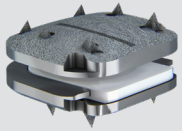
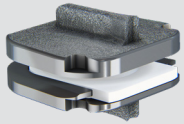
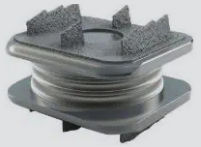
prodisc C Vivo & prodisc C SK

COMPETITIVE COMPARISON | vs. M6-C™

SINCE 1990 — 30+ YEARS OF CLINICAL SUCCESS

			Centinel Spine		Orthofix
	Company				
	Device		prodisc C Vivo	prodisc C SK	M6-C™
CLINICAL HISTORY	**Device Image**				
	1st Year of Clinical Use		2009	2019	2006
	Regulatory Approval		**FDA Approval:** 2022	**FDA Approval:** 2022	**FDA Approval:** 2019
	Indications		One-Level		One-Level
	Number of Implantations		Over 275,000 implantations of the prodisc technology platform[1]		Over 100,000 implantations of the M6 artificial disc technology[2] As of February 25, 2025, Orthofix has "decided to discontinue its M6-C™ artificial cervical disc and M6-L™ artificial lumbar disc product lines[3]
	Published Studies		Over 540 peer-reviewed published studies on the prodisc technology platform[4]		40[5]
	Summary		prodisc is the most studied and clinically proven TDR technology in the world. Since 1990, the prodisc design has been validated with over 275,000 device implantations worldwide[1] and more than 540 published papers[4]. Per U.S. complaint data since 2006, prodisc has a less than 1% reported revision rate.[6]		
DEVICE OVERVIEW	**Kinematics**	*Fact*	Ball & Socket: Fixed Core with an Optimized Core Radius		Artificial Nucleus and Annulus – Compressible Viscoelastic Nucleus with Dynamic Center of Rotation.[7]
		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.[8,9]		Marketed as a device designed to mimic the structure and movement of a natural disc.[10] Long term kinematic clinical outcomes yet to be determined.

References: [1] Data on file at Centinel Spine compiled from Spine Solutions, Synthes Spine, DePuy Synthes, and Centinel Spine. [2] Orthofix Announces Publication in The Spine Journal of Five-Year Data for the M6-C Artificial Cervical Disc. (2023, November 30). Retrieved August 15, 2024, from https://orthofix.com/blog/orthofix-announces-publication-in-the-spine-journal-of-five-year-data-for-the-m6-c-artificial-cervical-disc/. [3] Orthofix Reports Fourth Quarter and Full-Year 2024 Results and Provides 2025 Financial Guidance. (2025, February 25). Retrieved February 28, 2025, from https://ir.orthofix.com/news/news-details/2025/Orthofix-Reports-Fourth-Quarter-and-Full-Year-2024-Results-and-Provides-2025-Financial-Guidance/default.aspx. [4] Pubmed and peer-reviewed journals through 2024. [5] Pubmed and peer-reviewed journals through February 28, 2025. [6] Periodic Update Safety Report for prodisc is on file with Centinel Spine. [7] Phillips FM, Coric D, Sasso R, Lanman T, Lavelle W, Lauryssen C, Albert T, Cammisa F, Milam RA. Prospective, multicenter clinical trial comparing the M6-C compressible cervical disc with anterior cervical discectomy and fusion for the treatment of single-level degenerative cervical radiculopathy: 5-year results of an FDA investigational device exemption study. Spine J. 2024 Feb;24(2):219-230. doi: 10.1016/j.spinee.2023.10.020. Epub 2023 Nov 10. PMID: 37951477. [8] 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. [9] Bertagnoli, R., Marnay, T., Mayer, H.M., The PRODISC Book, 2003. [10] M6 website, The M6-C Artificial Disc Replacement Device – m6disc.com, accessed August 19, 2024. [11] M6-C Surgical Technique, Orthofix Holdings, MKT 0163 Rev. 02 M6-C-1911. [12] Summary of Safety and Effectiveness Data (SSED) for M6-C Artificial Cervical Disc. https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170036B.pdf. [13] Nunley, P., (2024, September 25-28). Contra-Indications: Complications and How to Avoid Them. R. Guyer, J. Shellock (chairs), Cervical and Lumbar Total Disc Replacement: Expanding Indications and When Not To [Symposium]. North American Spine Society (NASS) Annual Meeting, Chicago, IL, United States. [14] Scott-Young M, Rathbone E, Grierson L. Midterm osteolysis-induced aseptic failure of the M6-C™ cervical total disc replacement secondary to polyethylene wear debris. Eur Spine J. 2022 May;31(5):1273-1282. [15] Late Failure of Cervical Disc Arthroplasty Due to Osteolysis, Blumenthal, S L, et al. presented at North American Spine Society, 5/15/21. [16] Häckel S, Gaff J, Pabbruwe M, Celenza A, Kern M, Taylor P, Miles A, Cunningham G. Heterotopic ossification, osteolysis and implant failure following cervical total disc replacement with the M6-C™ artificial disc. Eur Spine J. 2024 Mar;33(3):1292-1299. doi: 10.1007/s00586-024-08129-5. Epub 2024 Feb 16. PMID: 38363365. [17] Australian Government, Department of Health Therapeutic Goods Administration, Reference RC-2020-RN-00478-1, System for Australian Recall Actions (SARA) database | Therapeutic Goods Administration (TGA), 2/6/2020.

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

	Device		prodisc C Vivo	prodisc C SK	M6-C™
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. Fin Cutting (using a separate fin cutting instrument) 5. Implant Loading 6. Implantation
		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 M6-C.		**Trialing:** M6-C 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 "fin cutter". Additional time and fluoroscopic images may need to be taken to correctly position the fin cutter to match the previous position of the trial.[11]
DEVICE OVERVIEW (CONT'D)	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. M6-C has a flat superior endplate, but it does not offer an option for a domed superior endplate.
		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 SK together have a broad offering of 36 implant options versus M6-C's 8 sizing options.[11]		
		Fact 1	**2 Endplate Options** — 5mm, 6mm, 7mm heights		**1 Endplate Option** — 6mm, 7mm heights
		Fact 2	**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		**4 Footprint Options per Height** Footprint: Medium / Medium-Long / Large / Large-Long Depth (mm): 12.5 / 15 / 14 / 16 Width (mm): 15 / 15 / 17 / 17
		Benefit	Additional sizing 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 and support fitting into more collapsed disc spaces. Lack of a smaller 5mm height for M6-C may be a real limitation in the system for some patients.
	Materials	*Fact*	**Endplates:** CoCrMo (Cobalt Chromium Molybdenum) **Core:** UHMWPE (Ultra High Molecular Weight Polyethylene) **Bone Contacting Surfaces:** Titanium Plasma Spray		**Endplates:** Titanium Alloy[12] **Core:** Artificial Nucleus & Sheath: PCU (Polycarbonate Urethane)[12] Artificial Annulus: UHMWPE Fiber Matrix[12] **Bone Contacting Surfaces:** Titanium Plasma Spray[12]
		Benefit	prodisc C has a low reported rate of osteolysis of 0.7%, which has identical materials to prodisc C Vivo & prodisc C SK.[13] 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		M6-C has a high reported rate of osteolysis, currently the highest of all the cervical TDRs on the US market (36.2%).[13] M6-C utilizes newer materials in a novel way, unproven clinically in the long-term in its current configuration. This has resulted in documented wear-induced osteolysis and substantial mid-term failure rates.[14] Multiple well-respected clinics have published/presented similar results.[15,16] Caution: Australian Government issued an "Urgent Product Defect Correction; and Implant Hazard Alert' as a result of post-market findings and encouraged 'routine long term clinical and radiographic monitoring of patients implanted".[17]
SUMMARY	Key areas of competitive focus versus M6-C: prodisc is extensively proven with long-term clinical safety and effectiveness, kinematics (prodisc CORE benefits), simplified surgical technique (4-5 steps vs. 6 steps), patient implant-fit (prodisc Match-the-Disc™ system), sizing options (36 vs. 8), and materials (prodisc proven total joint replacement materials).				