K950099

JAN 16 1997

510(k)
Summary of Safety and Effectiveness Information

Regulatory Authority:

Safe Medical Devices Act of 1990, 21 CFR 807.92

Company Name/Contract:

Company: CROSS® Medical Products, Inc.
5161-A Blazer Memorial Parkway
Dublin, Ohio 43017-1339
Phone: (614)718-0530
FAX: (614)718-0540

Medical Device Establishment
Registration Number: 1526354

Contact: Regulatory Affairs Department
CROSS® Medical Products, Inc.
5161-A Blazer Memorial Parkway
Dublin, Ohio 43017-1339
Phone: (614)718-0530
FAX: (614)718-0540

Device Name:

Trade Name: SYNERGY™ Posterior Spinal System

Common Name: Posterior Spine Implants
Universal Spine System

Classification Name: Appliance, Fixation, Spinal Interlaminal
Spondylolisthesis Spinal Fixation Device System

Establishment Registration:

Number: 1526354

Classification:

The Orthopedic and Rehabilitation Devices Panel assigned the unique device classification code 87KWP (Interlaminal uses) to this device system. The published physical description of these devices is in 21 CFR, 888.3050. In addition, they are presently Class II medical devices. Class II medical devices are subject to Performance Standards. This device is also categorized under 87MNH (Spondylolisthesis Spinal Fixation), which is unclassified.

Performance Standards:

Performance Standards applicable to the **SYNERGY™ Posterior Spinal System** have not been published by FDA. CROSS® Medical Products, Inc. produces this device according to the regulations and standards that are appropriate to the risk that Class II devices reasonably present. Voluntary performance standards, such as materials certifications, in-house SOP's and/or ASTM Standards are utilized as appropriate.

Substantially Equivalent Devices(s);

1. **TSRH® Spinal System**
   Danek Group
   K901005, K901587, K904243,
   K914306, K914966, K922520, K923242

2. **PWB Lumbosacral Spinal System**
   CROSS® Medical
   K920116, K924381

3. **Harrington Spine System**
   Zimmer, Inc.
   Preamendment Device

4. **Danek/Sofamor Group**
   Dyna-Lok Spine System
   K922617, K922767, K923239, K923241

Device Description:

Background: This document summarizes safety and effectiveness information about the **SYNERGY™ Posterior Spinal System** contained in the 510(k) Premarket Notification submitted to FDA in support of its substantial equivalence.

Purpose: The **SYNERGY™ Posterior Spinal System** implants are intended to be used as a temporary construct that assists normal healing and are not intended to replace normal body structures.

They are intended to stabilize the spinal operative site during the development of a solid fusion with bone graft, and are intended to be removed after the development of a solid fusion mass.

The implantable portions of the **SYNERGY™ Posterior Spinal System** are made from surgical implant grade stainless steel, commercially pure titanium, and titanium alloy meeting ASTM specifications.

In the stainless steel system, the screws and set screws are made from 22-13-5 stainless steel (ASTM F-1314) and the balance of the implants are made from 316 LVM stainless steel (F-138-86, grade 2). Stainless steel alloy of these types are particularly well suited for use as surgical implants. In addition to excellent strength, fatigue and corrosion resistance characteristics, it has a long history of use in the human body as an implant material.

In the titanium system the screws, nuts, and set screws are made from 6Al-4V ELI titanium alloy (ASTM F-136-92). The rods are made from 6Al-4V ELI titanium alloy and commercially pure titanium (ASTM F-67-89, Grade 2). Both of these titanium types have excellent strength, fatigue, and corrosion resistance characteristics. Titanium devices are also useful as an alternative to devices made from stainless steel for selected patients with reactions or sensitivity to stainless steel implants. The surface finish of the titanium implants is tiodized type II, type III, and/or satin finished.

CAUTION: Mixing of dissimilar metals can accelerate the corrosion process. The titanium and stainless steel components of the SYNERGY™ Posterior Spinal System should not be used together. No components of the CROSS® Medical - SYNERGY™ Posterior Spinal System should be used with the components from any other system or manufacturer.

The surgical instruments used to assist in the implantation of the system are made from 17-4, 420, 440 and 455 series stainless steels (ASTM F-899-84 and A276-91). Established medical grade plastics (Ultem and Radel) are used to construct the handles, cases, etc.

The **SYNERGY™ Posterior Spinal System** is made up of the following basic components:

The CROSS ® Medical - SYNERGY ™ Posterior Spinal System posterior application components are grouped as follows :

1. INTEGRAL ™ Open, Closed, and Reduction screws, and angled closed, iliac, and variable locking sacral screws with variable locking seats, hex nuts, and set screws. Only the INTEGRAL ™ Open, Closed, Reduction, and Variable Locking screws are intended for pedicle fixation. (See INDICATIONS)
2. Open and closed spinal hooks with sliders, c-rings, and set screws.
3. Adjustable and fixed transverse connectors with set screws.

4. Closed and Axial rod connectors with set screws.
5. Lateral connectors with set screws.
6. Rods.
7. Instruments
8. Sterilization case(s).

Note: While the variable locking screws and some fasteners (nuts and set screws) are used for both the 6.35 mm and 4.75 mm rod sizes, the remaining components are designed for specific rod diameters.

Note: The 5.5 and 8.0 mm diameter INTEGRAL ™ Open and Reduction Screws, as well as the Angled Closed Screws, and Iliac Screws are only for use with the 6.35 mm rod system.

INDICATIONS:

The **SYNERGY™ Posterior Spinal System**, when using the screws as pedicle screws, 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 screws 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 approach for the treatment of severe spondylolisthesis (Grade 3 and Grade 4) at the L5-S1 vertebral joint, the specific indications for the **SYNERGY™ Posterior Spinal System** are:

1. Degenerative Disc Disease (as defined by chronic back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
2. Idiopathic scoliosis.
3. Kyphotic deformities of the spine.
4. Paralytic scoliosis and/or pelvic obliquity treated in combination with anterior instrumentation.
5. Lordotic deformities of the spine.
6. Neuromuscular scoliosis associated with pelvic obliquity.
7. Vertebral fracture or dislocation.
8. Tumors.
9. Spondylolisthesis.
10. Stenosis.
11. Pseudarthrosis.
12. Unsuccessful previous attempts at spinal fusion.

For these indications, the SYNERGY™ screws and lateral connectors are intended for sacral/iliac attachment only. All of the SYNERGY™ hooks and transverse connectors are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use for the **SYNERGY™ Posterior Spinal System** are T1 to the Sacrum. The levels of screw fixation are L3 to ilium.

Note: The 4.75 mm diameter rod/hook constructs are intended only for patients weighing 70 pounds (32 kg) or less.

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

1. History of recent infection; systemic, spinal or localized.
2. Morbid obesity.
3. Mental illness.
4. Alcoholism or drug abuse.
5. Fever or leukocytosis.
6. Pregnancy.
7. Metal sensitivity/allergies to the implant materials.
8. Severe osteopenia.
9. Presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which prevents secure implant screw fixation and/or decreases the useful life of the device. Any condition where the device will interfere with anatomical structures or physiological performance, including inadequate tissue coverage over the operational site.
10. For pedicle screw cases, missing or congenitally deformed pedicles of the fifth lumbar (L5) vertebrae.
11. Patients unwilling or unable to follow post-operative care instructions.
12. Any circumstances not described under the heading INDICATIONS.

WARNINGS AND PRECAUTIONS:

Warnings:

- When used as a pedicle screw system, this device system is intended only for Grade 3 or 4 spondylolisthesis at the fifth lumbar-first sacral (L5-S1) vertebral joint.
- The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 vertebral joint.
- Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
- Potential risks identified with the use of this device system, which may require additional surgery, include:

  device component fracture,

loss of fixation,
non-union,
fracture of the vertebra,
neurological injury, and
vascular or visceral injury.

See Warnings and Precautions, and Potential Adverse Effects sections of the package insert for a complete list of potential risks.

In general, the SYNERGY™ Posterior Spinal System should only be implanted by surgeons fully experienced in the use of such implants and the required specialized surgery techniques. Even with the use of spinal implants, a successful result in terms of pain, function, or fusion is not always achieved in every surgical case.

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

This device system is not intended to be the sole means of spinal support. Its use without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass, and in this case, bending, loosening or fracture of the implant will eventually occur.

The proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be advised of this fact and warned of the consequences. Other poor candidates for spine fusion include obese, malnourished, poor muscle and bone quality, and nerve paralysis patients.

Pre-Operative:

1. Only those patients who meet the criteria of one or more of the INDICATIONS and do not have any conditions included in the CONTRAINDICATIONS should be selected for implantation.
2. The implant components should be handled and stored carefully, protected from any damage, including corrosive environments.
3. The surgeon must confirm that all necessary implants and instruments are on hand for the planned surgical construct. Components from other manufacturers should not be combined with components of the SYNERGY™ Posterior Spinal System.
4. All implants and instruments must be unpacked, inspected for damage, cleaned and sterilized prior to use in the operative field.

Intra-Operative:

1. The Instrumentation Technique Manual should be carefully followed.

2. Extreme caution should be used around the spinal cord and nerve roots, especially when inserting screws or hooks.
3. Breakage, slippage, misuse, or mishandling of the instruments or implant components, such as on sharp edges, may cause injury to the patient or operative personnel.
4. The implant must be handled and contoured carefully so as to avoid notching or scratching the surface.
5. Before closing the soft tissues, all of the nuts and set screws should be tightened firmly according to the operative technique. Recheck the tightness of all nuts and set screws after finishing to ensure that none loosened during tightening or manipulation of the other implants.
6. Explanted implants must never be reused.

Post-Operative

1. The surgeon must consider removing the implant after healing, as the implants can loosen, fracture or corrode even after fusion has occurred. The risks and benefits of a second surgery must be carefully evaluated.
2. The patient must be adequately instructed regarding the risks and limitations of the implant, as well as post-operative care and rehabilitation.
3. The patient should be instructed in the proper use of crutches, canes, external braces or any other weight bearing or assist devices that may be required, and limit those physical activities which would place excessive stresses on the implants or cause delay of the healing process. The patient should also be instructed in the proper methods to ambulate, climb stairs, get in and out of bed, and perform activities of daily living, while minimizing rotational and bending stresses.

POSSIBLE ADVERSE EFFECTS:

Pre-operatively, the patient should be made aware of the following possible adverse effects of spinal implant surgery. Additional surgery may be necessary to correct some of these effects.

1. Bending, loosening, or fracture of the implants or instruments.
2. Metal sensitivity to a foreign body, including possible tumor formation, auto-immune disease, metallosis and/or scarring.
3. Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications.
4. Nonunion or delayed union.
5. Infection.

6. Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage.
7. Gastrointestinal, urological, and/or reproductive system compromise, including sterility, impotency and/or loss of consortium.
8. Pain or discomfort.
9. Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery.
10. Hemorrhage of blood vessels and/or hematomas.
11. Misalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height.
12. Bursitis.
13. Bone graft donor site pain.
14. Inability to resume activities of normal daily living.
15. Death.

NOTE: The SYNERGY™ Posterior Spinal System Instrumentation Technique Manual should be carefully followed. It supplies important additional information on proper usage of the implants and instruments.

PACKAGING:

All packages containing implants or instruments should be sealed and intact upon receipt. The product should not be used and should be immediately returned to CROSS® Medical Products, Inc., if the package or product is damaged.

Sterilization/Resterilization:

All instruments and implants are supplied **Non-Sterile**. Non-Sterile instruments and implants are packaged in "clean only" condition. The labeling of the implants & instruments clearly indicates their sterility status. All packaging materials must be removed prior to sterilization. High temperature steam sterilization should be used, with the following cycle having been laboratory validated:

Method:	Steam
Cycle:	Gravity
Temperature:	250°F (121°C)
Exposure Time:	60 minutes

Note: It is recommended to dry and/or cool the parts to prevent condensation after the steam cycle.

Only sterile products should be used in the operative field. The recommended sterilization cycle is based on HIMA/AORN protocols. Other sterilization methods and cycles may also be suitable. However, individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.

INSTRUMENTATION:

Device specific instrumentation is necessary for the insertion and anchoring of the **SYNERGY™ Posterior Spinal System**. However, much of the surgical procedure is done with general orthopedic instrumentation of the appropriate size and type. **SYNERGY™ Posterior Spinal System** instruments are made from stainless steel meeting ASTM F899-84 and A276-91 standards.

PRODUCT COMPLAINTS:

Any dissatisfaction with the product quality, labeling or performance should be reported to CROSS® Medical Products, Inc. immediately by the customer or user. Furthermore, if any of the implants "malfunction" (i.e. do not meet any of their performance specifications or otherwise do not perform as intended) and may have caused or contributed to the death or serious injury of the patient, CROSS® Medical Products, Inc. should be notified immediately by telephone, fax, or written correspondence.

When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person fling the complaint. In addition, the nature of the complaint should be clearly communicated along with a notification of whether a written report from CROSS® Medical Products, Inc. is requested.

COMPARISON WITH PREDICATE DEVICE(S):

The **SYNERGY™ Posterior Spinal System** has similar design concept, materials, features, intended use and surgical approach as existing legally marketed posterior spine system such as the TSRH®, Harrington, Dyna-Lok, and PWB Lumbosacral Systems. All of these systems are used to treat similar or the same conditions, and all have essentially the same cautions and contraindications for use.

CONCLUSION:

Based on the basic design concept, the use of well known materials, feature comparisons, mechanical testing, indications for use, surgical approach, preproduction quality assurance planning and engineering analysis CROSS® Medical Products, Inc. believes that sufficient evidence exists to reasonably conclude that this device is substantially equivalent to existing legally marketed posterior spine systems.