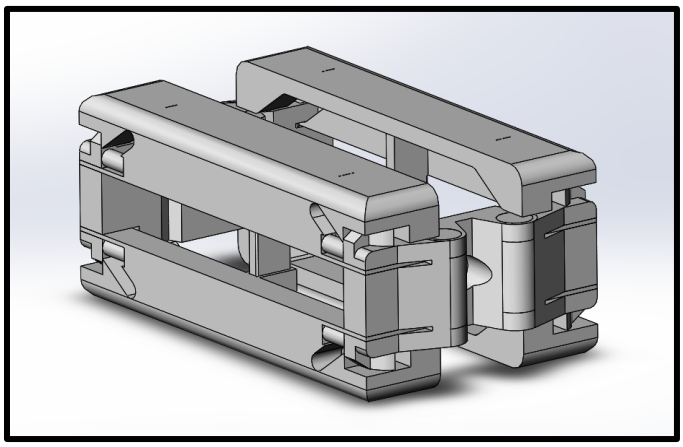
SPINE SPACE

SpineLock

LUMBAR INTERBODY SPACER



Spine Space
Rhodes Research Center, Clemson University
Clemson, SC 29632

Manufactured in Clemson, SC USA

STERILE

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Device Description

The SpineLock device is an interbody spacer utilized during lumbar spinal fusion surgery to replace a degenerated intervertebral disc. It has the ability to bidirectionally expand and to sustain bone graft. This is accomplished with paired angled slots in conjunction with multiple hinges, allowing expansion in both the cranial-caudle and medial-lateral directions. These are independently and completely controlled by the clinician.

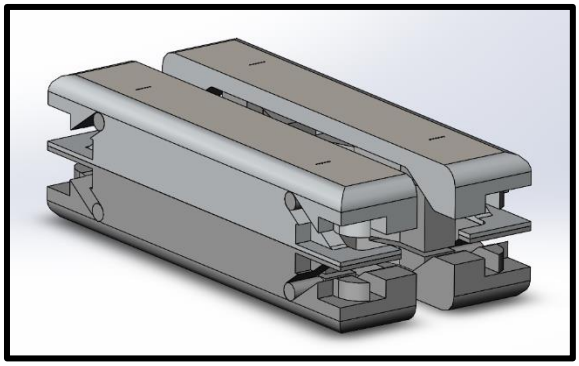

Figure 1. Collapsed SpineLock

The cage is made of titanium, Ti-6Al-4V specifically. It is supplied sterile and fully assembled. It will come in its unexpanded form, as seen in Figure 1. Once the SpineLock is inserted into the intervertebral disc space, it is expanded with the associated applicator. Figure 2 demonstrates the fully expanded device.

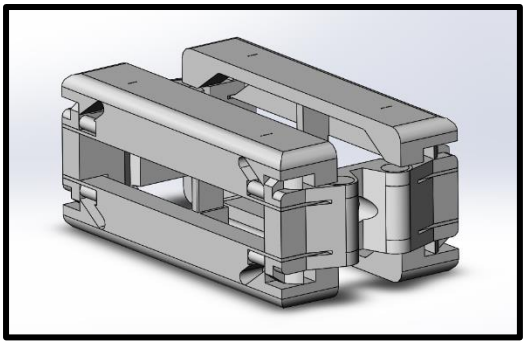

Figure 2. Fully Expanded SpineLock

SpineLock is the fully assembled cage that will be inserted into the disc space (Figure 3). The top shell corners (Part 6) and bottom shell corners (Part 7) act as the points of contact with the surrounding vertebrae and the main structures of support. Within the shells are two multi-hinge joints composed of the face plate (Part 1), two corners (Part 2) and two pegged plates (3). These are held together by the dowels and dowel caps (Parts 5 and 4). These function as the main expansion mechanism alongside the slots within each shell. When collapsed, the face plates are at maximum distance apart (Figure 1). As the device expands, the face plates get farther from each other and all other parts shift until both joints are parallel to one another as seen in Figure 2.

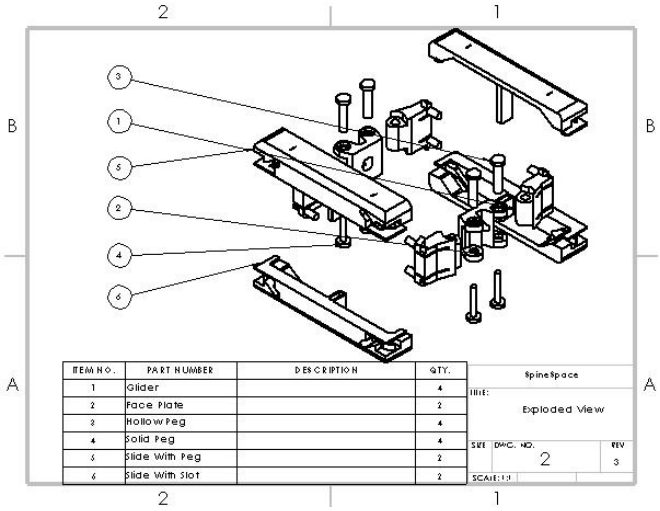

Figure 3. Bill of Materials

Material Specification

This device and its applicator are made of Titanium as per ISO 10993-1 and ASTM F136.

Indications for Use

The SpineLock is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1. The device is intended for use at either one or two contiguous levels for the treatment of degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The SpineLock may be used in patients with up to Grade I spondylolisthesis or retrolisthesis in addition to DDD. It is indicated for use in skeletally mature patients. The device is intended for use with supplemental fixation and autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

The SpineLock is indicated for single use only.

Contraindications

Contraindications for the SpineLock device used for intervertebral body fusion include the following:

1. Allergic reactions or sensitivities to implant materials
2. Infection of any kind
3. Patients with a compromised immune system
4. Conditions that affect bone remodeling and strength such as osteoporosis, bone absorption, osteopenia, or certain metabolic disorders
5. Morbid obesity
6. Vertebral fracture
7. Spondylolisthesis more severe than Grade 1
8. Substance abuse (smoking, drinking and any other drugs)
9. Pregnancy
10. Disorders which may cause patients to ignore the limitations of implant fixations
11. Fusions from prior procedures at the levels being treated
12. Conditions not specified in the Indications for Use

Precautions

1. Use of an improperly sized or expanded device in an area of high functional stresses may lead to implant failure or fracture.
2. The SpineLock has not been tested and evaluated for use in an MR environment. Therefore, its safety, compatibility, heating and migration properties are unknown.
3. When greater than one spinal level is treated, longer operative times and higher blood loss are likely to occur.
4. As the number of surgical procedures done on the spine increases, the potential for damage and tears in the dura increases.

5. Based on mechanical testing results and simulations, physicians should consider levels of implantation, patient weight, patient activity levels, and other relevant patient conditions that may affect SpineLock's performance.
6. The SpineLock is intended to fill the disc space only and should not be used to substitute for other parts of the spine that are not mentioned.
7. If the surgeon needs to adjust the SpineLock's position during surgery, they should fully collapse the device before repositioning and re-expansion.
8. Do not use instruments or devices that have not been properly maintained as this may lead to inadequate performance and damage to the device or patient.
9. SpineLock is a single-use device, DO NOT use implants that have been previously removed
10. Do not implant the SpineLock if its sterile packaging has been breached before its intended use.
11. The SpineLock and its applicator should not be used with any other systems.
12. Ensure SpineLock is properly locked onto the applicator before use.

Adverse Reactions

Device-specific complications may include:

1. Implant fracture, failure, loosening or migration
2. Fracture of the lumbar vertebrae
3. Allergic reaction to the device
4. Delayed fusion or non-union

Potential surgical complications may also include:

1. Pain
2. Pseudarthrosis
3. Revision surgery(s)
4. Bleeding at the surgical site
5. Infection
6. Tissue or nerve damage
7. Spinal fluid leakage
8. Paralysis related spinal cord impingement or damage
9. Scarring
10. Bone graft-related complications, including donor site morbidities

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Instructions for Use

The following instructions apply for the uses indicated above.

1. Ensure that the surgical procedure being done matches SpineLock's indications for use labelled on the packaging and usage documents.
    a. Degenerative Disc Disease
    b. Grade I Spondylolisthesis

    c. Retrolisthesis
2. Open package containing the unexpanded SpineLock and applicator.
3. After minimally invasive surgical incision and discectomy, undergo standard spinal disc height trialing procedures.
4. After size is determined, attach the SpineLock to the applicator by inserting the applicator through the non-threaded proximal end and screwing it into the distal threaded end.
5. Insert the collapsed SpineLock through the minimally invasive cut.
6. Position the device based on the results of trialing.
7. Once the proper positioning is attained, expand the SpineLock by pulling the exterior shaft of the applicator and pushing on the handle.
8. Inject graft material into the disc space via the applicator.
9. Ensure the device is properly locked in its expanded position.
10. Unscrew the applicator from the device and carefully remove it from the surgical site.
11. Add supplemental fixation to the proper vertebrae.
12. Dress the surgical cuts with standard procedures.
13. If the device needs to be collapsed at any point, push on the applicator handle and pull on the exterior shaft.

Sterilization

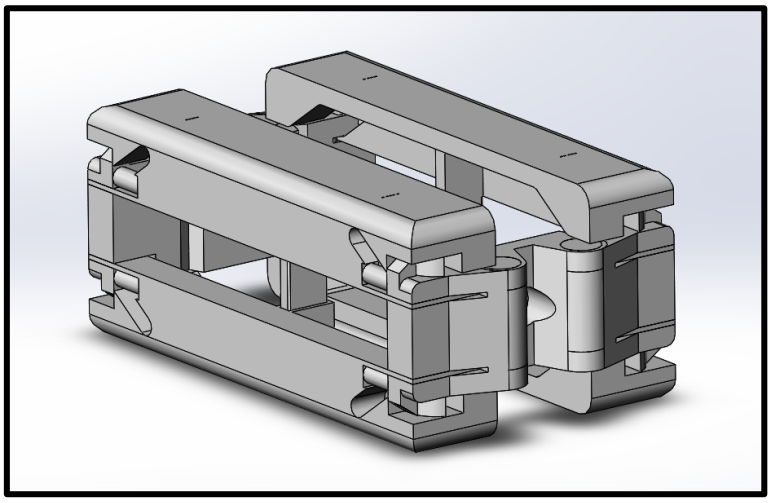
The SpineLock and its system are supplied STERILE.

Storage

1. SpineLock sterile packaging should be stored in a controlled room temperature away from direct sunlight.
2. Packaging should be inspected for damage and breaches before surgical use.
3. SpineLock sterile packaging has a shelf life of 5 years.
4. Avoid storing the SpineLock in damp areas.

For additional information about the SpineLock Lumbar Interbody Spacer and its use, please contact Spine Space:

Phone: (224) 343-7787
Email: spinelockspacer@spinespace.com



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