

Attachment B: Summary of Safety and Effectiveness Information [510(k) Summary]

Synthes (USA)
1690 Russell Road
Paoli, PA 19301

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

Synthes Universal Modular Spinal System, as compared to the Synthes Universal Spinal Hook, Rod and Pedicle/Sacral Screw Fixation System.

When used as a pedicle screw system, the Synthes Universal Modular Spinal System is intended for patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint (levels of screw fixation L3-S2); 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, Schuermann's disease); degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies; and fractures of the posterior thoracolumbar spine (levels T8-S2)

The overall levels of fixation are T8-S2.

The Synthes Universal Modular Spinal System includes a clamp with posterior nut and Schanz screws for use with the Synthes (USA) Universal Spinal Hook, Rod and Pedicle/Sacral Screw Fixation System. The clamp with posterior nut consists of a clamp body (jaw), a swing clamp bushing (collet), a serrated washer, a nut, and a set (hex) screw. The Schanz screw is placed in the sacral and lumbar spine up to and including L3 sacral for fixation over the L5-S1 joint. The clamp body is slid onto an unthreaded rod. The clamp assembly (nut, serrated washer, jaw and swing clamp bushing) with unthreaded rod is slid over the top, smooth part of the Schanz screw. The clamp is secured onto the unthreaded rod by the use of the set screw, and is locked against rotation by tightening the nut on top of the clamp assembly. The cephalad end of the rods attaches to the spine with a hook, collar and nut from the Universal Spinal Hook, Rod and Pedicle/Sacral Screw Fixation System. The system is manufactured from 316L stainless steel or Titanium alloy.

Synthes Universal Modular Spinal System is provided non-sterile; moist heat sterilization is recommended.

Based on the above, Synthes Universal Modular Spinal System is substantially equivalent to Synthes Universal Spinal Hook, Rod, and Pedicle/Sacral Screw Fixation System, Titanium TSRH Spinal System (Screws), and Synthes Modular Spinal Fixation System and Locking Hook Spinal Rod System.