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Federal law (USA) restricts this device to sale by or on the order of a physician.

The Spineology Interbody Fusion System (SIFS) is indicated for use as an adjunct to fusion in an intervertebral body fusion at one level in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. Eligible patients shall have undergone six (6) months of conservative (non-operative) care. SIFS with compatible allograft and autograft is intended for use with supplemental posterior fixation systems intended for use in the lumbar spine.

For a complete list of contraindications, precautions, and warnings please refer to the package insert.

At Spineology, we are dedicated to transforming spine surgery by providing innovative, anatomy-conserving technologies for surgeons and their patients. Our proprietary mesh technology is used in the OptiMesh and Duo implants, which expand in three dimensions to create large footprints and allow placement of anatomy-conforming interbody fusion devices through very small incisions. This technology preserves spinal anatomy, increases procedural efficiency, and accelerates patient recovery. Learn more at spineology.com

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anatomyconservingsurgery™

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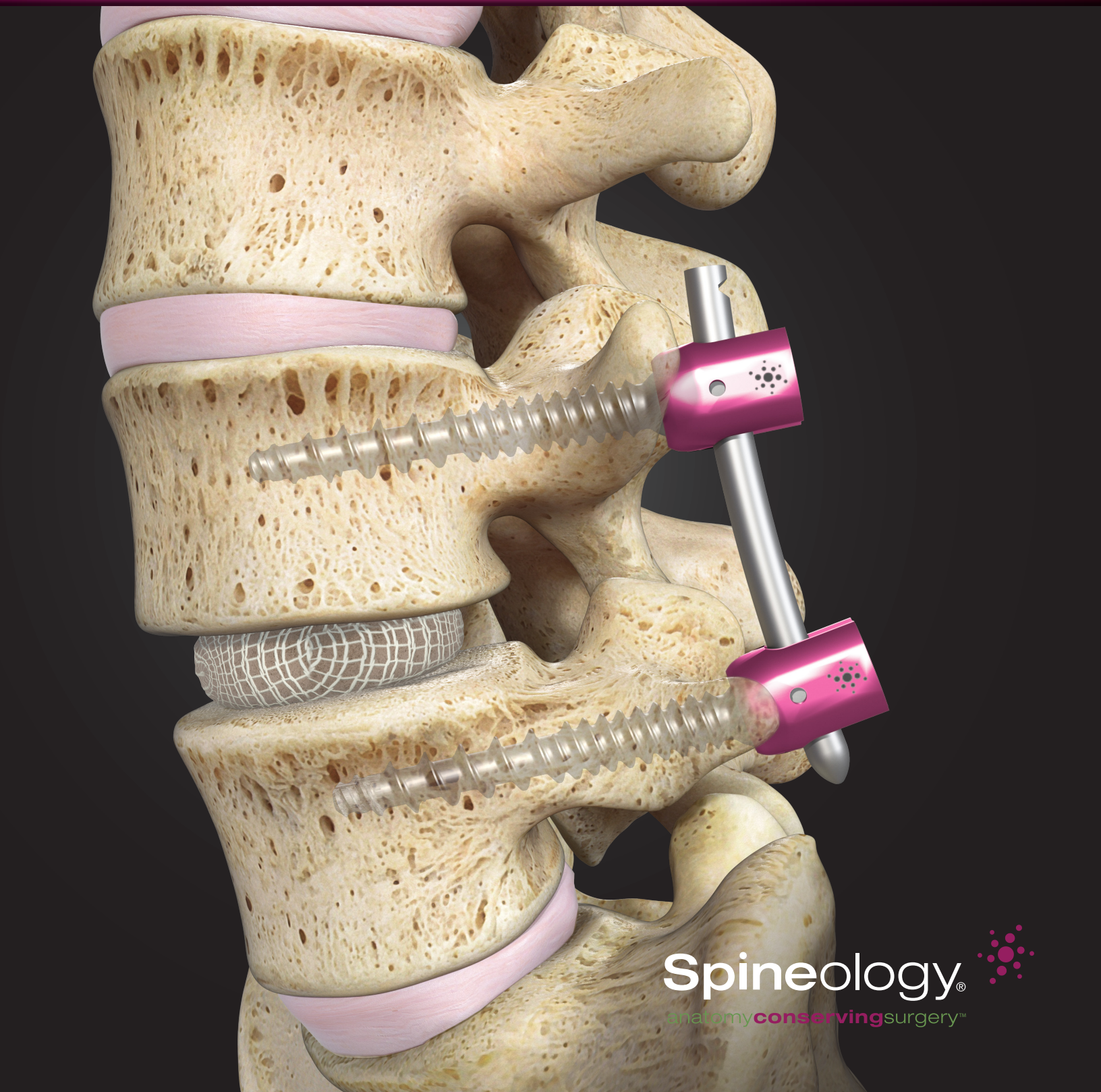
OptiLIF®



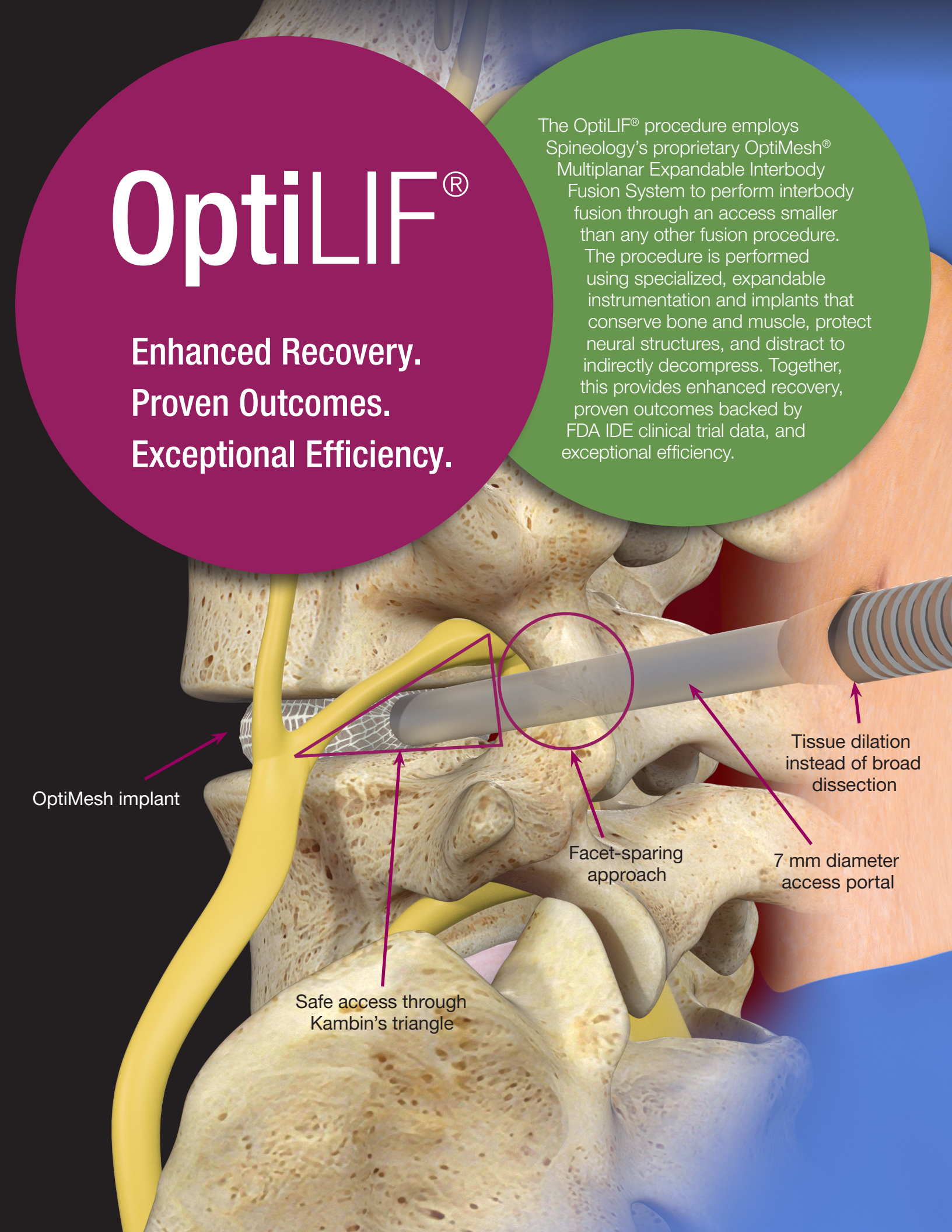
Spineology®

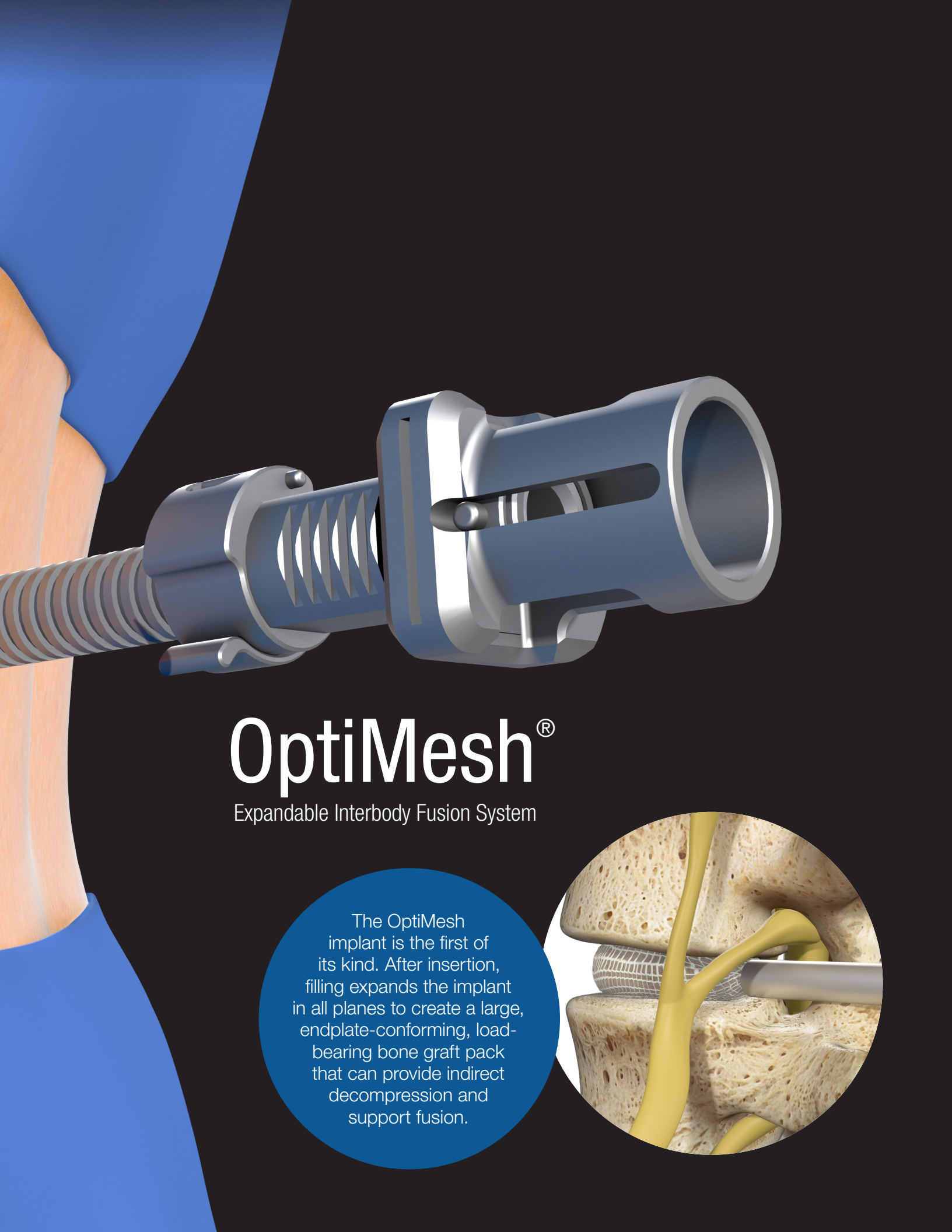
anatomyconservingsurgery™

OptiLIF®

Enhanced Recovery.
Proven Outcomes.
Exceptional Efficiency.

The OptiLIF® procedure employs Spineology's proprietary OptiMesh® Multiplanar Expandable Interbody Fusion System to perform interbody fusion through an access smaller than any other fusion procedure. The procedure is performed using specialized, expandable instrumentation and implants that conserve bone and muscle, protect neural structures, and distract to indirectly decompress. Together, this provides enhanced recovery, proven outcomes backed by FDA IDE clinical trial data, and exceptional efficiency.





OptiMesh®

Expandable Interbody Fusion System

The OptiMesh implant is the first of its kind. After insertion, filling expands the implant in all planes to create a large, endplate-conforming, load-bearing bone graft pack that can provide indirect decompression and support fusion.

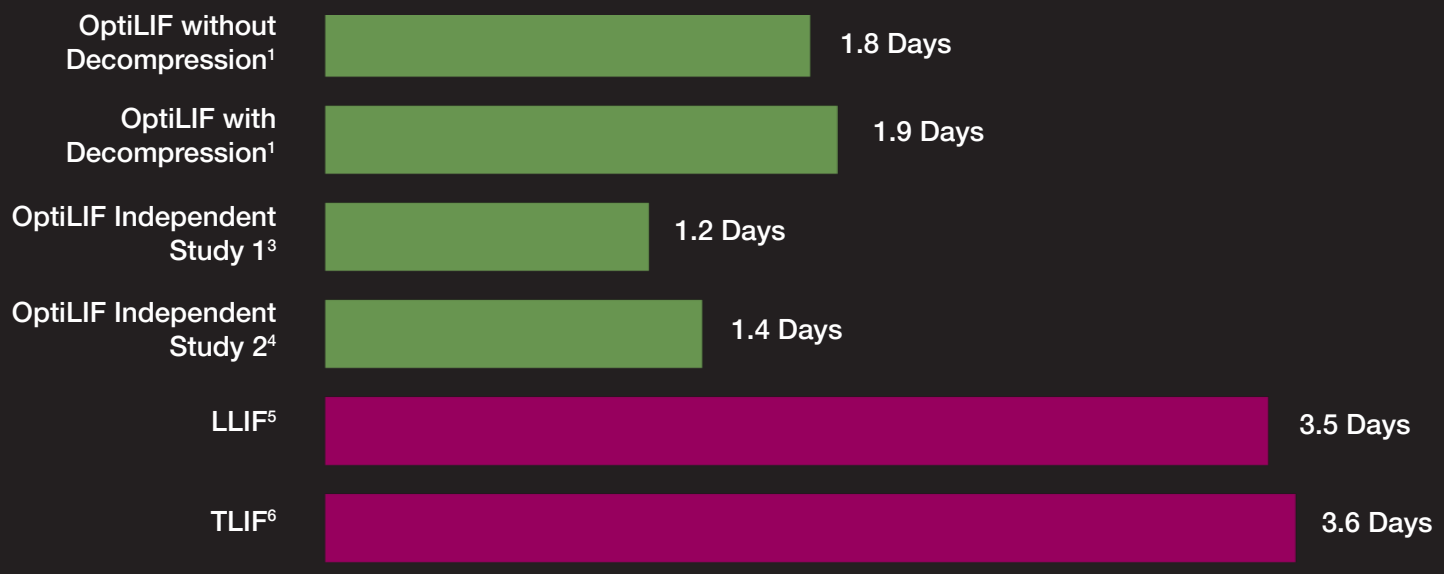
Enhanced Recovery

The OptiLIF procedure uses tissue dilation instead of broad dissection, a facet-sparing approach, and indirect decompression from the in situ filling and expansion of OptiMesh to conserve bone and muscle. This accelerates patient recovery, as demonstrated by:

- Short hospital stays[1]
- High postoperative patient satisfaction scores[2]
- Rapid return to work[2]
- Reduced use of narcotics over time[2]

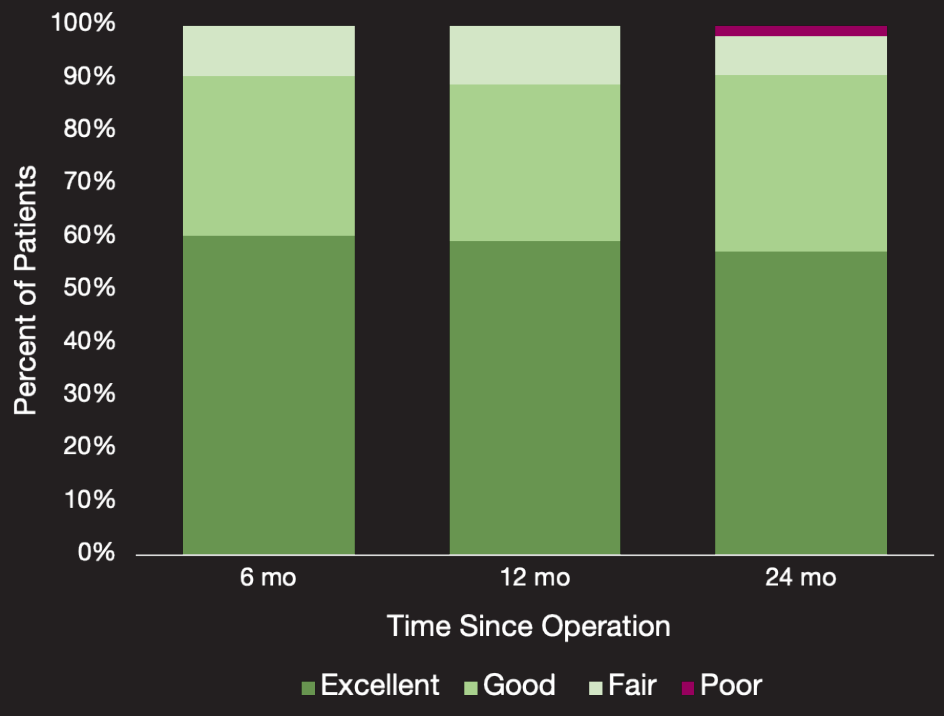
FDA IDE clinical trial data and peer-reviewed literature corroborate that patients experience quick pain relief and functional improvement following OptiLIF procedures.

Shorter Hospital Stay



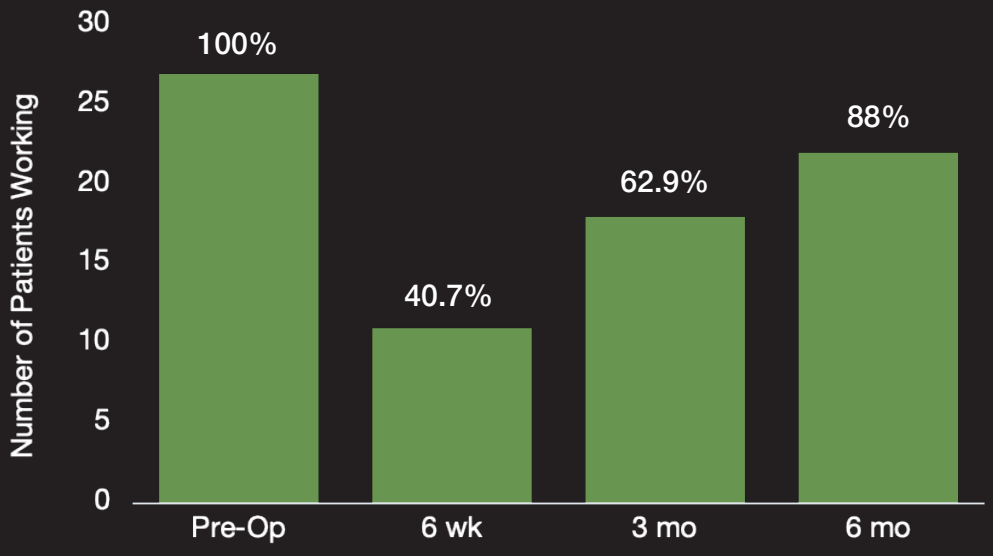
Patients experience a 50% reduction in hospital stay on average.

High Patient Satisfaction



Approximately 90% of patients reported excellent and/or good satisfaction at each follow-up.[2]

Rapid Return to Work

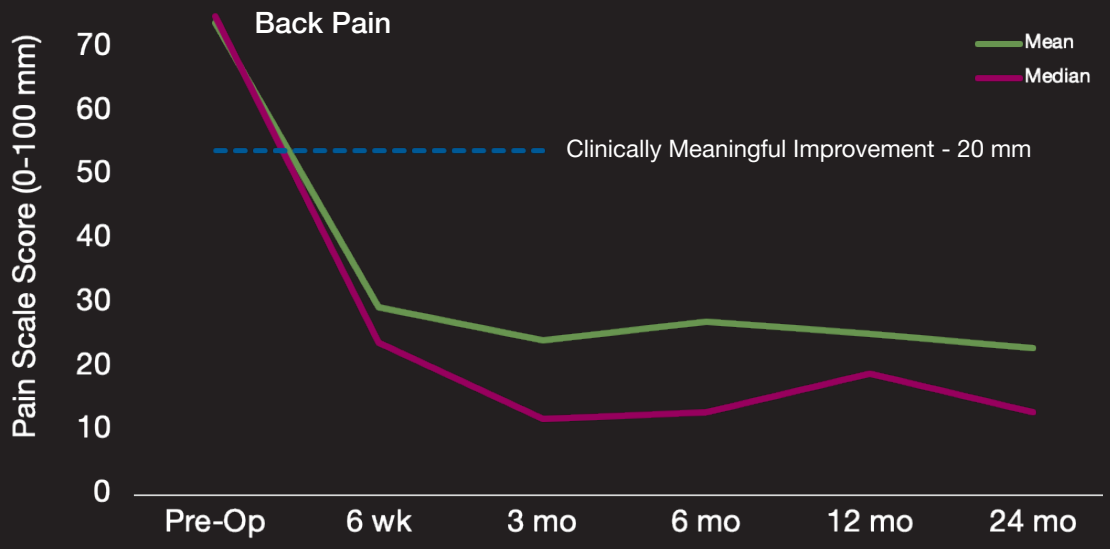


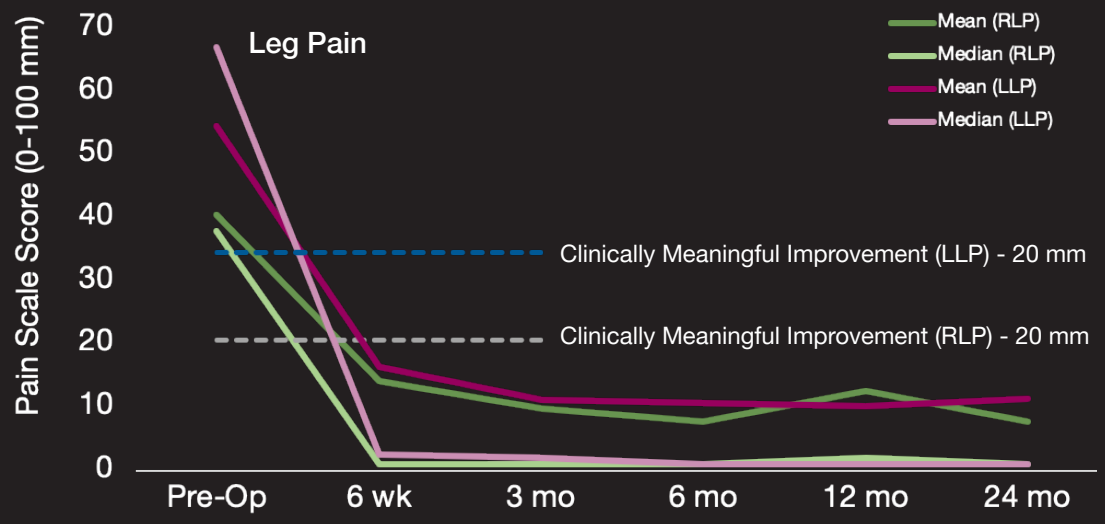
88% of working patients were back to work by their six-month follow-up.[1]

Proven Outcomes

Results of the OptiLIF subgroup analysis from the Spineology Clinical Outcomes (SCOUT) study, an FDA IDE clinical trial, and other independent studies demonstrate the efficacy, reproducibility, and safety of the OptiLIF procedure.[2–4, 7–15]

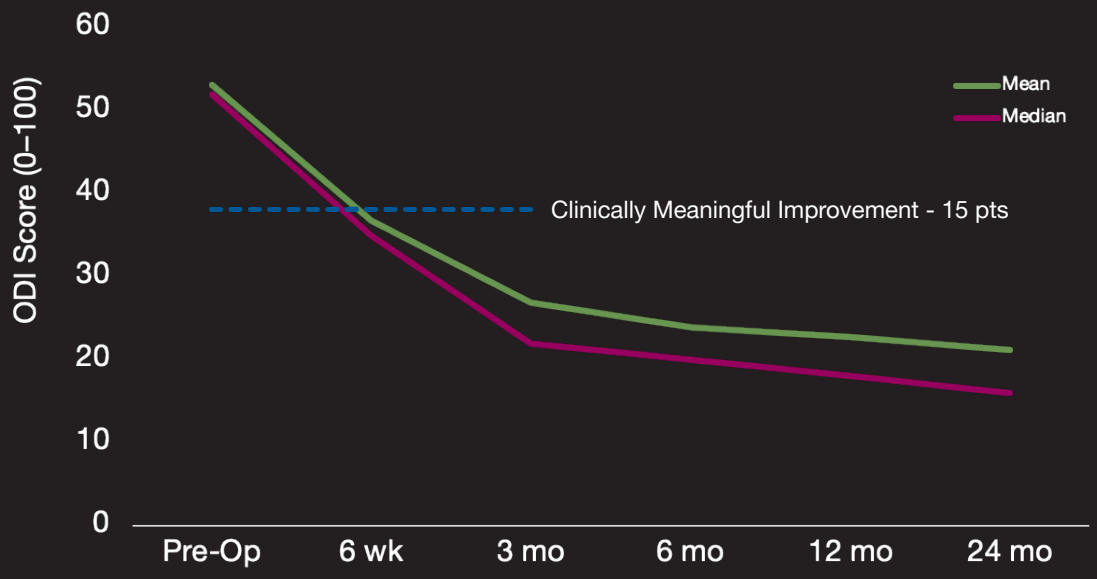
Substantial Improvement in Back and Leg Pain





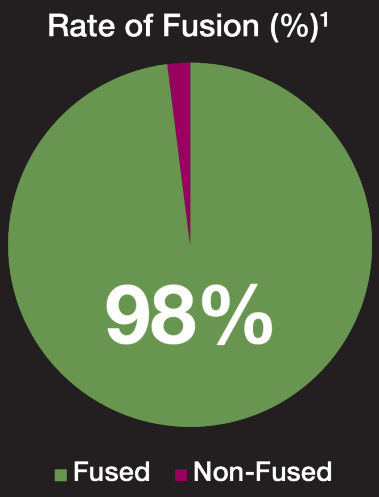
Patients demonstrated clinically meaningful improvements in back and leg pain by six weeks post-op.[2]

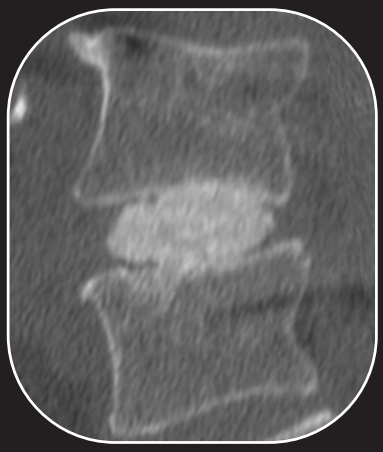
Substantial Improvement in Back Function



Patients demonstrated clinically meaningful improvements in back function shortly after surgery and continued to improve over time.[2]

Excellent Fusion





98% of patients in the SCOUT study who received an OptiLIF procedure demonstrated fusion on CT scans taken at their 12-month follow-up, as evaluated by two independent radiologists.[16]

Exceptional Safety Profile

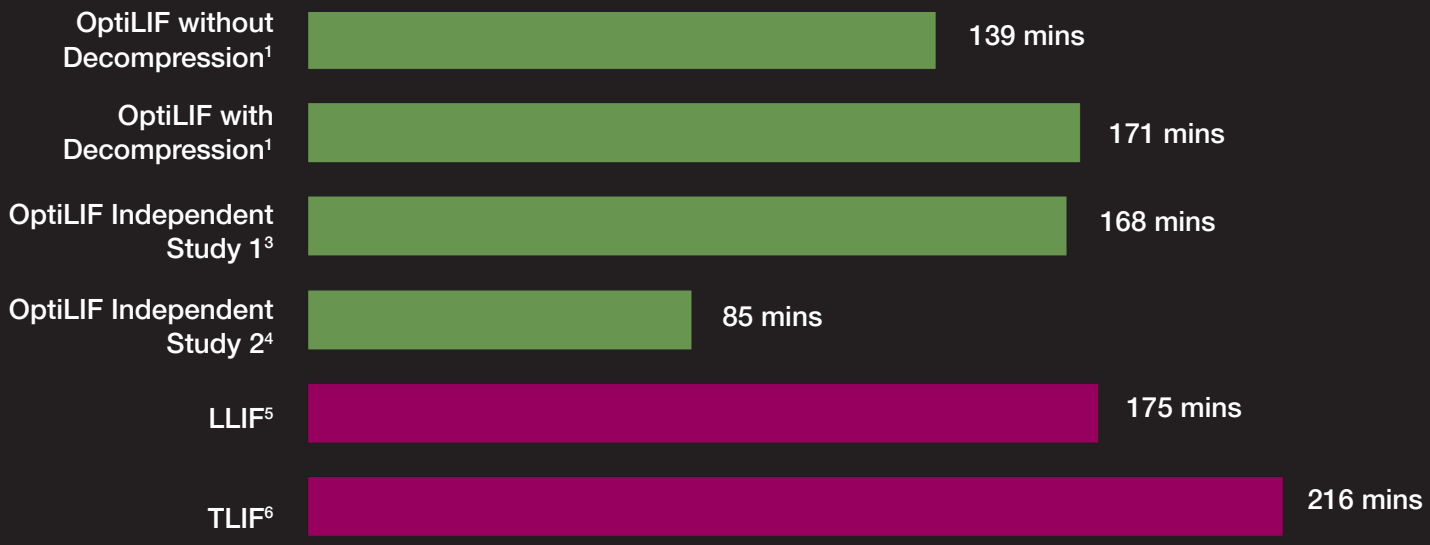
There were no device-related serious adverse events.[2]

Exceptional Efficiency

Concerns about patient welfare and healthcare economics demand the use of increasingly efficient procedures. The OptiLIF procedure includes specialized instrumentation and techniques that lead to exceptional efficiency in surgery and throughout the episode of care.

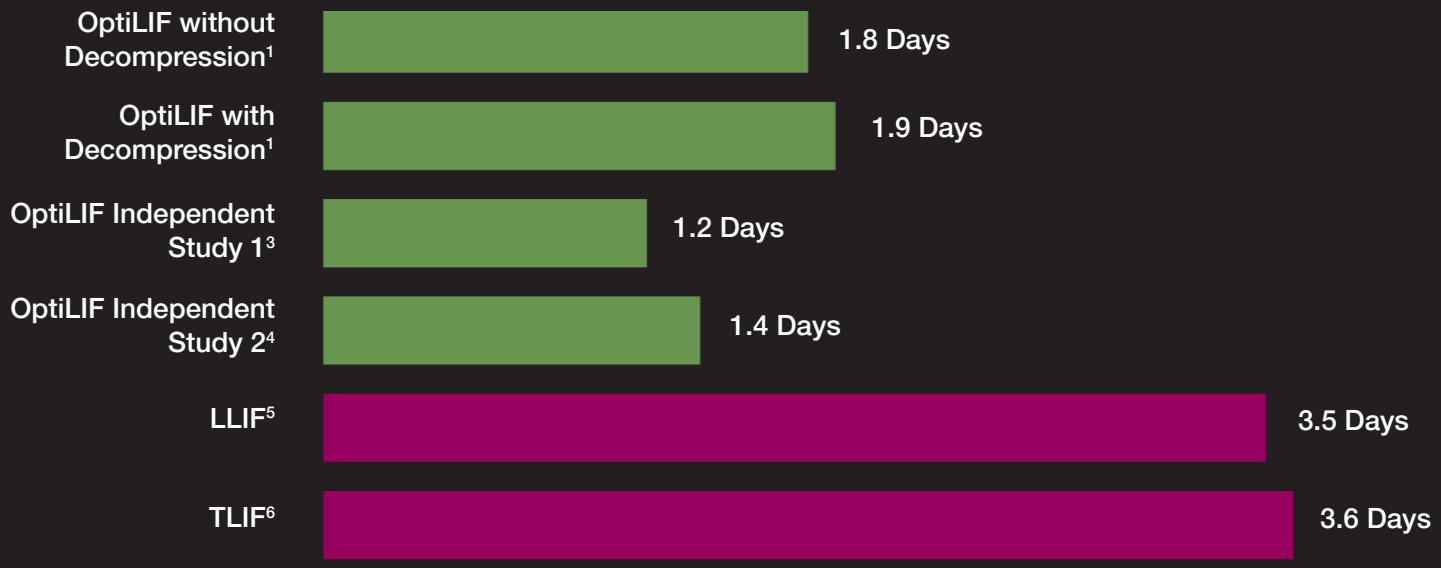
- Tissue dilation, instead of broad dissection, and use of a facet-sparing approach speed access to the disc space.
- In situ filling of an OptiMesh implant can provide indirect decompression or minimize the complexity of direct decompression, reducing procedural time.
- The OptiLIF access portal protects neural structures throughout the discectomy and OptiMesh placement, minimizing neurologic risk and operative complications that can extend the procedure.
- The minimal exposure dramatically speeds incision closure.
- Healthcare provider (HCP) care requirements are minimized due to shorter hospital stays.[1]

Shorter Operating Time



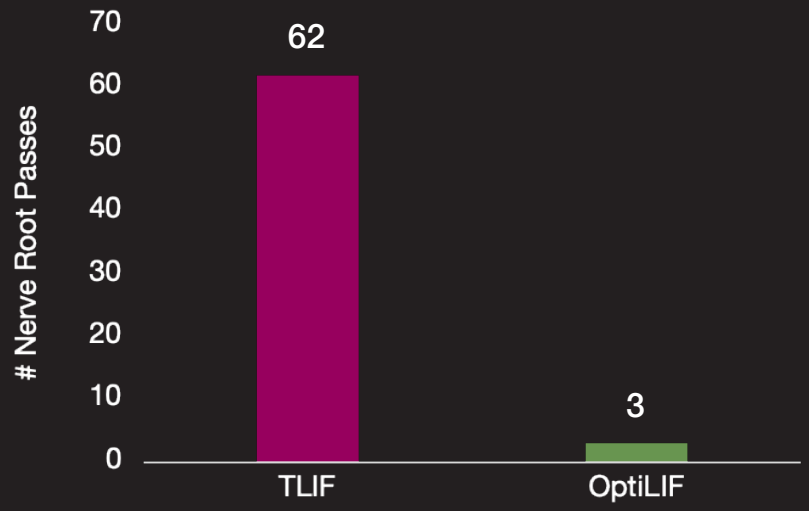
The operating room time for the OptiLIF procedure is shorter than that of comparable LLIF and TLIF procedures.

Shorter Hospital Stay



Healthcare provider (HCP) care requirements prior to discharge are minimized due to a reduction in hospital stay.

Fewer Nerve Root Passes



During an OptiLIF procedure, monitored dilators are used to safely place a small, 7 mm access portal into the disc space following three passes by the nerve root. The OptiLIF access portal protects the surrounding neural structures during the subsequent discectomy and implant placement. A TLIF discectomy using traditional instrumentation includes 62 instrument passes by the nerve root on average.[17] Reducing instrument passes by neural structures during an OptiLIF procedure minimizes neurologic risk and operative complications that can extend the procedure.

OptiMesh Implant

Porosity

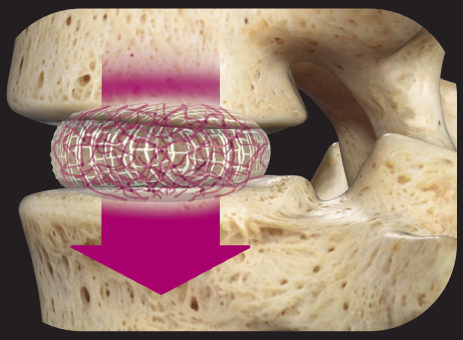
- OptiMesh has a 1500-micron pore size to facilitate graft containment while allowing for bony through-growth.[1,10–19]
- Granular bone graft creates interconnected, interstitial spaces throughout the graft pack, providing an osteoconductive scaffold to support fusion.

Endplate-Conforming

- OptiMesh will contour to the anatomy as it fills to create a large, endplate-conforming footprint.
- Load is shared across the entire implant interface, rather than point-loaded as with a monolithic implant, which may be beneficial in patients with poor bone quality.

Granular Mechanics

- OptiMesh derives its load-bearing capabilities from granular mechanics.[1]
- Hyper-compaction of bone granules creates force chains throughout the graft pack to transform the granular bone into a load-bearing pack.

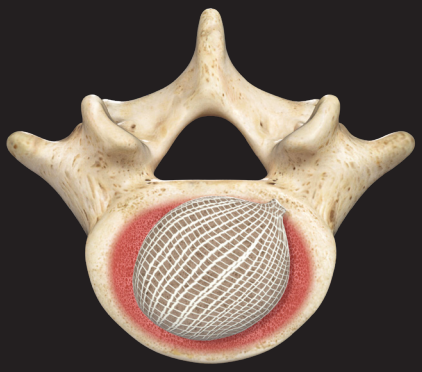


Anatomy Restoration

- During OptiMesh filling, the increasing volume of bone graft generates distractive forces capable of restoring disc height and providing indirect decompression.

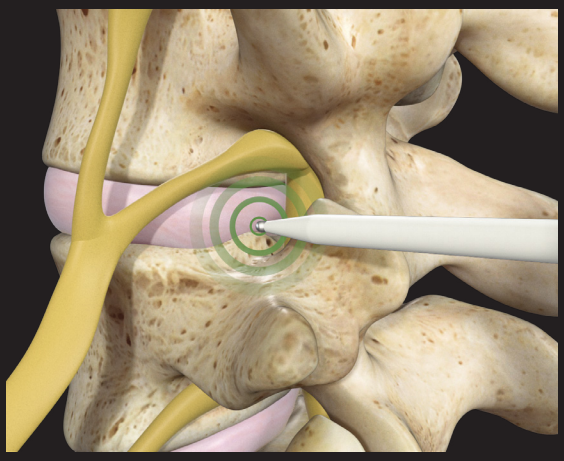
Maximum Footprint

- Once filled, the largest OptiMesh implant expands up to 34 mm in length and 29 mm in width.

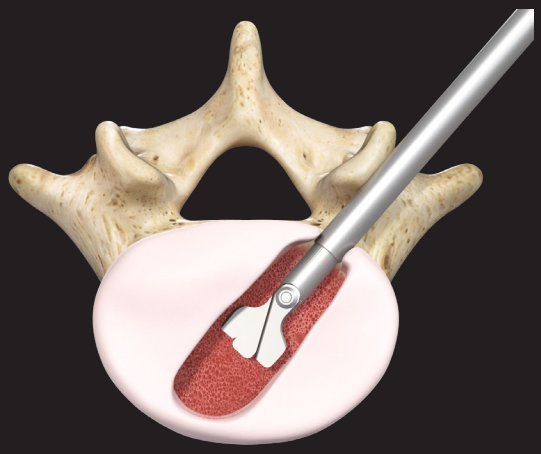


OptiMesh Instrumentation

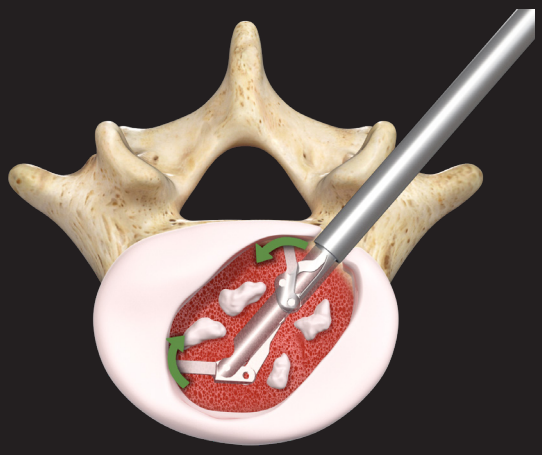
The OptiMesh system's access portal facilitates a facet-sparing approach through Kambin's triangle. Following access portal placement, expandable and articulating discectomy instruments create a broad, radical discectomy to ensure optimal pore distension and maximum footprint.



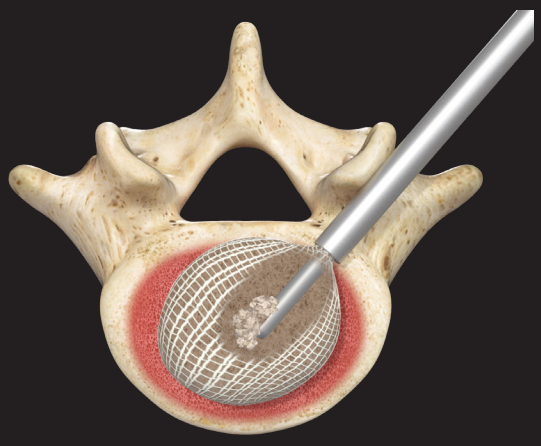
Neuromonitoring Probe gains safe access to disc space through Kambin's triangle.



Discectomy instruments sequentially remove disc material and prepare endplate for fusion.



Discectomy is broadened in preparation for OptiMesh delivery and filling.



OptiMesh is filled in situ.