

APR 21 1997

LIBERTY™ Posterior Spinal System

510(k) Summary

K964254

January, 1997

I. **Company:** Sofamor Danek USA
1800 Pyramid Place
Memphis, TN 38132
901-396-3133

II. **Proprietary Trade Name:** LIBERTY™ Posterior Spinal System

Classification Name: Pedicle Screw Fixation - Spondylolisthesis spinal fixation device system. Otherwise, spinal interlaminar fixation orthosis.

III. The LIBERTY™ Posterior Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors and connecting components. The LIBERTY™ Posterior Spinal System implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138 or its ISO equivalent. Alternatively, the LIBERTY™ Posterior Spinal System may be made from titanium alloy as described by such standards as ASTM F136 or its ISO equivalent. Do not use stainless steel and titanium implant components in the same construct. Sofamor Danek expressly warrants that these devices are fabricated from the foregoing material specifications. No other warranties, expressed, or implied, are made.

The LIBERTY™ Posterior Spinal System implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. Implant components comprising the LIBERTY™ Posterior Spinal System and those from other Sofamor Danek spinal systems which can be used with the LIBERTY™ Posterior Spinal System are listed in the following table.

Stainless Steel

LIBERTY™ Knurled Rods, 0.250" Diameter

LIBERTY™ Hooks

LIBERTY™ Closed Screws, 5.5mm, 6.5mm, and 7.5mm Diameters

LIBERTY™ Closed Screws with Oblique Canal, 6.5mm and 7.5mm Diameters

LIBERTY™ Open Screws, 5.5mm, 6.5mm, and 7.5mm Diameters

LIBERTY™ Lateral Connectors

LIBERTY™ Set Screw and Closure Saddle

TSRH® Flex Hex-End Rod, 0.250" Diameter, L=4cm-20cm

TSRH® Flex Hex-End Rod, 0.250" Diameter, L=20"

TSRH® Rigid Hex-End Rod, 0.250" Diameter, L=20
TSRH® Super Flex Hex-End Rod, 0.250" Diameter, L=20"
TSRH® Variable Angle Screws, 5.5mm, 6.5mm, 7.5mm Diameters
TSRH® Top Tightening Variable Angle T-Bolts
TSRH® CROSSLINK® PLATES, L=0.625"-1.125"
TSRH® CROSSLINK® MULTI-SPAN Plates, L=1.25"-3.75"
TSRH® CROSSLINK® Offset Plates (Left and Right), L=0.375" and 0.500"
TSRH® CROSSLINK® AXIAL Plate
TSRH® Low Profile CROSSLINK® Offset Plate, L=0.375"
TSRH® Low Profile CROSSLINK® Plates, L=0.625"-2.000"
TSRH® Fixed CROSSLINK® Plate, L=1.2"-2.7"
TSRH® CROSSLINK® Eyebolt, 1/4", Open and Closed
TSRH® CROSSLINK® Plate Locknuts
CD HORIZON™ Low Profile MULTI-SPAN™ CROSSLINK® Plates
TSRH® and CD HORIZON™ CROSSLINK® Set Screws
CCD™ Transverse link assembly with 60 mm bar
CCD™ Transverse link assembly with 120 mm bar
CCD™ Transverse link bar length 60 mm
CCD™ Transverse link bar length 120 mm
CCD™ Transverse link hook
CCD™ Chopin sacral block, left
CCD™ Chopin sacral block, right
CCD™ Chopin iliac extension
CCD™ Screws for sacral blocks, lengths 30 mm to 80 mm in 5 mm increments
CCD™ Domino with closed body, diameter 7 mm
CCD™ Cylinder, Diameter 7 mm

Titanium Alloy

LIBERTY™ Closed Screws, 6.5mm and 7.5mm Diameters
LIBERTY™ Breakoff Set Screw
TSRH® Spinal Rod, 0.250" Diameter
CD HORIZON™ Hooks
CD HORIZON™ Breakoff Set Screw

TSRH® Variable Angle Screws, 6.5 mm and 7.5 mm Diameters

TSRH® Top Tightening Variable Angle T-Bolts

TSRH® Low Profile CROSSLINK® Offset Plate, L=0.375"

TSRH® Low PROFILE CROSSLINK® Plates, L=0.625"-1.750

CD HORIZON™ Low Profile MULTI-SPAN™ CROSSLINK® Plates

TSRH® and CD HORIZON™ CROSSLINK® Plate Set Screws

IV. The LIBERTY™ Posterior Spinal System is intended to provide temporary stabilization and to help augment the development of a solid spinal fusion. Except for situations using pedicle screws in 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 (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass, the specific indications for the LIBERTY™ Posterior 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, and lordosis
6. Fracture
7. Unsuccessful previous attempts at spinal fusion
8. Tumor resection

The LIBERTY™ Posterior Spinal System is intended for use only in the thoracic, lumbar, and/or sacral levels of the posterior spine. The LIBERTY™ Posterior Spinal System is limited to non-cervical use. The LIBERTY™ Screws and TSRH® Variable Angle Screws, when used as pedicle screws with the LIBERTY™ Posterior Spinal System, 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. 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 LIBERTY™ screws and TSRH® Variable Angle Screws, when used with the LIBERTY™ Posterior Spinal System, are intended for sacral/iliac attachment only. The CCD™ Screws for Sacral Block are intended for sacral/iliac attachment only. All of the CD HORIZON™ and LIBERTY™ hooks are intended for thoracic and/or lumbar attachment only. TSRH® CROSSLINK® plates, CD HORIZON™ Low Profile MULTI-SPAN™ CROSSLINK® plates, and CCD™ Transverse links, domino, and cylinder are intended for posterior thoracic, lumbar, and/or sacral use only.

- V.** This 510(k) notification apprised the FDA of the addition of titanium alloy implant components to the system, as well as the use of several stainless steel components from other cleared Sofamor Danek systems with stainless steel LIBERTY™ components.

- VI.** Mechanical test data were supplied in support of this 510(k) notification. The LIBERTY™ Posterior Spinal System was declared to be substantially equivalent to several commercially available devices.

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