

K965102

VSP SYSTEM
AcroMed Pedicle Screw (4.75 mm)
510(k) SUMMARY

COMPANY: AcroMed Corporation
3303 Carnegie Avenue
Cleveland, OH 44115

TRADENAME: AcroMed Pedicle Screw

CLASSIFICATION: Spondylolisthesis Spinal Fixation Device
Unclassified, preamendment device system

DESCRIPTION: The AcroMed Pedicle Screw is composed of two sections: a long cancellous section with an integral fixed lower nut, and a machine threaded section topped with an hexagonal drive head. The integral nut serves two purposes: it creates a stronger bolt connection between the screw and plate and it eliminates the "claw hammer" effect associated with other screw designs. The upper surface of the integral nut is a transverse flat smooth surface to provide maximum contact area with the underside of the VSP spine plate.

The AcroMed Pedicle Screw is supplied with an adjustable tapered nut and an optional lock nut, which enables a pedicle screw and a slotted connector to be adjoined utilizing a locking nut system. The junction point of the adjustable integral nut and machine thread portion of the pedicle screw is also rounded to reduce potential stress concentration.

The screw is available in cancellous thread lengths from 25 mm to 50 mm, in 5 mm increments.

MATERIAL: The AcroMed Pedicle Screw is manufactured from implant grade stainless steel conforming to ASTM F1314 specifications.

INDICATIONS:

The AcroMed 4.75 mm Pedicle Screw is designed to be utilized with the VSP Spinal Fixation System. The VSP Spinal Fixation System is intended for use in grade 3 or 4 spondylolisthesis at L5-S1, utilizing autologous bone graft, having the device fixed or attached to the lumbar or sacral spine and intended to be removed after solid fusion is attained. Levels of attachment for this indication range from L3 to the sacrum.

**PERFORMANCE
DATA:**

Static and fatigue testing show the AcroMed pedicle screws (4.75 mm) to perform consistently with previously cleared components.

**SUBSTANTIAL
EQUIVALENCE:**

The AcroMed pedicle screw (4.75) are equivalent to other AcroMed pedicle screws as cleared under K951116.