X-spine Systems, Inc.
Irix-A™ Lumbar Integrated Fusion System

GENERAL INFORMATION

The Irix-A Lumbar Integrated Fusion System is a stand-alone intervertebral fusion device to restore biomechanical height and act as an aid in fusion of the lumbar spine in anterior discectomy procedures. The device is generally boxed shaped with teeth on the superior and inferior faces of the device. The Irix-A implant is manufactured from both titanium alloy (Ti6Al4V) in accordance with ASTM F136 and Invibio PEEK Optima LT1 in accordance with ASTM F2026, or from Ti6Al4V titanium alloy alone. The device will be supplied with the option of having the superior and inferior surfaces of the device plasma coated with medical-grade commercially pure titanium (CP Ti) per ASTM F1580. The device is then secured in location through the use of bone screws, also manufactured from titanium alloy (Ti6Al4V) per ASTM F136. The devices are provided in various sizes and screws are offered in multiple lengths to adjust for variations in patient anatomy. The spacers of the Irix-A System are supplied clean and STERILE. The screws and accompanying instruments of the Irix-A System are provided clean and non-sterile. (See Sterilization Instructions in this IFU.)

INDICATIONS FOR USE

The Irix-A Lumbar Integrated Fusion System is a stand-alone intervertebral body fusion device intended for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous levels of the lumbosacral spine (L2-S1 inclusive). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have had a previous non-fusion spinal surgery at the involved level(s) and may have had up to a Grade I spondylolisthesis or retrolisthesis at the involved level(s). The Irix-A System is intended to be used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft material, and is to be used with three titanium alloy screws included as part of the system.

Hyperlordotic implants >20° are intended for use with supplemental fixation (e.g. facet screws or posterior fixation).

CONTRAINDICATIONS

1. Patients with probable intolerance to the materials used in the manufacture of this device.
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness and other medical conditions which would prohibit beneficial surgical outcome.
3. Patients resistant to following post-operative restrictions on movement, especially in athletic and occupational activities.
4. Use with components from other systems or manufacturers.
5. Grossly distorted anatomy caused by congenital abnormalities.
6. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
7. Rapid joint disease, bone absorption, osteopenia. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
8. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
9. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.

10. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
11. Any case not described in the indications for use.
12. Reuse or multiple uses.
13. Prior fusion at the level(s) to be treated.

⚠ WARNINGS

1. Irix-A Spacers are supplied clean and STERILE. The screws and instruments are provided clean and non-sterile and must be sterilized before use. Validated sterilization cycle parameter protocols are noted in the STERILIZATION section of this insert.
2. As with all orthopedic and neurosurgical implants, none of the system components should ever be reused under any circumstances. Risks associated with reuse include infection, non-union (pseudarthrosis), serious patient injury or death.
3. The Irix-A Lumbar Integrated Fusion System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The Irix-A Lumbar Integrated Fusion System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
4. Potential risks associated with the use of this system, which may require additional surgery, include; device component neurological injury, and vascular or visceral injury. Discard all damaged or mishandled implants. Never reuse an implant, even though it may appear undamaged.
5. Internal fixation devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result.
6. Contouring and bending of a system component may reduce its fatigue strength and cause failure under load. If spinal screws are bent or otherwise damaged during insertion or adjustment, the screw should be explanted and replaced.

PRECAUTIONS

As with any surgical system the Irix-A Lumbar Integrated Fusion System should be used by experienced surgeons with specific training in the use of the spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome. Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants).

Patients who smoke have been shown to have an increased incidence of pseudoarthrosis. Such patients should be advised of this fact and warned of the potential consequences. Patients with previous spinal surgery at the level to

be treated may have different clinical outcomes compared to those without a previous surgery. Based on the fatigue testing results, the physician/surgeon should consider the level of implantation, patient weight, patient activity level, and other patient conditions, etc. which may have an impact on the performance of the system.

If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g. substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.

Physician Note*:* The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient. If requested, additional information, including surgical technique manuals, may be obtained through corporate sales representatives.

PREOPERATIVE MANAGEMENT

1. The surgeon should consider for surgery only those patients indicated for the use of this device.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. The surgeon should have a complete understanding of the device's indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument.
5. Device components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants and/or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
6. The type of implant to be used for the case should be determined prior to beginning the surgery.
7. The screws and instruments must be cleaned and sterilized before use.

INTRAOPERATIVE MANAGEMENT

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to these structures will cause loss of neurological function.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
4. Caution should be taken in handling the implants; Damage to the implants may affect their performance.
5. Implants should not be reused under any circumstances.

INSTRUCTIONS FOR USE

For additional instructions regarding the proper use and application of all Irix-A implants and instruments, please refer to the Irix-A Surgical Technique Manual (available at no charge upon request).

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning to and compliance by the patient, of the following is essential:

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. Postoperative patients should be instructed to limit activity.
3. Rigid external orthosis/bracing should be utilized until fusion is confirmed clinically and radiographically.
4. If required, the device may be disassembled for explantation. Care should be taken to avoid damaging the implant and surrounding tissue as little as possible. The explanted device should be cleaned and disinfected using the instructions provided for cleaning/disinfection of instruments. Information on the procedure and patient should be retained to assist in any investigation.
5. Retrieved implants should be properly disposed of and are not to be reused under any circumstances.

POTENTIAL COMPLICATIONS AND ADVERSE SIDE EFFECTS

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants.
4. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
5. Infection.
6. Dural tears, persistent CSF leakage, meningitis.
7. Loss of neurological function including paralysis (partial or complete), radiculopathy, and/or the development or continuation of pain, numbness, spasms, or sensory loss.
8. Cauda equina syndrome, neurological deficits, paraplegia, reflex deficits, irritation, and/or muscle loss.
9. Loss of bladder control or other types of urological system compromise.
10. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
11. Fracture, micro-fracture, resorption, damage, or penetration of any spinal bone.
12. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
13. Non-union (pseudarthrosis), delayed union, mal-union.
14. Cessation of any potential growth of the operated portion of the spine.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Death.

PACKAGING, LABELING, AND STORAGE

The spacers of the Irix-A Lumbar Integrated Fusion System are supplied clean and STERILE. The spacers are delivered packaged in double-wrapped Tyvek/PET pouches, boxed and individually labeled. The spacers may be delivered individually or in a complete set. Boxes and pouches should be inspected for damage that may affect the integrity of the sterile packaging prior to use.

The screws and accompanying instruments of the Irix-A System are supplied clean and NON-STERILE. They must be sterilized prior to use (see below). The screws and instruments are contained within specially designed trays or in boxes which can be sterilized directly. Use care in handling and storage of the implant components. Cutting, sharply bending, or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants.

Implants and instruments in storage should be protected from corrosive environments such as salt, air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if instruments or implants have been damaged during the storage processes.

STERILIZATION

Irix-A Lumbar Integrated Fusion System screws and all instruments are provided non-sterile and must be sterilized before use. All implants and instruments must be free of packaging material and bio-contaminants prior to sterilization. To achieve a sterility assurance level of not less than 10^{-6}, all non-sterile implants and instruments should be autoclave sterilized using the following validated cycle parameter:

> *Saturated steam method (pressure 41.9 psia, 205.5 kPa), pre-vacuum air removal (3 pulses), 270° F (132° C), 4-minute exposure time, 30-minute drying time, in a double–wrapped case configuration. Note:* Most sterilizers automatically control pressure to ensure saturated steam and may not be adjusted by the user.

Use FDA cleared sterilizers and sterilization packaging materials/accessories (wraps, biological indicators, chemical indicators, etc.) for sterilization of instruments.

Do not stack instrument trays during sterilization.

CLEANING OF INSTRUMENTS

⚠ Caution: Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided. Cleaning must be performed by personnel trained in the general procedures involving contaminant removal. Automated washer/disinfector systems are not recommended as the sole cleaning method for surgical instruments. An automated system may be used in addition to the following manual cleaning procedure.

1. Thoroughly clean all instruments prior to use and as soon as possible after use (within a maximum of 2 hours post-operation) with intensive rinsing under cool tap water (<40°C) to remove gross soil. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent (Enzol® Enzymatic Detergent or equivalent) to delay drying.
2. No instruments within this system require disassembly as part of the cleaning process.
3. The following table describes the required steps for thoroughly cleaning the system instruments:

Table 1: Cleaning Parameters

Step	Agent	Time (mm:ss)
	Instructions	
1. Initial Clean	Enzol Enzymatic Detergent Solution (or equivalent)	3:00
	Add one (1) ounce (30 mL) of Enzol to one (1) gallon (3.8 L) of tap water. Soak instruments immediately after use and flush detergent through all channels until evidence of organic material is removed. Soak for three (3) minutes. While submerged, use a soft bristle brush that is intended for use with surgical instruments to gently remove visible debris. Pay close attention to threads, crevices, lumens and hard to reach areas. If organic material is dried-on, extend soak time and use two (2) ounces (60 mL) of Enzol per one (1) gallon (3.8 L) of warm tap water.	
2. Rinse	Deionized water	1:00
	Thoroughly rinse each instrument with deionized water including all channels to remove detergent for one (1) minute.	
3. Ultrasonic Clean	Enzol Enzymatic Detergent Solution (or equivalent)	10:00
	Prepare a fresh solution by adding one (1) ounce (30 mL) of Enzol and one (1) gallon (3.8 L) of warm tap water to a sonication unit (Branson Bransonic® Ultrasonic Cleaner or equivalent). Fully immerse the instruments in the solution and sonicate for ten (10) minutes.	
4. Ultrasonic Rinse	Deionized water	1:00
	Thoroughly rinse each instrument with deionized water including all holes and cannulations to remove detergent for one (1) minute.	
5. Inspection	Unaided eye	
	Inspect each instrument for evidence of organic material. Repeat the manual and ultrasonic clean and rinse steps if needed.	

4. If the instruments are not dry, use filtered pressurized air or lint-free wipes to dry.

INSPECTION

1. Carefully inspect each instrument and tray to ensure all visible blood and soil has been removed. Repeat cleaning if necessary.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation. All markings should be legible.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your X-spine Systems representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your X-spine Systems representative for a replacement.

CAUTION: Federal Law (USA) restricts these devices to use by or on the order of a physician.

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