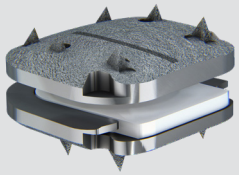
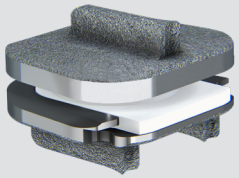
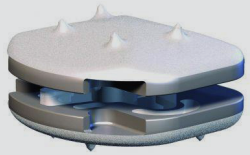
prodisc C Vivo & prodisc C Nova

COMPETITIVE COMPARISON | vs. CP-ESP® | FOR INTERNATIONAL USE ONLY

CENTINEL SPINE

	Company	**Centinel Spine**		**Spineway Group**
	Device	**prodisc C Vivo**	**prodisc C Nova**	**CP-ESP®**
CLINICAL HISTORY	**Device Image**			
	First Year of Clinical Use	2009	2009	2012
	Regulatory Approval	**FDA:** 2022 | **CE Mark:** 2011	**FDA:** 2022 | **CE Mark:** 2010	**FDA:** N/A | **CE Mark:** 2012
	Indications	Symptomatic Cervical Disc Disease*		Symptomatic Cervical Disc Disease*
	Number of Implantations	Over 250,000 implantations of the prodisc technology platform[1]		Over 20,000 implantations[2]
	Published Studies	Over 540 peer-reviewed published studies on the prodisc technology platform[3]		7[4]
	Summary	prodisc is the most studied and clinically proven 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[3]. Per U.S. complaint data since 2006, prodisc has a less than 1% reported revision rate.[5]		
DEVICE OVERVIEW	**Kinematics** *Fact*	Ball & Socket - Fixed Center of Rotation (COR) with an Optimized Core Radius		Elastomeric cushion between two titanium endplates. Marketed as a viscoelastic device with six degrees of freedom, shock absorption, and controlled resistance to rotational and translational movements.[6]
	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.[7,8]		Long-term kinematic outcomes evaluated through clinical study yet to be determined.

* For complete indications on each device see relevant Instructions for Use.

SINCE 1990 30+ YEARS OF CLINICAL SUCCESS

References: [1] Data on file at Centinel Spine compiled from Spine Solutions, Synthes Spine, DePuy Synthes, and Centinel Spine. [2] Spine Innovations Marks Milestone – Over 20,000 ESP Spinal Discs Implanted – as Global Demand Grows, Spineway Group website https://spine-innovations.com/spine-innovations-marks-milestone-over-20000-esp-spinal-discs-implanted-as-global-demand-grows, accessed 9/18/2024. [3] Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2024. [4] Search for "CP-ESP and LP-ESP" performed on Pubmed, 9/18/2024. [5] Periodic Update Safety Report for prodisc is on file with Centinel Spine. [6] Elastic Spine Pad, Spine Innovations, Reference: ESP_BRO1_EN_202206_B, June 2022 Revision. [7] 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. [8] Bertagnoli, R., Marnay, T., Mayer, H.M., The PRODISC Book, 2003. [9] Material Contact with Patient Tissues, Spine Innovations, Reference: 201808-FHO.com, ft-composition_eng_2. [10] Bandyopadhyay A, Mitra I, Goodman SB, Kumar M, Bose S. Improving Biocompatibility for Next Generation of Metallic Implants. Prog Mater Sci. 2023 Mar. [11] Obid P, Rakow A, Lang GM, Marx W, Niemeyer T, Rahim T. Clinical and Radiological Outcome of Disc Arthroplasty for the Treatment of Cervical Spondylotic Myelopathy. J Pers Med. 2023 Mar 28;13(4):592.

	Device		prodisc C Vivo	prodisc C Nova	CP-ESP®
DEVICE OVERVIEW (cont'd)	Materials	*Fact*	Titanium alloy TAN (Ti-6Al-7Nb) Endplates with Pure Titanium Coating, UHMWPE Inlay, CoCrMo (Co-28Cr-6Mo) Calotte Insert		Polycarbonate Urethane (PCU) cushion, Titanium alloy (TI-6AL-4V) endplates with Hydroxyapatite and Titanium plasma spray.[9]
		Benefit	prodisc utilizes proven materials used successfully in hip and knee joint replacement for decades.[10] The prodisc articulating material surfaces have a proven long-term track record—ultra-high molecular weight polyethylene (UHMWPE) on Cobalt Chrome (CoCrMo) alloy. Endplates are manufactured from Titanium alloy to improve MR imaging.		CP-ESP utilizes newer materials in a novel way, only proven clinically in the short-term in its current configuration. The study with the longest published clinical results has average follow-up of 28.2 months.[11]
	Patient-Implant Fit	*Fact*	prodisc C Vivo & prodisc C Nova 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 device optionality.
		Benefit	Implant optionality potentially reduces or eliminates the need to alter patient anatomy to fit the implant.		Limited single device configuration may potentially require altering patient anatomy to fit the device.
	Sizing Options	*Summary*	prodisc C Vivo & prodisc C Nova together provide a broad offering of 36 implant options versus CP-ESP's 9 sizing options.[6]		
		Fact	**5-7mm heights, 18 total sizing configurations per total disc system** 5mm Height – 6 Total Footprint Options 6mm Height – 6 Total Footprint Options 7mm Height – 6 Total Footprint Options		**5-7mm heights, 9 total sizing configurations only**[6] 5mm Height – 3 Total Footprint Options 6mm Height – 3 Total Footprint Options 7mm Height – 3 Total Footprint Options
		Benefit	Having access to more implant options makes it easier for the surgeon to match the patient anatomy.		Fewer endplate options and heights may reduce a surgeon's ability to optimize implant size and position within the disc space, and support fitting into more collapsed disc spaces.
SURGICAL TECHNIQUE	Instrument System	*Facts*	Full complement of prodisc implantation surgical instruments.		Limited selection of surgical instruments for trialing and implantation of the CP-ESP device.
		Benefit	The prodisc C Vivo & prodisc C Nova instrument systems include a wider array of implantation & implant-adjustment instruments (e.g. pin awl, slotted mallet, prodisc C Vivo inserter with or without stop, slide hammer, prodisc C Vivo repositioner clamps, etc.).		Technique requires precise positioning of implant to optimize center of rotation.
SUMMARY	Key areas of competitive focus versus CP-ESP: proven (prodisc is extensively proven with long-term clinical safety and effectiveness—i.e. versus unproven long-term elastomeric biomechanics), materials (proven long-term prodisc materials), patient implant-fit (prodisc Match-the-Disc™ system), and implant sizing (a full complement of prodisc heights and footprints).				

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