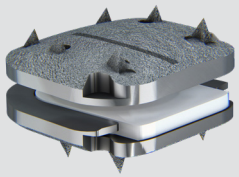
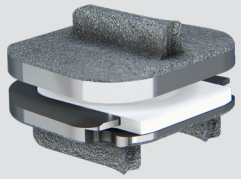
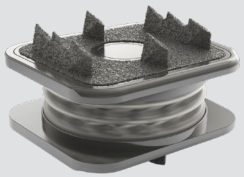
prodisc C Vivo & prodisc C Nova

COMPETITIVE COMPARISON | vs. M6-C™ | FOR INTERNATIONAL USE ONLY

CENTINEL SPINE

	Company	**Centinel Spine**		**Orthofix**
	Device	prodisc C Vivo	prodisc C Nova	M6-C™
CLINICAL HISTORY	**Device Image**			
	First Year of Clinical Use	2009	2009	2006
	Regulatory Approval	**FDA:** 2022 | **CE Mark:** 2011	**FDA:** 2022 | **CE Mark:** 2010	**FDA:** 2019 | **CE Mark:** 2006
	Indications	Symptomatic Cervical Disc Disease*		Symptomatic Cervical Disc Disease*
	Number of Implantations	Over 250,000 implantations of the prodisc technology platform[1]		Over 100,000 implantations[2]
	Published Studies	Over 540 peer-reviewed published studies on the prodisc technology platform[3]		36[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		Artificial Nucleus and Annulus – Compressible Viscoelastic Nucleus with Dynamic Center 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]		Marketed as a device designed to mimic the structure and movement of a natural disc.[9] Long term kinematic clinical outcomes yet to be determined.

* 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] Orthofix Inc, Nov. 30, 2023, Orthofix Announces Publication in The Spine Journal of Five-Year Data for the M6-C Artificial Cervical Disc. Orthofix Announces Publication in The Spine Journal of Five-Year Data for the M6-C Artificial Cervical Disc - Orthofix, accessed 8/15/24. [3] Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2024. [4] Search performed on Pubmed, 8/15/2024. [5] Periodic Update Safety Report for prodisc is on file with Centinel Spine. [6] 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. [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] M6 website, The M6-C Artificial Disc Replacement Device – m6disc.com, referenced 8/19/24. [10] M6 Surgical Technique, Orthofix Holdings, MKT 0163 Rev. 02 M6-C-1911. [11] Bandyopadhyay A, Mitra I, Goodman SB, Kumar M, Bose S. Improving Biocompatibility for Next Generation of Metallic Implants. Prog Mater Sci. 2023 Mar. [12] 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. [13] 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. [14] Late Failure of Cervical Disc Arthroplasty Due to Osteolysis, Blumenthal, S L, et al. presented at North American Spine Society, 5/15/21. [15] 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. [16] 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

SINCE 1990 30+ YEARS OF CLINICAL SUCCESS

			prodisc C Vivo	prodisc C Nova	M6-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		Polycarbonate Urethane (PCU) nucleus and sheath, UHMWPE woven into annulus, Titanium with Titanium plasma spray.[10]
		Benefit	prodisc utilizes proven materials used successfully in hip and knee joint replacement for decades.[11] 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. prodisc C has a low reported rate of osteolysis relative to other cervical TDRs currently on the US market (0.79%).[12]		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 midterm failure rates.[13] Multiple well-respected clinics have published/presented similar results.[14,15] 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".[16] M6-C has a high reported rate of osteolysis, currently the highest of all the cervical TDRs on the US market (32.95%).[12]
	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 M6-C's 8 sizing options.[10]		
		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		**6 & 7mm heights only, 8 total sizing configurations only**[10] 6mm Height – 4 Total Footprint Options 7mm Height – 4 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 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.
SURGICAL TECHNIQUE	Instrument System	*Fact*	Full complement of prodisc implantation surgical instruments.		Limited selection of surgical instruments for trialing and implantation of the M6-C device, requiring additional passes into the sterile field.
		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 also requires precise repositioning of instruments between steps to prep keel after trialing and before placement of implant.
SUMMARY	Key areas of competitive focus versus M6-C: prodisc is extensively proven with long-term clinical safety and effectiveness, proven prodisc materials (i.e. M6-C osteolysis cases), patient implant-fit (prodisc Match-the-Disc™ system), and a full complement of prodisc heights and footprints.				

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