Instructions For Use

Squale™

implanet
The permanent balance

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Squale™
Instructions For Use

IMPORTANT INFORMATION ABOUT SQUALE

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 SQUALE devices are indicated for use in cervical interbody fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from the C2-C3 disc to the C7-T1 disc. DDD is defined as neck pain of a discogenic origin with degradation of the disc confirmed by history and radiographic studies. The SQUALE devices are to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft, and are to be implanted via an open, anterior approach.

The SQUALE devices are to be used with supplemental fixation systems that have been cleared for use in the cervical spine. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

2. Description

The SQUALE device consists of Polyetherketoneketone (PEKK) (compliant with ASTM F2820 standard) cervical cages of various widths and heights, which can be inserted between two cervical or cervico-thoracic vertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be filled with autogenous and/or allogenic bone graft.

The materials used for the implant are:
- PEKK compliant with ASTM F2820 standard
- Tantalum for markers (ASTM F560),
- Titanium (ISO 5832-3) for spikes on the SQUALE width 14mm cages.

3. Contraindications

- 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, acute spinal osteoporosis, bone resorption, osteopenia, 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.
- 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 such as:

  - Taking steroids over a long period

  - 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.
  - Neurodegenerative disease
  - Any patient who may not be able to follow post-operative instructions

4. Warnings

- Do not use if package is opened or damaged or if expiration date has passed. 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.
- 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.
- 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.

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.
- 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.
- The opening of the packaging should be realized nearby surgical site.
- Before considering implanting a device, the surgeon must take into account the patient's general condition, any previous surgeries, and the effectiveness or the impossibility of using another non-operative or operative treatment.
- Do not combine SQUALE devices with devices from another manufacturer that may modify the physical integrity of the device.
- Choose the correct size and position the implant properly (if the implant is not being placed correctly, it is recommended to consider another treatment).
- Protection against radiation: the surgeon will take all necessary measures to assure the protection against the radiation caused by per-operative scopic control of the correct positioning of bone fragments and implants.
- An external support can be proposed for the post-operative comfort of the patient.
- 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.
- 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

Include but are not limited to :

- Infections
- Numbing
- Subcutaneous or epidural hematoma
- Complications at the donor site
- Postoperative pharyngitis
- Subsidence of the cage and/or collapse of the vertebral body
- Pseudarthrosis
- Adjacent segment degeneration, disease or ossification
- Recurrent of the pathology at the same level
- Dysphagia / Dysphonia
- Neuropathies or neurological deficit
- Wound infection or issue
- Dysesthesia
- Muscle spasm
- Graft collapse or dislodgment of graft
- Peroperative injury
- Transitorial hoarseness
- Swelling of pre-vertebral soft tissues
- Heterotopic ossification
- Reoperation at adjacent level
- Misplacement of the device
- Gastrointestinal complications
- Migration of the cage / Dislocation of the cage
- Pains
- Vein thrombosis
- Vascular, cardiovascular and cerebrovascular complications
- Headache
- Musculoskeletal complications (weakness)
- Spondylodisitis
- Hypo/Hypertension
- Carpal tunnel syndrome
- Limitation of movement amplitude
- Change of mental status
- Bleeding
- Allergic reaction to the materials or debris materials
- Instability of joined segments
- Pulmonary embolism
- Inflammation
- These side effects may sometimes cause a reoperation.

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.
- The instruments are delivered in container or individually.
- 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. Packaging

The implants are single use devices, provided sterile, and delivered in individual packages. The typical packaging used is double sealed bags. The packages must be intact at the time of receipt.

10. 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 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 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.

11. MRI Safety Information

The SQUALE 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 Squale 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.

12. Removal of implants

If fusion/bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the SQUALE cages are not intended to be removed unless the management of a complication or adverse event requires the removal. Implants can be removed with the instruments provided by IMPLANET. Additional general instruments may be required to assist in the removal of the device.
Surgeons who decide to remove the device should consider factors such as the risk of another procedure on the patient and difficulty with removal.

13. 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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REF	Reference
LOT	Batch number
	Use by date
	Do not reuse
STERILIZE	Do not resterilize
	Do not use if package is damaged
STERILE R	Sterilized using irradiation
	Keep away from sunlight
	Keep dry
Rx only	CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
MD	Medical device
	See Instructions for Use
	Manufacturer
	Distributor
FR	Country of manufacture / Date of manufacture
UDI	Unique Device Identification