Interventional Spine®
A New Pathway for Spine Therapy

Ø 4.5mm BONE-LOK® PLS IMPLANT
Instructions for Use

CE 0050

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REF 9024-00 (LSW-45-3040) Ø4.5mm BONE-LOK® PLS IMPLANT

DESCRIPTION:
The Ø 4.5mm BONE-LOK® PLS IMPLANT with CLASP® (Compression Locking Anchor with Secondary Purchase) Technology, with a self retaining washer is fabricated from a medical grade Titanium 6Al-4V alloy and is available in a 30-40mm length range.
The purpose of the implants is to stabilize the posterior elements of a spinal level, allowing for the normal healing process to create a solid bony fusion across the disc space. The devices are not intended to take the full load of the spinal segment or be loaded for the life of the patient. If there is delayed fusion or pseudoarthrosis, the implant could eventually break.
The operating surgeon must be thoroughly knowledgeable in the medical and surgical aspects, as well as the mechanical and metallurgical aspects of these implants. In order for successful final outcome, postoperative care is of extreme importance. The patient must be informed that non-compliance with postoperative instructions may lead to the loosening or breakage of the implant, requiring a possible revision procedure. Factors such as the patient's weight, activity level, and adherence to postoperative instructions, are all conductive to the life of the implant.

INDICATIONS FOR USE:
The Ø 4.5mm BONE-LOK® PLS IMPLANT is indicated for spondylolisthesis, spondylolysis, degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies, degeneration of the facets with instability and fracture, pseudoarthrosis, or failed previous fusion.
The intended use of the Ø 4.5mm BONE-LOK® PLS IMPLANT is to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The Ø 4.5mm BONE-LOK® PLS IMPLANT may be used to supplement legally marketed fusion products in order to create an anterior/posterior fixation as an aid to fusion. The Ø 4.5mm BONE-LOK® PLS IMPLANT is intended for lumbar bilateral facet fixation, with or without bone graft, at single or multiple levels from L1 to S1. The intended use of the associated manual surgical instruments is to aid in the implantation of the Ø 4.5mm BONE-LOK® PLS IMPLANT.

CONTRAINDICATIONS:
. - An allergy to titanium or titanium alloy
- Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in the body, such as:
  - significant instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.5 (of 4)
  - an ankylosed segment at the affected level(s)
  - acute fracture of the pars interarticularis
  - significant scoliosis
- Neural compression causing neurogenic bowel or bladder dysfunction;
- Diagnosis of severe osteoporosis
- Active systemic infection or infection localized to the site of implantation.

WARNINGS:
The following are specific warnings, precautions, and adverse effects, which must be understood by the operating surgeon and given to the patient. These warnings do not include all adverse effects, which may occur with the surgical procedure in general, but are important considerations, which are specific to metallic fixation devices. General surgical risks need to be explained to the patient, prior to the procedure.
The Ø 4.5mm BONE-LOK® PLS IMPLANTS are intended only for use as specified above in the **Indications for Use** section. In the lumbar spine the Ø 4.5mm BONE-LOK® PLS IMPLANT is intended only for the following: transfacet pedicular screw for bilateral posterior fixation (ranging from L1 to S1). If used with anterior fusion product the manufacturer's Indications for Use shall apply.
Correct implant selection - While proper selection of the implant is important in minimizing risks, the size and shape of the patient's bones also must be considered.
Failed Fusion – Metallic implant devices cannot withstand the same activity levels or loads equal to those placed on normal healthy spines. These devices are not designed to withstand the full weight bearing load. If fusion is delayed, or a pseudoarthrosis occurs, the implant may break. The patient should understand that stress on an implant, may in some cases result in failure of that implant.
Infection – This device is contra-indicated in the presence of an active infection.
Osteoporotic bone – Extremely osteoporotic bone may not be suitable for traditional forms of posterior spinal fixation and may increase the risk of implant failure. Should extremely osteoporotic bone be determined intraoperatively, the device may be removed and an alternative approach should be considered.
Conservative treatment – This device is contraindicated when conservative treatment is appropriate.
Corrosion – Metal implants in the human body are subjected to a chemical environment consisting of salts, acids and proteins that may cause corrosion due to galvanic corrosion effects. Dissimilar metals in contact with each other can accelerate the corrosion process; mixing of implant components from different manufacturers is never recommended for metallurgical, mechanical and functional reasons.
Histological conditions – Certain degenerative diseases or physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, and risk implant failure.
This device is packaged and sterilized for single use only. Do not reuse or reprocess. Reuse or reprocessing may compromise the structural integrity of the device, and/or lead to device failure that in turn may result in patient injury, illness or death. Also, reprocessing of single use devices may create a risk of contamination and/or patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

PRECAUTIONS:
The operating surgeon should be trained to the appropriate Surgical Technique, in order to produce a successful outcome.
Device performance – Based on the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system.
Implant re-usage – Implants should never be reused. An explanted metal implant must never be re-implanted.
Handling of Implants – Extreme care should be taken in the handling of the device. No bending or changing of the implants shape should be attempted. These may produce internal stresses, which may cause eventual breakage.
Implant removal after fusion – Metallic implants may loosen, fracture, corrode, migrate, cause pain, or stress shield bone once a fusion has occurred, particularly in active healthy patients. While the surgeon must make the final decision on implant removal, most experts recommend that whenever possible and practical for the patient, fixation devices should be removed once their service as an aid to fusion is accomplished. Implant removal should be followed by the appropriate postoperative management to ensure continued spinal stability.
Instructions to patient – Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful fusion management. The patient must be made aware of the limitations of the implant. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and with time will fracture under normal weight bearing or load bearing in the absence of a fusion. Mental or physical impairment, which compromises or prevents a patient's ability to comply with the necessary limitations or precautions, may place that patient at a particular risk during postoperative rehabilitation.

POTENTIAL CLINICAL RISKS:
- Nerve damage, damage to the implants can occur if excessive mechanical force is used.
- Titanium implants are non-magnetic material; they will not be affected by MRI. It is not necessary to wait several weeks to perform MRI procedure following implant. However, the implant has not been tested for safety, heating or migration in extreme MR environment (over 3 Telsa). The device will produce white images in X-Rays and CT scans.
- Failure to properly perform the cleaning and sterilization of the instruments may result in patient infection.
- This device is packaged and sterilized for single use only. Reuse of implant or use of the implant past the expiration date may result in implant contamination, patient infection, cross-contamination, and/or the implant may not perform as intended.
- Visually inspect implant and instrument before use for physical damage.