

MAKE YOUR COMEBACK



with prodisc. L

A Patient's Guide





Cheri P., Physician's Assistant, 16+ Years After Surgery with pro**disc**® L





THERE IS hope

- Do you have lower back pain with or without leg pain?
- Have you been diagnosed with degenerative disc disease or a lumbar disc herniation?
- Has your surgeon indicated that you might be a candidate for lumbar fusion or disc replacement?

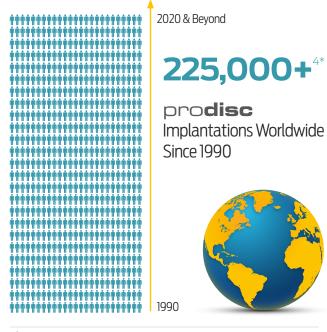
The prodisc® L Total Disc Replacement gives you an option.

This brochure is designed to provide you with answers to questions you may have about why prodisc may be the best option if you are considering disc replacement surgery or an alternative treatment.

WHY CONSIDER prodisc L?

The prodisc L technology is the most studied and clinically-proven total disc replacement system in the world. Beginning with clinical usage in 1990, the prodisc design has been validated with over 225,000 device implantations worldwide and more than 540 published papers.¹

prodisc L has been shown to facilitate a quicker return to active life.² It has also been shown to enable patients to retain their range of motion, enabling the spine to flex over the long-term.³



^{*} Worldwide implantations with prodisc technology platform



the most studied and clinically proven

TOTAL DISC REPLACEMENT IN THE WORLD 1

The number of published studies for competitive total disc replacement alternatives pale in comparison to the extensively researched and clinically proven success of the prodisc Total Disc Replacement technology platform.

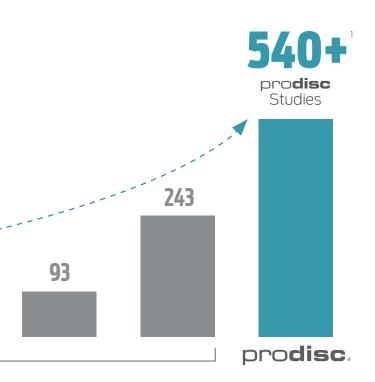
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48

81

Total Disc Replacement Alternatives







RETURN TO active life

Patients consider a total disc replacement to reduce pain and to provide a means of returning to active life.

Activities appropriate for military personnel were analyzed in a study of active-duty military patients that had received a prodisc or a fusion procedure. It was found that 25% more prodisc patients returned to active duty (80% vs 67%), and prodisc patients returned more rapidly—on average 38% faster.²

The results of this study on young, active military personnel is indicative of the superior clinical results experienced by prodisc patients across many published studies.

Results of Study of Active Duty Military Patients that Received a prodisc or a Fusion Procedure

Variable	pro disc L	Fusion
# of Patients	12	12
Average Age	37.3	40
# Returned to Full Duty	10	8
Time to Return to Full Duty (weeks)	22.6	32.4



Return to an Active Life



proven

SAFETY & EFFECTIVENESS

Two Investigational Device Exemption (IDE) studies were conducted in 2006 in the US in order to gain FDA approval for one- and two-level use. prodisc L is the only device in the world approved by the FDA for two-level lumbar disc replacement; validated with a rigorous clinical study of the safety and effectiveness of the device specifically with use at two-levels.

These two studies represented the highest level of evidence available for orthopedic medical devices, and compared the use of prodisc L to fusion, the standard of care at the time.

"Use of prodisc L at two levels showed durable clinical improvements during a minimum of nine years of clinical follow-up."

From long-term follow-up of IDE study conducted in 20015



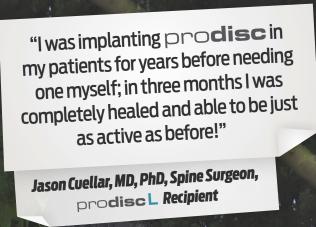
The IDE Studies evaluated the likelihood that a patient would require a re-operation after the implantation of the prodisc L. Patients were followed over two years and monitored for pain relief, mobility, and re-operation.

The resulting published papers and supplemental long-term follow-up papers showed that:

- prodisc L is a safe and effective surgical treatment
- prodisc L provides durable results
- Patients treated with prodisc L were nearly 4x less likely to experience adjacent level degeneration than fusion patients

NEARLY 4X LESS LIKELY

for prodisc L patients to experience changes in activities of daily living than fusion patients ⁶

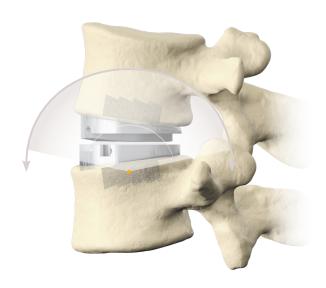




prodisc ENABLES motion

In the past, fusion was typically used to surgically treat patients with spine-related pain or loss of function. However, fusing a segment of the spine ultimately reduces mobility.

prodisc was developed as an alterative to spinal fusion, enabling controlled and predicable motion while providing stability in the spine.



prodisc L SUMMARY

prodisc L has been proven to be an effective solution for some individuals suffering from lower back pain with or without leg pain, loss of function, or neurological symptoms. Results from prodisc L studies over the last 30 years indicate a lower re-operation rate, quicker return to active life, and continued mobility at the operated level of the spine. Studies have also demonstrated high levels of patient satisfaction with the use of prodisc.



REFERENCES:

Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2018. ² Tumialan, L.M., et al., Arthroplasty in the military: a preliminary experience with ProDisc-C and ProDisc-L. Neurosurgical focus, 2010. 28(5): a El® ²Zigler, Delamarter R. Five-year results of the prospective, randomized, multicenter, Food and Drug Administration investigational device exemption study of the prodisc-L total disc replacement versus circumferential arthrodesis for the treatment of single-level degenerative disc disease, Neurosurg Spine, 2012, 17:493-501. ⁴ Data on file at Centinel Spine compiled from Spine Solutions, Synthes Spine, DePuy Synthes, and Centinel Spine. ⁵ Balderston J. et al., Long-term Outcomes of 2-Level Total Disc Replacement Using ProDisc-L. SPINE 39(11):906-910, 2014. ⁶ Zigler J. et al., Five-year adjacent-level degenerative changes in patients with single-level disease treated using lumbar total disc replacement with ProDisc-L versus circumferential fusion, J Neurosurg Spine 17:504-511, 2012.



Dr. Todd Lanman, Neurosurgeon & prodisc L Recipient



If you have questions...

Speak to your doctor or visit our website.



REGAIN YOUR LIFE™

www.rediscovermylife.org

For information about obtaining insurance reimbursement for the **prodisc L** Total Disc Replacement procedure, contact our Patient Access Program at **1-800-264-4623**.

About



CENTINEL SPINE offers a continuum of trusted, brand-name motion-preserving and fusion solutions backed by over 30 years of clinical success—providing the most robust and clinically-proven Total Disc Replacement and Integrated Interbody™ fusion portfolios in the world.



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