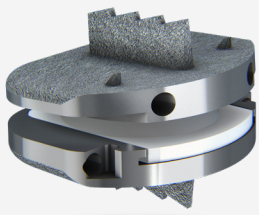
CENTINEL SPINE®

rediscover®
REGAIN YOUR LIFE®

# CHOOSE prodisc®

## FOR LUMBAR TOTAL DISC REPLACEMENT



THE MOST PROVEN DISC REPLACEMENT TECHNOLOGY IN THE WORLD

CHERI: After prodisc

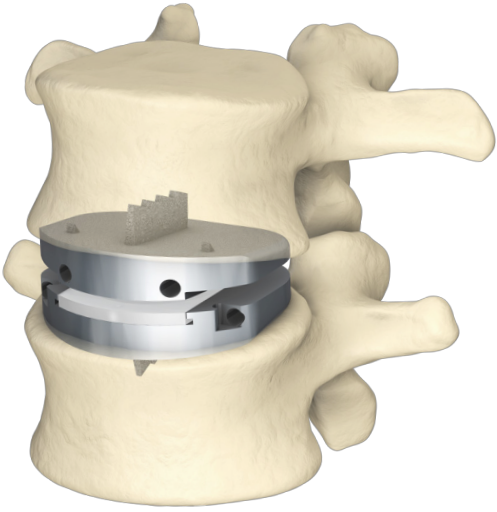
**300,000+** DEVICE IMPLANTATIONS[1]

**540+** PUBLISHED PAPERS[2]

**35+** YEARS OF CLINICAL USE

"A year after my surgery, I was back to doing everything I loved!"

**Cheri P., Physician's Assistant, 23+ Years After Surgery with prodisc® 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?*

***prodisc L for lumbar total disc replacement is a potential alternative to fusion.***

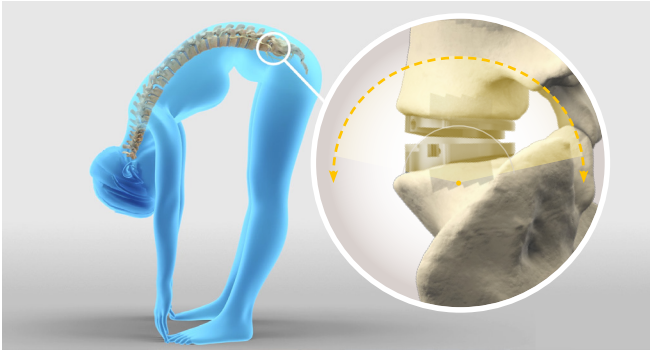
This brochure is designed to provide you with answers to questions you may have about why prodisc may be the best option if you are considering disc replacement surgery or an alternative treatment.

# prodisc ENABLES *motion*

Before prodisc was available, surgeons surgically treated patients with spine-related pain or loss of function with a fusion. In a fusion, the disc between the vertebrae, or spinal bones, is removed and the two bones are allowed to grow into a single bone without a joint.

However, in doing so, fusion reduces overall mobility in the spine, potentially increasing stress on the spinal discs above and below the fusion—contributing to what is known as "adjacent segment disease". This increased stress could potentially lead to a need for future surgeries to repair adjacent segments.[3]

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



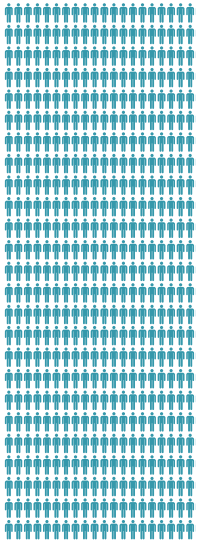
Unlike a rigid fusion, a total disc replacement allows increased mobility in the treated segment—and as studies have shown, this increased mobility may result in significantly fewer re-operations than fusion.[4]

# *why consider*

## TOTAL DISC REPLACEMENT WITH prodisc?

The prodisc 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 300,000 device implantations worldwide[1] and more than 540 published papers[2].

prodisc L has been shown to facilitate a quicker return to active life.[5] It has also been shown to enable patients to retain their range of motion, enabling the spine to flex over the long-term.[4]




**<1%**
**REVISION RATE**
for prodisc devices[6]

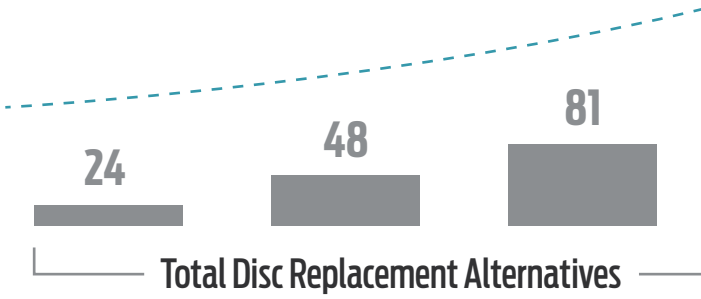
**300,000+**
prodisc Implantations Worldwide Since 1990[1]

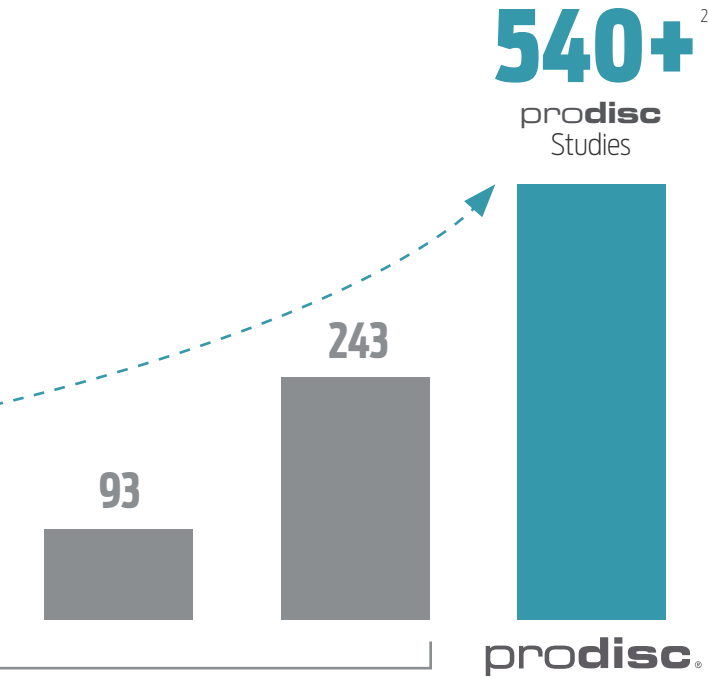
= 600 Implantations

# *the most studied & clinically proven*

## TOTAL DISC REPLACEMENT IN THE WORLD[2]

The number of published studies for other total disc replacement alternatives pale in comparison to the extensively researched and clinically proven success of the prodisc total disc replacement.





540+[2]
prodisc
Studies
243
93
prodisc.


"My back pain was debilitating and kept me from doing a lot of things in life, and I'm just happy I can be the person that I am now, completely pain-free!
Gara L.,
18+ Years After Surgery with
prodisc® L

# 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 underwent a prodisc total disc replacement or a fusion procedure. It was found that more of the prodisc L patients returned to active duty than the fusion patients. They also returned more rapidly—on average over 30% faster.[5]

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 Underwent a prodisc L or a Fusion Procedure*

| Variable | prodisc 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 |

*"Five of the 7 Navy SEALs in [the prodisc] group reported returning to free-fall parachute jumping and high-impact water entries."*[5]

"I'm so glad I did this surgery, I would do it again in a heartbeat!"

***Jeremy S.,***
***15+ Years After Surgery with***
prodisc® L

# *proven*
# SAFETY & EFFECTIVENESS

An Investigational Device Exemption (IDE) study was 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.

This study represents 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 2001***[7]


The IDE Study 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 & effective surgical treatment* [4]
- prodisc L *provides durable results* [4]
- *Patients treated with* prodisc L *were nearly 4x less likely to experience adjacent level degeneration than fusion patients* [8]

**NEARLY**

# 4X

**LESS LIKELY**

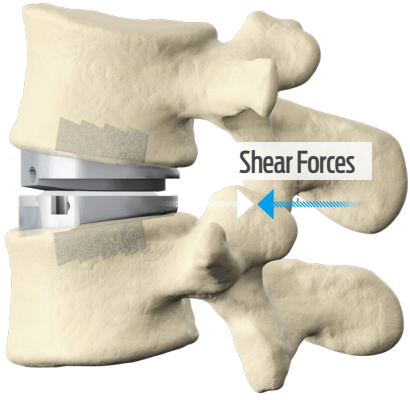
**for prodisc L patients to experience degeneration in adjacent levels than fusion patients** [8]

*"A year ago, before the operation, I couldn't have considered this dream of racing professionally... whereas now I can race all day, get out, go to the gym and then do it all over again the next day."*

***Henry D.,***
***Race Car Driver &***
**prodisc® L *Recipient***

# STABILITY & DURABILITY *at its core*

prodisc CORE

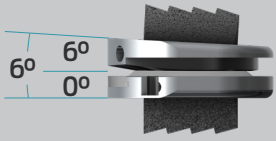
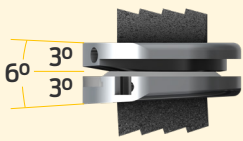
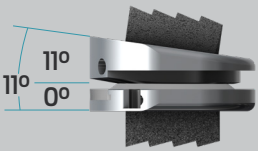
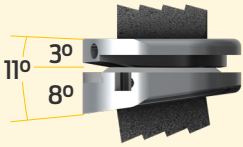



At the heart of each prodisc device is prodisc CORE Technology, the motion design feature that has provided the predictable clinical outcomes of every prodisc device after 35+ years and 300,000+ implantations.[1]

prodisc CORE provides each prodisc device with a fixed center of rotation that is intended to stabilize the spinal bones surrounding the implant while resisting forces on the device.[9,10]


# *match the* prodisc *to the patient*

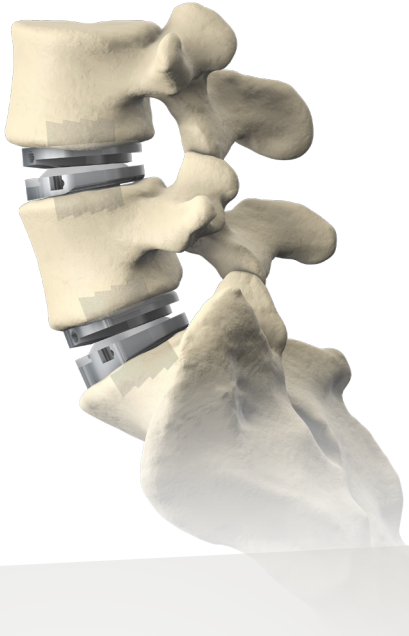
## WITH MULTIPLE prodisc OPTIONS

| Standard | Anatomic Endplates™ |
|---|---|
|   |   |
|   |   |

Patient anatomy varies, and prodisc L Anatomic Endplates™ are designed to better match patient anatomy and allow a customized fit throughout the entire range of indicated levels (L3-S1).

# prodisc 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 35 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:


[1] *Data on file at Centinel Spine compiled from Spine Solutions, Synthes Spine, DePuy Synthes, and Centinel Spine.* [2] *Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2024.* [3] *Nakajima, H., Watanabe, S., Honjoh, K. et al. Risk factors for early-onset adjacent segment degeneration after one-segment posterior lumbar interbody fusion. Sci Rep 14, 9145 (2024). https://doi.org/10.1038/s41598-024-59924-5.* [4] *Zigler, J, 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, J Neurosurg Spine, 2012, 17(6):493-501.* [5] *Tumialan, L.M., et al., Arthroplasty in the military: a preliminary experience with ProDisc-C and ProDisc-L. Neurosurgical focus, 2010. 28(5): p. E18.* [6] *Based upon U.S. complaint handling units for prodisc since launch in 2006.* [7] *Balderston J, et al, Long-term Outcomes of 2-Level Total Disc Replacement Using ProDisc-L, SPINE 39(11):906-910, 2014.* [8] *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(6):504–511, 2012.* [9] *Sears W, McCombe P, Sasso R. Kinematics of cervical and lumbar total disc replacement. Semin Spine Surg. 2006;18:117–129.* [10] *Bertagnoli, R., Marnay, T., Mayer, H.M., The PRODISC Book, 2003.*

"Every year, on the anniversary of my surgery, I celebrate by doing something that I could never do if it weren't for my new disc!"

***Kristin D., 13+ Years After Surgery with***
prodisc® L

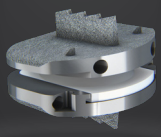
rediscover
REGAIN YOUR LIFE®

prodisc®

**THE MOST STUDIED & CLINICALLY PROVEN DISC REPLACEMENT IN THE WORLD**[1,2]

If you have further questions, speak to your doctor or to learn more about lumbar total disc replacement with prodisc:

Email **info@centinelspine.com**
or Visit **prodiscinfo.com**



**SCAN TO LEARN MORE**

## ABOUT

CENTINEL SPINE®

**CENTINEL SPINE** is a leading global medical device company addressing cervical and lumbar spinal disease by providing the most complete and clinically-proven total disc replacement (TDR) technology platform in the world (prodisc).

Learn more at:
**www.centinelspine.com**

SINCE 1990
35+ YEARS
OF CLINICAL SUCCESS

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