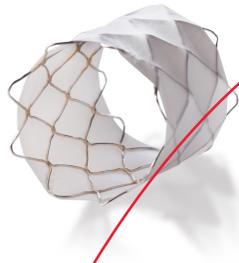


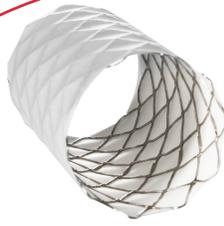
Covered CP Stent™

Coarctation of the Aorta and RVOT*

Available in 8 zig and 10 zig, unmounted or pre-mounted



8 ZIG
12mm to 24mm expansion



10 ZIG
26mm to 30mm expansion

Covered CP Stent™ Size Matrix

Configuration (Number of Zigs)	Diameter (mm)	Stent Length (cm)								
		1.6	2.2	2.8	3.4	3.9	4.5	5.0	5.5	6.0
8 ZIG	12	✓	✓	✓	✓	✓	✓	✓	✓	✓
	14	✓	✓	✓	✓	✓	✓	✓	✓	✓
	15	✓	✓	✓	✓	✓	✓	✓	✓	✓
	16	✓	✓	✓	✓	✓	✓	✓	✓	✓
	18	✓	✓	✓	✓	✓	✓	✓	✓	✓
	20	✓	✓	✓	✓	✓	✓	✓	✓	✓
	24	✓	✓	✓	✓	✓	✓	✓	✓	✓
10 ZIG	26					✓	✓	✓	✓	✓
	28					✓	✓	✓	✓	✓
	30					✓	✓	✓	✓	✓

Covered CP Stent™ Details

- Covered CP Stent™ is composed of 0.013" platinum-iridium wire arranged in either an 8 zig or 10 zig pattern that is laser welded at each joint and then over brazed with 24K gold. The stent is then covered with an expandable sleeve of ePTFE.
- The 8 zig configuration is expandable from 12mm - 24mm in diameter with lengths ranging from 1.6cm to 6.0cm
- The 10 zig configuration is expandable from 26mm - 30mm in diameter with lengths ranging from 3.9cm to 6.0cm
- The pre-mounted configuration is the Covered CP Stent™ mounted on a BIB® Catheter. This system will save the physician the time required to mount the stent on the catheter.

Stent Length (CM)	Configuration (Number of Zigs)	Covered Stent Catalog No.
1.6	8	CVRDCP8Z16
2.2	8	CVRDCP8Z22
2.8	8	CVRDCP8Z28
3.4	8	CVRDCP8Z34
3.9	8	CVRDCP8Z39
4.5	8	CVRDCP8Z45
5.0	8	CVRDCP8Z50
5.5	8	CVRDCP8Z55
6.0	8	CVRDCP8Z60
3.9	10	CVRDCP10Z39
4.5	10	CVRDCP10Z45
5.0	10	CVRDCP10Z50
5.5	10	CVRDCP10Z55
6.0	10	CVRDCP10Z60

Number of Zigs on Stent	BIB Delivery Catheter Balloon Diameter	Required Introducer with Covered CP Stent
8	12MM	12F
	14MM	12F
	15MM	12F
	16MM	12F
	18MM	14F
	20MM	14F
	24MM	14F
10	26MM	16F
	28MM	18F
	30MM	18F

NuMED recommends using the BIB Stent Placement Catheter

All of these stents are mounted by hand at NuMED, Inc. This may be critical in some cases of aneurysmal repair

Covered Mounted CP Stent System Specifications

Stent Length(cm)	Stent Configuration(Number of Zigs)	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Profile (Fr)	Rated Burst (ATM)	Covered Mounted CP Stent Catalog Number
1.6	8	12.0	2.5	12	7	CMCP001
1.6	8	14.0	2.5	12	6	CMCP002
1.6	8	16.0	2.5	12	5	CMCP003
2.2	8	12.0	2.5	12	7	CMCP004
2.2	8	14.0	2.5	12	6	CMCP005
2.2	8	16.0	2.5	12	5	CMCP006
2.2	8	18.0	2.5	14	4	CMCP007
2.8	8	12.0	3.0	12	7	CMCP038
2.8	8	14.0	3.0	12	6	CMCP008
2.8	8	16.0	3.0	12	5	CMCP009
2.8	8	18.0	3.0	14	4	CMCP010
2.8	8	20.0	3.0	14	4	CMCP011
3.4	8	12.0	3.5	12	7	CMCP035
3.4	8	14.0	3.5	12	6	CMCP012
3.4	8	16.0	3.5	12	5	CMCP013
3.4	8	18.0	3.5	14	4	CMCP014
3.4	8	20.0	3.5	14	4	CMCP015
3.4	8	22.0	3.5	14	3	CMCP016
3.9	8	12.0	4.0	12	7	CMCP036
3.9	8	14.0	4.0	12	6	CMCP017
3.9	8	16.0	4.0	12	5	CMCP018
3.9	8	18.0	4.0	14	4	CMCP019
3.9	8	20.0	4.0	14	4	CMCP020
3.9	8	22.0	4.0	14	3	CMCP021
3.9	8	24.0	4.0	14	3	CMCP022
4.5	8	14.0	4.5	12	6	CMCP023
4.5	8	16.0	4.5	12	5	CMCP024
4.5	8	18.0	4.5	14	4	CMCP025
4.5	8	20.0	4.5	14	4	CMCP026
4.5	8	22.0	4.5	14	3	CMCP027
4.5	8	24.0	4.5	14	3	CMCP028
4.5	8	12.0	5.0	12	7	CMCP037
4.5	8	14.0	5.0	12	6	CMCP029
4.5	8	16.0	5.0	12	5	CMCP030
4.5	8	18.0	5.0	14	4	CMCP031
4.5	8	20.0	5.0	14	4	CMCP032
4.5	8	22.0	5.0	14	3	CMCP033
4.5	8	24.0	5.0	14	3	CMCP034
5.0	8	12.0	5.5	12	7	CMCP059
5.0	8	14.0	5.5	12	6	CMCP060
5.0	8	16.0	5.5	12	5	CMCP061
5.0	8	18.0	5.5	14	4	CMCP062
5.0	8	20.0	5.5	14	4	CMCP063
5.0	8	22.0	5.5	14	3	CMCP064
5.0	8	24.0	5.5	14	3	CMCP065
5.5	8	12.0	6.0	12	7	CMCP066
5.5	8	14.0	6.0	12	6	CMCP067
5.5	8	16.0	6.0	12	5	CMCP068
5.5	8	18.0	6.0	14	4	CMCP069
5.5	8	20.0	6.0	14	4	CMCP070
5.5	8	22.0	6.0	14	3	CMCP071
5.5	8	24.0	6.0	14	3	CMCP072
6.0	8	12.0	6.0	12	7	CMCP073
6.0	8	14.0	6.0	12	6	CMCP074
6.0	8	16.0	6.0	12	5	CMCP075
6.0	8	18.0	6.0	14	4	CMCP076
6.0	8	20.0	6.0	14	4	CMCP077
6.0	8	22.0	6.0	14	3	CMCP078
6.0	8	24.0	6.0	14	3	CMCP079
3.9	10	26.0	4.0	16	3	CMCP040
3.9	10	28.0	4.0	18	2	CMCP041
3.9	10	30.0	4.0	18	2	CMCP042
4.5	10	26.0	5.0	16	3	CMCP044
4.5	10	28.0	5.0	18	2	CMCP045
4.5	10	30.0	5.0	18	2	CMCP046
5.0	10	26.0	5.5	16	3	CMCP048
5.0	10	28.0	5.5	18	2	CMCP049
5.0	10	30.0	5.5	18	2	CMCP050
5.5	10	26.0	6.0	16	3	CMCP052
5.5	10	28.0	6.0	18	2	CMCP053
5.5	10	30.0	6.0	18	2	CMCP054
6.0	10	26.0	6.0	16	3	CMCP056
6.0	10	28.0	6.0	18	2	CMCP057
6.0	10	30.0	6.0	18	2	CMCP058

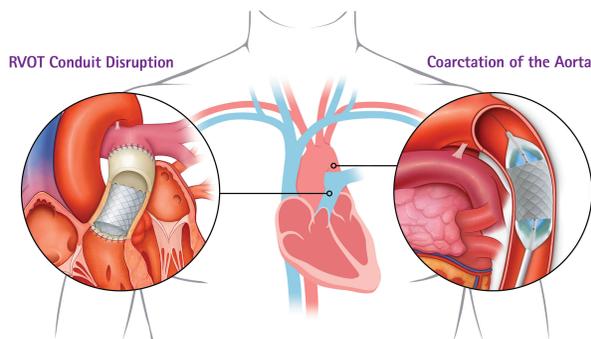


**10 ZIG
Covered CP Stent
mounted on a
BIB Catheter**

All catheters have a usable length of 110cm and use a 0.035" Guidewire

*Refer to the Instructions For Use for the complete listing of indication, contraindications, warnings, and precautions.

The Covered CP Stent™ and Covered Mounted CP Stent™
Approved for Treatment of:



Note: the Bare CP Stent™ is not approved for the treatment of RVOT conduit disruptions.

CP Stent® Balloon Sizing Chart

INNER BALLOON	Balloon Pressure (atm)	8 zig Stent Configuration								10 zig Stent Configuration		
		12mm Diameter	14mm Diameter	15mm Diameter	16mm Diameter	18mm Diameter	20mm Diameter	22mm Diameter	24mm Diameter	26mm Diameter	28mm Diameter	30mm Diameter
1	2.75	2.75	3.22	3.49	3.75	3.94	4.02	4.2	4.28	10.25	10.94	11.96
2	2.85	2.85	3.32	3.59	3.85	4.36	4.13	4.33	4.5	10.77	11.39	12.42
3	5.85	5.85	6.91	6.89	7.79	8.54	9.2	10.16	10.57	11.27	11.87	12.89
4	6.12	7	7	7.02	7.95	8.71	9.63	10.4	11.08	12.05	12.97	13.81
4.5								10.84	11.94			
5	6.2	7.08	7.1	8.04	8.91	10						

OUTER BALLOON	Balloon Pressure (atm)	8 zig Stent Configuration								10 zig Stent Configuration		
		12mm Diameter	14mm Diameter	15mm Diameter	16mm Diameter	18mm Diameter	20mm Diameter	22mm Diameter	24mm Diameter	26mm Diameter	28mm Diameter	30mm Diameter
0.5											22.85	24.84
1	10.73	13.08	13.45	14.87	16.85	17.91	20.52	22.79	21.62	23.87	25.8	
1.5										24.87	26.81	
2	10.86	13.27	14.16	15.1	17.06	18.38	21.46	23.95	23.34	27.44	29.94	
3	11.15	13.5	14.55	15.68	17.64	19.42	21.98	24.68	25.44			
4	11.33	13.68	14.88	15.93	18.06	20.07						
5	11.62	13.87	15.06	16.19								
6	11.8	13.98										
7	12.04											

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	5.5	6	
		Stent Length After Expansion (PERCENTAGE SHORTENING)									
8 ZIG	12	1.61cm (2.8%)	2.18cm (0.8%)	2.62cm (4.4%)	3.23cm (3.1%)	3.72cm (1.9%)	4.17cm (3.8%)	4.71cm (6.2%)	5.25cm (5.0%)	5.84cm (4.5%)	
	14	1.54cm (6.5%)	2.08cm (5.4%)	2.56cm (6.8%)	3.15cm (5.4%)	3.66cm (3.6%)	3.97cm (8.4%)	4.58cm (8.7%)	5.11cm (7.6%)	5.67cm (7.3%)	
	15	1.51cm (8.5%)	2.02cm (7.9%)	2.51cm (8.6%)	3.10cm (7.0%)	3.54cm (6.6%)	3.94cm (9.2%)	4.50cm (10.3%)	4.98cm (10.0%)	5.55cm (9.2%)	
	16	1.48cm (10.6%)	1.98cm (10.1%)	2.45cm (10.7%)	3.00cm (9.8%)	3.48cm (8.2%)	3.84cm (11.4%)	4.42cm (11.9%)	4.91cm (11.2%)	5.43cm (11.2%)	
	18	1.43cm (13.7%)	1.89cm (14.0%)	2.38cm (13.3%)	2.88cm (13.5%)	3.20cm (15.6%)	3.71cm (14.5%)	4.21cm (16.1%)	4.70cm (15.1%)	5.20cm (14.9%)	
	20	1.32cm (20.0%)	1.80cm (17.9%)	2.30cm (16.3%)	2.63cm (20.9%)	2.96cm (21.9%)	3.27cm (24.7%)	3.96cm (21.0%)	4.43cm (20.0%)	4.92cm (19.5%)	
	22	1.23cm (25.4%)	1.67cm (23.9%)	2.09cm (24.0%)	2.46cm (26.0%)	2.85cm (25.0%)	3.15cm (27.3%)	3.71cm (26.0%)	4.09cm (26.1%)	4.55cm (25.5%)	
	24	1.05cm (36.4%)	1.46cm (33.8%)	1.91cm (30.3%)	2.07cm (37.9%)	2.27cm (40.1%)	2.83cm (34.9%)	3.33cm (33.5%)	3.72cm (32.8%)	4.14cm (32.3%)	
10 Zig	26					3.17cm (18.33%)	3.44cm (22.09%)	4.10cm (17.34%)	4.24cm (23.32%)	4.85cm (20.20%)	
	28					2.96cm (23.68%)	3.24cm (26.75%)	3.71cm (25.11%)	4.00cm (27.58%)	4.39cm (27.87%)	
	30					2.58cm (33.45%)	3.09cm (30.16%)	3.26cm (34.34%)	3.64cm (34.17%)	4.11cm (32.55%)	

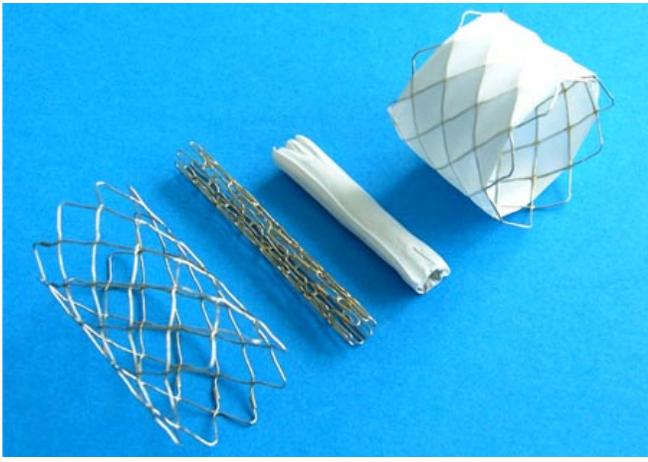
SAFETY AND EFFECTIVENESS CLINICAL DATA:

Coarctation Of the Aorta Stent Trial (COAST: NCT00552812) The CP Stent® was tested and found to be safe and effective to widen the narrow part of the aorta related to coarctation of the aorta.

Covered CP Stents for the Prevention or Treatment of Aortic Wall Injury Associated With Coarctation of the Aorta (COASTII: NCT 01278303) The Covered CP Stent® was tested and found to be safe and effective to repair aortic wall injuries and widen the narrow part of the aorta related to coarctation of the aorta.

Pulmonary Artery Repair With Covered Stents (PARCS: NCT01824160) The Covered CP Stent® was tested and found to be safe and effective to use as a 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 (TPVR).

Reference the IFU for a complete listing of indications, contraindications, warnings and precautions.



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