INNOVASIS
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Innovasis, Inc.
614 East 3900 South
Salt Lake City, UT 84107 U.S.A.
Tel +1.801.261.2236
Fax +1.801.261.0573
www.innovasis.com

Name of the device:
Kestrel® Buttress Plate System

Model of the device: *See patient implant card*

Intended purpose:
Innovasis implants in the Buttress Plate system(s) named above is/are a temporary implant(s) used to prevent allograft or autograft extrusion or IBFD expulsion and is intended for use in the lumbar spine (L1-S1). The Buttress Plate system is also intended to provide stabilization and augment development of a solid spinal fusion. The Kestrel Buttress Plate System fixates to the anterior portion of the lumbar vertebral body. The construct may be employed alone or with other anterior, or anterolateral spinal systems made of compatible materials.

Intended patient:
The Buttress Plate system is indicated for use to stabilize the allograft or autograft at one level (L1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion. It may be used alone or with other anterior, or anterolateral spinal systems made of compatible materials. This device is not intended for load bearing applications.

Intended performance:
The *Kestrel Buttress Plate System* is indicated for use to stabilize the allograft or autograft at one level (L1-S1) as an aid to spinal fusion and to provide temporary stabilization and augment development of a solid spinal fusion.

Potential adverse effects:
The following potential adverse effects associated with the procedure have been shown to occur with the use of similar spinal systems. Patients should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects.
Potential adverse effects include, but are not limited to:

- Loss of proper spinal curvature, correction, height, and/or reduction
- Infection
- Nonunion or delayed union
- Foreign body reaction to the implants
- Hemorrhaging
- Loss of neurological function, dural tear, pain, and/or discomfort
- Bone graft fracture, vertebral body fracture or discontinued growth of fusion at, above and/or below the surgery level
- Bending, loosening, fracture, disassembly, slippage and/or migration of the components
- Pain or discomfort
- Change in mental status
- Bursitis
- Bone loss and/or bone fracture due to stress shielding
- Inability to resume normal daily activities
- Revision surgery
- Death

Consult your doctor if you experience any of the above adverse effects.

WARNINGS

1. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of success of union, loads produced by weight bearing, and activity levels will among other conditions, dictate the longevity of the implant.

PRECAUTIONS

1. Patients who smoke have been shown to have an increased level of non-unions.
2. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient should limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration of the devices and damage to nerves or blood vessels. The patient must be adequately instructed/informed that fusion of vertebrae may result in stress on adjacent levels.
3. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

MRI SAFETY INFORMATION

The implants are manufactured from implant grade materials that are nonferromagnetic. The devices have not been evaluated for safety in the MR environment. They have not been tested for heating or unwanted movement in the MR environment. The safety of the devices 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.

Please report any device related incidents to the manufacturer (listed at the top of this leaflet).

For Australian patients, please also report device related incidents to the Australian Therapeutic Goods Administration (TGA) at https://www.tga.gov.au/.

POSTOPERATIVE IMMOBILIZATION AND MONITORING

Postoperative external immobilization (such as bracing) is recommended, at the surgeon's discretion. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure (refer to Precautions above). Patients are encouraged to follow surgeon's recommendations for follow-up examinations at requested intervals to prevent unwanted clinical outcomes and increase the likelihood of achieving the intended purpose.

Lifetime of the Device:

Innovasis considers this to be until the device is explanted, for the lifetime of the patient, or 75 years.

System(s)	Kestrel®
Implant Materials	▪ Titanium 6Al 4V (ELI)

