

Synthes (USA)
1690 Russell Road
Paoli, PA 19301

DEC 9 1996

(610) 647-9700
Contact: Angela Silvestri
November 1996

The Synthes (USA) Universal Spinal Parallel Connector is part of the Universal Spinal Hook, Rod and Pedicle/Sacral Screw Fixation System, and is compared to the Sofamor Danek Texas Scottish Rite Hospital (TSRH) Pedicle Spinal Screw System Crosslink Axial Plate, and the Titanium TSRH Spinal System (Screws) Crosslink Axial Plate, and the Cotrel Dubosset (CD) System Domino.

The Synthes (USA) Universal Hook, Rod, and Pedicle/Sacral Screw Fixation System consists of rods, various hooks and screws, a trans-connector system, transverse bars and a parallel connector. The hooks and screws attach to the rod via a collar and a nut. The trans-connector system consists of a trans-connector bar and two trans-connector clamps. The trans-connector clamps attach to each rod; the trans-connector bar attaches to the trans-connector clamps, and the clamps attach to the rod via a collar and a nut. There are additional components to the Synthes (USA) Universal Spinal System: transverse bars. It is manufactured from Ti-6Al-7Nb and 316L stainless steel.

When used as a pedicle screw system, the Synthes Universal Spinal Parallel Connector is intended for patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; who are receiving fusions using autogenous bone graft only; who are having the device fixed or attached to the lumbar and sacral spine; and who are having the device removed after the development of a solid fusion.

When used as a nonpedicle screw system, it is also intended for scoliotic, lordotic, or kyphotic deformities (such as scoliosis, Schuereemann's disease); degenerative disk disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies; and fractures of the posterior thoracolumbar spine (levels T8-S2)

The overall levels of fixation are T8-S2.

The Texas Scottish Rite Hospital (TSRH) Crosslink Axial Plate has the same intended use and is manufactured from stainless steel and Ti-6Al-4V. This system is similar in component dimensions and sizes to the Synthes (USA) Universal Spinal Parallel Connector.

The Synthes Universal Spinal Parallel Connector is provided non-sterile; moist heat sterilization is recommended.

Based on the above, the Synthes (USA) Universal Spinal Parallel Connector is substantially equivalent to the Texas Scottish Rite Hospital (TSRH) Crosslink Axial Plate, and the Cotrel Dubosset (CD) System Domino.