Instructions for use

ISS-JAZZ
Screw System

implanet

IMPORTANT INFORMATION ON THE ISS-JAZZ SCREW SYSTEM

Before use, it is essential to be familiar with the information in this leaflet and the data on the label.

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

1. INDICATIONS

• Indications for Use

The ISS-JAZZ Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The ISS-JAZZ Screw System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, spinal deformities (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudoarthrosis, or revision of a failed fusion attempt.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ISS-JAZZ Screw System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

2. DESCRIPTION

The ISS-JAZZ Screw System is a spinal fixation device. The ISS-JAZZ Screw System is composed of smooth fusion rods, pedicle screws, blockers, transverse connectors, rod to rod connectors, sub S1 connectors and screws, and spinal hooks. The implants in the system are composed of Ti6Al4V titanium alloy described by ISO 5832-3 and Cobalt-chromium-molybdenum alloy conforming to ISO 5832-12. The implants meet the requirements for design, manufacture, and inspection in the ISO 13485 standard.

The ISS-JAZZ Screw System may be used for posterior pedicle screw fixation in pediatric cases. The chart below identifies the components and sizes appropriate for pediatric population:

Component	Size	Appropriate for pediatric population
Monoaxial Screws and Blocker - Ti6Al4V titanium alloy	all	yes
Polyaxial Screws and Blocker - Ti6Al4V titanium alloy	all	yes
Union rods - Ti6Al4V titanium alloy	all	yes
Union rods - CrCo alloy	all	yes
Transverse Connectors - Ti6Al4V titanium alloy	all	yes
Hooks - Ti6Al4V titanium alloy	all	yes
Rod to rod connectors - Ti6Al4V titanium alloy	all	yes
Sub S1 connectors and screws - Ti6Al4V titanium alloy	all	yes

The specific instruments are provided by IMPLANET and must be used to ensure proper and accurate implantation of the system.

3. CONTRAINDICATIONS

Contraindications include:

- Bone metabolism disorders that potentially compromise the mechanical support expected for this type of implant (any abnormality affecting normal functioning of bone tissue, including, but not limited to, acute spinal osteoporosis, bone resorption, primary or metastatic tumors or other conditions that would prevent secure component fixation that has the potential to decrease the useful life of the device, active infection at the site, and some metabolic disorders that affect osteogenesis).
- Insufficient quality and quantity of bone, which would limit the efficacy of osteosynthesis.
- Active local or systemic infections, or recent history of local or systemic infections that may jeopardize the outcome of the operation.
- Major local inflammation.
- Open wounds.
- Immunosuppressive diseases. Any other medical or surgical condition that might limit the potential benefits of the procedure such as the presence of a tumor, congenital anomalies, an elevated sedimentation rate not explained by other diseases, and leukocytosis or marked abnormalities of the white blood cell differential.
- Pregnancy.
- Sensitivity to implant materials or foreign bodies. If there is any suspected sensitivity to the materials used, the patient should have the appropriate tests before selection and implantation of

the material.

Any other relative contraindication including:

- Obesity. A person who is overweight or obese can overload the system leading to failure of fixation or breakage of the material.
- Excessive physical activity. Intense occupational level or activity level of the patient or a state of senility, mental illness, or other use of psychoactive substances. These conditions, along with others, may lead the patient to neglect surgeon recommendations, in turn leading to failure of the fixation or rupture of the material.
- Any neuromuscular deficit that would result in an unusual overload of the system during the consolidation period.
- Patients with insufficient muscle or tissue coverage of the operative site.

4. WARNINGS

- 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 (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
- Do not use if package is opened or damaged or if expiration date has passed.
- Do not use damaged implants.
- Never reuse an implant. Even if it seems to be intact, a previously used implant can have imperfections or defects that could reduce its lifetime.
- Resterilization of this implant is strictly prohibited. If a single-use product is reused, the performance, cleaning and sterility of the device are no longer assured. This can in particular result in failure of the procedure or risks of infection that can lead to death of the patient.
- It is essential to adhere to aseptic conditions when opening the protective packaging and extracting the implant.
- It is extremely important to handle implants carefully. The surgeon and the surgeon's assistants should avoid nicking or scratching the components.
- All implants should be used in the original form unless specifically stated.

If applicable, any modification of the implant is exclusively the surgeon's responsibility.

- Only proper use of the specific accessory equipment for the implant ensures satisfactory implant placement. Before use, check that the instruments are intact and functioning completely properly.
- Do not combine IMPLANET products with items of another origin.
- Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with the ISS-

JAZZ Screw System, must be made from like or compatible metals.

- Do not reverse bend the rods, since this may compromise the mechanical integrity of the rod.

- **Additional Warnings for Pediatric Patients**

- The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
- The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the «crankshaft phenomenon») due to continued differential growth of the anterior spine.
- Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients, and pediatric patients may be at increased risk for device-related injury because of their smaller stature.

5. PRECAUTIONS

- 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 information in these instructions is necessary but not sufficient for using this system. This information in no way takes the place of the professional judgment, expertise, and experience of the surgeon in patient selection, preoperative planning and the choice of implant size, knowledge of the anatomy and biomechanics of the spine, knowledge of the materials and understanding of the mechanical characteristics of the implants used, training and expertise in spinal orthopedic surgery, the use of accessory instruments for implantation, and patient commitment to follow an appropriate postoperative plan and having the expected postoperative exams.
- Brochures on the surgical technique are available from Customer Service of IMPLANET or its distributors. Before a surgical procedure, it is suggested that users with brochures more than two years old should check for the availability of updates.
- A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. The device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event,

bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

- Before using the implant, it is absolutely essential to check the integrity of the packaging and to check the expiration date on the label, which guarantees that sterility has been maintained.
- Only physicians who are familiar with and trained on the techniques for using IMPLANET instruments are authorized to use them.
- Instruments must be checked before the procedure to be sure that they are not worn or damaged.
- Before use, it is advisable to check that the instruments are intact and functioning completely properly.
- Surgeons should ensure that they are not using instruments that could cause inappropriate tension on the spinal column or on the implants and must scrupulously follow the operative protocol described in the surgical technique brochure that is available from IMPLANET Customer Service. This means, for example, that surgeons must avoid injuring the patient from pressure exerted during in-situ repositioning of the instrument.
- To reduce the risk of breaking, the implants should not be bent, folded, struck, or scratched with instruments unless the surgical technique recommended by IMPLANET specifies otherwise.
- Instruments should be used with extreme caution near vital organs, nerves, and blood vessels.
- The instruments can be reused after decontamination, cleaning, and sterilization unless particularly specified.
- When hypersensitivity is known or suspected, it is recommended to check the skin tolerance of the implant's materials before implantation.
- The waste resulting from the operation (packaging, explants, etc) must be dealt with in the same way as the health facility deals with any other medical waste.
- 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 on the performance of the system.

- **Additional Precautions for Pediatric Patients**
- The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients 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, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.
- The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

6. POTENTIAL ADVERSE EVENTS

- Deformation, disassembly, or breakage of one or more components of the device.
- Fatigue fracture of spinal fixation devices including screws and rods.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on the skin by implants if there is inadequate tissue coverage over the implant, with extrusion from the skin.
- Dural breach requiring surgical repair.
- Disorders and instability of adjacent segments.
- Loss of spinal curvature, loss of correction (height or reduction of listhesis).
- Delayed fusion or pseudoarthrosis. Spinal fixation devices are intended to stabilize the spinal column and to bear loads applied to the spine until fusion or consolidation is achieved. In the case of delayed or failed consolidation or fusion, in the case of inability to immobilize the components of the pseudoarthrosis, implants will be subjected to excessive and repeated stresses that can result in disassembly, deformation, and fatigue fracture of the material. The success of the fusion and the load produced by lifting and other physical activities influence implant longevity. If there is pseudoarthrosis or if the implants disassemble, deform, or break, replace or remove the device(s) immediately before lesions occur.
- There can be disassembly of the components of the internal spinal fixation. Premature disassembly can occur if the initial fixation is defective or if there is a latent infection, premature overload on the internal fixation, or trauma. Late disassembly can occur if there is trauma, infection, biological complications, or mechanical problems, and it can cause bone erosion, migration, and/or pain.
- Peripheral neuropathy, nerve injury, heterotopic bone formation, or neurovascular injury can occur including paralysis, loss of the functions of the center, or a steppage gait.
- Any surgical procedure on the spine involves risks of severe complications including particularly genitourinary, reproductive, gastrointestinal, cardiovascular, and pulmonary disorders including bronchopulmonary thrombus as well as embolism, bursitis, hemorrhage, myocardial infarction, infection, paralysis, and death.
- Neurologic, vascular, or soft tissue injury directly related to the unstable nature of the fracture or to surgical trauma.
- Incorrect or inappropriate surgical implantation of this device can result in a reduction of load on the graft or the bone graft or stress shielding, which can disrupt bone fusion.
- Reduction of bone fusion due to stress shielding.
- There is an intraoperative risk of injury, crack, and spine fracture caused by implants. A postoperative fracture of the bone graft, the intervertebral area, the pedicle, or the sacrum that is above and/or below the operative level can occur as a result of trauma, the presence of bone defects,

or insufficient bone mass.

- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
- Urinary retention or loss of bladder control or other types of urological system compromise.

- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Inability to perform the activities of daily living.

- **Additional Potential Adverse Events for Pediatric Patients**
- Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy)
- Pedicle screw malpositioning, with or without neurological or vascular injury
- Proximal or distal junctional kyphosis
- Pancreatitis
- Discontinuation of spinal growth at the fused part.

7. STORAGE CONDITIONS AND EXPIRATION

- Storage and handling conditions must ensure the integrity of the implant and its packaging.
- Before using the implant, it is absolutely essential to check the integrity of the packaging and to check the expiration date on the label, which guarantee that sterility has been maintained.
- The implant is vacuum packaged, and the user must make sure of the integrity of the vacuum packaging before use. Any deterioration of this specific packaging could permanently compromise product sterility.

8. STERILIZATION

- This implant is for single use and was sterilized by gamma irradiation in accordance with the standards in effect.
- Appropriate processes to allow reuse of instruments including cleaning, disinfection and sterilization parameters are described in the Instructions For Use delivered and dedicated to the reusable instrumentation.

9. INSTRUCTIONS TO BE GIVEN TO THE PATIENTS BY THE SURGEON

The surgeon must inform the patient of all restrictions and physical and psychological consequences involved in the use of this material and particularly the program of rehabilitation, physical therapy, and wearing of an appropriate orthosis prescribed by the physician. It is particularly important to

address the issue of premature weight-bearing, physical activities, and the need for regular medical follow up.

The patient must be informed of the surgical risks and the potential adverse reactions. The patient must be aware that the system cannot and does not reproduce the flexibility, strength, or durability of normal healthy bone, that the implant can be broken or damaged by strenuous exercise or trauma, and that the system can require replacement in the future. If the patient's job or leisure activities involve excessive stress on the implant (for example, a lot of walking, running, lifting, or significant muscle exertion), the resulting forces can cause the material to break. It has been proven that non-fusion is more common in patients who smoke. These patients must be informed of it and warned about the potential consequences. For patients with degenerative disc disease, the degenerative disc disease may be advanced enough at the time of the implantation to reduce the expected life of the device. If so, internal fixation can be used only as a delaying technique or to provide temporary relief.

During any treatment or test near the implant (injection, CT scan, MRI, etc.), the patient must report that he/she has a prosthesis. The surgeon should advise the patient to have another consultation for any symptoms that seem abnormal.

10. MRI INFORMATION

The ISS-JAZZ Screw System has not been evaluated for safety and compatibility in the MR environment. The ISS-JAZZ Screw System has not been tested for heating or migration in the MR environment.

11. REMOVAL OF IMPLANTS

These implants are temporary internal fixation systems intended to stabilize the operative side during the consolidation process. After consolidation, the devices have no further functional utility and may be removed. Removal may also be recommended in other cases such as:

- Failure of fusion.
- Implant migration with pain and/or neurologic, joint, or tissue injury.
- Pain or abnormal sensations due to the presence of the device.
- Infection, inflammatory reaction, corrosion with reactive pain.
- Reduction of bone density due to different distributions of mechanical and physiological stresses.
- Failure or poor fixation of the implant.
- Restrictions of bone growth due to the presence of implants (in pediatric use).

Implants can be removed with the instruments provided by IMPLANET. Surgeons who decide to

remove the internal fixation device should consider factors such as the risk of another procedure on the patient and difficulty with removal. Specific instruments can be essential. This technique may require prior training. Implant removal should have appropriate postoperative follow-up to avoid fracture or repeat fracture. Implant removal is recommended after fracture consolidation. Implants can disassemble, deform, break, corrode, or migrate leading to pain or stress shielding.

12. QUALITY INFORMATION

Any healthcare professional who has complaints about or is dissatisfied with the quality of a product, its technical characteristics, reliability, product life, safety, or efficacy must inform IMPLANET or its distributor. IMPLANET or is distributor must be informed immediately of any problem or any suspected problem with a device.

If there is a problem with an IMPLANET device during a procedure or if one of its products might have cause or contributed to causing a serious injury or the death of a patient, IMPLANET or its distributor must be informed as soon as possible by phone, fax, or mail. If there is a complaint, please include the name of the device, the catalog number, the lot number of the component or components, the name and address of the contact person, and a comprehensive description of the incident.

For more information or for complaints, please contact our Customer Service and Quality Assurance Departments or the IMPLANET US Distributor. Additional information also is available on our internet site.

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