

prodisc[®] Facts

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- **prodisc** is one of the most widely used artificial discs in the world. Since the first generation was implanted in Montpelier, France in November 1990, **prodisc** has been implanted in more than 125,000 spinal levels in 43 countries.
- Centinel Spine is the only provider of artificial discs in the US for both lumbar and cervical disc replacement.
- **prodisc** is the most studied total disc, with over 420 published studies, detailing over 14,000 patient results.
- **prodisc L** was approved by the FDA after an extensive clinical trial in 2006, in which results with 236 patients were analyzed. The multi-centered randomized trial compared results with **prodisc L** versus fusion. **prodisc L** received FDA approval in August of 2006, making it the lumbar total disc replacement with the longest history of continuous use in the US.
- **prodisc C** was approved by the FDA after an extensive clinical trial in 2007, in which results with 209 patients were analyzed. The multi-centered randomized trial compared results with **prodisc C** versus fusion. **prodisc C** received FDA approval in December of 2007, making it the cervical disc with the longest history of continuous use in the US.
- **prodisc C** and **L** are made with two Cobalt Chromium alloy endplates that are plasma sprayed with Titanium, and an Ultra High Molecular Weight Polyethylene plastic insert (UHMWPE). These are proven materials that have been used in orthopedic applications for over 60 years.
- **prodisc C** and **L** are designed with a patented keel to provide immediate implant stability while the patient's bone grows onto the device post-operatively to provide additional implant immobilization.
- The **prodisc C** Total Disc Replacement is intended to replace a diseased and/or degenerated intervertebral disc of the cervical spine in patients with symptomatic cervical disc disease (SCDD). The **prodisc C** Total Disc Replacement procedure is intended to significantly reduce pain by allowing for the removal of the diseased disc while restoring disc height and providing the potential for motion at the affected vertebral segment.
- The **prodisc L** Total Disc Replacement is intended to replace a diseased and/or degenerated intervertebral disc of the lumbosacral region in patients with discogenic pain associated with degenerative disc disease (DDD) at one lumbar spinal segment level between L3 and S1. The total disc replacement procedure is intended to significantly reduce discogenic pain and improve patient function by allowing for the removal of the diseased disc while restoring the normal disc height and providing the potential for motion at the affected vertebral segment.
- Disc damage needs to be confirmed by a doctor's examination and review of CT, MRI, or x-ray images. A doctor should always be consulted for proper indications and use of **prodisc**.

prodisc – How it Works

Mechanism of Action

- **prodisc** is designed to restore a normal (physiologic) range of motion and functionality by replacing a diseased spinal disc.
- **prodisc** designs are intended to restore stability, while providing controlled and predictable motion, as diseased motion segments can be subject to hypermobility.
- Highly conforming surfaces of the endplate with the inlay prevent the endplates from translating independently. Translation is limited to rotation of the superior endplate around the ball on the inlay – intended to protect the facets from shear forces.
- **prodisc** is composed of three components: two cobalt chromium alloy endplates, and an ultra-high-molecular-weight polyethylene inlay.