Signature ORTHOPAEDICS

Brisbane and Gladstone ALIF Cage

Instructions for Use W31-04-0002 Rev. A Issue Date: OCT -16

Caution:

Carefully read all the instructions and be familiar with the surgical technique(s) prior to use of the system. Additional warnings and precautions may be included in the surgical technique or on the label. This product must only be used by trained, qualified persons, aware of the directions for use.

Federal law restricts this device to sale, distribution and use by or on the order of a physician.

1 Device Descriptions

Brisbane and Gladstone ALIF cages are supplied individually sterile packed and are intend for single patient use only. Additionally, the subject devices are available in a range of sizes to allow correct selection to match the patient's anatomy.

Material: The Brisbane and Gladstone ALIF cages are manufactured from polyether ether ketone (PEEK) polymer per ASTM F2026 and the X-ray markers are manufactured from unalloyed Tantalum bead per ASTM-F560. The screws are manufactured from Ti6Al4V per ISO 5832-3 and ASTM-F136. Titanium Plasma spray coating on Brisbane ALIF cage is per ASTM-F1580.

The devices are intended to restore disc height and support loading during intervertebral body fusion. The devices consist of wedge-shaped geometry to restore lordosis of the fused vertebral bodies, and serrated teeth on the inferior and superior surfaces to resist expulsion. The centre of the devices are hollow to accept bone graft (autogenous) to promote arthrodesis. The TPS coating on Brisbane cage helps with bone ongrowth.

2 Indications

The Signature Orthopaedics Brisbane ALIF, and Gladstone ALIF systems are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated. These implants may be implanted via a laparoscopic or an open anterior approach. The Brisbane and Gladstone ALIF systems may be used as a stand-alone devices or in conjunction with supplemental fixation. When used as a stand-alone device the subject devices are intended to be used with the bone screws provided.

3 Contraindications

The Signature Orthopaedics Brisbane and Gladstone ALIF cages are contraindicated for use under the following conditions:

- Osteoporosis
- Active systemic infection or infection localized to the site of the proposed implantation
- Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, osteopenia, obesity, or foreign body sensitivity.
- Patients whose activity, mental capacity, mental illness, or lifestyle may interfere with their ability to follow postoperative restrictions

4 Patient Selection Precautions

The following factors may be relevant to the success of the procedure:

- The patient's body mass. An obese patient may place increased loads on the intervertebral body device which can lead to failure of the device or subsidence into the vertebral body. The risk increases with smaller size implants and increasing patient weight.
- The patient's regular type and level of activity or employment may affect the durability of the components. If the patient's occupation or activity includes significant impact loads, the increased force can cause failure of the implant or failure of the fixation of the device to bone. High levels of physical activity over time can accelerate the normal wear process that occurs with contacting surfaces of the implant.
- Mental illness, or substance dependence which may tend to reduce the patients compliance with prescribed precautions and limitations on physical activities, which may cause implant failure or other complications.
- Material sensitivity. Patients should be screened for potential sensitivity to the constituent materials composing the device. If sensitivity is suspected, Preoperative tests should be conducted.

5 Possible Adverse Effects

Following are specific adverse effects which should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that may occur in surgery, but are important considerations particular to the devices included in this document.

- Nonunion (pseudarthrosis)
- Bending or fracture of implant.
- Early or late loosening of the implant
- Metal sensitivity, or allergic reaction to the implant
- Early or late infection
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Various nerve and vascular damage due to the proximity of the implant to major structures
- Bursitis
- Paralysis
- Dural tears experienced during surgery could result in the need for further surgery, a chronic CSF leak or fistula and possible meningitis
- Death
- Damage to lymphatic vessels and/or lymphatic fluid
- Spinal cord impingement or damage
- Cessation of growth of the operated portion of the bone
- Fracture of bony structures, or penetration of the implant into the bone
- Bone formation around and through the implant making removal difficult
- Screw back out, possibly leading to implant loosening, and/or reoperation for device removal
- Post operative change in spinal curvature, loss of correction, height and / or reduction
- Degenerative changes or instability in segments adjacent to fused vertebral levels

6 Patient Consent

As with all surgical procedures, the patient should be made aware of the risks and possible adverse effects. In particular the patient should be warned of limitations of the devices being implanted, including the limited expected service life of the device and the possible requirement for revision surgery to replace worn or damaged implant or to correct device malfunctioning.

7 Preoperative

Care should be taken when handling the Brisbane and Gladstone ALIF cages to avoid damaging the devices. Denting, notching or scratching can greatly reduce the compression strength, fatigue resistance or wear properties of the components potentially

leading to fracture or failure of the devices. Surgical technique information is available for Brisbane and Gladstone cages. The surgeon should familiarise themselves thoroughly with the technique prior to consideration of the use of the devices for any specific patient.

Implants are only to be used with approved Signature Orthopaedics instrumentation. The surgical instrumentation prescribed within the technique for the implantation of these devices should not be used for any other device or in a manner contrary to its intended use. Failure or breaking of instruments can occur. Instruments have a limited service life and should be examined for wear or damage and replaced prior to surgery if required.

Instrumentation should be sterilised according to the manufacturer's protocols. Do not resterilise component parts which have been assembled, or implants connected to surgical instruments. Do not cool hot components in cold water.

The Signature Orthopaedics Brisbane and Gladstone cages have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. Signature Orthopaedic does not recommend MR imaging for any patients implanted with product from their spinal implant range without prior consultation with an expert radiologist for assessment of potential adverse events such as device movement, localized burns, torsional or shear strain on the implanted device.

Signature Orthopaedics' Brisbane and Gladstone ALIF cages are non-pyrogenic. The implants have had non-pyrogenicity validated to endotoxin levels below 20EU/device, thus meeting USP guidelines for non-pyrogenicity.

8 Intraoperative

Correct implant selection is extremely important. The use of preoperative imaging, templating and the intraoperative use of trial components is recommended to facilitate the choice of an optimum size. The patients overall anatomical and medical condition should also be considered in conjunction with age, expected activity level, life expectancy and potential for future revision surgeries. The incorrect selection of implant size may result in failure of the device and/or bone.

Implants should be inspected before use. Do not use any implants that have visible damage such as chipping or bending. Do not use any implants that have been dropped on the floor.

Implants removed from the patient at revision surgery should never be reimplanted as the fatigue state of the implant cannot be determined by visual examination. Removed implants must be treated as biological hazards and are required to be treated or disposed of according to the country's waste regulations where the implant is removed.

The wound site should be thoroughly cleaned of bone and other debris before closure.

9 Postoperative Care

External immobilization is recommended until X-rays confirm the formation of the fusion mass. Instructions to the patient to reduce stress on the implants are an important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

10 Packaging and Labeling

Components should only be used if the factory packaging and labeling are intact. If the sterile barrier has been broken, return the component to Signature Orthopaedics.

11 Cleaning and Sterilization

A complete guide for reprocessing reusable instruments may be provided upon request.

12 Storage and Handling

Implants and instruments are to be stored in dry, clean surroundings at room temperature, in their original packaging or sterilisation tray respectively.

13 Limited Warranty / Liability

Signature Orthopaedics products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

Signature Orthopaedics Europe Ltd. shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Signature Orthopaedics Europe Ltd. neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Signature Orthopaedics Europe Ltd. intends that these instruments should be used only by physicians with appropriate training in orthopaedic surgical techniques.

14 Contact Information

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate Signature Orthopaedics location for current information. For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate Signature Orthopaedics location as listed below:

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15 Label Symbol Legend

REF	Product code	STERILE EO	Sterilized by Ethylene Oxide
LOT	Batch number	STERILE R	Sterilized by radiation
	Consult instructions for use		Manufacture date
	Do not resterilize		Manufacturer
	Single Use		Expiration date
	Do not use if package damaged		Warning

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