INNOVASIS
INNOVATE / INVOLVE / INVENT

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:

AxHA® Stand-Alone ALIF System
AxTiHA® Stand-Alone ALIF System
LxHA® PEEK Lateral IBF System
PxHA® PEEK IBF System
TxHA® PEEK IBF System
TxTiHA® IBF System

Model of the device: *See patient implant card*

Intended purpose:

Innovasis implants in the systems named above are intervertebral body fusion devices intended to stabilize a spinal segment to promote fusion using bone graft, in order to restrict motion and decrease pain.

Intended patient:

These intervertebral body fusion devices are for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbar spine (L2-S1). 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 at least six (6) months of non-operative treatment. In addition, these patients may have up to a Grade 1 spondylolisthesis or retrolisthesis at the involved levels(s).

Intended performance:

These implants are used to facilitate fusion in the lumbar spine. *AxHA* and *AxTiHA* and are placed via an anterior (ALIF) approach. *LxHA* is placed via a lateral (LLIF) approach. *PxHA* is placed via a posterior (PLIF) or modified transforaminal (T-PLIF) approach. *TxHA* and *TxTiHA* are placed via a transforaminal (TLIF) approach.

Potential adverse effects:

- Bending or fracture of implant; loosening of the implant
- Implant material sensitivity, or allergic reaction
- Decrease in bone density due to resorption or stress shielding, or adjacent level disc deterioration
- Infection, early or late
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia (“pins and needles” sensation).
- Spinal cord impingement or damage
- Fracture of bony structures
- Reflex sympathetic dystrophy
- Degenerative changes or instability in segments adjacent to fused vertebral levels.
- Vascular damage could result in catastrophic or fatal bleeding. Mal-positioned implants adjacent to arteries or veins could cause erosion of these vessels and catastrophic bleeding in the later postoperative period.
- Dural tears experienced during surgery could result in need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
- Bursitis
- Paralysis
- Death
- If a pseudarthrodesis occurs coupled with the IBF system, a mechanical grinding action could possibly occur which might generate wear debris. Most types of wear debris have shown the potential of initiating local osteolysis in articulating joints.

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)	AxHA®	AxTiHA® and TxTiHA®	LxHA®, PxHA®, and TxHA®
Implant Materials	▪ HA PEEK (Hydroxyapatite Polyether Ether Ketone) ▪ Titanium 6Al 4V (ELI) ▪ Tantalum	▪ Titanium 6Al 4V (ELI) ▪ Hydroxyapatite	▪ HA PEEK (Hydroxyapatite Polyether Ether Ketone) ▪ Tantalum

