

CP Stent®

- › Bare & Covered
- › Mounted Bare & Covered
- › NuDEL™
- › BIB®



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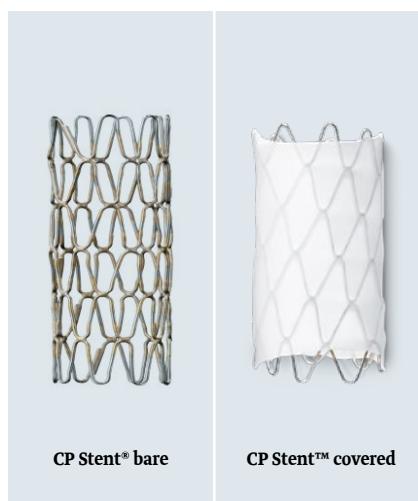
**NEW SIZES
AVAILABLE**



CP Stent™ covered

The **CP Stent®** is composed of 0.013“ Platinum/Iridium wire that is arranged in a “zig” pattern, laser welded at each joint and over brazed with 24K Gold. It allows expansion from 12.0 mm to 30.0 mm. The Covered CP Stent™ is comprised of the Bare CP Stent that is covered with an expandable sleeve of ePTFE.

CP Stent®



Benefits

High quality

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

High expansion range

It has an expansion range of 12.0 - 24.0 mm for the 8zig and 26.0 - 30.0 mm for the 10zig.

Bare & Covered

The CP Stent® is available in a bare version or covered with an expandable sheath of ePTFE.

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.

Technical Data

	CP Stent® bare	CP Stent™ covered
CE	Class III	
Wire	0.013" Platinum/iridium	
Connection/Welding	24K Gold	
Stent length (cm)	8zig: 1.6 - 6.0 10zig: 3.9 - 6.0	
Indication Indicated for implantation in the native and/or recurrent coarctation of the aorta on patients with the following clinical conditions:	<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 	<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 <p>Indicated for treatment of right ventricle to pulmonary artery (Right Ventricular Outflow Tract) conduit disruptions that are identified during conduit predilatation procedures performed in preparation for transcatheter pulmonary valve replacement.</p>
References	Page 11	
Ordering information	Page 6	

The Special **Balloon-in-Balloon catheter (BIB®)** is used to insert stents in a two-stage implantation process. This enables stents to be opened or expanded evenly and positioned correctly. The inner balloon of the BIB® Catheter is half the diameter of the outer balloon and is 1.0 cm shorter in length.

BIB®



Benefits

Stent placement with BIB® reduces the risk of asymmetric stent opening and stent dislodgement.¹

Inner balloon inflation

When the inner balloon is inflated, the stent expansion begins from the center of the stent. The stent is firmly gripped on to the balloon to allow for fine positioning before the final expansion by inflating the outer balloon.

Outer balloon inflation

If the stent is placed in the right position, the outer balloon can be inflated.

Technical Data

BIB*

Details	Special Balloon-in-Balloon catheter for two-stage placement of stents The diameter of the inner balloon is half the diameter of the outer balloon diameter. The length of the inner balloon is 1.0 cm shorter than the outer balloon length.
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CE Class III

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 – 30.0

Balloon length (cm) 2.5 – 6.0

Outer Balloon Rated Burst Pressure (ATM) 2 – 7

Introducer Size (FR) 8 – 16

Indication ▶ Indicated for stent placement in vessels over 8 mm in diameter.

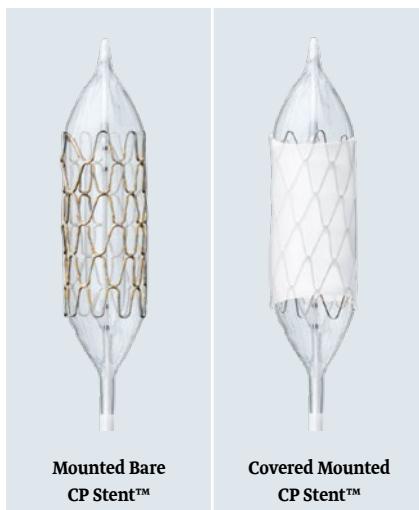
References Page 11

Ordering information Page 6 – 7

¹ Marc Gewillig, Werner Budts, Derize Boshoff & Geert Maleux, Percutaneous interventions of the aorta. Future Cardiol. (2012)8(2), 251-269

The **Mounted Bare and Mounted Covered CP Stent™** consists of a bare/covered CP Stent® premounted on a BIB® Catheter. This system allows the physician the flexibility of using the pre-mounted complete system and will save the time required to mount the stent on the catheter.

Mounted Bare & Mounted Covered CP Stent™



Benefits

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.

High expansion range

It has an expansion range of 12.0 - 24.0 mm for the 8zig and 26.0 - 30.0 mm for the 10zig.

Bare & Covered

The CP Stent® is available in a bare version or covered with an expandable sheath of ePTFE.

Adjustable fit

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

Premounting saves time and reduces risk of dislodgement.

Technical Data

	Mounted Bare CP Stent™	Mounted Covered CP Stent™ (CMCP)
CE	Class III	
Wire	0.013" Platinum/Iridium	
Connection/Welding	24K Gold	
Stent length (cm)	8zig: 1.6 - 6.0 10zig: 3.9 - 6.0	
Indication Indicated for implantation in the native and/or recurrent coarctation of the aorta on patients with the following:	<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 	<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
		Indicated for treatment of right ventricle to pulmonary artery (Right Ventricular Outflow Tract) conduit disruptions that are identified during conduit predilatation procedures performed in preparation for transcatheter pulmonary valve replacement.

Ordering information Page 8 - 9

The NuDEL™ is an all-in-one stent delivery system which is designed for the efficient and effective treatment of coarctation of the Aorta and Right Ventricular Outflow Tract. 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.

NuDEL™



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 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.

Technical Data

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 3 - 7

Burst Pressure (ATM)

Indication

Indicated for implantation in the native and/or recurrent coarctation of the aorta on patients with the following clinical conditions:

- ▶ 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

Indicated for treatment of right ventricle to pulmonary artery (Right Ventricular Outflow Tract) conduit disruptions that are identified during conduit pre-dilatation procedures performed in preparation for transcatheter pulmonary valve replacement.

Ordering Information**Bare CP Stent® and Covered CP Stent™***** NEW SIZES**

REF Bare CP Stent®	REF Covered CP Stent™	Stent Length (cm)	Configuration (Number of Zigs)	Platinum Wire (Inches)
CP8Z16	CVRDCP8Z16	1.6	8	0.013
CP8Z22	CVRDCP8Z22	2.2	8	0.013
CP8Z28	CVRDCP8Z28	2.8	8	0.013
CP8Z34	CVRDCP8Z34	3.4	8	0.013
CP8Z39	CVRDCP8Z39	3.9	8	0.013
CP8Z45	CVRDCP8Z45	4.5	8	0.013
CP8Z50	CVRDCP8Z50	5.0	8	0.013
CP8Z55	CVRDCP8Z55	5.5	8	0.013
CP8Z60	CVRDCP8Z60	6.0	8	0.013
CP10Z39	CVRDCP10Z39	3.9	10	0.013
CP10Z45	CVRDCP10Z45	4.5	10	0.013
CP10Z50	CVRDCP10Z50	5.0	10	0.013
CP10Z55	CVRDCP10Z55	5.5	10	0.013
CP10Z60	CVRDCP10Z60	6.0	10	0.013

Stent Placement BIB*

REF	Balloon Diameter (mm)	Balloon Length (cm)	Introducer Size (FR)	Shaft Size (FR)	Usable Length (cm)	Guide Wire (Inches)	Outer Balloon Rated Burst (ATM)
BB003	12.0	2.5	8	8	110	0.035	7
BB006	12.0	3.0	8	8	110	0.035	7
BB009	12.0	3.5	8	8	110	0.035	7
BB033	12.0	4.0	8	8	110	0.035	7
BB037	12.0	4.5	8	8	110	0.035	7
BB034	12.0	5.0	8	8	110	0.035	7
BB051	12.0	5.5	8	8	110	0.035	7
BB022	14.0	2.5	8	8	110	0.035	6
BB052	14.0	3.0	8	8	110	0.035	6
BB025	14.0	3.5	8	8	110	0.035	6
BB038	14.0	4.0	8	8	110	0.035	6
BB035	14.0	4.5	8	8	110	0.035	6
BB039	14.0	5.0	8	8	110	0.035	6
BB053	14.0	5.5	8	8	110	0.035	6
BB054	15.0	2.5	9	9	110	0.035	5
BB055	15.0	3.0	9	9	110	0.035	5
BB056	15.0	3.5	9	9	110	0.035	5
BB057	15.0	4.0	9	9	110	0.035	5
BB058	15.0	4.5	9	9	110	0.035	5
BB059	15.0	5.0	9	9	110	0.035	5
BB060	15.0	5.5	9	9	110	0.035	5
BB023	16.0	2.5	9	9	110	0.035	5
BB010	16.0	3.0	9	9	110	0.035	5
BB026	16.0	3.5	9	9	110	0.035	5

Ordering Information

Stent Placement BIB*

REF	Balloon Diameter (mm)	Balloon Length (cm)	Introducer Size (FR)	Shaft Size (FR)	Usable Length (cm)	Guide Wire (Inches)	Outer Balloon Rated Burst (ATM)
BB013	16.0	4.0	9	9	110	0.035	5
BB016	16.0	4.5	9	9	110	0.035	5
BB028	16.0	5.0	9	9	110	0.035	5
BB019	16.0	5.5	9	9	110	0.035	5
BB024	18.0	2.5	10	9	110	0.035	4
BB040	18.0	3.0	10	9	110	0.035	4
BB027	18.0	3.5	10	9	110	0.035	4
BB041	18.0	4.0	10	9	110	0.035	4
BB029	18.0	4.5	10	9	110	0.035	4
BB030	18.0	5.0	10	9	110	0.035	4
BB031	18.0	5.5	10	9	110	0.035	4
BB011	20.0	3.0	10	9	110	0.035	4
BB042	20.0	3.5	10	9	110	0.035	4
BB014	20.0	4.0	10	9	110	0.035	4
BB017	20.0	4.5	10	9	110	0.035	4
BB032	20.0	5.0	10	9	110	0.035	4
BB020	20.0	5.5	10	9	110	0.035	4
BB061	22.0	3.0	11	9	110	0.035	3
BB062	22.0	3.5	11	9	110	0.035	3
BB063	22.0	4.0	11	9	110	0.035	3
BB064	22.0	4.5	11	9	110	0.035	3
BB065	22.0	5.0	11	9	110	0.035	3
BB066	22.0	5.5	11	9	110	0.035	3
BB012	24.0	3.0	11	9	110	0.035	3
BB067	24.0	3.5	11	9	110	0.035	3
BB015	24.0	4.0	11	9	110	0.035	3
BB018	24.0	4.5	11	9	110	0.035	3
BB036	24.0	5.0	11	9	110	0.035	3
BB021	24.0	5.5	11	9	110	0.035	3
BB077	24.0	6.0	11	9	110	0.035	3
BB068	26.0	4.0	16	11	110	0.035	3
BB069	26.0	5.0	16	11	110	0.035	3
BB070	26.0	6.0	16	11	110	0.035	3
BB071	28.0	4.0	16	11	110	0.035	2
BB072	28.0	5.0	16	11	110	0.035	2
BB073	28.0	6.0	16	11	110	0.035	2
BB074	30.0	4.0	16	11	110	0.035	2
BB075	30.0	5.0	16	11	110	0.035	2
BB076	30.0	6.0	16	11	110	0.035	2

Ordering Information**Mounted Bare CP Stent™ (MCP) and Covered Mounted CP Stent™ (CMCP)**

REF MCP	REF CMCP	Stent Length (cm)	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Introducer Size (FR)		Usable Length (cm)	Number of Zigs	Guide Wire (Inches)	Rated Burst (ATM)
					MCP	CMCP				
MCP001	CMCP001	1.6	12.0	2.5	10	12	110	8	0.035	7
MCP002	CMCP002	1.6	14.0	2.5	10	12	110	8	0.035	6
MCP003	CMCP003	1.6	16.0	2.5	11	12	110	8	0.035	5
MCP004	CMCP004	2.2	12.0	2.5	10	12	110	8	0.035	7
MCP005	CMCP005	2.2	14.0	2.5	10	12	110	8	0.035	6
MCP006	CMCP006	2.2	16.0	2.5	11	12	110	8	0.035	5
MCP007	CMCP007	2.2	18.0	2.5	11	14	110	8	0.035	4
MCP038	CMCP038	2.8	12.0	3.0	10	12	110	8	0.035	7
MCP008	CMCP008	2.8	14.0	3.0	10	12	110	8	0.035	6
MCP009	CMCP009	2.8	16.0	3.0	11	12	110	8	0.035	5
MCP010	CMCP010	2.8	18.0	3.0	11	14	110	8	0.035	4
MCP011	CMCP011	2.8	20.0	3.0	12	14	110	8	0.035	4
MCP035	CMCP035	3.4	12.0	3.5	10	12	110	8	0.035	7
MCP012	CMCP012	3.4	14.0	3.5	10	12	110	8	0.035	6
MCP013	CMCP013	3.4	16.0	3.5	11	12	110	8	0.035	5
MCP014	CMCP014	3.4	18.0	3.5	11	14	110	8	0.035	4
MCP015	CMCP015	3.4	20.0	3.5	12	14	110	8	0.035	4
MCP016	CMCP016	3.4	22.0	3.5	12	14	110	8	0.035	3
MCP036	CMCP036	3.9	12.0	4.0	10	12	110	8	0.035	7
MCP017	CMCP017	3.9	14.0	4.0	10	12	110	8	0.035	6
MCP018	CMCP018	3.9	16.0	4.0	11	12	110	8	0.035	5
MCP019	CMCP019	3.9	18.0	4.0	11	14	110	8	0.035	4
MCP020	CMCP020	3.9	20.0	4.0	12	14	110	8	0.035	4
MCP021	CMCP021	3.9	22.0	4.0	12	14	110	8	0.035	3
MCP022	CMCP022	3.9	24.0	4.0	12	14	110	8	0.035	3
MCP023	CMCP023	4.5	14.0	4.5	10	12	110	8	0.035	6
MCP024	CMCP024	4.5	16.0	4.5	11	12	110	8	0.035	5
MCP025	CMCP025	4.5	18.0	4.5	11	14	110	8	0.035	4
MCP026	CMCP026	4.5	20.0	4.5	12	14	110	8	0.035	4
MCP027	CMCP027	4.5	22.0	4.5	12	14	110	8	0.035	3
MCP028	CMCP028	4.5	24.0	4.5	12	14	110	8	0.035	3
MCP037	CMCP037	4.5	12.0	5.0	10	12	110	8	0.035	7
MCP029	CMCP029	4.5	14.0	5.0	10	12	110	8	0.035	6
MCP030	CMCP030	4.5	16.0	5.0	11	12	110	8	0.035	5
MCP031	CMCP031	4.5	18.0	5.0	11	14	110	8	0.035	4
MCP032	CMCP032	4.5	20.0	5.0	12	14	110	8	0.035	4
MCP033	CMCP033	4.5	22.0	5.0	12	14	110	8	0.035	3
MCP034	CMCP034	4.5	24.0	5.0	12	14	110	8	0.035	3

Ordering Information

Mounted Bare CP Stent™ (MCP) and Covered Mounted CP Stent™ (CMCP)										* NEW SIZES
REF MCP	REF CMCP	Stent Length (cm)	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Introducer Size (FR)		Usable Length (cm)	Number of Zigs	Guide Wire (Inches)	Rated Burst (ATM)
					MCP	CMCP				
MCP059	CMCP059	5.0	12.0	5.5	10	12	110	8	0.035	7
MCP060	CMCP060	5.0	14.0	5.5	10	12	110	8	0.035	6
MCP061	CMCP061	5.0	16.0	5.5	11	12	110	8	0.035	5
MCP062	CMCP062	5.0	18.0	5.5	11	14	110	8	0.035	4
MCP063	CMCP063	5.0	20.0	5.5	12	14	110	8	0.035	4
MCP064	CMCP064	5.0	22.0	5.5	12	14	110	8	0.035	3
MCP065	CMCP065	5.0	24.0	5.5	12	14	110	8	0.035	3
MCP066	CMCP066	5.5	12.0	6.0	10	12	110	8	0.035	7
MCP067	CMCP067	5.5	14.0	6.0	10	12	110	8	0.035	6
MCP068	CMCP068	5.5	16.0	6.0	11	12	110	8	0.035	5
MCP069	CMCP069	5.5	18.0	6.0	11	14	110	8	0.035	4
MCP070	CMCP070	5.5	20.0	6.0	12	14	110	8	0.035	4
MCP071	CMCP071	5.5	22.0	6.0	12	14	110	8	0.035	3
MCP072	CMCP072	5.5	24.0	6.0	12	14	110	8	0.035	3
MCP073	CMCP073	6.0	12.0	6.0	10	12	110	8	0.035	7
MCP074	CMCP074	6.0	14.0	6.0	10	12	110	8	0.035	6
MCP075	CMCP075	6.0	16.0	6.0	11	12	110	8	0.035	5
MCP076	CMCP076	6.0	18.0	6.0	11	14	110	8	0.035	4
MCP077	CMCP077	6.0	20.0	6.0	12	14	110	8	0.035	4
MCP078	CMCP078	6.0	22.0	5.0	12	14	110	8	0.035	3
MCP079	CMCP079	6.0	24.0	6.0	12	14	110	8	0.035	3
MCP040	CMCP040	3.9	26.0	4.0	16	16	110	10	0.035	3
MCP041	CMCP041	3.9	28.0	4.0	16	18	110	10	0.035	2
MCP042	CMCP042	3.9	30.0	4.0	16	18	110	10	0.035	2
MCP044	CMCP044	4.5	26.0	5.0	16	16	110	10	0.035	3
MCP045	CMCP045	4.5	28.0	5.0	16	18	110	10	0.035	2
MCP046	CMCP046	4.5	30.0	5.0	16	18	110	10	0.035	2
MCP048	CMCP048	5.0	26.0	5.5	16	16	110	10	0.035	3
MCP049	CMCP049	5.0	28.0	5.5	16	18	110	10	0.035	2
MCP050	CMCP050	5.0	30.0	5.5	16	18	110	10	0.035	2
MCP052	CMCP052	5.5	26.0	6.0	16	16	110	10	0.035	3
MCP053	CMCP053	5.5	28.0	6.0	16	18	110	10	0.035	2
MCP054	CMCP054	5.5	30.0	6.0	16	18	110	10	0.035	2
MCP056	CMCP056	6.0	26.0	6.0	16	16	110	10	0.035	3
MCP057	CMCP057	6.0	28.0	6.0	16	18	110	10	0.035	2
MCP058	CMCP058	6.0	30.0	6.0	16	18	110	10	0.035	2

Ordering Information**NuDEL™**

REF	Stent Length (cm)	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Introducer Size (FR)	Usable Length (cm)	Number of Zigs	Guide Wire (Inches)	Rated Burst (ATM)
DEL001	1.6	12	2.5	12	100	8	0.035	7
DEL002	1.6	14	2.5	12	100	8	0.035	6
DEL003	1.6	16	2.5	12	100	8	0.035	5
DEL004	2.2	12	2.5	12	100	8	0.035	7
DEL005	2.2	14	2.5	12	100	8	0.035	6
DEL006	2.2	16	2.5	12	100	8	0.035	5
DEL007	2.2	18	2.5	14	100	8	0.035	4
DEL008	2.8	14	3.0	12	100	8	0.035	6
DEL009	2.8	16	3.0	12	100	8	0.035	5
DEL010	2.8	18	3.0	14	100	8	0.035	4
DEL011	2.8	20	3.0	14	100	8	0.035	4
DEL012	3.4	14	3.5	12	100	8	0.035	6
DEL013	3.4	16	3.5	12	100	8	0.035	5
DEL014	3.4	18	3.5	14	100	8	0.035	4
DEL015	3.4	20	3.5	14	100	8	0.035	4
DEL016	3.4	22	3.5	14	100	8	0.035	3
DEL017	3.9	14	4.0	12	100	8	0.035	6
DEL018	3.9	16	4.0	12	100	8	0.035	5
DEL019	3.9	18	4.0	14	100	8	0.035	4
DEL020	3.9	20	4.0	14	100	8	0.035	4
DEL021	3.9	22	4.0	14	100	8	0.035	3
DEL022	3.9	24	4.0	14	100	8	0.035	3
DEL023	4.5	14	5.0	12	100	8	0.035	6
DEL024	4.5	16	5.0	12	100	8	0.035	5
DEL025	4.5	18	5.0	14	100	8	0.035	4
DEL026	4.5	20	5.0	14	100	8	0.035	4
DEL027	4.5	22	5.0	14	100	8	0.035	3
DEL028	4.5	24	5.0	14	100	8	0.035	3

References

BIB*

Percutaneous interventions of the aorta.

- *Gewillig M, Budts W, Boshoff D, Maleux G. Future Cardiology (2012); March; 8 (2): pp. 251-69.*

CP Stent® (Bare/Covered)

Stenting of aortic coarctation: acute, intermediate, and long-term results of a prospective multi-institutional registry - Congenital Cardiovascular Interventional Study Consortium (CCISC).

- *Holzer R, Qureshi S, Ghasemi A, Vincent J, Sievert H, Gruenstein D, Weber H, Alday L, Peirone A, Zellers T, Cheatham J, Slack M, Rome J. Catheterization and Cardiovascular Interventions (2010); October; 76 (4): pp. 553-63.*

Covered stents in patients with complex aortic coarctations.

- *Butera G, Piazza L, Chessa M, Negura DG, Rosti L, Abella R, Delogu A, Condoluci C, Magherini A, Carminati M. American Heart Journal (2007); October; 154 (4): pp. 795-800.*

Results and mid-long-term follow-up of stent implantation for native and recurrent coarctation of the aorta.

- *Chessa M, Carrozza M, Butera G, Piazza L, Negura DG, Bussadori C, Bossone E, Giamberti A, Carminati M. European Heart Journal (2005); December; 26 (24): pp. 2728-32.*

Initial experience using the NuMED Cheatham Platinum (CP) stent for interventional treatment of coarctation of the aorta in children and adolescents.

- *Haas NA, Lewin MA, Knirsch W, Nossal R, Ocker V, Uhlemann F. Zeitschrift für Kardiologie (2005); February; 94 (2): pp. 113-20.*

Immediate Outcomes of Covered Stent Placement for Treatment or Prevention of Aortic Wall Injury Associated With Coarctation of the Aorta (COAST II).

- *Taggart NW, Minahan M, Cabalka AK, Cetta F, Usmani K, Ringel RE; COAST II Investigators. JACC Cardiovasc Interv. 2016 March 14; 9(5): pp. 484-93*

Contact

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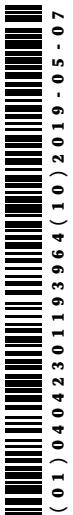
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CP Stent® Foreshortening Chart

Stent Configuration (Number of Zigs)	Inflated Balloon Diameter (mm)	Stent length (cm)								
		1.6	2.2	2.8	3.4	3.9	4.5	5.0	5.5	6.0
		Stent Length after expansion (Percentage Shortening)								
8	12	1.61 (2.8%)	2.18 (0.8%)	2.62 (4.4%)	3.23 (3.1%)	3.72 (1.9%)	4.17 (3.8%)	4.71 (6.2%)	5.25 (5.0%)	5.84 (4.5%)
	14	1.54 (6.5%)	2.08 (5.4%)	2.56 (6.8%)	3.15 (5.4%)	3.66 (3.6%)	3.97 (8.4%)	4.58 (8.7%)	5.11 (7.6%)	5.67 (7.3%)
	15	1.51 (8.5%)	2.02 (7.9%)	2.51 (8.6%)	3.10 (7.0%)	3.54 (6.6%)	3.94 (9.2%)	4.50 (10.3%)	4.98 (10.0%)	5.55 (9.2%)
	16	1.48 (10.6%)	1.98 (10.1%)	2.45 (10.7%)	3.00 (9.8%)	3.48 (8.2%)	3.84 (11.4%)	4.42 (11.9%)	4.91 (11.2%)	5.43 (11.2%)
	18	1.43 (13.7%)	1.89 (14.0%)	2.38 (13.3%)	2.88 (13.5%)	3.20 (15.6%)	3.71 (14.5%)	4.21 (16.1%)	4.70 (15.1%)	5.20 (14.9%)
	20	1.32 (20.0%)	1.80 (17.9%)	2.30 (16.3%)	2.63 (20.9%)	2.96 (21.9%)	3.27 (24.7%)	3.96 (21.0%)	4.43 (20.0%)	4.92 (19.5%)
	22	1.23 (25.4%)	1.67 (23.9%)	2.09 (24.0%)	2.46 (26.0%)	2.85 (25.0%)	3.15 (27.3%)	3.71 (26.0%)	4.09 (26.1%)	4.55 (25.5%)
	24	1.05 (36.4%)	1.46 (33.8%)	1.91 (30.3%)	2.07 (37.9%)	2.27 (40.1%)	2.83 (34.9%)	3.33 (33.5%)	3.72 (32.8%)	4.14 (32.3%)
10	26	-	-	-	-	3.17 (18.3%)	3.44 (22.1%)	4.10 (17.3%)	4.24 (23.3%)	4.85 (20.2%)
	28	-	-	-	-	2.96 (23.7%)	3.24 (26.8%)	3.71 (25.1%)	4.00 (27.6%)	4.39 (27.9%)
	30	-	-	-	-	2.58 (33.5%)	3.09 (30.2%)	3.26 (34.3%)	3.64 (34.2%)	4.11 (32.6%)

NuMED recommends using the BIB® Stent Placement Catheter

Required Introducer Size

BIB® delivery catheter balloon diameter and introducer size	Required introducer with Bare CP Stent™	Required introducer with Covered CP Stent™
12 mm (8FR)	10FR	12FR
14 mm (8FR)	10FR	12FR
15 mm (9FR)	11FR	12FR
16 mm (9FR)	11FR	12FR
18 mm (10FR)	11FR	14FR
20 mm (10FR)	12FR	14FR
22 mm (11FR)	12FR	14FR
24 mm (11FR)	12FR	14FR
26 mm (16FR)	16FR	16FR
28 mm (16FR)	16FR	18FR
30 mm (16FR)	16FR	18FR

CP Stent® Balloon Sizing Chart

INNER BALLOON	ATM	8 ZIG								10 ZIG		
		12 mm Ø	14 mm Ø	15 mm Ø	16 mm Ø	18 mm Ø	20 mm Ø	22 mm Ø	24 mm Ø	26 mm Ø	28 mm Ø	30 mm Ø
	1.0	2.75	3.22	3.49	3.75	3.94	4.02	4.20	4.28	10.25	10.94	11.96
	2.0	2.85	3.32	3.59	3.85	4.36	4.13	4.33	4.50	10.77	11.39	12.42
	3.0	5.85	6.91	6.89	7.79	8.54	9.20	10.16	10.57	11.27	11.87	12.89
	4.0	6.12	7.00	7.02	7.95	8.71	9.63	10.40	11.08	12.05	12.97	13.81
	4.5	-	-	-	-	-	-	10.84	11.94	-	-	-
	5.0	6.20	7.08	7.10	8.04	8.91	10.00	-	-	-	-	-
OUTER BALLOON	ATM	8 ZIG								10 ZIG		
		12 mm Ø	14 mm Ø	15 mm Ø	16 mm Ø	18 mm Ø	20 mm Ø	22 mm Ø	24 mm Ø	26 mm Ø	28 mm Ø	30 mm Ø
	0.5										22.85	24.84
	1.0	10.73	13.08	13.45	14.87	16.85	17.91	20.52	22.79	21.62	23.87	25.80
	1.5										24.87	26.81
	2.0	10.86	13.27	14.16	15.10	17.06	18.38	21.46	23.95	23.34	27.44	29.94
	3.0	11.15	13.50	14.55	15.68	17.64	19.42	21.98	24.68	25.44		
	4.0	11.33	13.68	14.88	15.93	18.06	20.07					
	5.0	11.62	13.87	15.06	16.19							
	6.0	11.80	13.98									
	7.0	12.04										

Represents the stent ID @ Rated Burst Pressure.