CP STENT™

Large Diameter, Balloon Expandable Stent

NuMED

Interventional Systems
B|BRAUN
SHARING EXPERTISE

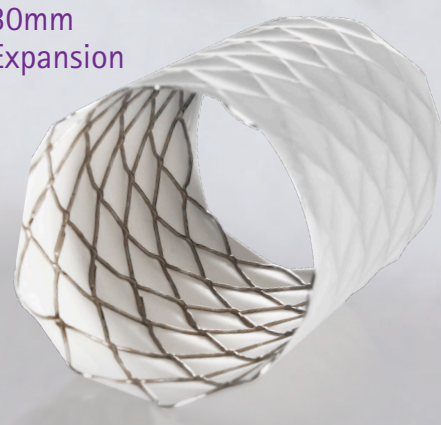
CP Stent™ Foreshortening Chart

Stent Length (cm)		1.6	2.2	2.8	3.4	3.9	4.5	5	5.5	6
Stent Configuration (number of zigs)	Inflated Balloon Diameter (mm)	Stent length after expansion (cm)	Stent length after expansion (cm)	Stent length after expansion (cm)	Stent length after expansion (cm)	Stent length after expansion (cm)	Stent length after expansion (cm)	Stent length after expansion (cm)	Stent length after expansion (cm)	Stent length after expansion (cm)
8 zig	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 zig	26					3.17 (18.33%)	3.44 (22.09%)	4.10 (17.34%)	4.24 (23.32%)	4.85 (20.20%)
	28					2.96 (23.68%)	3.24 (26.75%)	3.71 (25.11%)	4.00 (27.58%)	4.39 (27.87%)
	30					2.58 (33.45%)	3.09 (30.16%)	3.26 (34.34%)	3.64 (34.17%)	4.11 (32.55%)

Purple indicates percentage of shortening

8 zig
12mm to 24mm Expansion

10 zig
26mm to 30mm Expansion



CP Stent™ Balloon Sizing Chart

INNER BALLOON Balloon Pressure (atm)	8 zig Stent Configuration 12mm Diameter	14mm Diameter	15mm Diameter	16mm Diameter	18mm Diameter	20mm Diameter	22mm Diameter	24mm Diameter	10 zig Stent Configuration 26mm Diameter	28mm Diameter	30mm Diameter
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 Balloon Pressure (atm)	8 zig Stent Configuration 12mm Diameter	14mm Diameter	15mm Diameter	16mm Diameter	18mm Diameter	20mm Diameter	22mm Diameter	24mm Diameter	10 zig Stent Configuration 26mm Diameter	28mm Diameter	30mm Diameter
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.

*This data is based on testing performed using the BIB® Stent Placement Catheter.
FOR ALL NuMED CATHETERS AN INFLATION DEVICE WITH PRESSURE GAUGE SHOULD BE USED.

CP Stent™ Indications for Use:
The CP Stent is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving a compliant aortic isthmus or first segment of the descending aorta where there is adequate size and patency of at least one femoral artery and balloon angioplasty is contraindicated or predicted to be ineffective.

The Covered CP Stent is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta where there is adequate size and patency of at least one femoral artery associated with one or more of the following: acute or chronic wall injury; nearly atretic descending aorta of 3 mm or less in diameter; a non-compliant stenotic aortic segment found on pre-stent balloon dilation; a genetic or congenital syndrome associated with aortic wall weakening or ascending aortic aneurysm.

The Covered CP Stent is indicated for use in the 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.

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician. **Contraindications:** Clinical or biological signs of infection. Active endocarditis. Pregnancy. **Contraindications (CoA only):** Patients too small to allow safe delivery of the stent without compromise to the systemic artery used for delivery. Unfavorable aortic anatomy that does not dilate with high pressure balloon angioplasty. Curved vasculature. Occlusion or obstruction of systemic artery precluding delivery or the stent. Known allergy to aspirin, other antiplatelet agents, or heparin. **Contraindications (RVOT only):** Patients too small to allow safe delivery of the stent without injury to a systemic vein or to the right side of the heart. **Warnings / Precautions:** Radiofrequency heating during MRI scans on overlapped, 10 zig CP Stents has not been evaluated. Excessive force while crimping may weaken welds of the stent. Crimping the 8 zig stent on a balloon catheter smaller than 12mm, and the 10 zig on a balloon catheter smaller than 26mm, may cause damage to the stent. The stent is rigid and may make negotiation through vessels difficult. **Warnings / Precautions (CoA only):** Coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta should be confirmed by diagnostic imaging. The NuMED CP Stent has not been evaluated in patients weighing less than 20kg. As with any type of implant, infection secondary to contamination of the stent may lead to aortitis, or abscess. Over-stretching of the artery may result in rupture or aneurysm formation. **Warnings / Precautions (Covered CP Stent only):** Excessive handling and manipulation of the covering while crimping the stent may cause the covering to tear off of the stent. Crimping the device in the opposite direction of the folds in the covering may cause the covering to catch while inserting into the hemostasis tool and introducer. This could cause the covering to tear off the stent. Pulling the Covered stent back through the introducer and/or hemostasis valve may cause the covering to catch and tear off of the stent. **Warnings / Precautions (RVOT only):** During the Premarket Approval study the Medtronic Melody valve was used for valve restoration. The safety and effectiveness of the Covered CP Stent for pre-stenting of the right ventricular outflow tract (RVOT) landing zone (i.e. prophylaxis or prevention of either RVOT conduit rupture or TPVR fracture; use as a primary RVOT conduit) in preparation of a transcatheter pulmonary valve replacement (TPVR) has not been evaluated. As with any type of implant, infection secondary to contamination of the stent might lead to endocarditis, or abscess formation. The Covered Stent can migrate from the site of implant potentially causing obstruction to pulmonary artery flow. Over-stretching of the RVOT may result in rupture or aneurysm of the RV-PA conduit or the native pulmonary artery. The inflated diameter of the stent should at least equal the diameter of the intended implant site. **Reference the IFU for a complete listing of indications, contraindications, warnings and precautions. www.bisusa.org**

Rx only

CV-9045 1/18

~~LATEX~~ Not made with natural rubber latex
~~PVC~~ Not made with PVC
~~DEHP~~ Not made with DEHP
~~BPA~~ Not made with BPA

For more information or to place an order, contact your B. Braun Interventional Systems Inc. representative or call 1-877-836-2228.

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