

APR -3 1997

**AcroMed Anterior Cervical Stabilization System**  
510(k) Summary

**COMPANY:** AcroMed Corporation  
3303 Carnegie Avenue  
Cleveland, Ohio 44115

**TRADE NAME:** AcroMed Anterior Cervical Stabilization System

**CLASSIFICATION:** Orthosis, fixation, spinal cervical intervertebral body. Class II

**DESCRIPTION:**

The AcroMed Anterior Cervical Stabilization System, in its fully assembled form, consists of two laterally placed rods joined by platforms which lie on the anterior vertebral surface. The system is anchored to the vertebrae with screws. The implanted construct provides rigid stability in all planes.

The following types of components are available in the system: Rods, Platforms, Screws and Cross Connectors. All components are manufactured from implant grade Titanium alloy which conforms to ASTM F136 specifications. Assemblies are also available for convenience of the surgeon. These are pre-assembled partial constructs consisting of one Platform, one Cross Connector, two Rods and two Locking Screws.

An instrument set is available specifically designed for use with the AcroMed Anterior Cervical Stabilization System.

**Rod:**

Precontoured Rods comprise the longitudinal structures of the system. All Rods have a 3mm outer diameter and an integral head. Eight lengths are available: 21mm, 36mm, 43mm, 51mm, 58mm, 65mm, 85mm and 110mm. Two rods are required for each construct. Rods may be cut to the appropriate length during the procedure if required. The Rods are precontoured to a curvature consistent with the cervical lordosity, but additional contouring using the Construct Bender contained in the instrument set may be performed if required.

**Platform:**

Five Platform designs are available which are designed to connect the Rods and anchor to the vertebral bodies with bone screws. All Platforms may be used with either Solid Bone Screws (for bicortical fixation) or the combination of Outer and Inner Bone Screws (a hollow outer bone screw used with a solid inner locking screw designed for unicortical fixation). Screw selection is determined by physician preference. All Platforms are designed to be used with two Rods in forming the construct.

Three Platforms are designed for angled insertion of the screw into the vertebral body. The resulting screw angle is thirty degrees and may be directed either rostrally or caudally. These Platforms have a fin feature on one side which engages the vertebra from within the disk space for optimal positioning and fixation. Two of these three Platforms are lockable and thus may be utilized at either the rostral or caudal end of the construct. Lockable Platforms (Type C and Type H) have extensions which accept Platform / Cross Connector Locking Screws for securing the Platform to the Rods. Selection of Type C versus Type H Platforms is based on physician preference and patient anatomy. The third Platform for Angled Screws does not lock to the Rods, and is intended for fixation to intermediate vertebral bodies in multilevel constructs.

Two Platforms are designed for straight (perpendicular) insertion of the screw into the vertebral body. They are available in both lockable and non-locking designs. As described above, the Lockable Platform for Straight Screws may be used on either the rostral or caudal end of the construct, as it provides for fixation of the Platform to the vertebral body and it connects and locks to the Rods. The Non-Locking Platform for Straight Screws provides fixation to intermediate vertebral bodies in multilevel constructs.

One Platform design is available for fixation of the construct to an intervertebral graft. This Platform features a horizontal slot and spherical nest to accommodate variation in screw entry site and in trajectory into the graft.

**Assembly:**

As mentioned in the overall device description, Assemblies are pre-assembled, partial constructs consisting of one Platform, one Cross Connector, two Rods and two Platform / Cross Connector Locking Screws. They are provided for the convenience of the surgeon. Assemblies are provided in five lengths ranging from 36mm to 65mm. All five available Assemblies utilize a Platform for Angled Screws, Lockable, Type H.

**Cross Connector:**

Cross Connectors are used to connect and lock to the two Rods. They have a “band clamp” design in which the upper and lower halves of the Cross Connector are squeezed together by the Platform / Cross Connector Locking Screws, clamping the Cross Connector to the Rod. The Cross Connector does not provide for fixation to the vertebra. It is intended to provide torsional stability in longer constructs.

**Outer Bone Screw:**

Outer Bone Screws are designed to be used in conjunction with Inner Bone Screws. They are available in three diameters: 3.75mm, 4.0mm and 4.35mm. Each diameter is available in four lengths: 10mm, 12mm, 14mm and 16mm. The Outer Bone Screw has an expanding screw head which locks to the Platform. It also has a screw tip which, like the screw head, expands upon full insertion of the Inner Bone Screw. The combination of Outer and Inner Bone Screws is intended for unicortical fixation.

**Inner Bone Screw:**

Inner Bone Screws are available in four lengths: 10mm, 12mm, 14mm and 16mm. Insertion of the Inner Bone Screw into the Outer Bone Screw results in expansion of the Outer Bone Screw head (thus, locking the screw to the Platform) as well as expansion of the Outer Bone Screw tip.

**Solid Bone Screw:**

Solid Bone Screws are available in two diameters: 3.75mm and 4.0mm. Each diameter is available in eight lengths ranging from 16mm to 24mm. The Solid Bone Screw is designed for bicortical fixation.

**Platform / Cross Connector Locking Screw:**

The Platform / Cross Connector Locking Screw is designed for two purposes. First, it is used to tighten together the two sides of the Cross Connector (“band clamp” design), thus locking it to the Rods. Second, it is used to lock a Platform to the Rods. It is available in only one size.

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**Graft Screw:**

The Graft Screw is a solid screw design which is specifically designed to be used with the Platform for Graft Fixation. It is available in only one size, with a diameter of 3.5mm and a length of 10mm. The head of the Graft Screw is designed to match the Platform for Graft Fixation.

**PERFORMANCE DATA:**

**Non-Clinical:**

Static and dynamic bending compression and torsion were performed on the system to characterize its mechanical properties. Additionally, testing was also performed to characterize fatigue life.

**INTENDED USE:**

The AcroMed Anterior Cervical Stabilization System is intended for anterior cervical intervertebral body fixation. This system is indicated for patients in which stability is desired following anterior cervical fusion for the indications listed below. The intended levels for treatment range from C2 to T1.

Indications include symptomatic cervical spondylosis, trauma (including fracture), post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), re-operation for failed fusion, or instability following surgery for the above indications.

**SUBSTANTIAL EQUIVALENCY**

TOP Cervical Spine Stabilization System