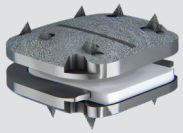
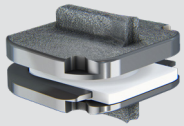
prodisc C Vivo & prodisc C SK

COMPETITIVE COMPARISON | vs. Simplify®

SINCE 1990 — 30+ YEARS OF CLINICAL SUCCESS

	Company	**Centinel Spine®**		**Globus Medical®**
	Device	prodisc C Vivo	prodisc C SK	**Simplify®**
CLINICAL HISTORY	**Device Image**			
	1st Year of Clinical Use	2009	2019	2015[1]
	Regulatory Approval	**FDA Approval:** 2022	**FDA Approval:** 2022	**FDA Approval:** 2020
	Indications	**One-Level**		**One-Level:** 2020 | **Two-Level:** 2021
	# of Implantations	Over 250,000 implantations of the prodisc technology platform[2]		No published data
	Published Studies	Over 540 published studies on the prodisc technology platform[3]		7[4]
	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[2] 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 Core with an Optimized Core Radius		Mobile Core: Allowing for +/- 1.6mm 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 design, free translation may occur, resulting in unstable and unpredictable motion. Shear forces are therefore resisted by the facets.[7]
	Materials — *Fact*	**Endplates:** CoCrMo (Cobalt Chromium Molybdenum) **Core:** UHMWPE (Ultra High Molecular Weight Polyethylene) **Bone Contacting Surfaces:** Titanium Plasma Spray		**Endplates:** PEEK (Polyether ether ketone) **Core:** ZTA (Zirconia-Toughened Alumina Ceramic) **Bone Contacting Surfaces:** Titanium Plasma Spray
	Materials — *Benefit*	prodisc C has a reported rate of osteolysis of 0.79%, which has identical materials to prodisc C Vivo & prodisc C SK.[9] 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.		Simplify has a reported rate of osteolysis of 15.55%, currently the 2nd highest of all cervical TDRs on the US market.[9] Based on publicly available information as of September 4, 2024, this is the first PMA approved joint prosthesis utilizing a ZTA on PEEK bearing. There are no published clinical results of this material combination beyond 5 years.[10]

References: [1] PR Newswire. (2015, February 17). Simplify Medical Announces CE Mark for New MRI Compatible Cervical Artificial Disc. Retrieved July 15, 2024, from https://www.prnewswire.com/news-releases/simplify-medical-announces-ce-mark-for-new-mri-compatible-cervical-artificial-disc-300028361.html. [2] Data on file at Centinel Spine compiled from Spine Solutions, Synthes Spine, DePuy Synthes, and Centinel Spine. [3] Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2024. [4] Pubmed search, July 2024. [5] Data on file at Centinel Spine. [6] Source: SPINEMarketGroup. "Simplify Medical: Simplify Disc in Motion." YouTube, 7 Oct. 2020, www.youtube.com/watch?v=LhuR3MHc6NE. Accessed 2 Aug. 2024. [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] Mangual, D., Nunley, P., (2024, April 26-28). Rates of Osteolysis for Commercially Available Cervical Disc Arthroplasty Devices in the US - A MAUDE Database Analysis [Conference presentation]. ISASS24 24th Annual Conference, Miami Beach, FL, United States. [10] Guyer, Richard, et al. "167. Five-Year Follow-up of a Prospective FDA IDE Trial Evaluating a PEEK-On-Ceramic Cervical Disc Replacement." The Spine Journal, vol. 23, no. 9, 1 Sept. 2023, pp. S86–S86, https://doi.org/10.1016/j.spinee.2023.06.189. Accessed 26 Aug. 2024. [11] NuVasive. (2022). Simplify Cervical Disc Surgical Technique Guide. [12] Data on file at Centinel Spine, ref MKT-1000.

	Device		prodisc C Vivo	prodisc C SK	Simplify®
DEVICE OVERVIEW (CONT'D)	Sizing Options	*Summary*	prodisc C Vivo & prodisc C SK together have a broad offering of 36 sizing options to accommodate anatomical variation versus Simplify's 12 sizing options.[11]		
		Fact 1	**2 Endplate Options** 5mm, 6mm, 7mm heights		**1 Endplate Option** 4mm, 5mm, 6mm heights
		Fact 2	The apex height of a 5mm prodisc C SK Implant is 5.3mm, which is 0.9mm smaller than a 4mm Simplify (apex height of 6.2mm).[12]		
		Fact 3	**6 Footprint Options per Height** Footprint: M / MD / L / LD / XL / XLD Depth (mm): 12 / 14 / 14 / 16 / 16 / 18 Width (mm): 15 / 15 / 17 / 17 / 19 / 19		**2-3 Footprint Options per Height** Footprint: Small * / Medium *† / Large† Depth (mm): 12 / 14 / 16 Width (mm): 15 / 16 / 18 ** Available in 4mm height. † Lordotic option available for 5mm & 6mm height.*
		Benefit	Additional sizing options makes it easier for the surgeon to match the patient anatomy.		Limited sizing options may reduce a surgeon's ability to optimize implant size and position within the disc space, and prevent fitting into more collapsed disc spaces.
	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 intraoperatively that best fits the patient anatomy and the surgeon's preference.		No intraoperative device optionality. Simplify has a domed superior endplate, but it does not offer an option for flat endplates.[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 altering patient anatomy to fit the device.
SURGICAL TECHNIQUE	Surgical Technique Steps	*Facts*	1. Discectomy/Decompression 2. Trialing 3. Implant Loading 4. Implantation	1. Discectomy/Decompression 2. Trialing 3. Keel Cutting (over the trial) 4. Implant Loading 5. Implantation	1. Discectomy/Decompression 2. Trialing 3. Trial Removal 4. Slot Cutting (using a separate slot cutting instrument) 5. Implant Loading 6. Initial Implantation 7. Tamp into Final Position
		Benefit 1	**Trialing:** prodisc C SK does not require the surgeon to remove the trial to cut the keel channels. Once the trial is correctly positioned, it is used as a guide for the chisel. The chisel is placed over the trial and the keel channels are cut, precisely guided by the placement of the trial. Which may result in less OR time compared to Simplify.		**Trialing:** Simplify requires the surgeon to spend time correctly positioning the trial in the disc space under fluoroscopy. The surgeon is then required to remove the trial and introduce a "slot-cutter". Additional time and fluoroscopic images may need to be taken to correctly position the slot cutter to match the previous position of the trial.[11]
		Benefit 2	**Implantation:** prodisc C Vivo & prodisc C SK requires one instrument assembly to fully insert either device, potentially reducing OR time and fewer passes in and out of the surgical field.		**Implantation:** The Simplify insertion process requires the inserter to be removed when the implant is approximately halfway into the disc space. A tamp must be used to advance the implant to the final position.[11]
SUMMARY	Key areas of competitive focus versus Simplify: kinematics (prodisc CORE benefits), materials (prodisc proven total joint replacement materials), sizing options (36 vs. 12), patient implant-fit (prodisc Match-the-Disc™ system), simplified surgical technique (4-5 steps vs. 7 steps).				

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