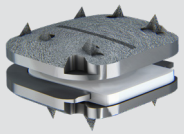
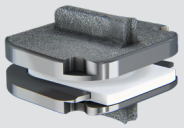
prodisc C Vivo & prodisc C SK

COMPETITIVE COMPARISON | vs. Prestige™ LP

SINCE 1990 — 30+ YEARS OF CLINICAL SUCCESS

	Company	**Centinel Spine®**		**Medtronic®**
	Device	prodisc C Vivo	prodisc C SK	**Prestige™ LP**
CLINICAL HISTORY	**Device Image**			
	1st Year of Clinical Use	2009	2019	2004
	Regulatory Approval	**FDA Approval:** 2022	**FDA Approval:** 2022	**FDA Approval:** 2014
	Indications	**One-Level**		**One-Level:** 2014 | **Two-Level:** 2019
	# of Implantations	Over 250,000 implantations of the prodisc technology platform[1]		No published data
	Published Studies	Over 540 published studies on the prodisc technology platform[2]		110[3]
	Summary	prodisc is the most studied and clinically proven total disc replacement (TDR) technology in the world. Since 1990, the prodisc design has been validated with over 250,000 device implantations worldwide[1] and more than 540 published papers[2]. Per U.S. complaint data since 2006, prodisc has a less than 1% reported revision rate.[4]		
DEVICE OVERVIEW	**Kinematics** — *Fact*	Ball & Socket: Fixed Center of Rotation (COR) with an Optimized Core Radius		Ball & Trough: Variable COR - Allowing for +/- 2mm of AP translation, independent of rotation.[5]
	Kinematics — *Benefit*	All prodisc devices utilize prodisc CORE technology: a fixed core and an optimized core radius that together provide stability while resisting shear forces and facilitate controlled motion to protect the facet complex.[6,7]		When a shear force is applied to a total disc replacement implant with a mobile core design, free translation may occur. Shear forces are therefore resisted by the facets.[5] The Prestige LP two-level SSED (Summary of Safety and Effectiveness Data) reports a higher incidence of secondary revisions due to continued or new radiculopathy[8] compared to prodisc C[9], which has identical kinematics to prodisc C Vivo & prodisc C SK.
	Materials — *Fact*	**Endplates:** CoCrMo (Cobalt Chromium Molybdenum) **Core:** UHMWPE (Ultra High Molecular Weight Polyethylene) Inlay is provided pre-assembled & snap-locked into the inferior endplate		**Titanium Ceramic Composite** (metal-on-metal) 90% Titanium Alloy 10% Titanium Carbide
	Materials — *Benefit*	prodisc utilizes materials that have been used successfully in large total joint replacements (hips and knees) for decades and for 30+ years in total disc replacement (spine). These materials have a proven long-term track record of success.		Per the Prestige LP IFU, metal-on-metal materials have potential disadvantages: "Devices with metal-on-metal articulating surfaces (such as the Prestige LP Cervical Disc) may release wear debris, metallic particles or metal ions locally near the device and/or systemically. The short and long term effects of the wear debris, metallic particles and metal ions on the body are not known, but certain groups of patients may be at a higher risk including patients who are pregnant, patients who are planning to get pregnant, and patients who have renal disease."[10]

	Device		prodisc C Vivo	prodisc C SK	Prestige™ LP
DEVICE OVERVIEW (CONT'D)	Design Features	*Fact*	Zero profile (i.e. no anterior tabs/stops)		Not zero profile: anterior tabs (Tabs are used to attach the implant to the implant inserter)
		Benefit	1. prodisc C Portfolio implants can be positioned within the disc space per the surgeon's discretion, to align the COR of the implant with the COR of the motion segment. 2. No additional steps are required to fit the device to the patient anatomy, potentially reducing OR time.		1. Anterior tabs act as stops, limiting the positioning of the implant within the disc space. The surgeon may not be able to advance the implant into the disc space as desired. 2. Vertebral body preparation might be required to adjust the patient anatomy to accommodate for the anterior tabs.[11]
	Patient-Implant Fit	*Fact*	prodisc C Vivo & prodisc C SK technologies are part of Centinel Spine's Match-the-Disc™ System, which enables surgeons to choose a device that best fits the patient anatomy and the surgeon's preference.		No intraoperative device optionality. Prestige LP recommends an additional surgical step to alter the patient's anatomy to "ensure maximum implant/end plate interface". [11]
		Benefit	Multiple disc options may eliminate additional OR time required to fit the patient anatomy to the device.		Limited single device configuration may require additional OR time to fit the patient anatomy to the device.
	Sizing Options	*Summary*	Each prodisc C Portfolio device has a broad offering of 18 sizing options versus Prestige LP's 10 sizing options.[11]		
		Fact	**5-7mm heights, 18 total sizing configurations** 5mm Height – 6 Total Footprint Options 6mm Height – 6 Total Footprint Options 7mm Height – 6 Total Footprint Options		**5-7mm heights, 10 total sizing configurations**[6] 5mm Height – 3 Total Footprint Options 6mm Height – 4 Total Footprint Options 7mm Height – 3 Total Footprint Options
		Benefit	Having access to almost double the sizing options makes it easier for the surgeon to match the patient anatomy.		Limited footprints may reduce the surgeon's ability to optimize implant size and position within the disc space.
SURGICAL TECHNIQUE	Summary		Overall, prodisc C Vivo & prodisc C SK devices have fewer steps in the required surgical technique compared to Prestige LP. Prestige LP has 3 additional steps[11] compared to Vivo & 2 compared to SK. prodisc C Vivo & prodisc C SK could result in less OR time compared to Prestige LP.		
	Surgical Technique Steps		1. Discectomy/Decompression 2. Trialing 3. Implant Loading 4. Implantation	1. Discectomy/Decompression 2. Trialing 3. Keel Cutting 4. Implant Loading 5. Implantation	1. Discectomy/Decompression with Vertebral Body Preparation 2. Endplate Preparation 3. Trialing 4. Rail Preparation with Drill Guide & Drill Bit 5. Rail Cutting 6. Implant Loading 7. Implantation
SUMMARY	Key areas of competitive focus versus Prestige LP: kinematics (prodisc CORE benefits), materials (prodisc proven materials), implant sizing options (almost 2x more size options with prodisc), patient implant-fit (prodisc Match-the-Disc™ system).				

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] Pubmed search, July 2024. [4] Data on file at Centinel Spine. [5] Medtronic. (2021). Prestige LP Kinematics/Motion Brochure. [6] Sears, R., et al., (2006) Kinematics of Cervical and Lumbar Total Disc Replacement, Seminars Spine Surgery, 18(2). 117-129. https://doi.org/10.1053/j.semss.2006.03.013. [7] Bertagnoli, R., Marnay, T., Mayer, H.M., The PRODISC Book, 2003. [8] FDA. (2014, July 24). Summary of Safety and Effectiveness Data (SSED) for Prestige LP Cervical Disc. https://www.accessdata.fda.gov/cdrh_docs/pdf9/p090029b.pdf. [9] FDA. (2007, December 17). Summary of Safety and Effectiveness Data (SSED) for prodisc-C Total Disc Replacement. https://www.accessdata.fda.gov/cdrh_docs/pdf7/P070001B.pdf. [10] Medtronic. (2020, July). Indications, Safety, and Warnings: Prestige LP Cervical Disc. https://www.medtronic.com/us-en/healthcare-professionals/products/spinal-orthopaedic/cervical-arthroplasty/Prestige LP/indications-safety-warnings.html. [11] Medtronic. (2017). Surgical Technique for Prestige LP Cervical Disc System with Streamlined Instruments.

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