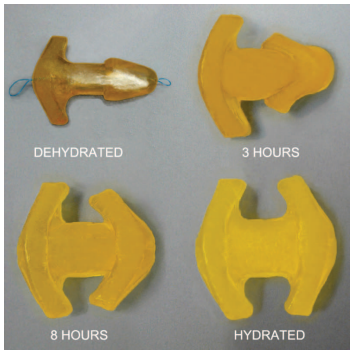
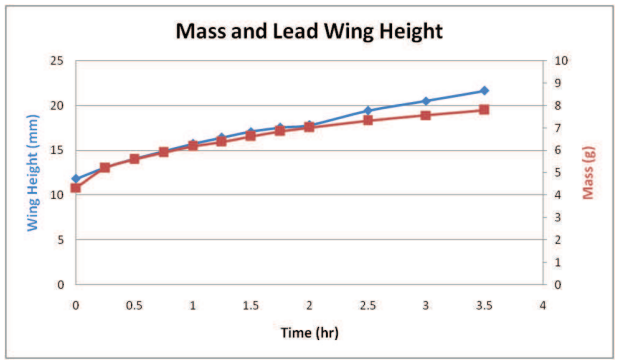
Biocompatible Hydrogel

The GelFix™ Interspinous Spacer is a one piece posterior spinal distraction implant made from HPAN; a biocompatible hydrogel which exhibits desirable mechanical properties. Implanted between the spinous processes through a small incision, GelFix™ acts as a dynamic spacer restricting painful extension without adversely affecting other segmental motion. GelFix™ provides a soft distraction, in contrast with more rigid conventional materials such as titanium and polyether ether ketone (PEEK). Once implanted, extension at the painful segment is reduced, providing relief for patients experiencing discomfort from degenerative spinal stenosis. GelFix™ is available in four spacer sizes.

Single dehydrated GelFix™ implant





Key Features

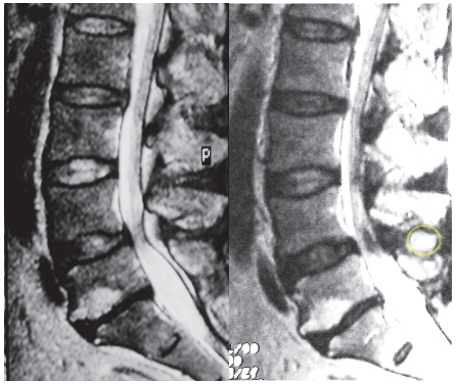
- Single piece elastic construct
- Increases space between spinous processes in order to maintain flexion and reduce painful motion
- No moving parts
- Prevents/reduces nerve root impingement
- Stabilizes the painful segment of the spine
- Small incision, minimally invasive procedure
- Supraspinous ligament remains intact

GelFix™ Scientific and Clinical Rationale

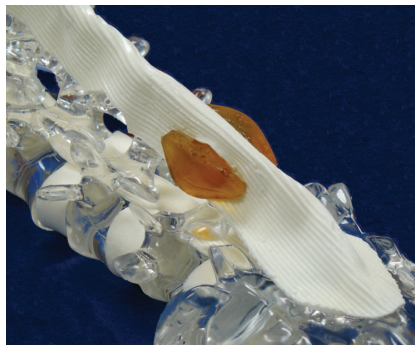
GelFix™ The Perfect Fix

Spinal Stenosis

The most common cause of serious back pain in adults age 60 and older is stenosis[2]. By the age of 50[1] degenerative spinal changes can be observed in nearly 95% of the population. Over time, bony overgrowths can form around spinal joints and the ligamentum flavum may harden and thicken. These two factors lead to lumbar spinal stenosis (LSS), a narrowing of the spinal canal and neural foramen. As the spinal canal narrows, nerves emanating from the spinal cord are compressed leading to numbness and pain in the lower back and legs. Stenosis is often associated with other degenerative changes commonly referred to as degenerative disc disease (DDD). Studies have shown that a form of biomechanical intervention which limits extension is effective in reducing back and leg pain associated with stenosis and DDD.



L4/5 stenosis (left) and 6 months post GelFix™ implantation (right).



GelFix™ prevents painful extension

Softer Solution

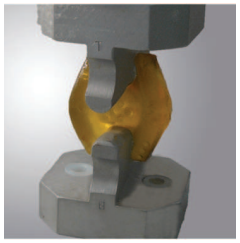
Treatments for spinal stenosis and DDD range from nonsurgical pain management such as simple physical therapy or steroid injections to serious surgical interventions as in decompression laminectomy and fusion. Although commonly performed, both of these surgical solutions to lumbar spinal stenosis involve inherent risks.[3,4] An alternative therapy uses an interspinous spacer to distract the two adjacent spinous processes at the afflicted level thereby preventing or reducing the painful motion. Over the past five years, Interspinous Spacer Devices (ISDs) have become a popular solution to managing nerve root compression from stenosis[5] and alleviating back pain associated with DDD. More recently however, ISD surgery has been associated with a higher rate of early postoperative spinous process fracture. These fractures, often concealed by the metallic wings of certain commercial devices, can go unnoticed and are frequently responsible for poor outcomes following surgery[6].

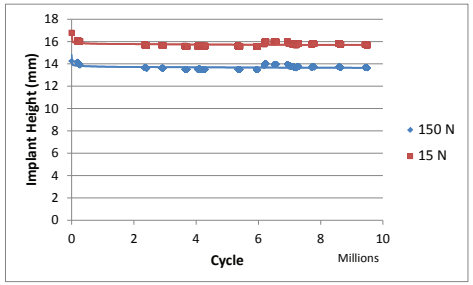
Replication Medical Inc. has developed the GelFix™ Interspinous Spacer to provide a simpler, softer answer to spinal stabilization[7]. The GelFix™ hydrogel is flexible and provides posterior support without a "hard" stop in extension.

REPLICATION Medical, Inc

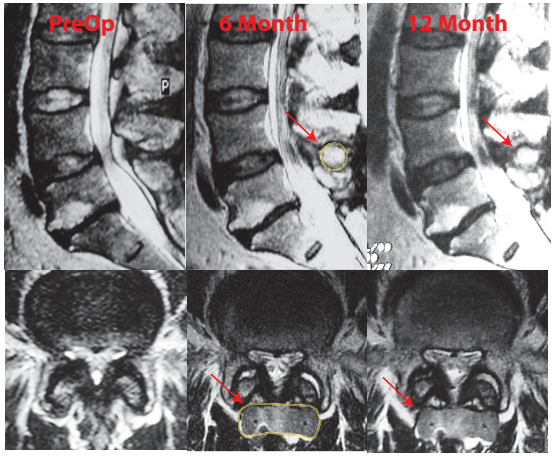
Fatigue Testing

GelFix™ Interspinous Process Devices were cyclically loaded between 150 and 15 N over 10 million cycles.[8] Over the equivalent of 80 to 100 years of normal use[9,10], the GelFix™ decreased in height by approximately 1 mm with no damage. Wear particles were small (1.30 to 2.12 µm) and with a high roundness factor (0.65) making them non-inflammatory. The GelFix™ maintained consistent loading amplitude of approximately 2 mm demonstrating the long term dynamic response. Studies have shown the mean loading of interspinous spacers to be 45.8N.[11] The GelFix™ resisted compressive loads three times greater than expected in vivo loads.





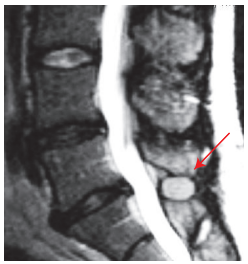
GelFix™ maintains height and dynamic response after 10 million cycles.



Sagittal and axial T2 MRIs preoperative, 6 months (implant highlighted in yellow) and 1 year.

Clinical Experience

A twenty-five patient clinical outcomes study was initiated to assess the ability of GelFix™ to reduce back and leg pain associated with spinal stenosis[12]. The primary inclusion criterion for this study was painful stenosis that is relieved in flexion, but patients with discogenic pain were also included. The twenty-five patients treated thus far show a significant decrease in both leg and back pain on the Visual Analog Scale and Oswestry Disability Index.

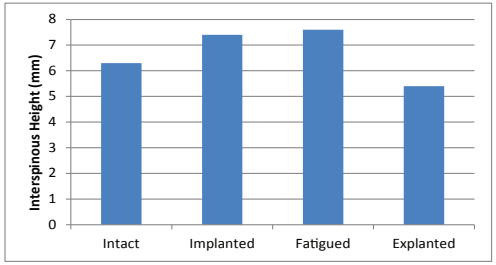


GelFix has been used to treat L5/S1 with prominent S1 process.

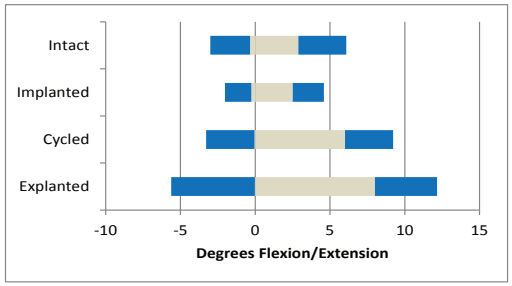
GelFix™ Scientific and Clinical Rationale

GelFix™ Maintains Normal Motion

L4/5 cadaveric motion segment was analyzed under four conditions: 1) intact, 2) implanted with a GelFix™ and hydrated, 3) with hydrated GelFix™ after 130,000 cycles of 500 N loading coupled with 5 N·m moments and 4) explanted removing the GelFix™ while leaving all other tissue intact. Lateral x-rays were digitized and used to determine interspinous height. The GelFix™ increased height and maintained it through cyclic loading/bending. The pronounced decrease in height after implant removal demonstrates that the GelFix™ remained effective as soft tissue degraded.

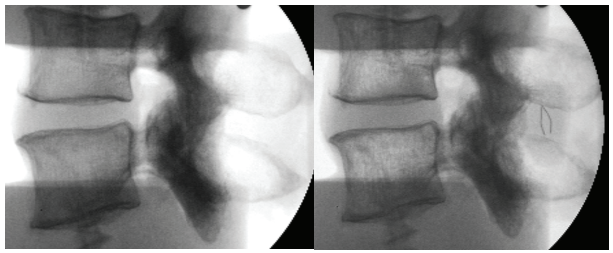


Interspinous height with a 50N preload.



Range of Motion and Neutral Zone at 7.5 Nm flexion/extension.

Range of motion (ROM) testing was performed on the spinal unit at 7.5 N·m moments. The GelFix™ maintained the neutral zone (NZ) while stabilizing both flexion and extension. Cyclic loading increased the NZ and ROM. ROM of the explanted specimen was even larger demonstrating that the GelFix™ performed a significant role in stabilizing the segment.



Intact segment (left) and implanted segment (right) with 50N preload.

1. Place the patient in a lateral decubitus position or in a prone position using a flexion inducing frame. Use fluoroscopic imaging to verify levels of dissection and to visualize the spinous processes and vertebral bodies. Mark positions using a skin marker. Sterilely prep and drape the area.

2. Using a direct posterior approach, make a lumbar midline incision and carefully dissect the lateral lamina(e). Leave the midline supraspinous ligament intact. Exposure of one side of the lamina should include a subperiosteal dissection to assist in the identification of the interspinous space. The contralateral lamina does not necessarily require extensive soft tissue dissection unless so desired.

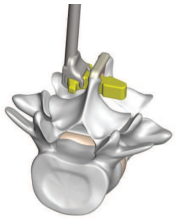
3. Using the Small Dilator, puncture the interspinous ligament as anterior as possible and then remove the instrument.

4. Using the Large Dilator, further dilate the defect in the interspinous ligament.

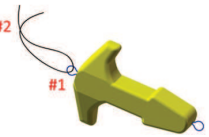
5. Insert the Sizing Distractor into the space created by the dilator. Slowly open the Sizing Distractor until the elastic limit of the ligaments is reached. Distraction can be performed under lateral fluoroscopic imaging to verify movement of the adjacent vertebrae. Once the desired distraction has been achieved, read the letter (or numerical value corresponding to the distraction space) size indicator on the Sizing Distractor and select the corresponding implant. Remove the Sizing Distractor.

Distractor Indication	Functional Implant Size
A	8mm
B	10 mm
C	12 mm
D	14 mm

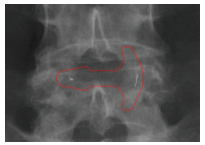
6. Grip a sterile GelFix™ with the Implant Inserter. Maneuver the implant so that the tip is aligned with the interspinous space at the point of dilation and then push it laterally through the interspinous ligament. Insertion may be easier after removing retractors.



7. Optional: Secure the implant to the surrounding soft tissues using the non-absorbable suture loop at the end of the implant (#1). Tie a resorbable suture (#2) through the loop #1 and affix to facet capsule or the intertransverse ligament.

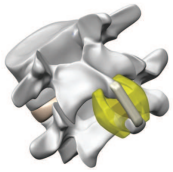


8. Verify the positioning of the implant using fluoroscopy. The two platinum-iridium markers should appear equal distance from the midline.



9. Irrigate the wound using saline. Suitable prophylactic local antibiotics (such as Gentamicin) may be premixed with the saline. Close using standard layered fashion. A drain is usually not required unless a decompressive procedure was performed.

10. Care should be taken to avoid twisting or bending motions for the first four hours after surgery. Subsequently, twisting and bending motions should be minimized for the next 24 hours.



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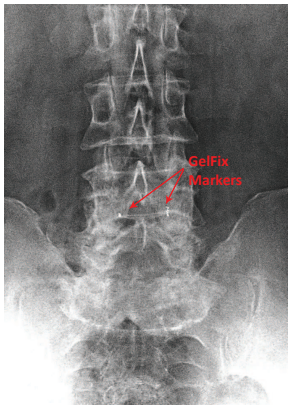
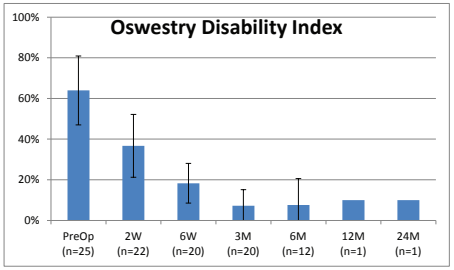
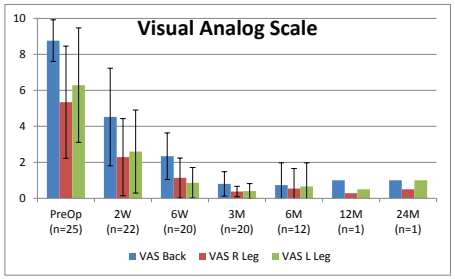
GelFix™ Scientific and Clinical Rationale

Post-operative T2 weighted MRIs demonstrate posterior height increase and a resulting increase in the central canal. The longest term follow-up is two years and measurements of leg and back pain showed significant drops in both VAS (89%) and ODI (55%) at this point in time. It is important to note that although the product is not specifically indicated for the treatment of back pain, nearly every patient experienced a reduction in back pain (as measured using ODI and VAS) at all timepoints. The average improvement in Zurich Claudication Questionaire (ZCQ) scores for symptom severity and physical function at 6 months were 63.0% and 54.2% respectively. The 92% ZCQ patient satisfaction with an average raw score of 1.19 demonstrates a high treatment success rate at 6 months.



X-Ray 6 months post GelFix™ implantation at L4/5. Implant is visable through Pt-Ir markers.





The GelFix™ hydrogel implant provides an attractive alternative to traditional materials, such as PEEK and titanium, when treating degenerative lumbar stenosis. Both animal studies and human clinical experience demonstrate the safety and biocompatibility of the hydrogel. Capitalizing on the shape memory properties to facilitate minimally invasive surgery, implants based upon hydrogel have been developed to treat spinal stenosis and low back pain associated with degenerative disc disease. Early findings from human clinical data are promising and suggest that hydrogel implants will one day figure prominently in the continuum of care between conservative, non-operative treatment and major surgery.

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