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ISOLA SYSTEM
ISOLA Twister Connector (Titanium)
510(k) SUMMARY

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COMPANY:

AcroMed Corporation
3303 Carnegie Avenue
Cleveland, OH 44115

TRADENAME:

ISOLA Twister Connector
used with the ISOLA System

CLASSIFICATION:

Labeled for pedicle screw use:
Spondylolisthesis spinal fixation device system;
Unclassified, preamendments device system

Labeled for previously cleared uses:
Spinal interlaminal fixation orthosis;
Class II

DESCRIPTION:

The two piece Twister connector design utilizes the attributes of the one piece slotted connectors. It consists of a slotted transverse member with splines which mate with the splines of the V Groove body. Together these two pieces create the slotted connector assembly. The spline connection or joint is the medium by which the screw/connector interface can be manipulated and secured. This two piece design allows for intraoperative sagittal alignment in 7° increments.

The slotted portion of each design provides further surgical latitude for placement of the screw. The machine threaded portion of the screw is locked to the connector with a nut.

MATERIAL:

All implant components are manufactured of ASTM F 136 titanium alloy.

INDICATIONS:

The ISOLA Spinal System, when used with pedicle screws, is intended for use in grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral vertebral (L5-S1) joint utilizing autologous bone graft, having the device fixed or attached to the lumbar and sacral spine and intended to be removed after solid fusion is attained.

Benefit of spinal fusions utilizing any pedicle screw fixation has not been adequately established in patients with stable spines.

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.

The ISOLA Spinal System, when not used with pedicle screws, is intended for hook, wire, and/or sacral/iliac screw fixation from T1 to the ilium/sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture and previous failed surgery.

As a whole, the ISOLA Spinal System is intended for T1-sacral fixation. Screw fixation is from L3-S1.

PERFORMANCE DATA:

Static and fatigue testing shows the constructs of the ISOLA Twister Connector to perform consistently with previously cleared components.

SUBSTANTIAL EQUIVALENCE:

The ISOLA Twister Connector manufactured from titanium alloy is equivalent to the ISOLA Twister Connector manufactured from implant grade stainless steel and other AcroMed Slotted Connectors in intended use and attachment.