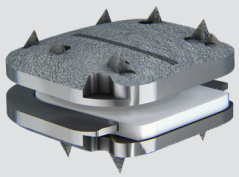
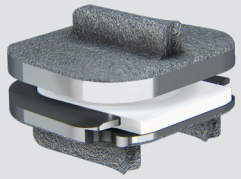
prodisc C Vivo & prodisc C Nova

COMPETITIVE COMPARISON | vs. Mobi-C® | FOR INTERNATIONAL USE ONLY

CENTINEL SPINE

	Company	**Centinel Spine**		**Highridge Medical**
	Device	**prodisc C Vivo**	**prodisc C Nova**	**Mobi-C®**
CLINICAL HISTORY	**Device Image**			
	First Year of Clinical Use	2009	2009	2004
	Regulatory Approval	**FDA:** 2022 | **CE Mark:** 2011	**FDA:** 2022 | **CE Mark:** 2010	**FDA:** 2013 | **CE Mark:** 2004
	Indications	Symptomatic Cervical Disc Disease*		Symptomatic Cervical Disc Disease*
	Number of Implantations	Over 250,000 implantations of the prodisc technology platform[1]		Over 200,000 implantations[2]
	Published Studies	Over 540 peer-reviewed published studies on the prodisc technology platform[3]		94[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		Mobile Core - Variable Center of Rotation - Allowing for approximately 1mm of AP translation independent of rotation.[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]		When a shear force is applied to a total disc replacement implant with a mobile core, free translation may occur—resulting in unstable and unpredictable motion. Shear forces are therefore resisted by the facets.[7]

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

References: [1] Data on file at Centinel Spine compiled from Spine Solutions, Synthes Spine, DePuy Synthes, and Centinel Spine. [2] ZimVie Inc, Jan. 30, 2023, ZimVie Announces Over 200,000 Cervical Discs Have Been Replaced with Mobi-C®, [Press Release], ZimVie Announces Over 200,000 Cervical Discs Have Been Replaced with Mobi-C® (yahoo.com). [3] Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2024. [4] Search performed on Pubmed, 8/9/2024. [5] Periodic Update Safety Report for prodisc is on file with Centinel Spine. [6] LDR Spine, 2013, Summary of Safety and Effectiveness Data, Mobi-C® P110009. [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] Mobi-C Surgical Technique, Zimmer Biomet, 2018, MB ST 2 REV D 0718. [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] Ahmad FU, Sidani C, Fourzali R, Wang MY. Postoperative magnetic resonance imaging artifact with cobalt-chromium versus titanium spinal instrumentation: presented at the 2013 Joint Spine Section Meeting. Clinical article. J Neurosurg Spine. 2013 Nov;19(5):629-36.

SINCE 1990 30+ YEARS OF CLINICAL SUCCESS

	Device		prodisc C Vivo	prodisc C Nova	Mobi-C®
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		CoCrMo (Co- 28Cr-6Mo) Endplates with Titanium/ Hydroxyapetite Coating, UHMWPE Inlay[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.		Mobi-C utilizes endplates solely constructed of CoCrMo. Post-operative imaging (MRI) of CoCrMo endplates may yield artifacts making it more difficult to visualize key anatomic features.[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 Mobi-C's 32 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		**4.5, 5, 6 & 7mm heights, 32 total sizing configurations**[6] 4.5mm Height – 8 Total Footprint Options 5mm Height – 8 Total Footprint Options 6mm Height – 8 Total Footprint Options 7mm Height – 8 Total Footprint Options
		Benefit	Having access to more implant options makes it easier for the surgeon to match the patient anatomy.		Fewer endplate options may reduce a surgeon's ability to optimize implant size and position within the disc space.
SURGICAL TECHNIQUE	Instrument System	*Fact*	Full complement of prodisc implantation surgical instruments.		Full complement of surgical instruments.
		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.).		The Mobi-C instrument systems include a comprehensive array of implantation & implant-adjustment instruments.
SUMMARY	Key areas of competitive focus versus Mobi-C: kinematics (prodisc CORE benefits), materials (prodisc endplate MRI compatibility), patient implant-fit (prodisc Match-the-Disc™ system). Also consider height considerations, as demonstrated in the Mobi-C Technical Comparison (MKT-0999).				

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