Ennovate Spinal System - Lumbar/Deformity

General Info

The Ennovate Spinal System is an implant system used to correct spinal deformity and facilitate the biological process of spinal fusion. This system is intended for posterior use in the thoracic, lumbar and sacral areas of the spine. This system includes polyaxial screws of varying diameters and lengths, fixed screws of varying diameters and lengths, rod to rod connectors in varying lengths and styles, and cross connectors in varying lengths and styles. All implant components are top loading and material. Contraindications include, but are not limited to, the following:

1. Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies),
2. Spondylolisthesis,
3. Trauma (i.e., fracture or dislocation)
4. Spinal Stenosis,
5. Deformities or Curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. Tumor,
7. Pseudoarthrosis, and
8. Failed previous fusion

Materials

The Ennovate Spinal System is manufactured from titanium alloy (Ti-6Al-4V), conforming to ISO 5832-3.

Indications

The Ennovate Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation. Fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The Ennovate System can be used in both an Open and Minimally Invasive Surgery (MIS) The device is indicated for treatment of the following acute and chronic instabilities or deformities.

The Ennovate Spinal System is indicated for treatment of the following acute and chronic instabilities or deformities:

- Spinal Stenosis,
- Trauma (i.e., fracture or dislocation)
- Spondylolysis, and
- Failed previous fusion

Caution/Precautions

Precaution: Components of competitive spinal fixation systems should not be used with components of the Ennovate Spinal System. Components of dissimilar material should not be used together due to the potential for accelerating the corrosion process by mixing of dissimilar materials.

Warning: 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 neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Contraindications

Contraindications of the Ennovate Spinal System are similar to other commercially available posterior spinal fixation systems of similar design and material. Contraindications include, but are not limited to, the following:

1. Use in the Cervical Spine
2. Active systemic or local infection
3. Obesity
4. Pregnancy
Precaution: 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.

Precaution: Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may implant on the performance of the system.

The Ennovate Spinal System should be implanted only by surgeons experienced in the use of spinal fixation systems. This system should only be used with instrumentation specifically designed for this system and the surgeon should be familiar with the surgical technique.

Warning: The Ennovate Spinal System is not intended to be used without bone graft which is required to provide additional spinal support. Use of this product without bone graft or in cases that develop into a non-union will eventually be unsuccessful. A successful result is not always achieved in every surgical case. No posterior spinal fixation system can withstand body loads without the support of bone. In the event that bone is not provided to facilitate fusion, bending, loosening, disassembling, and/or breakage of the implant will eventually occur.

In addition to the above specified warnings and precautions, general surgical risks should be explained to the patient prior to surgery.

Complications and possible adverse effects
Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential for additional surgery to correct these effects:
1. Loosening, disassembly, bending or breakage of components
2. Tissue sensitivity to implant material
3. Potential for skin breakdown and/or wound complications
4. Non-union or delayed union
5. Infection
6. Nerve damage, including loss of neurologic function, dural tears, paralysis, paresthesia, and cerebral spinal fluid leakage
7. Fracture of vertebrae
8. Loss of fixation
9. Vascular or visceral injury
10. Chance of abnormal spinal curvature
11. Gastrointestinal, urological and/or reproductive system compromise
12. Pain or discomfort
13. Bursitis
14. Decrease in bone density due to stress shielding
15. Loss of bone or fracture of bone above or below the level of surgery
16. Bone graft donor site pain, fracture, and/or delayed wound healing
17. Restriction of activities
18. Lack of effective treatment of symptoms for which the surgery was intended
19. Death

Preoperative
1. Only patients that meet the criteria described in Indications section and do not have any conditions included in the Contraindication section of this package insert should be selected for surgery.
2. Implants of this system must be handled and stored to avoid damage. Implants should be protected from damage including scratches, nicks and corrosive environments.
3. The surgeon should be instructed on the proper use of instruments and implants.
4. All implants and instruments of the system must be inspected for damage, cleaned, and sterilized prior to use. Components of other systems should not be used with the Ennovate Spinal System.

Intraoperative
1. The surgeon must follow the instructions provided in the surgical technique manual for the Ennovate Spinal System. Extreme caution must be used around the spinal cord and nerve root, especially during insertion of screws and hooks.
2. The implants must be handled and contoured carefully to avoid scratching of the implant surface. Contouring of the rods should only be performed with the proper equipment. In addition, scratching, notching, or reverse bending of the implants should be avoided. X-rays should be taken to assist in identifying the precise location of implant placement.
3. Due to sharp edges, the implants and instruments must be handled carefully to avoid injury to the patient or operative personnel. All implants of this system should be tightened securely as defined in the surgical technique manual and rechecked prior to tissue closure.
4. Implants removed from a patient or that contact body tissues or fluids should never be reused.

Application
- To avoid trauma to the spinal column and nerve roots due to incorrect application, position instruments and insert pedicle screw only with the aid of a radiographic visualization or navigation system.
- To avoid internal stress on, and weakening of, the implant: avoid scoring or scratching of implant components.
- Do not alter the shape of any metal implants except for the rods of the Ennovate Spinal System.
- Do not rebend or excessively bend the rods.
- Do not bend the rod connectors.
- Always use the bending instruments of the Ennovate Spinal System instrument set for bending the rods.
- Always use the set screw insertion instrument for positioning the set screws.
- Always use the screwdriver and counteracting instrument for loosening the set screw.

There is a risk of injury if the set screw is improperly mounted
- Set the set screw in place correctly.
- Make certain that rods are correctly positioned on the floor of the groove.
- Always use the torque wrench and the counteracting instrument to fully tighten the set screw.
A loss of correction can occur with insufficient fixation of the polyaxial head.
- Never loosen the connection of the polyaxial head, once it has been tightened with the set screw.
- Tighten the set screw only after every necessary correction maneuver has been performed.
- Make sure that the pin is correctly positioned on the floor of the groove.
- For tightening the set screws of the rod connector, always use the torque wrench and countering instrument intended for this purpose.

Implantation of the rod connectors requires the following steps:
- Position the rod connector on the rod at the location indicated by the operating surgeon.
- Do not remove the set screw from the rod connector assembly.
- Do not reassemble the set screw with the rod connector components.
- Do not implant the rod connector if the set screw is missing.

Caution: The parallel rod connector is unusable due to the set screw being removed or missing.
- If the set screw is removed or missing, select another parallel rod connector for implantation.
- Make certain the rod connector is correctly positioned before tightening the set screw.
- For tightening and loosening of the set screw, always use the screwdriver and countering instrument provided for this purpose.
- Always tighten the set screw with the 5 Nm torque wrench (SZ297R) intended for this purpose.

Warning: There is a risk of injury if the set screw provides insufficient clamping stability.
- Check that no patient tissue is lodged within the rod connector assembly.
- Position the rod connector correctly.
- Check that the rods are fully inserted into the parallel rod connector.
- Tighten the set screw with the 5 Nm torque wrench (SZ297R) intended for this purpose.

Warning: There is a risk of injury if the set screw is over-/under-tightened.
- Always apply exactly the specified torque of 5 Nm when tightening the set screw.

Warning: Inadequate fixation can occur due to incorrect rod position.
- Always position the rod connector so that the rod is fully inserted into the connector.
- Always position the rods in such a way that the hexalobe or the tip is outside the rod connector clamping region.

Warning: Inadequate fixation can occur due to patient tissue being lodged within the rod connector assembly.
- Check that no patient tissue is lodged within the rod connector assembly.
- Dislodge patient tissue from the rod connector assembly or select another rod connector for implantation.
- Only allow axial load on the set screw during tightening. Avoid induction of lateral forces when tightening or loosening the set screw.

Warning: Damage to the hexalobe socket in the set screw can occur due to incorrect application of the screwdriver or torque wrench.
- Make certain the hexalobe tip of the screwdriver or torque wrench is fully inserted in the hexagonal socket of the set screw when tightening or loosening the set screw.

Further information about Aesculap Implant Systems are available from Aesculap or the Aesculap office responsible.

Postoperative
1. Implant removal must be considered after fusion has occurred due to the possibility of implant loosening, fracture or corrosion.
2. The risk and benefit of a second surgical procedure must be evaluated carefully. The surgeon is expected to supply postoperative care and management instructions to the patient. The patient should be advised that non-compliance with postoperative instructions could lead to poor results, including implant failure.
3. The patient must be adequately instructed regarding the risks and limitations of this implant system, and the patient must be made aware that this system is not expected to support the spine if fusion does not occur.
4. The patient must be made aware of the risk of failure of the implant if fusion does not occur. Additional surgeries may be required if fusion does not occur and implant failure occurs.
5. Patient must be instructed on the physical limitations that are required to avoid placing excessive stress on the implants causing implant failure or delays in recovery.
6. The patient must be informed that the risks of multiple complications to exist.
7. Components of this system are only intended to support the spine during the period required to achieve solid spinal fusion. The device will eventually fail if fusion does not occur.

Note
The Ennovate Spinal System Surgical Technique Manual should be followed carefully. Important information on the proper usage of implants and instruments are included.

Sterility
- The implants are delivered unsterile
- The implant components are delivered in individual packaging.
- Store the implant components in their original packaging and only remove them from such packaging immediately before use.
**NON STERILE DEVICES:** The following applies to the implants provided unsterile:

- The implants have to be pre-cleaned and steam-sterilized (according to the respective hospital guidelines for the provision of sterile materials) before use.
- Refer to the proceeding section – Sterilization method and parameters.

**Sterilization method and parameters**

- Use the implant system storage trays for sterilization and sterile preparation.
- Aesculap does not recommend the device be sterilized by “Flash” or chemical sterilization.
- Surgical instruments may also be placed within an Aesculap rigid sterilization container (sterile container) for processing under generally accepted hospital in-use conditions.

For the non-sterile implants and instruments, sterilization is accomplished by steam. To Achieve a sterility assurance level of $10^{-6}$, Aesculap Implant Systems recommends the following parameters:

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Temperature</th>
<th>Minimum exposure time</th>
<th>Full Cycle time</th>
<th>Sterile Container System</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum</td>
<td>270°F (132°C)</td>
<td>4 min</td>
<td>20-30 min.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The above parameters have been validated for sterility in an Aesculap STERILCONTAINER System. The cycle times for wrapped product are based on the recommendations of the AAMI Guidelines ST79 for steam sterilization.

**Note:** Time and temperature parameters required for steam sterilization may vary according to the type of sterilizer, cycle design, and packaging/containerization. The manufacturer’s instructions must be followed for each sterilization chamber.

**Additional Information**

The Surgical Technique Manual for the implantation of the Ennovate Spinal System is available upon request. Further information on Aesculap Implant Systems are available from Aesculap or the Aesculap office responsible.

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**Caution:** Federal law restricts these devices to sale by or on the order of a physician.

**Distributor in the US/Contact in Canada for product information and complaints**

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