Instructions for use

SPINAL IMPLANT
JAZZ LOCK

implanet

US

SPINAL IMPLANT "JAZZ LOCK"
Single use sterile implant
Instructions for use for surgeons

IMPORTANT INFORMATION ABOUT THE JAZZ LOCK SPINAL IMPLANT

It is essential that before use, one become familiar with the information in this notice and with the data on the label.

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

1. INDICATIONS

JAZZ LOCK is a temporary implant to be used in orthopedic surgery. JAZZ LOCK is a bony anchor designed to provide temporary stabilization of the spine for bony fusion or consolidation of a fracture.

JAZZ LOCK is designed for a posterior approach. The indications for use include the following applications:

- Spinal trauma surgery: Jazz Lock implants can be used in sublaminar wiring technique;
- Spinal degenerative surgery: Jazz Lock implants may be used as an adjunct to spinal fusions with bone graft (autograft or allograft) at level(s) of use.

2. DESCRIPTION

JAZZ LOCK spinal implants from IMPLANET are spinal fixation devices. They are made of the following components: locking base, locking insert. They must be used in combination with the Implanet Jazz braid.

The materials used for these implants are:

- Titanium alloy Ti6Al4V conforming to ISO 5832-3 (locking base)
- PEEK Optima LT1 conforming to ASTM F-2026 (locking inert)

Important: The buckle and the strip that are assembled with the Jazzbraid are made of stainless steel type1.4404 (316L) and 1.4306 (304L). These metal elements must not be implanted. They must be removed once the assembly is positioned and the braid correctly placed under tension.

JAZZ LOCK spinal implant satisfies the design requirements, manufacturing, and monitoring as described in the standard ISO 13485.

The specific instruments are supplied by IMPLANET and must be used to guarantee a

correct and precise implantation of the system.
JAZZ LOCK is intended to be used with the JAZZ polyester braid and cannot be used stand alone.

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

Do not use JAZZ LOCK implants in the presence of any contraindication:
- Local or general infections,
- Patient metal allergy or intolerance,
- Major local inflammation,
- Pregnancy,
- Immunodepressive diseases,
- Bone metabolism disorders that potentially compromise the mechanical support expected from this type of implant,
- Inadequate tissue coverage of implant site,
- Interference with other critical anatomical structures.

These contraindications may be relative or absolute and must be taken into account during the decision process of the practitioner. This list is not exhaustive.

4. WARNINGS

- Do not use if the package is open, damaged, or beyond the date of expiration.
- Any damaged implant should not be used.
- An implant should never be reused. Even if it seems intact, an implant that has already been used may have imperfections or defects that may reduce its lifetime.
- I**mportant: Re-sterilization of this implant is formally proscribed. If a single use product is reused, the performance, cleaning, and the stability**

of the device are not guaranteed. In particular this may mean a failure of the operation or the risk of infection, possibly leading to the death of the patient.

- It is crucial that one respects the conditions of asepsis once the protective package is opened and the implant is removed.
- It is extremely important to use the implants with caution. The surgeon and the assistants should avoid cutting or scratching the various components.
- Every implant should be used in its original form except when specifically mentioned otherwise. Where appropriate, any modification of the implant is the sole responsibility of the surgeon.
- Only the correct use of the specific ancillary material for the implant will guarantee satisfactory positioning. One is advised to verify before use that the instruments are intact and are in perfect functioning order.
- We formally advise against using our products with items made elsewhere.
- Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with the JAZZ LOCK system, must be made from like or compatible materials.
- **Important: The metallic elements (buckle and strap) assembled together with the braid are made of stainless steel type 1.4404 (316L) and 1.4306 (304L) and are not implantable. These metallic elements serve only to put the implant in place and MUST be removed once the assembly is positioned and the braid 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 LOCK operating technique.**

5. PRECAUTIONS

Preoperative

- Patient weight: Excess of weight is responsible for additional loading, which, in association with other factors, can lead to rupture of the implants.
- Physical activity of the patient: Intense physical exercise during the period of consolidation increases the risk of mobilization, deformation or rupture of implants and failure to achieve fusion.
- Mental handicaps: Risks are increased in patients who are incapable of observing surgeon recommendations. Physical handicaps require particular attention, even adaptation of the postoperative rehabilitation program.
- Hypersensitivity to foreign bodies and/or to metallic ions: When hypersensitivity is suspected or known, the patient's tolerance to the materials composing the implant

should be tested before the operation.

- Smoking has been shown to have negative effects on bone fusion, increasing the risk of non- fusion. Smokers must be informed of that.

Per-operative

- The implants must be used with the instruments designed and supplied for this purpose according to the installation technique specific to each implant, the details of which are given in the Operative Technique supplied by IMPLANET.
- Bone quality: Osteoporosis or any other bone tissue disorder that may alter the mechanical qualities of the vertebrae must be taken into account when making the decision to use JAZZ LOCK implants.

Postoperative

The surgeon must warn the patient of the precautions to be taken following implantation of the device. A rigid external orthosis is not usually required. However, the surgeon has to make this decision taking into account the specific characteristics of each patient (bone quality, treated and associated diseases, activity and weight of the patient, etc.).

Only physicians familiar with the use of IMPLANET instruments and trained to this end are authorized to use such instruments.

- In rare cases, a per-operative rupture of the instruments may occur. Instruments that are used many times are susceptible to breakage or to deterioration, depending on precautions taken during operations, the number of procedures, and the attention paid in storing them.
- It is necessary to verify before the operation that the instruments are not worn out or damaged.
- It is advisable to check before use that the instruments are intact and in a perfect functioning state.
- Every surgeon should make sure that he is not using instruments that might cause inappropriate tension on the spinal column or on the implants; he should scrupulously respect the operating protocol described in the technical surgical brochure that is available from IMPLANET customer service. For example, one should avoid pressure resulting from repositioning the instrument in situ in order not to injure the patient.
- In order to reduce the risk of breakage, one should not deform, bend, strike, or scratch the implants with the instruments, unless the surgical technique recommended

by IMPLANET specifies otherwise.

- Even though the lifetime of the implants is difficult to estimate, it is limited. These implants are made of foreign materials implanted for fusion or consolidation of the spine and to reduce pain. However, because of numerous biological, mechanical, and physical-chemical factors that affect devices but which cannot be evaluated in vivo, the implants cannot indefinitely resist active use and loads in the way that a healthy bone can.
- The instruments should be used with extreme caution near vital organs, nerves, and blood vessels.
- The instruments may be reused after having been decontaminated, cleaned and sterilized, unless specified otherwise.
- When hypersensitivity is suspected or known, it is recommended to verify that the cutaneous tolerance of the materials composing the implant before their implantation.
- Trash resulting from the operation (packaging, items removed, etc.) should be managed like any other medical trash by the establishment giving the care.

6. POTENTIAL ADVERSE EVENTS

- As for any medical device, some undesirable side effects can occur, listed below but not limited to:
- Deformation, disassembly, or rupture of one or several components of the device.
- Rupture due to fatigue of the spinal fixation devices.
- Pain, discomfort, or abnormal sensations resulting from the presence of the device.
- Pressure on the skin by the implants in the case of an inadequate tissue covering over the implants, with cutaneous extrusion.
- Dural breach requiring surgical repair.
- Disorders and instability of adjacent segments.
- Interruption of the spinal growth at the level of the fused section.
- Loss of spinal curvature, loss of correction (increase or reduction of lysthesis).
- Delayed fusion or pseudarthrosis: The spinal fixation devices are intended to stabilize the spinal column and to support weight on the spine until fusion or healing is achieved. If healing or fusion is delayed or non-existent, or if there is inability to immobilize the elements of the pseudarthrosis, the implants will be subject to repeated excessive constraints that may result in disassembly, deformation, or rupture due to material fatigue. The success of the fusion, and the load produced by lifting weight

and other physical activities have an effect on the longevity of the implant. In case of pseudarthrosis or if the implants deteriorate, deform, or break, the device or devices should be replaced or removed immediately before lesions appear.

- Disassembly of the components of the spinal osteosynthesis may occur. A premature disassembly may occur in the case of a defective initial fixation, a latent infection, a load prematurely placed on the osteosynthesis, or in the case of trauma. A late disassembly may occur in the case of trauma, infection, biological complications, or mechanical problems, all of which may cause a bony erosion, migration, and/or pain.
- In peripheral neuropathies, or a nerve, heterotopic, or neurovascular lesion, including paralysis, a loss of seating functions or a "stepping" problem may occur.
- Any surgery on the spine involves risks of serious complications, in particular comprising genitourinary problems, gastrointestinal problems, cardiovascular problems, and pulmonary problems. The problems extend to a bronchopulmonary thrombus, embolism, bursitis, hemorrhaging, myocardial infarct, infection, paralysis, and death.
- Neurological or vascular lesion or of the soft tissue directly connected to the unstable nature of the fracture or to surgical trauma.
- An erroneous surgical implantation or inappropriate implantation of this device may mean graft discharge or a bony graft or the effect of "stress shielding" which may disturb the success of the bony fusion.
- Reduction of the bony fusion due to an effective "stress shielding".
- The risk exists of lesion, fissure, per-operative fracture of the spine, all caused by the implants. A post-operative fracture of the bony graft, of the intervertebral zone, or of the laminas, situated above and/or below the operative level, may occur as a result of trauma, as a result of the existence of bony defects, or of insufficient bony mass.
- Reaction to a foreign body (allergy) due to implants, debris, products of deterioration (starting from cracks, wear and tear, and or general deterioration), including metallosis, staining, the formation of tumors, and/or an autoimmune disease.
- Urinary retention or a loss of bladder control or other types of failure of the urologic system.
- Formation of a scar may cause neurological problems or compression around the nerves and/or pain.
- The inability to carry out the activities of daily life.

Note: These undesirable effects may require a second operation or a revision of the first one.

7. STORAGE CONDITIONS AND EXPIRATION

- Storage conditions and conditions of handling should allow one to assure the integrity of the implant and its packaging.
- Moreover, before use, the user should check the integrity of the packaging and monitor the expiration date that appears on the label; these guarantee the maintenance of the sterile state.
- Essentially, any deterioration of any part of the packaging will definitely compromise the sterility of the product.

8. STERILIZATION

- This implant is for one time use, and was sterilized in conformity with applicable standards by gamma radiation («R» notation shown on the label).
- The appropriate treatments allowing the reuse of the instruments include the type of cleaning, disinfection, and sterilization, are all described in the particular instructions for use delivered with the reusable instruments.

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

The surgeon should inform the patient about all the restrictions and the physical and psychological consequences that are involved in the use of this material. He should in particular discuss the program of reeducation, kinetic therapy, and the use of a proper orthosis prescribed by the physician. It is particularly important to mention the question of premature load bearing, of physical activities, and of the necessity of regular medical follow-up.

The patient should be informed of the surgical risks and potential undesirable side effects. He should know that the system cannot and will not reproduce flexibility, resistance, or the durability of a normal healthy bone, that the implant can be broken or damaged by serious activity or by trauma, and that the system may require a replacement in the future. If the patient is engaged in a professional or non-professional activity that involves the constraint of excessive exercise on the implant (for example, extensive walking, running, lifting weights, and serious muscular effort), resulting forces may cause the rupture of the material. It has been proven that the cases of non-fusion are more frequent in patients who are smokers. These patients should be informed and should be warned about the potential consequences. For patients who have degenerative discopathy, the progression of the degenerative discopathy may be so advanced at the time of implantation that the point has been reached of diminishing the lifetime predicted for the device. In this case, osteosynthesis should be used only as

a retarding technique or to give temporary relief. At the time of any treatment or study near the implant (injection, scanner, MRI, etc.), the patient should announce that he is wearing the implant.
The surgeon should advise the patient to come in for another consultation for any symptom that does not seem normal.

10. REMOVAL OF IMPLANTS

These implants are systems of temporary internal fixation designed to stabilize the operative site during the process of consolidation. After consolidation, these devices no longer have any functional utility and may be removed.
Their removal may also be recommended in other cases, such as:

- Failure of the fusion.
- Migration of the implant, with pain and/or neurological, joint, or tissue lesions.
- Pain and abnormal sensations due to the presence of the device.
- Injection, inflammatory reaction, deterioration with painful reaction.
- Reduction of the bone density due to various distributions of the mechanical and physiological constraints.
- Restriction of a bony growth due to the presence of implants (in pediatric use).
- Failure or poor fixation of the implant.

The implants may be removed with the instruments furnished by IMPLANET. The surgeon who decides to remove the internal fixation device should take into consideration such factors as the risk of a new operation for the patient as well as the difficulty of the removal. Certain specific instruments may be indispensable. This technique may require prior training. Removal of the implant should be the object of an adequate post-operative follow-up in order to avoid any fracture or re-fracture. The removal of the implant is recommended after consolidation of a fracture. The implants may come apart, become deformed, break, deteriorate, migrate, or cause pain or the effect of "stress shielding".

11. QUALITY INFORMATION

Any health professional who has complaints or reasons to be dissatisfied with the quality of the product, its technical characteristics, its reliability, its lifetime, its safety, or its effectiveness should notify IMPLANET or his distributor. These latter should be notified immediately of any dysfunction or of any suspicion of dysfunction of the device.
In the case of dysfunction of an IMPLANET device at the time of an operation, or if one of its products causes or helps the cause a serious injury or the death of a patient, IMPLANET or its

distributor should be informed as soon as possible by telephone, fax, or e-mail. In case of a claim, please note the name of the device, its catalog number, the batch number of the components, the name and address of the reference person, and an extensive 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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