

**Titanium CD HORIZON™ Spinal System****510(k) Summary****K962708****February, 1997**

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**K962708**

- I. **Company:** Sofamor Danek USA  
1800 Pyramid Place  
Memphis, TN 38132  
(901) 396-3133
- II. **Proposed Proprietary Trade Name:** Titanium CD HORIZON™ Spinal System.
- III. The Titanium CD HORIZON™ Spinal System consists of the following implant components which can be rigidly locked into a variety of configurations, with each resulting spinal implant construct being tailor-made for the individual case.

- CD HORIZON™ rod (commercially pure titanium), 6.35mm diameter
- CD HORIZON™ knurled rod (titanium alloy), 6.35mm diameter
- CD HORIZON™ hooks (titanium alloy)
- CD HORIZON™ screws (titanium alloy): 5.5mm, 6.5mm, and 7.5mm diameters
- CD HORIZON™ Break-Off Set Screw (titanium alloy)
- CD HORIZON™ Low Profile MULTI-SPAN™ CROSSLINK® Plates (titanium alloy)

In addition, the following Titanium TSRH® Spinal system implants can be used with the Titanium CD HORIZON™ Spinal System.

- TSRH® rod (titanium alloy), 6.35mm diameter
- TSRH® Variable Angle Screws (titanium alloy): 6.5mm and 7.5mm diameters
- TSRH® Top Tightening Variable Angle T-Bolts with Locking Screw (titanium alloy): small, medium, and large
- TSRH® Low Profile CROSSLINK® Offset Plate (titanium alloy)
- TSRH® Low Profile CROSSLINK® Plates (titanium alloy)
- TSRH® Low Profile CROSSLINK® Plate Set Screws (titanium alloy)

The Titanium CD HORIZON™ Spinal System components and the others mentioned above are made out of titanium alloy described by ASTM Standard F136 or its ISO equivalent. The Titanium CD HORIZON™ Spinal System also features a rod fabricated from commercially pure titanium conforming to ASTM F67 or its ISO equivalent. Titanium CD HORIZON™ implant components must not be used with implant components fabricated from stainless steel or any other alloy in a construct. The Titanium CD HORIZON™ implants may be sold sterile or non-sterile.

Instruments are available to facilitate the use of the device.

The Titanium CD HORIZON™ Spinal System, when using screws for pedicle fixation, is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

Except for situations where screws are attached to the pedicles of the lumbar and sacral spine via a posterior surgical approach in a Titanium CD HORIZON™ construct for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) at the L5-S1 vertebral joint, the specific indications for the Titanium CD HORIZON™ Spinal System are the following:

1. Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).
2. Pseudoarthrosis
3. Stenosis
4. Spondylolisthesis
5. Spinal deformities: scoliosis, kyphosis, lordosis
6. Fracture
7. Unsuccessful previous attempts at spinal fusion
8. Tumor resection

**NOTA BENE:** The Titanium CD HORIZON™ Spinal System is limited to non-cervical use. The titanium alloy CD HORIZON™ screws and the titanium alloy TSRH® Variable Angle Screws, when used as pedicle screws with the Titanium CD HORIZON™ Spinal System, are intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. When used for pedicle screw fixation as described above, the screws are indicated only for insertion no higher than L3 and not lower than the sacrum. Otherwise the titanium alloy CD HORIZON™ screws and the titanium alloy TSRH® Variable Angle Screws, when used with the Titanium CD HORIZON™ Spinal System, are intended for sacral/iliac attachment only. All of the titanium alloy CD HORIZON™ hooks are intended for thoracic and/or lumbar attachment only. The titanium alloy TSRH® Low Profile **CROSSLINK®** Offset Plate, the titanium alloy TSRH® Low Profile **CROSSLINK®** plates, and the titanium alloy CD HORIZON™ Low Profile **MULTI-SPAN™** **CROSSLINK®** plates are intended for posterior thoracic, lumbar, and/or sacral use only.

- V. The Titanium CD HORIZON™ Spinal System was declared substantially equivalent to other predicate or preamendments devices. Mechanical test data were provided in the application.