

S4 Spinal System – Lumbar/Deformity

General Info

The S⁴ Spinal System is a temporary 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. Implants of this system consist of screws connected to rods and are intended to be removed after solid fusion has occurred. This system includes polyaxial screws of varying diameters and lengths, fixed screws of varying diameters and lengths, rods in varying lengths, and parallel/domino and axial rod connectors. All implant components are top loading and top tightening. The implants in this system are manufactured from titanium alloy (Ti-6Al-4V ELI), conforming to ASTM F 136 and CP Titanium conforming to ASTM F 67.

The S⁴ Spinal System is a spinal rod and screw system. This system's polyaxial and fixed screws can be rigidly locked into a wide range of configurations, therefore allowing each construct to be formed to the needs of an individual patient. Rods of this system are shaped intraoperatively to correct or maintain proper spinal curvature. The parallel/domino, and axial rod connectors can be used to join one rod in parallel or end-to-end, respectively, to another rod, thereby extending the construct to adjacent spinal segments.

The implants of this system are for single use only. An implant should never be reused after being removed from the body or re-sterilized after coming into contact with body fluids or tissues.

Indications

The S⁴ 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 device is indicated for treatment of the following acute and chronic instabilities or deformities.

- 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 S4 Spinal System is manufactured from titanium/titanium alloy (Ti6Al4V) in accordance with ASTM F-136 and ASTM F-67.

Contraindications

Contraindications of the S⁴ 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

5. Mental illness
6. Severe osteoporosis or osteopenia
7. Metal sensitivity/ allergies to the implant material
8. Alcohol or drug abuse
9. Patients unwilling or unable to follow postoperative instructions
10. Neuromuscular diseases/ disorders
11. Soft tissue deficit not allowing wound closure
12. Any medical or physical condition that would preclude the potential benefit of spinal implant surgery
13. Congenital abnormalities, tumors or other conditions that would prevent secure component fixation that has the potential to decrease the useful life of the device.
14. Any medical or mental condition which would exclude the patient or put the patient at high risk from surgery of this severity.
15. For pedicle screw cases, inadequate pedicles of the fifth lumbar (L5) vertebrae.

Caution/Precautions

Precaution: Components of competitive spinal fixation systems should not be used with components of the S⁴ 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.

No component of the S⁴ Spinal System should be reused after being removed from the body. An implant should never be re-sterilized after contact with body tissues or body fluids.

Damage to the implant can occur if the clamping screw is overtightened. Do not tighten the clamping screw without using the counteracting instrument or screw head expansion can occur.

Damage to the implant can occur when implant set screw is over torqued.

Damage to the implant can occur if the repositioning instruments are positioned too high in relation to the implant. Always apply repositioning instruments (e.g. distraction and compression forceps) below the rod at the implant.

Precaution: Over insertion of the S4 / Element Polyaxial screws may result in contact between the polyaxial screw body and the bone surface. This contact may result in damage to the implant or instrumentation.

During derotation, screw head expansion may occur if derotation Sleeves are not used.

The implant can be damaged by spondylolisthesis repositioning through the clamping screw. Always use the rod persuader for spondylolisthesis repositioning.

Precaution: The S4 system has not been evaluated for safety and compatibility in the MR environment. The s4 system has not been tested for heating or migration in the MR environment.

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 (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

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 impact on the performance of the system.

The S⁴ 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 S⁴ 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.

Refer to the system's surgical technique for detailed implantation/explanation of information. To obtain a surgical technique guide, please contact Aesculap Implant Systems Customer Service Department at (866) 229-3002 or your Sales Representative.

The patients should be made aware that a successful result, as defined by reduced pain, increased function, and the establishment of solid fusion, is not always achieved in every surgical case. Proper patient selection will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-union. These patients should be informed of this increased risk and counseled to discontinue tobacco use prior to and immediately after surgery. Obese, malnourished, and/ or nerve paralysis are also poor candidates for spinal fusion.

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. Change of normal 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
- Bone graft donor site pain, fracture, and/ or delayed wound healing

16. Restriction of activities
17. Lack of effective treatment of symptoms for which the surgery was intended
18. 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 S⁴ Spinal System.

Intraoperative

1. The surgeon must follow the instructions provided in the surgical technique manual for the S⁴ 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 and polyaxial 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 and transverse connectors of the S⁴ Spinal System
- Do not rebend or excessively bend the rods and transverse connectors.
- Always use the bending instruments of the S⁴ Spinal System instrument set for bending the rods and transverse connectors.
- Always use the clamping screw insertion instrument for positioning the clamping screws.
- Always use the screwdriver and countering instrument for loosening the clamping screw

There is a risk of injury if the clamping screw is improperly mounted

- Set the clamping screw in place correctly.
- Make certain that rods are correctly positioned on the floor of the groove.
- Always use the torque wrench and the countering instrument to fully tighten the clamping screw
- Break off the flanks only when the clamping screws have been fully tightened (does not apply to S4 Element).

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.
- Tighten the clamping screw only after every necessary correction maneuver has been performed.
- Always use the special flank breaking forceps for removing the flanks (does not apply to S4 Element)
- Make sure that the pin is correctly positioned on the floor of the groove.
- When using a clamp (hook, counter hook and connecting pin), use special S⁴ Spinal System mounting instruments.
- The counterhook clamping screw has to be adequately tightened.
- For tightening the locking screws of the cross connector, always use the torque wrench and countering instrument intended for this purpose.

Implantation of the parallel 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 clamping screw from the rod connector assembly.
- Do not reassemble the clamping screw with the rod connector components.
- Do not implant the rod connector if the clamping screw is missing.

Caution: The parallel rod connector is unusable due to the clamping screw being removed or missing.

- If the clamping screw is removed or missing, select another parallel rod connector for implantation.
- Make certain the rod connector is correctly positioned before tightening the clamping screw.
- For tightening and loosening of the clamping screw, always use the screwdriver and countering instrument provided for this purpose.
- Always tighten the clamping screw with the 4 Nm torque wrench (FW207R) intended for this purpose.

Warning: There is a risk of injury if the clamping 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 clamping screw with the 4 Nm torque wrench (FW207R) intended for this purpose.

Warning: There is a risk of injury if the clamping screw is over-/under- tightened.

- Always apply exactly the specified torque of 4 Nm when tightening the clamping 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 hexagon 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 clamping screw during tightening. Avoid induction of lateral forces when tightening or loosening the clamping screw.

Warning: Damage to the hexagonal socket in the clamping screw can occur due to incorrect application of the screwdriver or torque wrench.

- Make certain the hexagonal tip of the screwdriver or torque wrench is fully inserted in the hexagonal socket of the clamping screw when tightening or loosening the clamping 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 S⁴ 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, except for the parallel rod connectors, which are delivered sterile.
- 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.

STERILE DEVICES: The following applies to the implants provided sterile:

- The parallel rod connectors have been sterilized by gamma irradiation.
- Prior to use, check the use-by-date and the integrity of the sterile packaging.
- Do not use implant components whose use-by-date has been expired or whose packaging is damaged.

Warning: For implants provided sterile, damage to the implants can occur by processing and resterilization.

- Do not process or resterilize the implants.

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:

Sterilization Method	Temperature	Minimum exposure time		
		Wrapped	Full Cycle time Sterile Container System	Minimum Dry Time
Pre-vacuum	270°F (132°C)	4 min	4 min	20-30 min.

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 S⁴ Spinal System is available upon request. Further information on Aesculap Implant Systems are available from Aesculap or the Aesculap office responsible.

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

Aesculap Implant Systems, LLC.

3773 Corporate Parkway
Center Valley, PA 18034
USA
(866) 229-3002

Caution

United States (Federal) law restricts these devices to sale by or on the order of a physician.