(English) **SYNERGY™ SPINAL SYSTEM**

**WARNING**: The FDA has placed labeling limitations on this device.

**INDICATIONS-FOR-USE**

The **SYNERGY** 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 fusion procedures and should be removed after fusion.

The implants are attached to the spine posteriorly by means of hooks and/or screws joined with rods and anteriorly by means of vertebral screws joined with rods.

As a pedicle screw system, the **SYNERGY** 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 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. The levels of screw fixation are L3 to S1/ilium.

In addition, the pedicle screw system may also be used to provide immobilization and stabilization of spinal segments, in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

As a posterior, non-pedicle, screw and hook system, and an anterolateral, intervertebral body screw system, the specific indications for the **SYNERGY** 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.
4. Paralytic scoliosis and/or pelvic obliquity.
5. Lordotic deformities of the spine.
7. Vertebral fracture or dislocation.
8. Tumors.
10. Stenosis.
11. Pseudarthrosis.
12. Unsuccessful previous attempts at spinal fusion.

For posterior, non-pedicle, screw use, the **SYNERGY** screws and lateral connectors are intended for sacral/iliac attachment only, and the **SYNERGY** hooks and transverse connectors are intended for posterior thoracic and/or lumbar use only. As a whole, the levels of use are T1 to the Sacrum/ilium.

The Adjustable Length Rod is intended for in situ adjustment after placement of the hooks or screws during spinal fusion surgery.

For anterior use, the recommended levels of attachment are: T10 to L3 for the double rod constructs and T5 to L5 for the single rod constructs. The 4.75mm diameter rod system can be used in single and double rod constructs while the 6.35mm diameter rod system is to only be used in single rod constructs. In all cases, instrumentation must be at least 1cm from any major vessel.
PRODUCT CONFIGURATIONS
The SYNERGY Spinal System devices are provided nonsterile and should be cleaned and sterilized prior to use.

Implantable portions of the SYNERGY Spinal System may be made from either titanium or stainless steel. The titanium version consists of surgical implant grade titanium alloy as described by ASTM Standard F-136 (Ti 6Al-4V ELI), and commercially pure titanium, grade 2 as described by ASTM Standard F-67 (CP Ti, Gr. 2). The stainless steel version consists of surgical implant grade stainless steel as described by ASTM Standard F-138, Grade 2 (316 L Stainless Steel), and surgical implant grade stainless steel as described by ASTM Standard F-1314 (22-13-5 Stainless Steel).

DESCRIPTION OF DEVICE
The SYNERGY Spinal System components are grouped as follows:

Posterior Application:
1. INTEGRAL™ Open, Closed, Angled Closed and Reduction Screws, Variable Locking Screws with Variable Locking Seats, and Iliac Screws with Hex Nuts and Set Screws. Caution: Only the INTEGRAL Open, Closed, Reduction and Variable Locking Screws are intended for pedicle fixation.
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 and Adjustable Length Rods with Set Screws.
7. Instruments.
8. Sterilizer case(s).

Anterior Application:
1. INTEGRAL Open and Closed Screws and Variable Locking Screws with Variable Locking Seats, with Hex Nuts and Set Screws.
2. Vertebral Washers.
3. Fixed Transverse Connectors with Set Screws.
4. Rods.
5. Instruments.
6. Sterilizer case(s).

NOTE: While the Variable Locking Screws and some fasteners (nut and set screws) are used for both the 6.35mm and 4.75mm rod sizes, the remaining components (except for those connector components that are designed to join the two rod sizes) are designed for specific rod diameters.

NOTE: The Adjustable Length Rod is intended for in situ adjustment after placement of the hooks or screws during spinal fusion surgery.

The Adjustable Length Rod is intended for use as part of either a single or double rod assembly. The Adjustable Length Rod allows for distraction at a central location once the bone anchors have been secured.

INSTRUCTIONS-FOR-USE
Caution: The SYNERGY Spinal System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques. Refer to the SYNERGY Spinal System Instrumentation Technique Manual for complete instructions-for-use.

CONTRAINDICATIONS
Contraindications include, but are not limited to: history of recent infection, systemic, spinal or localized; morbid obesity; mental illness; alcoholism or drug abuse; fever or leukocytosis;
pregnancy; metal sensitivity/allergies to the implant materials; severe osteopenia; presence of congenital abnormalities, vague spinal anatomy, tumors, or any other condition which prevents secure implant 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; for pedicle screw cases, missing or congenitally deformed pedicles of the fifth lumbar (L5) vertebrae; patients unwilling or unable to follow postoperative care instructions; and any circumstances not described in the Indications-For-Use section.

WARNINGS
1. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
2. For the Posterior Application Components, the 4.75mm diameter rod/hook constructs are intended only for patients weighing 32kg or less.
3. The 4.0mm - 6.0mm diameter screws for use with the 4.75mm rod and the 4.0mm - 5.0mm diameter screws for use with the 6.35mm rod are intended for use anteriorly from T5 – L5 and posteriorly from T1 – T12 only. They should not be used for attachment or fixation to the posterior elements (pedicles) of the lumbar or cervical spine.
4. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct. No components of the SYNERGY Spinal System should be used with the components from any other system or manufacturer. As with all orthopaedic implants, the SYNERGY Spinal System components should never be reused under any circumstances.
5. 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 nonunion will not be successful. No spinal implant can withstand the loads of the body without maturation of a solid fusion mass. If there is no solid fusion, the spinal implant will eventually bend, loosen, or fracture.
6. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.

PRECAUTIONS
Preoperative Precautions:
The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The surgeon must confirm that all necessary implants and instruments are on hand for the planned surgical construct. The implant components should be handled and stored carefully, protected from any damage, including corrosive environments. They should be carefully unpacked and inspected for damage. The implants and instruments must be cleaned and sterilized prior to use.

Carefully inspect all instruments prior to use. Do not use an instrument that is severely marred and/or worn, or a cutting instrument with dull edges. Note that at some point in time, instruments may wear out and should be replaced.

Intraoperative Precautions:
Extreme caution should be used around the spinal cord and nerve roots, especially when inserting screws or hooks. 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.
The implants must be handled and contoured carefully so as to avoid notching or scratching the surface.

Prior to 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.

**Postoperative Precautions:**
The patient must be adequately instructed regarding the risks and limitations of the implant, as well as postoperative care and rehabilitation.

The patient should be instructed in the limitations of 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 use of any required weightbearing or assist devices as well as in the proper methods of ambulation, climbing stairs, getting in and out of bed and performing activities of daily living, while minimizing rotational and bending stresses.

The surgeon must consider removal of the implant after healing, as the implants can loosen, fracture or corrode even after fusion has occurred. The risk and benefits of a second surgery must be carefully evaluated.

**COMPLICATIONS**
Possible adverse effects include, but are not limited to:
1. bending, loosening or fracture of the implants or instruments
2. loss of fixation
3. sensitivity to a metallic foreign body, including possible tumor formation
4. skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications
5. nonunion or delayed union
6. infection
7. nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage
8. gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium
9. pain or discomfort
10. bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery (fracture of the vertebra)
11. hemorrhage of blood vessels and/or hematomas
12. malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height
13. bursitis
14. bone graft donor site pain
15. inability to resume activities of normal daily living
16. reoperation or death

**STERILIZATION**
All SYNERGY Spinal System components are provided nonsterile. All packaging should be sealed and intact upon receipt. If the package or product is damaged, it should not be used and should be returned immediately.

High temperature steam sterilization should be used. All packaging materials must be removed prior to sterilization. The following cycles have been laboratory validated:

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>250°F (121°C)</td>
<td>60 minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>Prevac</td>
<td>270°F (132°C)</td>
<td>8 minutes</td>
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</tbody>
</table>
Drying Time: 20 minutes
Note: Allow for Cooling

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

INFORMATION
For further information, please contact the Customer Service Department at:
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US Patent Numbers: 5,360,431; 5,466,237; 5,474,555; 5,496,321; 5,624,442; 5,697,929; 5,556,092;
D377,895; 6,443,953; 6,616,668; 6,685,412; 6,733,502

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