INNOVATE / INVOLVE / INVENT

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Name of the device:
CxHA® PEEK Cervical IBF System
HAcancellous™ PEEK-C Porous HA PEEK Cervical IBF System
HAtetracell™-C Titanium Cervical 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 cervical interbody fusion devices are intended for procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These devices are to be used in patients who have had six weeks of non-operative treatment.

Intended performance:
These implants are used to stabilize a spinal segment to promote fusion. *CxHA* is implanted via an anterior approach.

Potential adverse effects:
- Nonunion.
- Delayed union.
- Bending or fracture of implant; loosening of the implant
- Implant material sensitivity, or allergic reaction
- Degenerative changes or instability in segments adjacent to fused vertebral levels.
- 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.
- Spinal cord impingement or damage
- Fracture of bony structures
- Reflex sympathetic dystrophy
- Erosion of blood vessels due to the proximity of the device. Such erosion could lead to vessel hemorrhage.
- 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

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. 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)	CxHA®	HAcancellous PEEK-C	HAtetracell-C
Implant Materials	▪ HA PEEK (Hydroxyapatite Polyether Ether Ketone) ▪ Tantalum	▪ HA PEEK (Hydroxyapatite Polyether Ether Ketone) ▪ Tantalum	▪ Titanium 6Al 4V (ELI) ▪ Hydroxyapatite

