

prodisc C Vivo & prodisc C Nova

COMPETITIVE COMPARISON | vs. Simplify® | FOR INTERNATIONAL USE ONLY



Company		Centinel Spine®		Globus Medical®
Device		prodisc C Vivo	prodisc C Nova	Simplify®
CLINICAL HISTORY	Device Image			
	1st Year of Clinical Use	2009	2009	2015 ¹
	Regulatory Approval	FDA: 2022 CE Mark: 2011	FDA: 2022 CE Mark: 2010	FDA: 2020 CE Mark: 2015
	Indications	Symptomatic Cervical Disc Disease*		Symptomatic Cervical Disc Disease*
	# of Implantations	Over 250,000 implantations of the prodisc technology platform ⁷		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
		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
		Benefit	prodisc C has a reported rate of osteolysis of 0.79%, which has identical materials to prodisc C Vivo & prodisc C Nova. 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

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

Device		prodisc C Vivo	prodisc C Nova	Simplify®																																	
DEVICE OVERVIEW (CONT'D)	Summary	prodisc C Vivo & prodisc C Nova 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 Nova Implant is 5.3mm, which is 0.9mm smaller than a 4mm Simplify (apex height of 6.2mm). ¹²																																			
	Sizing Options	6 Footprint Options per Height			2-3 Footprint Options per Height																																
		Fact 3	<table border="1"> <thead> <tr> <th>Footprint</th> <th>M</th> <th>MD</th> <th>L</th> <th>LD</th> <th>XL</th> <th>XLD</th> </tr> </thead> <tbody> <tr> <td>Depth (mm)</td> <td>12</td> <td>14</td> <td>14</td> <td>16</td> <td>16</td> <td>18</td> </tr> <tr> <td>Width (mm)</td> <td>15</td> <td>15</td> <td>17</td> <td>17</td> <td>19</td> <td>19</td> </tr> </tbody> </table>	Footprint	M	MD	L	LD	XL	XLD	Depth (mm)	12	14	14	16	16	18	Width (mm)	15	15	17	17	19	19	<table border="1"> <thead> <tr> <th>Footprint</th> <th>Small *</th> <th>Medium **</th> <th>Large †</th> </tr> </thead> <tbody> <tr> <td>Depth (mm)</td> <td>12</td> <td>14</td> <td>16</td> </tr> <tr> <td>Width (mm)</td> <td>15</td> <td>16</td> <td>18</td> </tr> </tbody> </table>	Footprint	Small *	Medium **	Large †	Depth (mm)	12	14	16	Width (mm)	15	16	18
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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 Nova 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	Fact	<ol style="list-style-type: none"> Discectomy/Decompression Trialing Implant Loading Implantation 	<ol style="list-style-type: none"> Discectomy/Decompression Trialing Keel Cutting (over the trial) Implant Loading Implantation 	<ol style="list-style-type: none"> Discectomy/Decompression Trialing Trial Removal Slot Cutting (using a separate slot cutting instrument) Implant Loading Initial Implantation Tamp into Final Position 																																
		Benefit 1	Trialing: prodisc C Nova 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																																
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).																																				

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 Periodic Update Safety Report for prodisc is on file with Centinel Spine. ⁶ Source: SPINEMarketGroup. "Simplify Medical: Simplify Disc in Motion." YouTube, 7 Oct. 2020. www.youtube.com/watch?v=LhuR3MH6NE. Accessed 2 Aug. 2024. ⁷ Sears, R., et al., (2016) 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.



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