NOOSA, NAMBUCCA and CAIRNS Anterior Lumbar Plates

Instructions for Use W31-091-004 Rev. A Issue Date: Dec -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

All devices described herein are supplied individually sterile packed and are intend for single patient use only. Additionally, all devices described herein are available in a range of sizes to allow correct selection to match the patient's anatomy.

NOOSA Anterior Lumbar Plate

Material: Titanium 6-Aluminium 4-vanadium alloy per ASTM F136

The NOOSA Anterior Lumbar Plate System is a temporary supplemental fixation device available in a variety of sizes to fit the patients differing anatomy. The subject plate is low profile and anatomically designed to provide optimal fit from anterior, lateral or anterolateral approach. The NOOSA system features anti-angulation locking cams to help restrict the angular movement of the screw within the screw holes of the plate.

NAMBUCCA Anterior Lumbar Plate

Material: Titanium 6-Aluminium 4-vanadium alloy per ASTM F136

The NAMBUCCA Anterior Lumbar Plate System is a temporary supplemental fixation device available in a variety of sizes to fit the patients differing anatomy. The subject plate is low profile and anatomically designed to provide optimal fit from anterior, lateral or anterolateral approach. The NAMBUCCA system features anti-angulation locking cams to help restrict the angular movement of the screw within the screw holes of the plate.

CAIRNS Anterior Lumbar Plate

Material: Titanium 6-Aluminium 4-vanadium alloy per ASTM F136

The CAIRNS Anterior Lumbar Plate Systems is a temporary supplemental fixation device available in a variety of sizes to fit the patients differing anatomy. The subject plate is low profile and anatomically designed to provide optimal fit from anterior, lateral or anterolateral approach. The CAIRNS screw comes with circlip that prevent the screw from backing-out after implantation.

2 Indications

The Signature Orthopaedics NOOSA, NAMBUCCA and CAIRNS Anterior Lumbar Plate Systems are indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels. The devices are intended as a temporary fixation devices until fusion is achieved. The subject systems are indicated in the treatment of lumbar or lumbosacral (L1-S1) fixation for the following indications: degenerative disc disease (DDD)(as define by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) spondylolisthesis, trauma (i.e. fracture or dislocation), deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

3 Contraindications

The Signature Orthopaedics NOOSA, NAMBUCCA and CAIRNS anterior lumbar plates are contraindicated for use under the following conditions:

- Extensive calcification of the great vessels
- Retroperitoneal fibrosis
- High-grade spondylolisthesis
- Tumor or trauma necessitating multiple vertebral segment stabilization
- Active systematic infection or infection localised 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 weight. An obese patient may place increased loads the device which can lead to premature failure of the device
- The patient's occupation or activity. If the patient is involved in an occupation or activity that involves demanding loading or articulation of the operated spinal segment they should not return to these activities until bony fusion has occurred. Depending on the extent of the activity, or the quality of the bony fusion, the patient may not be able to return to such occupation or activity.
- 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 NOOSA, NAMBUCCA and CAIRNS anterior lumbar plate systems components 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 the subject devices. 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 anterior lumbar plates 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' anterior lumbar plates 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

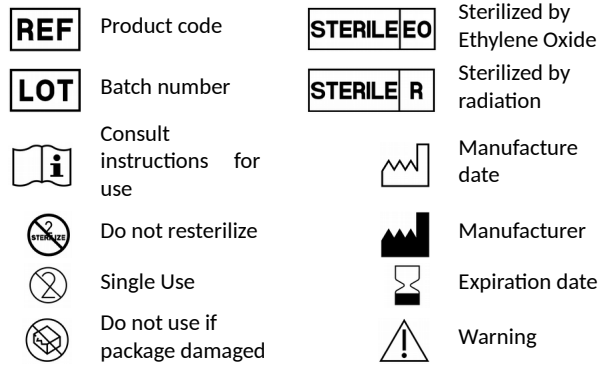
If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate Signature Orthopaedics location for current information. For further information or questions pertaining to sales and service, please contact your local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

Signature Orthopaedics Australia Pty Ltd
7 Sirius Road
Lane Cove, NSW 2066
Sydney Australia
Tel +61 2 9428 5181
Fax +61 2 8456 6065

Signature Orthopaedics Europe Ltd
88 Harcourt Street
Dublin 2, Ireland
Tel: +353 1 6915500

Signature Orthopaedics USA LLC
46 Chagrin Plaza, #118
Chagrin Falls, Ohio 44022
USA
Tel: 661 349 8502
Fax: 440 543 2174

15 Label Symbol Legend



Signature ORTHOPAEDICS