

Indications for Use

510(k) Number (if known)
K243916

Device Name
Primus Spinal Fixation System

Indications for Use (Describe)

The Primus Spinal Fixation System is intended to provide immobilization and stabilization of the spine in skeletally mature patients as an adjunct to fusion for procedures of the thoracic, lumbar, and sacral spine (T1-S1). Screws may be placed from the thoracic spine through the sacral spine and into the ilium. This system is intended for anterior/ anterolateral non-pedicle fixation, posterior non-pedicle fixation, and posterior pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

The Spinal Elements Primus Spinal Fixation System may be used in conjunction with the Spinal Elements Overwatch System. In order to achieve additional levels of fixation, the Primus or Overwatch Fixation Systems may be connected to the Lotus Posterior Cervical/Thoracic rod connectors. Transition rods with differing diameters may also be used to connect the Lotus Posterior Cervical/Thoracic Spinal System to the Primus or Overwatch Spinal Systems. Refer to the Lotus Posterior Cervical/Thoracic Spinal System package insert for a list of Lotus indications for use.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Primus and Overwatch implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach.

Spinal Elements' fenestrated screws are intended to be used with saline or radiopaque dye.

These devices are intended to be used with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Spinal Elements' Navigated Instruments are intended to be used during the preparation and placement of Spinal Elements' Primus screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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