.
35. Death.

Additional Possible Adverse Effects Specific to Pediatric Patients

1. Inability to use pedicle screw fixation due to anatomic limitations.
2. Pedicle screw malpositioning, with or without neurological or vascular injury.
3. Proximal or distal junctional kyphosis.
4. Pancreatitis.
5. Implant prominence (symptomatic or asymptomatic).
6. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain.
7. Post-operative change in spinal curvature, loss of correction, height or reduction.
8. Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).

PRODUCT COMPLAINTS

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or SpineCraft. Further, if any of the implanted ASTRA Spine System component(s) ever "malfunctions", (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any SpineCraft product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

LIMITED WARRANTY AND DISCLAIMER: ASTRA SPINE SYSTEM 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.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT SPINECRAFT FOR CURRENT INFORMATION at +1 630-920-7300.

SURGICAL TECHNIQUE MANUAL COULD BE OBTAINED BY CONTACTING SPINECRAFT CUSTOMER SERVICE at +1 630-920-7300. ALSO, IT COULD BE DOWNLOADED DIRECTLY FROM THE COMPANY WEBSITE USING THE SURGEON LOG-IN.

Manufactured by:

SpineCraft
777 Oakmont Lane
Westmont, IL 60559 USA
Phone: +1 630 920 7300
Fax: +1 630 920 7310
Toll Free: 877-731-SPINE (877-731-7746)
www.spinecraft.com

Distributed by

WishBone Medical
100 Capital Drive
Warsaw, IN 46582
Phone: +1-574-306-4006
Fax: +1-574-566-1600
www.WishBoneMedical.com

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