INNOVASIS
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Name of the device:
Oryx® Cervical Plate System

Model of the device: *See patient implant card*

Intended purpose:
The Cervical Plate system(s) is/are intended for use in Anterior Cervical Discectomy and Fusion (ACDF) procedures.

Intended patient:
The Innovasis® *Oryx Cervical Plate System* is intended for use in anterior cervical fixation for the following indications:

- Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e., fracture or dislocation),
- Spinal stenosis,
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- Tumor,
- Pseudoarthrosis; and
- Previous failed fusion.

The Innovasis Oryx Cervical Plate System is indicated for stabilizing the cervical spine from C2 to C7.

Intended performance:
These implants are used to facilitate fusion in the cervical spine. The *Oryx Cervical Plate System* implants are placed via an anterior approach in Anterior Cervical Discectomy and Fusion (ACDF) procedures.

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:

- Infection
- Nonunion or delayed union
- Metal sensitivity or allergic foreign body reaction to the implants
- Pain, discomfort, or other abnormal sensations due to the device.
- Dysphagia
- Hemorrhaging due to erosion of blood vessels in proximity to the device
- Loss of neurological function, dural tear, pain, and/or discomfort
- Bending, loosening, fracture, disassembly, slippage and/or migration of the components
- Pain, discomfort, or other abnormal sensations due to the device
- Bursitis
- Bone loss and/or bone fracture due to stress shielding
- Inability to resume normal daily activities
- Revision surgery
- Paralysis
- 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 devices 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 some of the most critical aspects of successful bone healing. Physical activity and full weight bearing may cause premature failure of internal fixation devices by loosening, bending, or fracture. The patient must be instructed that an implant does not have the strength of normal healthy bone, and that device failure may occur if excessive loading is placed on the implant.
3. Particularly in young active patients, implants may loosen, fracture, corrode, migrate, increase the risk of infection, cause pain, or stress shield bone – even after normal healing. Implant removal should be followed by careful postoperative management to avoid re-fracture. For certain patients, the surgeon may elect to not remove the implant in order to eliminate the risks of another surgery.
4. 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

Careful patient handling for the first two to four months following the operation is very important while the fusion mass matures and becomes able to share load with the implant. Instructing the patient how to reduce stress on the implants is an important part of the effort to avoid clinical problems that may accompany failed fixation (refer to Precautions above). Postoperative external immobilization (such as bracing) is recommended at the surgeon's discretion until the maturation of the fusion mass is confirmed radiographically. Once the fusion mass has healed, the supplemental fixation device may be removed to prevent stress-shielding of the fused bone. As in all patient care issues, this is left to the discretion of the operating surgeon. 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)	Oryx®
Implant Materials	▪ Titanium 6Al 4V (ELI)

