

K962615
ISOLA SYSTEM
ISOLA Twister Connector
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 interlaminar 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-138 stainless steel.

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 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.

Contraindications for the use of the ISOLA System include active systemic infection or infection localized to the site of the proposed implantation. Severe osteoporosis may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other posterior spinal instrumentation system.

Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia are relative contraindications. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, may place undue stresses on the implant.

**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 is equivalent to other AcroMed Slotted Connectors in intended use and attachment.