

LEGAL & REGULATORY AND REIMBURSEMENT

PRODISC L WINS FDA APPROVAL FOR TWO-LEVEL USE

WALTER EISNER • MON, APRIL 27TH, 2020



ProDisc L Lumbar Total Disc Replacement System / Courtesy of Centinel Spine

Eighteen years after the first clinical trial implantation, the FDA has given its approval for a two-level indication for Centinel Spine, LLC's **prodisc**® L Lumbar Total Disc Replacement (TDR) system. The **prodisc** first received FDA approval in 2006.

In an April 4, 2020 press release, the company said they are now the only company with an FDA approved lumbar TDR device that has been clinically reviewed and found safe and effective for two level use.

*Trial and Studies*

Jack Zigler, M.D. at the Texas Health Center for Diagnostics and Surgery, Texas Back Institute (TBI), Plano, Texas, performed the first two-level implantation in the U.S. on January 22, 2002 as a part of a two-level study. The company said results from the study have been published in numerous papers and "are part of the over 540 published studies on the ProDisc technology platform."

Zigler said patients with two-level **prodisc** L disc replacements "have done remarkably well in long-term follow-up." He added that TBI began two-level **prodisc** L implantations in January 2002 as an enrolling site in the FDA study. "I have now seen multiple two-level disc replacement patients with over 15-year follow-up who are still delighted with their clinical results—and have not needed additional surgery that is commonly required after initial fusion surgery. Patients with two-level disc replacement are among my most grateful patients."

Centinel Spine's new CEO Steve Murray said the longevity of the **prodisc** technology, "is due to the design principles of a stable bone interface, a consistent mechanism of action enabling guided motion, and instrumentation that facilitates efficient and reliable implantation."

"The **prodisc** platform now consists of six devices, including an anterior and anterior-lateral approach lumbar disc replacement and four cervical disc replacement implants with a variety of endplate configurations "designed to enable surgeons to better suit patient anatomy."

Developments include a recently initiated clinical trial comparing the **prodisc** C Vivo and **prodisc** C SK devices with an approved TDR product as a control, in order to validate their safety and effectiveness in an FDA IDE study.

*prodisc and Centinel Spine Provenance*

In December 2017, the company acquired the **prodisc** platform from DePuy Synthes. Centinel Spine is one of the companies owned by Viscoglosi Bros., LLC. The V brothers, Anthony, Marc and John, were the original investors of **prodisc** and sold it to Synthes in 2003 for \$350 million.

In 1999 the brothers and the German firm Aesculap AG & Co. KG, jointly created Spine Solutions, Inc., to bring to market the ProDisc developed by French orthopedic surgeon, Dr. Thierry Marnay.

In June 2019, the company entered into partnership with Tiger Woods. Woods underwent spinal fusion surgery by Zigler's TBI partner, Rick Guyer, M.D., using Centinel Spine's STALIF M-Ti Anterior Lumbar Integrated Interbody fusion product in April 2017. Woods quickly went on to win the Masters.

On March 16, 2020, Chairman & CEO John Viscoglosi, stepped down to return to the Viscoglosi Brothers, LLC. Mothership.

Keep control.

Advertisement

SHARE YOUR THOUGHTS

Your email address will not be published. Required fields are marked

Name

Email Address (will not be published)

Website

☐

Save my name, email, and website in this browser for the next time I comment.

Comment

SUBMIT

This site uses Akismet to reduce spam. [Learn how your comment data is processed.](#)



Advertisement

GREAT DEBATES



The Cementless Tibia: A Viable Fixation Alternative

Can virtual reality give surgical trainees the confidence to perform well in the OR?

Sept 16th  
8:00 PM EST | 5:00 PM PST

Register Today

SPONSORED BY:  
VIRTUAL REALITY SYSTERS  
precisionos

ROBIN YOUNG  
Ortho Recruiters

Struggling to Find Top Talent in Orthopedics or Spine?

- 45 Years' Experience
- 1 Year Candidate Replacement Guarantee
- Pre-Hire Testing
- Unparalleled Reference Checks
- Thousands Of Successful Executive Orthopedic And Spine Placements

Contact With Us

Tim Schmidt  
Neal Hightower

Advertisement Advertisement

FEATURED NEWS

Could Vertebral Tethering Dethrone Fusion in Most Patients?

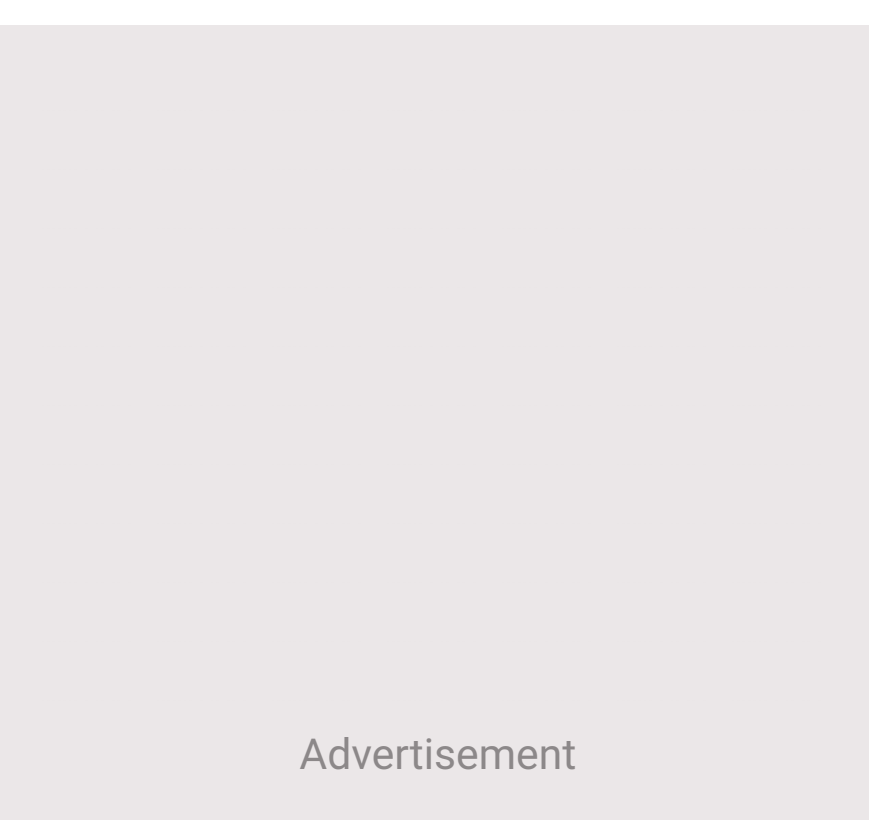
Castellvi Spine, The Premier Small Spine Meeting, September 10

With a Recent FDA Ruling, Cerapedics Takes Aim at Infuse

Wrong-Level Spine Surgery: Unsettling Stats and Advice

New AI and Augmented Reality TKA Platform Cleared by FDA

Camille Farhat's 3-Year Legacy in Orthopedics



MOST POPULAR

Working From Home May Be Hazardous to Your Back and Joints

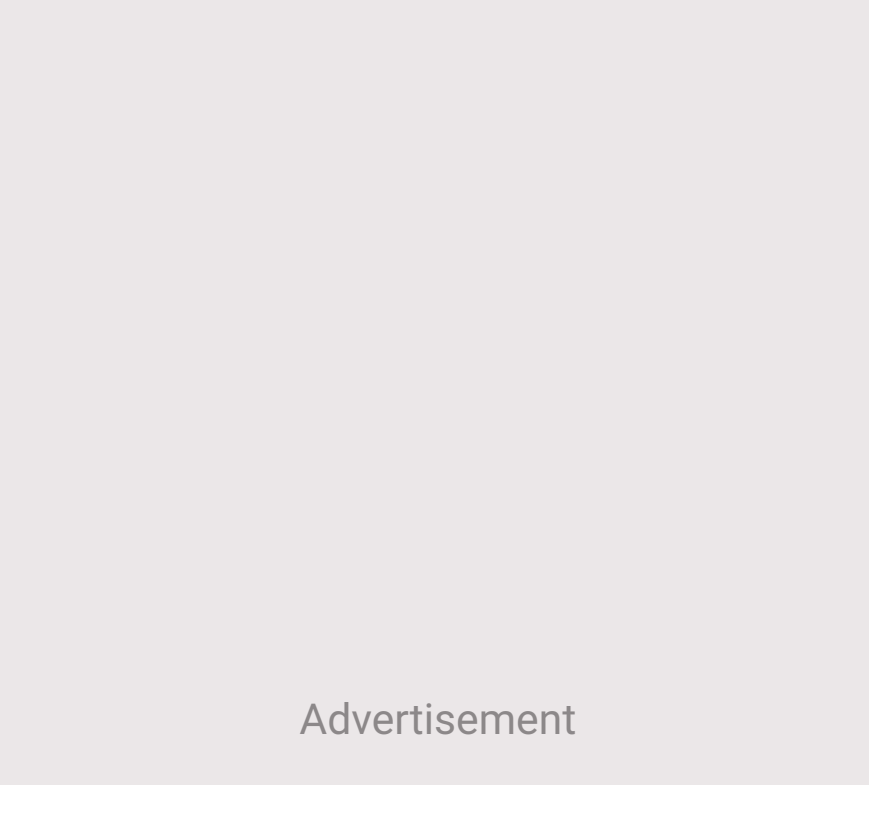
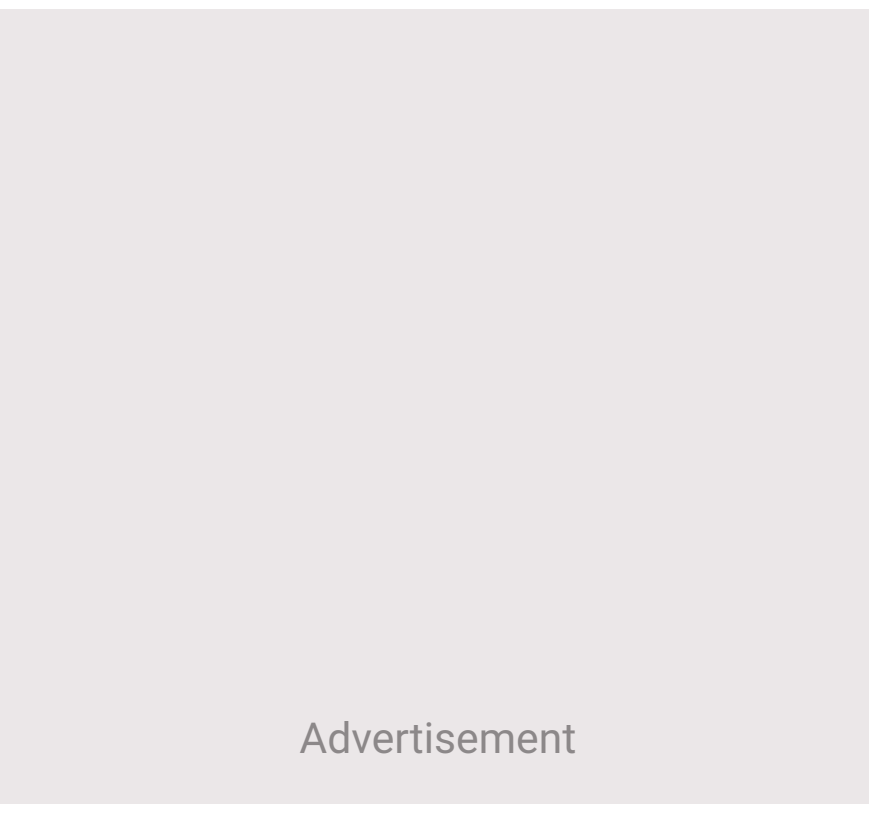
Spine Surgeon Sues Emory Healthcare and Surgeon for Defamation

Judge Orders Clinical Study Sponsors to Come Clean

Delivering Effective, Remote Rehab PLUS Tracking During COVID-19

Outpatient Rotator Cuff Repair Less Risky Than Inpatient?

Extreme Older THA Patients: Outcome Data



YOU MIGHT ALSO LIKE...

Fibula Treatment Added to Previously Cleared IlluminOss System

IlluminOss' photodynamic bone stabilization system for fibula fractures receives FDA 510(k) clearance.

Missouri Surgeon and Kansas Distributor Plead Guilty to Kickbacks

Spine surgeon and distributor settle with Department of Justice on kickback scheme.

Spine Surgeon Sues Emory Healthcare and Surgeon for Defamation

Spine surgeon and Emory Healthcare sued by a spine surgeon for defamation and other claims.

Judge Orders Clinical Study Sponsors to Come Clean

FDA has not shown any interest in enforcing compliance with trial registry reporting requirements.

Aetna Attempts to Shut Down ConforMIS Lawsuit

Aetna battles with ConforMIS over denial of claims for the use of customized total knee implants.

Titanium Nitrate Coated Shoulder Implants Cleared by FDA

FX Shoulder receives 510(k) clearance for new version of humeral head and glenosphere shoulder implants.

Advertisement