Instructions for use

JAZZ SYSTEMS

implanet

IMPORTANT INFORMATION ABOUT THE JAZZ MULTI-PURPOSE SPINAL CONNECTOR
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

The JAZZ systems (including the JAZZ Claw Connector) are temporary implants to be used in orthopedic surgery. The JAZZ systems are intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures.
The indications for use include the following applications:
1. Spinal trauma surgery, used in sublaminar or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as adolescent idiopathic scoliosis, adult scoliosis, kyphosis and spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.
The JAZZ Systems may also be used in conjunction with other medical implants made of titanium alloy or Cobalt-chromium-molybdenum alloy whenever «wiring» may help secure the attachment of other implants.
The Jazz Claw System (hooks and rods) and the Jazz Frame System are 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 Jazz Claw System (hooks and rods) and the Jazz Frame System are intended for posterior 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, pseudarthrosis or revision of a failed fusion attempt.
The Jazz Claw System (hooks and rods) and the Jazz Frame System 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 JAZZ Systems from the IMPLANET company is a spinal fixation device. JAZZ is a thoraco-lumbarimplant designed for a posterior approach.
They are made of the following components: stirrup, screw, rod, hook, connector, blocker and polyester braid.
The materials used for the implant are:
- Titanium alloy Ti6Al4V conforming to ISO 5832-3
- Cobalt-chromium-molybdenum alloy conforming to ISO 5832-12
- Polyester (polyethylene-terephtalate) braid
- PEEK Optima LT1 conforming to ASTM F-2026

Important: The buckle and the strip that are assembled with the braid are made of stainless steel type 1.4404 (316L) and 1.4306 (304L), and are thus not implantable. These metal elements may not be implanted. They must be removed once the connector is positioned and correctly placed under tension.
The JAZZ Systems satisfy the design, manufacturing and control requirements as described in standard ISO 13485.
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 the normal functioning of bone tissue including, but not limited to, bone resorption, primary or metastatic tumors of the spine, 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. Severe fractures such that segments may not be maintained in satisfactory proximate reduction).
• 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.
• In any situation where implant utilization would interfere with anatomical structures or expected physiological performance, such as impinging on vital structures.
• 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.
• Disease conditions that have been shown to be safely and predictably managed without the use of fixation devices.

4. WARNINGS

• 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.
• Additional fixation is required at the cephalad and caudal ends of the construct in scoliosis surgery, especially in case of obesity, extreme kyphosis or muscular weakness, except where additional fixation would increase the risk to the patient.
• Depending on the resistance of the patient's bone, do not apply an excessive strength on the braid that could lead to crack the lamina and/or transverse process.
• 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.
• The inside diameter of the JAZZ systems connectors must correspond to the chosen rod diameter.
• Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with the JAZZ Systems, must be made from like or compatible metals.
• 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 metallic elements (buckle and strip) assembled together with the braid are made of stainless steel type 1.4306 (304L) and 1.4404 (316L) and therefore are not implantable. These metallic elements serve only to put the implant in place and MUST be removed once the connector is positioned and is correctly placed under tension. This removal is performed by ablating the ends of the braid on which these metallic elements are mounted; it is described in the JAZZ operating technique.

5. PRECAUTIONS

• The implantation of this type of implant should be performed only by experienced spinal surgeons with specific training in the use of this 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.

6. POTENTIAL ADVERSE EVENTS

• Deformation, disassembly, or breakage of one or more components of the device.
• Fatigue fracture of spinal fixation device.
• Pains, 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).
• Non-fusion, 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.
• Bone forming around the implant making removal difficult or impossible.
• Cessation of bone growth in the operated portion of bone.

Note: These adverse reactions can necessitate a second operation or revision.

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.
• 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 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 nonfusion is more common in patients who smoke. These patients must be informed of it and warned about the potential consequences. For patients with degenerative disease, the degenerative 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 JAZZ systems have not been evaluated for safety and compatibility in the MR environment. The JAZZ systems have 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 site 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 and 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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	: Do not use if package is damaged
	: Sterilized using irradiation

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