Instructions For Use

Jazz™ Spinal System

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The permanent balance

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IMPORTANT INFORMATION ON JAZZ SPINAL SYSTEM

Caution: Federal law restricts this device to sale by or on the order of a physician.

INTENDED USE:

The Jazz Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

DESCRIPTION:

The Jazz Spinal System consists of a variety of shapes and sizes of rods, screws, crosslinks, set screws and connecting components, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. Please note that certain components are specifically designed to connect to Ø5.5mm. Care should be taken so that the correct components are used in the spinal construct.

The Jazz Spinal System is intended for posterior use only.

The Jazz Spinal System implant components are fabricated from medical grade titanium alloy, unalloyed titanium, or medical grade cobalt-chromium-molybdenum alloy.

Medical grade titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy and/or medical grade cobalt chromium-molybdenum alloy with stainless steel in the same construct.

To achieve best results, do not use any of the Jazz Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another IMPLANET document. As with all orthopaedic and neurosurgical implants, none of the Jazz Spinal System components should ever be reused under any circumstances.

INDICATIONS:

The Jazz Spinal System is intended for posterior, non-cervical fixation as an adjunct to fusion for skeletally mature patients 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; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

In addition, when used as a pedicle screw fixation system, the Jazz Spinal System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral, L5-S1 vertebra, who are receiving fusion by autogenous bone graft only, who are having the device attached to the lumbar and sacral spine (levels may be from L3 to the sacrum/ilium), who are having the device removed after the attainment of a solid fusion.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

1. Active infectious process or significant risk of infection (immunocompromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion.
11. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
12. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
13. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
14. Any patient unwilling to follow postoperative instructions.
15. Any case not described in the indications.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

1. **Severe bone resorption.**
2. **Osteomalacia**
3. **Severe osteoporosis.**

POTENTIAL ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is 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, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Duraltears,pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. 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.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Cessation of any potential growth of the operated portion of the spine.
16. Loss of or increase in spinal mobility or function.
17. Inability to perform the activities of daily living.
18. Bone loss or decrease in bone density, possibly caused by stresses shielding.
19. Graft donor site complications including pain, fracture, or wound healing problems.
20. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
22. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
23. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

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 degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses.

In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend or fracture as a result of exposure to every day mechanical stresses.

A device that has been implanted should never be reused, reprocessed or resterilized under any circumstances. Reuse, reprocessing, or resterilization may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death.

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.

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. This 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.

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 by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

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.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

MAGNETIC RESONANCE (MR) ENVIRONMENT:

The Jazz Spinal System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Jazz Spinal System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

IMPLANT SELECTION

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION

In cases where a percutaneous posterior approach is used refer to the Jazz Spinal System surgical technique.

The JAZZ Spinal System instrumentation contains 5.5mm rods and implants, which are intended to be used with device specific instruments.

For break-off set screw, always hold the assembly with the Counter Torque device. Tighten and break-off the head of the set screw to leave the assembly at optimum fixation security. After the upper part of the break-off set screw has been sheared off, further re-tightening is not necessary and not recommended. The head part should not remain in the patient. After the upper part of the break-off set screw has been sheared off, re-adjustment is not possible unless the set screw is removed and replaced with a new one.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The Jazz Spinal System components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Utilize an imaging system to facilitate surgery.
5. To insert a screw properly, a guide wire should first be used, followed by a sharp tap. Caution: Be careful that the guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide-wire does not advance during tapping or screw insertion. Remove the guide-wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.
6. Caution: Do not overtap or use a screw that is either too long or too large. Overtapping, using an incorrectly sized screw, or accidentally advancing the guidewire during tap or screw insertion, may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws are being inserted into spinal pedicles, use as large a screw diameter as will fit into each pedicle.
7. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
8. To assure maximum stability, two or more crosslink on two bilaterally placed, continuous rods, should be used whenever possible.
9. Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws, especially screws or nuts that have a break-off feature. Once this is completed go back and firmly tighten all of the screws and nuts. Recheck the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
6. The Jazz Spinal System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and 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; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the Jazz Spinal System components should never be reused under any circumstances.

Visual Inspection:

Visual inspect the device before use. If the device is damaged. Please contact IMPLANET for return information.

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 should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to IMPLANET. 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, which have been previously in the operation area. This process must be performed before handling or returning products to IMPLANET.

Cleaning and Decontamination:

All implants and instruments must be thoroughly cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to IMPLANET.

Manual cleaning followed by ultrasonic cleaning and/or automatic cleaning are recommended as detailed below.

<u>Ultrasonic cleaning</u>:

1. Rinse devices in cold tap water thoroughly for a minimum of two (2) minutes, using a soft bristled brush to clean device.
2. Soak device in neutral pH enzymatic cleaner or detergent solution for a minimum of ten (10) minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality, and concentration.
3. Rinse with cold water for a minimum of two (2) minutes, using a syringe, pipette, or water jet to flush lumens and channels.
4. Manually clean device for minimum of five (5) minutes in freshly prepared neutral pH enzymatic cleaner or detergent using soft-bristled brush.
5. Rinse thoroughly with deionized (DI) or purified (PURW) water for a minimum of two (2) minutes using a syringe, pipette, or water jet to flush lumens and channels.
6. Visually inspect device assuring no visible residual soil.
7. Follow with ultrasonic cleaning for a minimum of fifteen (15) minutes in a freshly prepared neutral pH enzymatic cleaner or detergent. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality, and concentration.
8. Rinse thoroughly with DI or PURW for a minimum of two (2) minutes using a syringe, pipette, or water jet to flush lumens and channels.
9. Visually inspect device assuring no visible residual soil.
10. Perform final rinse using DI or PURW water for a minimum of 15 seconds.
11. Dry device using clean, soft, lint free cloth or clean compressed air.

Automatic cleaning:

1. Rinse devices under running cold tap water thoroughly for a minimum of one (1) minute.
2. Manually clean device for minimum of five (5) minutes in freshly prepared neutral pH enzymatic cleaner or detergent using soft-bristled brush. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality, and concentration,
3. Rinse thoroughly with cold to lukewarm running tap water for a minimum of one (1) minute using a syringe, pipette, or water jet to flush lumens and channels.
4. Follow with ultrasonic cleaning for a minimum of fifteen (15) minutes in a freshly prepared neutral pH enzymatic cleaner or detergent. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality, and concentration.
5. Rinse thoroughly with DI or PURW for a minimum of two (2) minutes using a syringe, pipette, or water jet to flush lumens and channels.
6. Visually inspect device assuring no visible residual soil.
7. Automatically clean the devices using the following parameters:

Cycle	Minimum Time (minutes)	Minimum Temperature/Water	Type of Detergent
Pre-wash	2	Cold tap water	N/A
Wash I	2	Cold to warm tap water	Neutral enzymatic pH between 7 and 9
Wash II	5	Warm tap water (> 104°F / 40°C)	Detergent with pH between 7 and 9
Rinse	2	Warm DI or PURW (> 104°F / 40°C)	N/A
Dry	40	194°F (90°C)	N/A

For automated cleaning, thermal disinfect at 199°F (93°C) for minimum of 2 minutes and 30 seconds.

For further information, please contact IMPLANET.

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. Some instruments may require disassembly before cleaning, in which case, disassembly and reassembly instructions will be provided in the product surgical technique guide. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

Sterilization:

Unless marked "sterile" and clearly labeled as such in an unopened sterilized package provided by the company, all implants and instruments used in surgery are provided nonsterile and must be sterilized by the hospital prior to use. Only use FDA-cleared sterilization wrap shall be used to wrap containers prior to sterilization. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. These products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	20 Minutes
Steam	Pre-vacuum*	273°F (134°C)	4 Minutes

*The 273°F (134°C) pre-vacuum sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. 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 FDA for the selected sterilization cycle specifications (time and temperature).

Allow all components a dry time of 30 minutes prior to use.

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.

Product Complaints:

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify IMPLANET. Further, if any of the implanted spinal 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 IMPLANET 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 and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

Further Information:

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact IMPLANET.

Explanation of symbols and abbreviations used on product

	Manufacturer
	CAUTION: federal law restricts this device to sale by or on the order of a physician
	Country of manufacture / Date of manufacture
	Medical device
	Lot number
	Catalogue number
	Unique Device Identification
	Single use
	Consult instructions for use
	Non-sterile

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