

K953978

**ALC Dynamized Fixation System**  
510(k) Summary

COMPANY: **AcroMed Corporation** FEB 19 1997  
3303 Carnegie Avenue  
Cleveland, Ohio 44115

TRADE NAME: **ALC Dynamized Fixation System**

CLASSIFICATION: **Spinal intervertebral body fixation orthosis. Class II**

DESCRIPTION:

The Anterior Dynamized system is a construct consisting of implant grade titanium alloy dynamized closed screws, closed transverse fixator connector, anterior rods and a closed blocker. The Anterior Dynamized construct allows continual compression of the bone graft while avoiding hyperextension type forces on the construct. The components of the Anterior Dynamized system have been designed with anatomic limitations in mind.

**Dynamized Closed Screws:**

The dynamized closed screw is manufactured from a single rod of implant grade titanium alloy material into two distinct sections; the cancellous thread and rod interface. Multiple lengths are available to allow for surgeon latitude. The closed screw allows superior to inferior or inferior to superior placement of a rod. Closed screws used in the caudal portion of the construct contain a set screw which is designed to affix the rod into the opening of the closed screw. Closed screws used in the cephalad portion of the construct do not use a set screw to allow for longitudinal movement of the construct along the rods. The set screw is precision machined from the same implant grade titanium alloy material. The dynamized closed screw is placed into the vertebral body of the spine. Four dynamized closed screws are used per construct.

#### Closed Transverse Fixator Connector:

The closed transverse fixator connector is composed of two closed transverse connectors and a transverse fixator plate. The closed transverse connectors are designed with the patented V-Groove Hollow-Ground (VHG) design to allow proper seating of the titanium rod. A transverse fixator plate is used to span the gap between the connectors. The fixator plates are machined with two elongated slots which facilitate horizontal positioning of the plate. The transverse plates are available in two sizes, small and large. The rod is secured to the connector and transverse plate with a set screw and hex nut. Two closed transverse fixator connectors are used per construct.

#### Closed Blocker:

The closed blocker is of the same design as a closed transverse connector. Using a set screw, the closed blocker is attached to the anterior rod above the dynamized closed screw. The closed blocker is designed to stop hyperextension type forces on the construct. One closed blocker is required per construct.

#### Anterior Rod:

The titanium alloy rod is offered in 1/4 inch outer diameter and two lengths are available for that diameter; 18.0mm and 24.0mm. Two rods are required in the construct and are cut to the appropriate length during the procedure

#### PERFORMANCE DATA:

##### Non-Clinical:

Static compression bending and torsion were performed on the Anterior Dynamized bi-level construct to characterize the properties of stiffness, strength, and maximum applied moment (torque). Dynamic bending compression testing was also performed to characterize fatigue life.

**INDICATIONS:**

The Anterior Dynamized system is intended for use in anterior decompression instrumentation and fusion for kyphotic deformities, post traumatic kyphotic deformities, degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), burst fractures, tumors and previous failed surgery of the spine. The intended levels for treatment range from T10 to L3.

**SUBSTANTIAL  
EQUIVALENCY:**

Dwyer Spinal Instrumentation  
Kaneda Anterior System  
ISOLA Anterior System