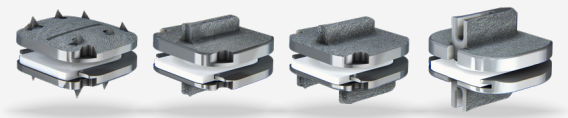
CENTINEL SPINE®

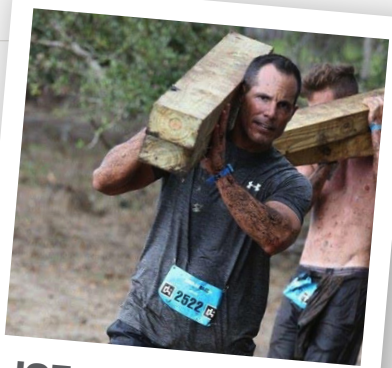
rediscover™
REGAIN YOUR LIFE™

CHOOSE prodisc®

FOR CERVICAL TOTAL DISC REPLACEMENT



THE MOST PROVEN DISC REPLACEMENT TECHNOLOGY IN THE WORLD



JOE: After prodisc

Note: All individuals portrayed have received a prodisc cervical family device. These devices are indicated and FDA-approved for 1 level.

250,000+ DEVICE IMPLANTATIONS[1]

540+ PUBLISHED PAPERS[2]

30+ YEARS OF CLINICAL USE

"I was in constant pain. It started to affect my daily life and I was unable to play golf. I knew I wanted a total disc replacement in order to maintain my range of motion and continue to function at a high level."

Brian Gay, 5-Time US PGA Tour Winner & prodisc Recipient

THERE IS *hope*

- *Do you have neck or arm pain and/or a loss of function or neurological symptoms such as numbness or weakness?*
- *Have you been diagnosed with a herniated disc, osteophytes, osteoarthritis, or loss of disc height?*
- *Has your surgeon indicated that you are a candidate for cervical fusion?*

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

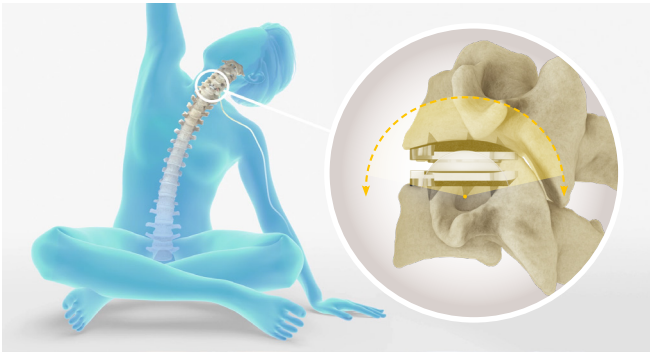
This brochure is designed to provide you with answers to questions you may have about why prodisc may be the best option if you are considering disc replacement surgery or fusion.

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 250,000 device implantations worldwide[1] and more than 540 published papers[2].

prodisc C 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]

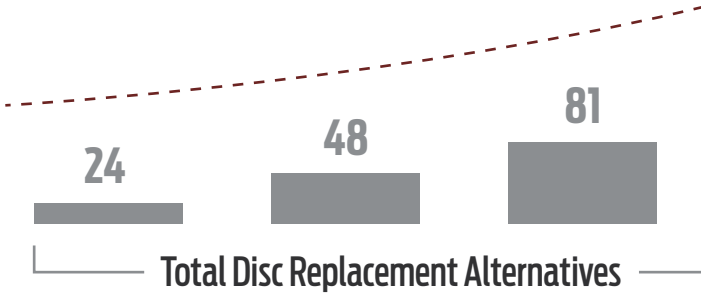
250,000+
prodisc Implantations Worldwide Since 1990[1]

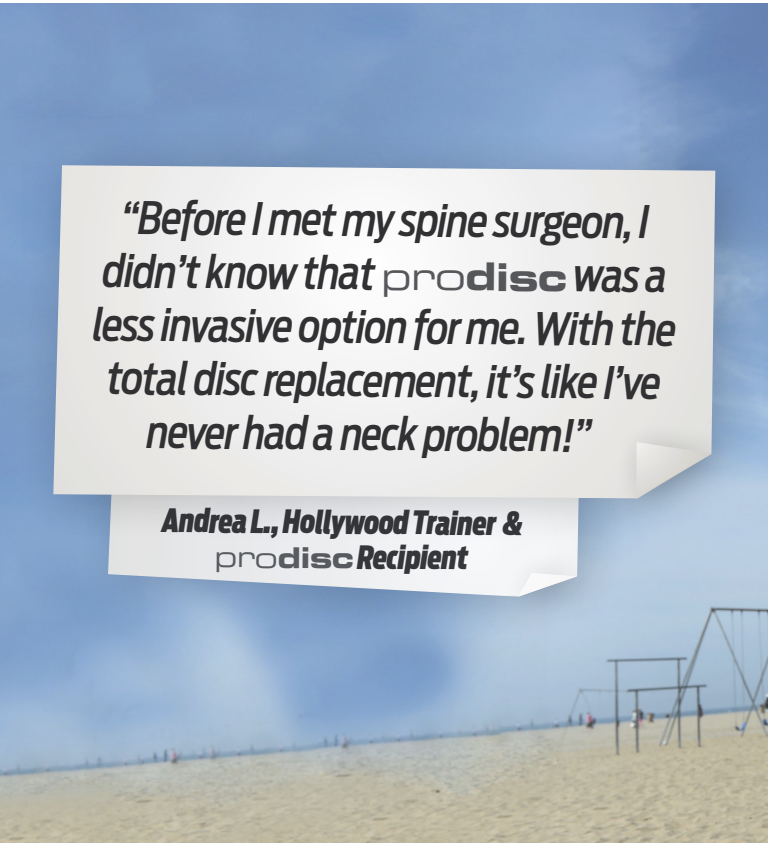
= 400 Implantations

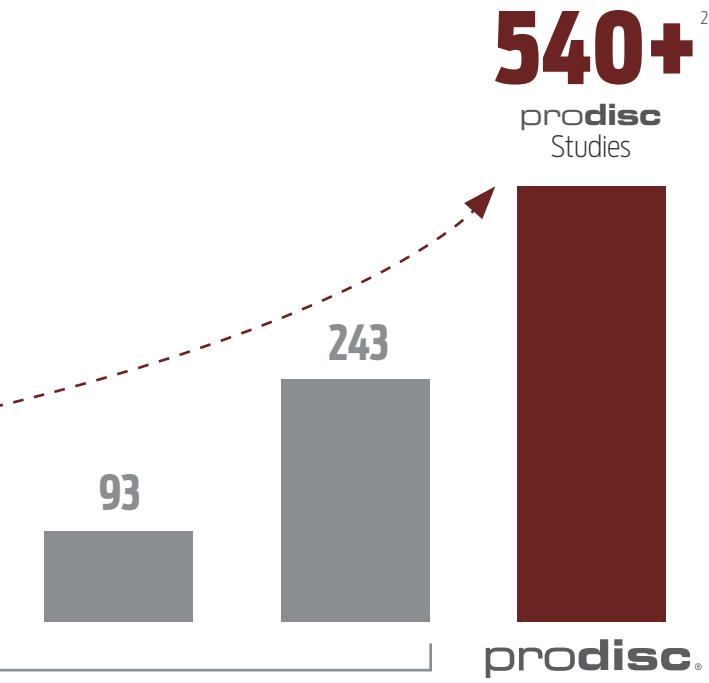
the most studied & clinically proven

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.

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 while all of the patients returned to active duty, prodisc patients returned more rapidly—on average 38% 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 or a Fusion Procedure

Variable	prodisc C	Fusion
# of Patients	*12*	*12*
Average Age	*36.5*	*36.1*
# Returned to Full Duty	*12*	*12*
Time to Return to Full Duty (weeks)	*10.3*	*16.5*

Return to an Active Life

proven
SAFETY & EFFECTIVENESS

Many studies have determined that prodisc for cervical total disc replacement is safe and effective[4,7,8], with a less than 1% revision rate[6]. The study with the longest follow-up data is from the U.S. Investigational Device Exemption (IDE) study, conducted to gain FDA approval of prodisc C in 2007.[4] This IDE Study compared the use of prodisc C to fusion, the standard of care at the time.

4x
FEWER
RE-OPERATIONS

with prodisc C at
7 years compared to fusion[4]

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

The resulting published papers showed that:

> *"Overall, it appears that total disc arthroplasty with prodisc C has similar clinical and patient outcomes, has a higher device survival rate, and is followed by fewer secondary surgical procedures than fusion."* [9]

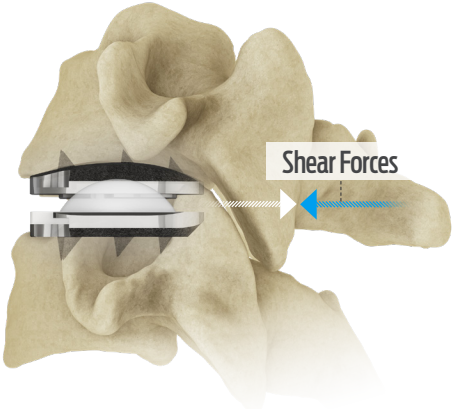
4x FEWER

INCIDENCES OF ADJACENT SEGMENT DISEASE

with prodisc C at 7 years compared to fusion with a plate & bone [4]

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 30+ years and 250,000+ implantations.

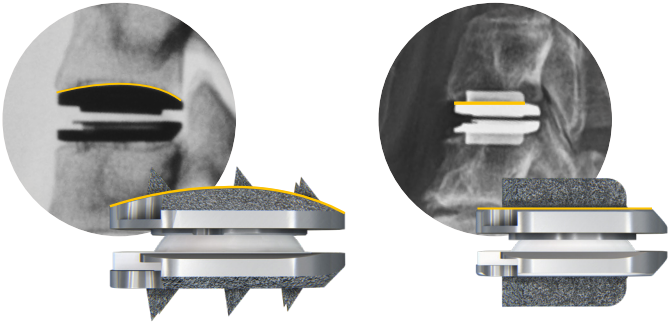
prodisc CORE provides each prodisc device with a fixed center of rotation that is intended to stabilize the spinal bones surrounding the implant while resisting forces on the device.[10]

"I've been an advocate of prodisc *from the very beginning. Being a patient myself, I understand what the journey is like. This procedure allows my patients to return to their lives."*

Dr. Robert Masson, Neurosurgeon & prodisc **Recipient**

match the prodisc *to the patient*

WITH MULTIPLE prodisc OPTIONS

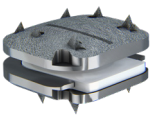


Patient anatomy varies, and the prodisc cervical total disc replacement system is unique in that it provides a range of implant options to better match patient anatomical needs throughout the entire range of indicated levels.

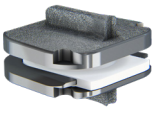
prodisc is the only total disc replacement system available today that enables surgeons to alter their choice of disc replacement implant during the procedure based on patient anatomy or other factors.

prodisc summary

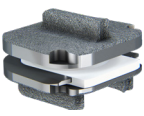
prodisc for cervical disc replacement has been proven to be an effective solution for some individuals suffering from upper extremity or neck pain, loss of function, or neurological symptoms. Results from prodisc studies over the last 30 years indicate a lower re-operation rate[4], quicker return to active life[4], and continued mobility at the operated level of the spine[12]. Studies have also demonstrated high levels of patient satisfaction after the use of prodisc.[5]



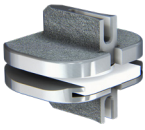
prodisc. C Vivo



prodisc. C SK



prodisc. C Nova



prodisc. C

*Not all devices are available in all markets.

REFERENCES:

[1] Data on file at Centinel Spine. [2] Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2023. [3] Biomechanical Evaluation of Primary Implant-to-Bone Fixation of Four Design Configurations of the prodisc® C Total Disc Replacement Prosthesis: Resistance to Shear Force Expulsion. Neurosurg Focus. 2004 Sep 15;17(3):E7. [4] Janssen ME, et al, ProDisc-C Total Disc Replacement Versus ACDF for Single-Level Symptomatic Cervical Disc Disease, JBJS, 2015, 97:1738-47. [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] Cao S, Zhao Y, et al. Single-Level Cervical Arthroplasty with Prodisc-C Vivo Artificial Disc: Five-Year Follow-Up Results from One Center, Spine (Phila Pa 1976), 2022 Jan 15;47(2):122-127. [8] Pehlivanoglu, T et al, Clinical and Radiographic Outcome of Patients With Cervical Spondylotic Myelopathy Undergoing Total Disc Replacement, Spine, Oct. 2019, Vol 44; 20 pp 1403-1411. [9] Murrey D, et al, Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. The Spine Journal, 9 (2009), 275-286. [10] Sears W, McCombe P, Sasso R. Kinematics of cervical and lumbar total disc replacement. Semin Spine Surg. 2006;18:117–129. [11] Bertagnoli, R., Marnay, T., Mayer, H.M., The PRODISC Book, 2003. [12] Zigler JE, Delamarter R, Murrey D, Spivak J, Janssen M. ProDisc-C and anterior cervical discectomy and fusion as surgical treatment for single-level cervical symptomatic degenerative disc disease: five-year results of a Food and Drug Administration study, Spine (Phila Pa 1976), 2013 Feb 1;38(3):203-9.

"This surgery changed my life significantly... I would say I'm a huge advocate for a disc replacement because my outcome has been so positive in so many ways."

Loren Vandergriff, Orthopedic Nurse Practitioner & prodisc Recipient

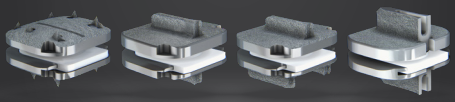
rediscover™
REGAIN YOUR LIFE™

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 cervical total disc replacement with prodisc:

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

30+ YEARS OF CLINICAL SUCCESS

US Headquarters: 900 Airport Rd, Ste. 3B, West Chester, PA 19380 USA
International Office: Grafenauweg 8, 6300 Zug, Switzerland

Email: info@centinelspine.com
Web: www.centinelspine.com

MKT1013 Rev 1 (02/2024)

℞ ONLY CE 2797