For treatment of Coarctation of the Aorta and
Right Ventricular Outflow Tract Conduit Disruption

NuMED For Children

Interventional Systems
B|BRAUN
SHARING EXPERTISE

G-ARMOR STENT® PORTFOLIO

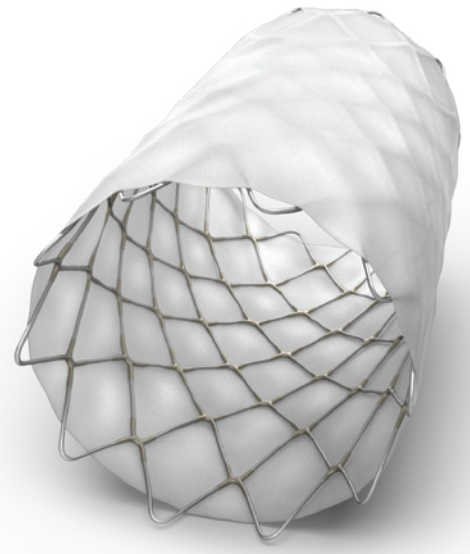
Part of the CP Stent® Family

Large Diameter, Balloon Expandable Stent

G-ARMOR Stent® Foreshortening Chart

G-ARMOR Stent® (Bare) and G-ARMOR Covered Stent™ Foreshortening Chart

Stent Configuration (zig)	Inflated Balloon Diameter (mm)	Stent Length Before Expansion			
		4.6cm	5.2cm	5.7cm	6.3cm
		Stent Length After Expansion Percentage Foreshortening			
8 zig	12	4.43cm 3.61%	4.98cm 3.43%	5.49cm 3.62%	6.02cm 4.08%
	14	4.37cm 4.92%	4.91cm 4.83%	5.39cm 5.32%	5.92cm 5.66%
	15	4.32cm 6.05%	4.85cm 6.00%	5.33cm 6.39%	5.85cm 6.71%
	16	4.27cm 7.07%	4.80cm 6.87%	5.26cm 7.54%	5.77cm 7.96%
	18	4.16cm 9.41%	4.66cm 9.66%	5.13cm 9.95%	5.64cm 10.15%
	20	4.03cm 12.30%	4.54cm 12.00%	4.95cm 13.01%	5.44cm 13.36%
	22	3.91cm 14.99%	4.37cm 15.25%	4.77cm 16.27%	5.23cm 16.58%
	24	3.75cm 18.37%	4.15cm 19.60%	4.53cm 20.38%	4.98cm 20.54%
10 zig	26	3.97cm 14.14%	4.43cm 14.70%	4.89cm 14.79%	5.33cm 15.23%
	28	3.85cm 16.76%	4.31cm 17.04%	4.72cm 17.77%	5.14cm 18.25%
	30	3.74cm 19.15%	4.16cm 19.90%	4.56cm 20.51%	4.94cm 21.44%



8 zig
12.0 - 24.0mm expansion

10 zig
26.0 - 30.0mm expansion

G-ARMOR Stent® Balloon Sizing Chart

	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
INNER BALLOON	1.0	4.5	5.73	5.59	6.47	7.37	7.97	8.72	9.57	11.35	12.29	12.79
	2.0	4.84	5.99	5.78	6.85	7.58	8.31	9.22	10.15	11.91	12.99	13.37
	3.0	5.03	6.18	6.06	7.17	7.91	8.77	9.83	10.67	12.4	13.5	14.07
	4.0	5.3	6.36	6.31	7.5	8.33	9.22	10.37	11.17	12.98	14.27	14.61
	4.5							10.79	11.71			
	5.0	5.54	6.56	6.59	7.94	8.77	9.81					

	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
OUTER BALLOON	1.0	10.09	12.13	13.54	14.23	16.48	18.24	19.87	21.66	23.78	26.57	28.62
	2.0	10.64	12.61	14.03	14.77	17.07	19.09	20.77	22.78	25.08	28.27	30.12
	3.0	11.08	13.13	14.7	15.34	17.76	19.89	22.22	24.05	26.33		
	4.0	11.64	13.6	15.02	15.87	18.34	20.59					
	5.0	12.09	14.05	15.53	16.46							
	6.0	12.34	14.37									
	7.0	12.62										

This data is based on testing performed using the BIB® Stent Placement Catheter.

Represents the stent ID @ Rated Burst Pressure.

G-ARMOR Stent® Indications for Use:

Indications

G-ARMOR Stent®, G-ARMOR Covered Stent™, G-ARMOR Mounted Stent™, G-ARMOR Covered Mounted Stent™

The G-Armor 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 G-ARMOR Covered 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 G-ARMOR Covered 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 G-ARMOR 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 G-ARMOR 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 (G-ARMOR Covered 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 G-ARMOR 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. and/or hemostasis valve may cause the covering to catch and tear off of the stent.

Rx Only.

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

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