INNOVATE / INVOLVE / INVENT

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Name of the device:
Excella-P Spinal System
Excella II® Spinal System
Excella 3® Spinal System
Excella MIS® Spinal System
Excella III-D® Spinal Deformity System

Model of the device: *See patient implant card*

Intended purpose:
Innovasis implants in the pedicle screw systems named above are designed for spinal fixation procedures in skeletally mature patients and are intended to stabilize a spinal segment in the non-cervical area of the spine to provide an optimal environment for spinal fusion in the thoracolumbar region.

Intended patient:
The Innovasis® Excella® Spinal System, when used as a posterior pedicle screw system, is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD—defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- Degenerative spondylolisthesis with objective evidence of neurologic impairment
- Scoliosis
- Fracture or dislocation
- Kyphosis
- Spinal tumor
- Pseudoarthrosis and failed previous fusion

The Innovasis Excella Spinal System, is also indicated for treatment of severe spondylolisthesis (Grades 3 & 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used as a posterior non-pedicle screw fixation system, the Innovasis Excella® Spinal System is intended for the treatment of:

- Degenerative disc disease (DDD—defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- Spinal stenosis
- Spondylolisthesis
- Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's disease)
- Fracture
- Pseudoarthrosis
- Tumor resection
- Failed previous fusion.

Overall levels of fixation are T1-sacrum/ilium.

When used as an anterolateral thoracolumbar system, the Innovasis Excella® Spinal System is intended for anterolateral screw fixation for the following indications:

- Degenerative disc disease (DDD—defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- Spinal stenosis
- Spondylolisthesis

- Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis)
- Fracture or dislocation of the thoracolumbar spine
- Pseudoarthrosis
- Tumor resection
- Failed previous fusion.

Levels of screw fixation are T8-L5.

Intended performance:

The Excella Spinal Systems are designed for spinal fixation procedures in skeletally mature patients performed through a posterior or anterolateral approach, and are intended to assist in the temporary stabilization of spinal segments in order to provide an optimal environment for spinal fusion in the thoracolumbar region.

Potential adverse effects:

- Bending or breaking of the instruments or implants
- Nerve or vascular damage due to surgical trauma
- Mal-alignment of anatomical structures
- Hemorrhage of the blood vessels and/or hematomas
- Gastrointestinal, urological and/or reproductive system compromise (including sterility, impotency and/or loss of consortium)
- Skin or muscle sensitivity in patients with inadequate tissue coverage
- Pain or discomfort
- Sensitivity to a metal foreign body (including possible tumor formation)
- Bone graft donor site pain
- Loss of fixation
- Infection
- Bursitis
- Non-union or delayed union
- Bone loss due to resorption or stress shielding, or adjacent level disc deterioration
- Inability to resume normal daily living activities
- Re-operation
- Death

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

WARNINGS

The safety and effectiveness of pedicle screw systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

MRI SAFETY INFORMATION

The *Excella Spinal System* implants are manufactured from implant grade materials that are nonferromagnetic. The *Excella Spinal System* has 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 *Excella Spinal System* 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 care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient should be aware that there are risks and limitations of the implant and should follow surgeon instruction for postoperative care, rehabilitation and follow-up examinations at requested intervals to prevent unwanted clinical outcomes and increase the likelihood of achieving the intended purpose. The patient should be aware of the limitations of physical activities, which would place excessive stresses on the implant or cause delay in the healing process. The patient should follow instruction for proper use of weight-bearing or assist devices as well as the proper methods of ambulation, climbing stairs, getting into/out of bed or other daily activities while minimizing rotational and bending stresses and to 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 them, 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.

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)	Excella-P, Excella II®, Excella 3®, Excella MIS®	Excella III-D®
Implant Materials	• Titanium 6Al 4V (ELI)	• Titanium 6Al 4V (ELI) • CoCr [Cobalt Chrome]

