

Streamline[®] MIS

Spinal Fixation System



Streamlined
versatility.

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The Streamline MIS Spinal Fixation System allows a rigid construct to be created in the thoracolumbar spine via a percutaneous or mini-open approach using cannulated pedicle screws, set screws and rods. The system offers a broad range of implants and instruments providing the ability to tailor treatment to a specific patient for a more efficient, streamlined procedural experience.

➤ Efficient

Double lead thread designed for faster screw implantation and instrumentation for quick screw engagement and disengagement

➤ Intuitive

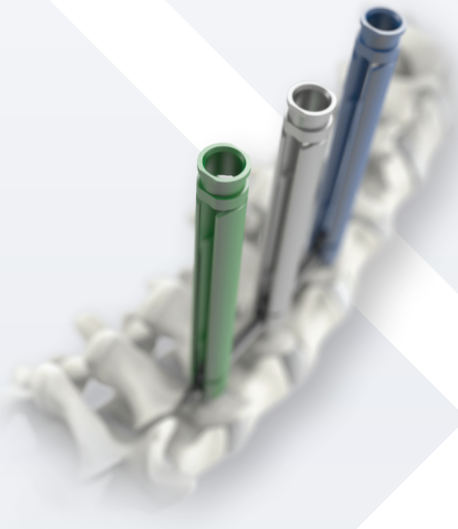
A shared T-25 drive is included across the system to simplify the instrumentation, creating fluid surgical flow. With intuitive visual markings for depth and position reference.

➤ Versatile

Streamline MIS offers multiple instrumentation options for screw and rod insertion to address surgeon preference. Screw diameter options from 4.5 to 9.5mm and length options up to 100mm. The robust reduction instrumentation options allow for up to 30mm of controlled reduction, and powerful compression and distraction at the vertebral bodies.

➤ Navigation

Available instrumentation allows Streamline TL to seamlessly navigate pedicle preparation and screw placement with the Medtronic[®] StealthStation[®] Navigation System.



Indications for Use: The Streamline MIS Spinal Fixation System is intended for posterior, noncervical pedicle fixation, T1-S2 or sacral/ilic screw fixation. Pedicle screw fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion. The device is indicated for all the following indications: degenerative disc disease (DDD) (defined as discogenic back pain 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 failed previous fusion. Streamline MIS Instrumentation, when used with the Streamline MIS Spinal Fixation System, is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery. This remains unchanged from K130286 except for addition of "or sacral/ilic screw fixation" in alignment with RTI's K140696 Streamline TL Spinal Fixation System.

Device Description: Streamline MIS Spinal Fixation System is a temporary, multiple component cannulated pedicle screw system comprised of a variety of components that allow the surgeon to build a spinal implant construct through an open or percutaneous approach. The implant components include rods, extended tab cannulated polyaxial pedicle screws, crosslinks, and locking set screws that are fabricated from titanium alloy (ASTM F136) and provided nonsterile. The components are available in various sizes to accommodate differing patient anatomy. The system is attached to the pedicles by means of screws to the posterior, noncervical spine. The spinal construct is K192396 Page 1 of 3 completed by connecting the screws with titanium alloy rods. Crosslinks can be used if additional stabilization is necessary. The locking set screw for use with the subject system is the same as that cleared through K130286, and will continue to be labeled with the Streamline TL trade name. Similarly, the crosslinks used with the subject system were previously cleared as part of predicate system K130286 and will continue to be labeled with their respective trade names, Streamline TL Crosslinks and Quantum X-Links. The Streamline MIS Spinal Fixation System includes instrumentation to provide the surgeon with a minimally invasive approach for posterior spinal surgery. Class I manual instruments are also included. This remains unchanged from K130286.

Limited Warranty and Disclaimer: Xtant Medical products have a limited warranty against defects and workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are disclaimed.
WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

Caution: USA Law restricts these devices to sale by or on the order of a physician.

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