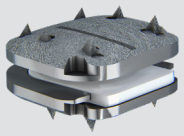
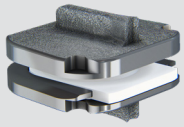
prodisc C Vivo & prodisc C SK

COMPETITIVE COMPARISON | vs. Mobi-C®

SINCE 1990 — 30+ YEARS OF CLINICAL SUCCESS

			Centinel Spine®		Highridge Medical™
	Company				
	Device		prodisc C Vivo	prodisc C SK	Mobi-C®
CLINICAL HISTORY	**Device Image**				
	1st Year of Clinical Use		2009	2019	2004
	Regulatory Approval		**FDA Approval:** 2022	**FDA Approval:** 2022	**FDA Approval:** 2013
	Indications		**One-Level**		**One-Level:** 2013 | **Two-Level:** 2013
	# of Implantations		Over 250,000 implantations of the prodisc technology platform[1]		225,000[2]
	Published Studies		Over 540 published studies on the prodisc technology platform[3]		85[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[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 Core with an Optimized Core Radius		Mobile Core: +/- 1mm of AP & lateral translation[6]
		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]
	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. To accommodate varying patient anatomy, Mobi-C recommends an additional surgical step: "if the inferior endplate of the superior vertebra is flat, use a curette to prepare room for the dome of the device".[9]
		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.

References: [1] Data on file at Centinel Spine compiled from Spine Solutions, Synthes Spine, DePuy Synthes, and Centinel Spine. [2] What is the Mobi-C Cervical Disc? (n.d.). Retrieved October 22, 2024, from https://www.cervicaldisc.com/about-mobi-c/what-is-the-mobi-c-cervical-disc. [3] Pubmed and peer-reviewed journals through 2024. [4] Pubmed and peer-reviewed journals through October 22, 2024. [5] Data on file at Centinel Spine. [6] FDA. (2013, August 23). Summary of Safety and Effectiveness Data (SSED) for Mobi-C Cervical Disc Prosthesis. https://www.accessdata.fda.gov/cdrh_docs/pdf11/P110009B.pdf. [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] ZimVie. (April 2023). Mobi-C Cervical Disc Surgical Technique Guide. [10] Bandyopadhyay A, Mitra I, Goodman SB, Kumar M, Bose S. Improving Biocompatibility for Next Generation of Metallic Implants. Prog Mater Sci. 2023 Mar.

CENTINEL SPINE®

US Headquarters: 900 Airport Rd, Ste. 3B, West Chester, PA 19380 USA
International Office: Grafenauweg 8, 6300 Zug, Switzerland

Email (US): info@centinelspine.com
Web: www.centinelspine.com

℞ ONLY

	Device		prodisc C Vivo	prodisc C SK	Mobi-C®
SURGICAL TECHNIQUE	Surgical Technique Steps	*Fact 1*	The introducer tip for prodisc C Vivo & prodisc C SK does not extend beyond the lateral aspects of the implant. The introducer tip engages with the anterior aspect of implant.		The PEEK cartridge extends beyond the lateral aspects of the Mobi-C implant. The PEEK cartridge engages with the lateral aspect of the implant. After removing the PEEK cartridge, one or both of the plates may require adjustment using the plate impactor/tamp.[9]
		Benefit 1	Streamlined introducer tip design may limit tissue interference and increases efficiency of the introducer release.		The wide implant holder may potentially cause tissue interference and decrease efficiency of the inserter release. Tissue interference may potentially alter the implant position.
		Fact 2	To disengage the introducer from the prodisc C Vivo & prodisc C SK implant, the proximal knob of the introducer must be rotated 3 full turns. A secondary instrument is not required to fully release the implant.		To disengage the PEEK cartridge/Mobi-C implant assembly from the inserter, the unlocking key must be turned "approximately 20 times to fully release the screw from the PEEK cartridge." [9] Extraction forceps are required to release the PEEK cartridge from the implant. "If the PEEK cartridge is difficult to extract, rotate one side of the cartridge 90º caudal, then remove with forceps. Repeat on the remaining side." [9]
		Benefit 2	The prodisc C Vivo & prodisc C SK introducer is designed to efficiently disengage from the implant, potentially reducing OR time compared to Mobi-C.		Requiring 7 times more turns to release the implant from the inserter, followed by a secondary instrument to fully release the implant from the PEEK cartridge may potentially require additional OR time compared to prodisc C Vivo & prodisc C SK.
		Fact 3	**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.** Prepare Endplate for Dome of the Device (if applicable) **4.** Implant Assembly to the Implant Inserter **5.** Implantation **6.** PEEK Cartridge Removal
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 Mobi-C's 28 sizing options.[9]		
		Fact 1	**2 Endplate Options**	5mm, 6mm, 7mm heights	**1 Endplate Option** 4.5mm, 5mm, 6mm, 7mm heights
		Fact 2	**6 Footprint Options per Height** **Footprint** / **Depth (mm)** / **Width (mm)**: M 12 / 15; MD 14 / 15; L 14 / 17; LD 16 / 17; XL 16 / 19; XLD 18 / 19		**7 Footprint Options per Height** **Depth (mm)**: 13, 13, 15, 15, 15, 17, 17 **Width (mm)**: 15, 17, 15, 17, 19, 17, 19
		Benefit	Additional sizing options makes it easier for the surgeon to match the patient anatomy.		Fewer sizing options may reduce a surgeon's ability to optimize implant size and position within the disc space without altering patient anatomy.
	Materials	*Fact*	**Endplates:** CoCrMo (Cobalt Chromium Molybdenum) **Core:** UHMWPE (Ultra High Molecular Weight Polyethylene) **Bone Contacting Surfaces:** Titanium Plasma Spray Coating		**Endplates:** CoCrMo (Cobalt Chromium Molybdenum)[6] **Core:** UHMWPE (Ultra High Molecular Weight Polyethylene)[6] **Bone Contacting Surfaces:** Hydroxyapatite (HA) Plasma Spray Coating[6]
		Benefit	prodisc & Mobi-C both utilize materials that have been used successfully in large total joint replacements (hips and knees) for decades[10] and for 30+ years in total disc replacement (spine). These materials have a proven long-term track record of success.		
SUMMARY	Key areas of competitive focus versus Mobi-C: kinematics (prodisc CORE benefits), patient implant-fit (prodisc Match-the-Disc™ system), surgical technique with streamlined instrumentation.				