



NuDEL™

The NuDEL™ is an all-in-one stent delivery system which is designed for the efficient and effective treatment of coarctation of the Aorta. It includes the proven technologies of the Covered CP Stent™, mounted on a Balloon-In-Balloon catheter (BIB®), which is then covered by a sheath.

Benefits

Pre-loaded system All components are already pre-loaded. This saves time and allows quick actions in emergency situations.

All-in-one Aortic stent system

The NuDEL includes a BIB® balloon catheter and a Covered CP Stent™, which is then covered by a sheath.

High quality The CP Stent™ is made of a 0.013" thick Platinum/Iridium wire mesh arranged in a zig-zag pattern. Every point of intersection is laser welded and brazed with 24K Gold.

Adjustable fit Thanks to its considerable capacity for expansion, the stent just needs to be re-dilated to accommodate the child's natural growth. Therefore no extra stent needs to be implanted.

	NuDEL™
CE	Class III
Wire	0.013" Platinum/Iridium
Connection/Welding	24K Gold
Stent length (cm)	1.6 – 4.5
Catheter Body	Polymeric, DEHP-free, Latex-free
Balloon	Thermoplastic Elastomer (Non-compliant – The balloon will not exceed +/- 10% of the given balloon size at Rated Burst Pressure), DEHP-free, Latex-free
Image Band	Platinum Iridium
Balloon Diameter (mm)	12.0 – 24.0
Balloon length (cm)	2.5 – 5.0
Outer Balloon Rated Burst Pressure (ATM)	3 – 7
Indication	<p>Indicated for implantation in the native and/or recurrent coarctation of the aorta on patients with the following clinical conditions:</p> <ul style="list-style-type: none"> • Stenosis of the aorta resulting in significant anatomic narrowing as determined by angiography or non-invasive imaging, i.e. echocardiography, magnetic resonance imaging (MRI), CT Scan • Stenosis of the aorta resulting in hemodynamic alterations, resulting in systolic pressure gradient, systemic hypertension or altered left ventricular function • Stenosis of the aorta where balloon angioplasty is ineffective or contraindicated • Stenosis diameter < 20% of the adjacent vessel diameter • Stenosis that would present increased risk of vascular damage or disruption • Aneurysm associated with coarctation of the aorta
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