NuMED For Children

Interventional Systems
B BRAUN
SHARING EXPERTISE

G-ARMOR STENT® PORTFOLIO

Part of the CP Stent® Family

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

Treat a Broader Range of Patients

G-ARMOR STENT®

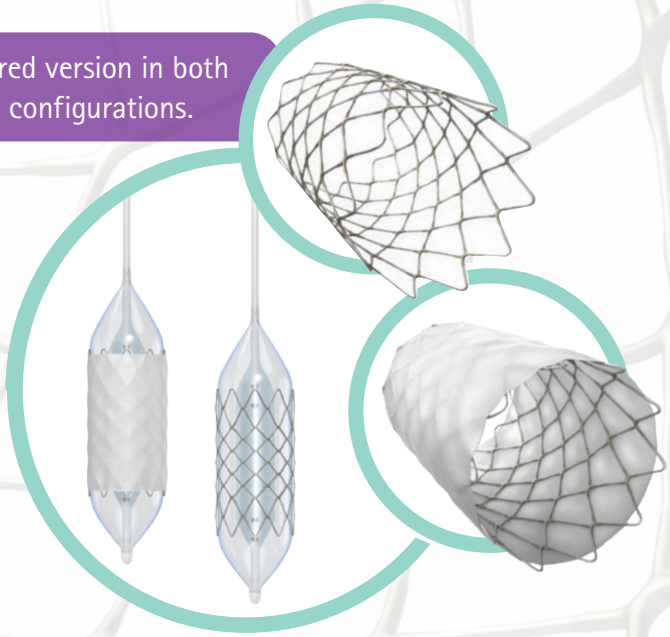
The G-ARMOR Stent®, part of the CP Stent® Family, is the latest large diameter, balloon expandable stent technology.

Composed of platinum-iridium wire arranged in a unique, laser welded 8 or 10 "zig" pattern and over brazed with 24K gold.

Available in a Bare and an Expandable ePTFE Covered version in both Pre-Mounted (on a BIB® Catheter) and Unmounted configurations.

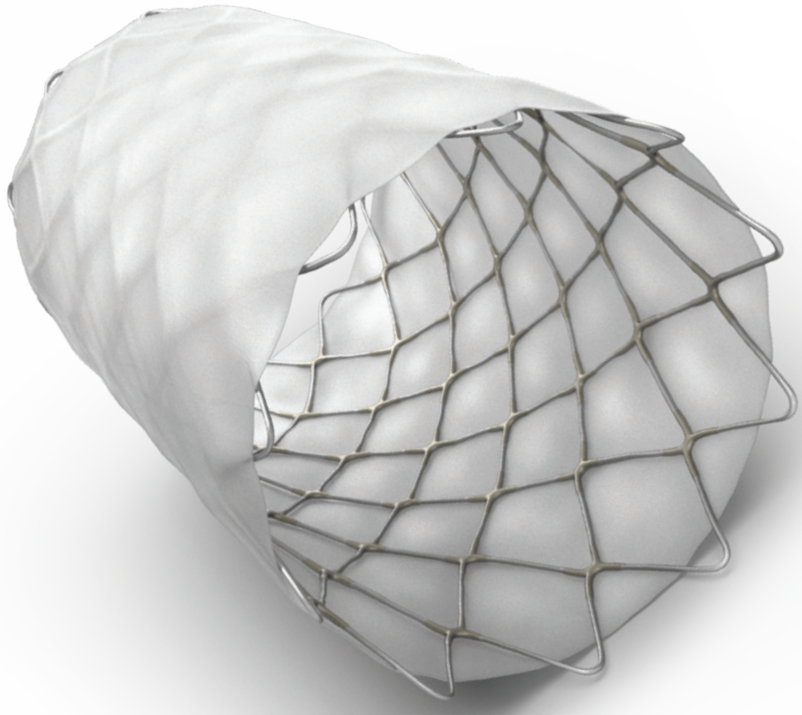
The G-ARMOR Stent® is compatible with introducers ranging from 13 - 18F.

12.0mm – 30.0mm stent diameters
4.6cm – 6.3cm stent lengths



G-ARMOR Stent® Portfolio

B. Braun Interventional Systems offers a comprehensive portfolio that complements the proven and trusted original CP Stent® and BIB® Catheter platforms designed to optimize the long-term, effective, accurate and efficient treatment of Coarctation of the Aorta and RVOT Conduit Disruption.



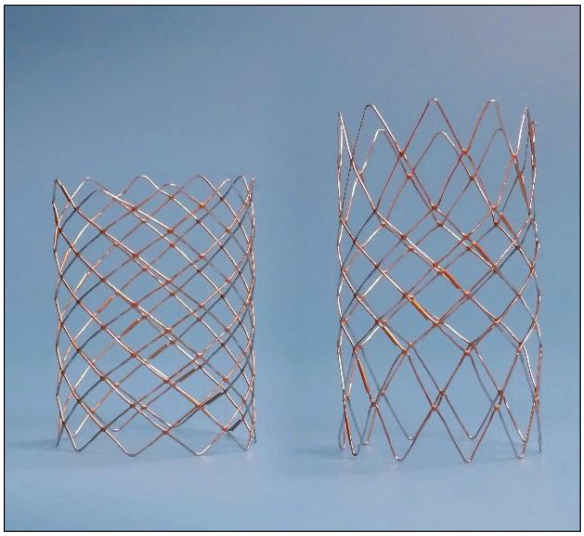
G-ARMOR STENT®

Offers Considerable Capacity for Expansion to Accommodate a Patient's Natural Growth and Potentially Reduce the Need for Additional Stent Implantation:

- The 8 zig G-ARMOR Covered Stent™ has an expansion range of 12.0 - 24.0mm
- The 10 zig G-ARMOR Covered Stent™ has an expansion range of 26.0 - 30.0mm

G-ARMOR Covered Stent™	
Expansion Diameter (mm)	Recommended Introducer Size (Fr)
12	14
14	14
15	14
16	14
18	14
20	16
22	16
24	16
26	16
28	18
30	18

G-ARMOR Stent® (Bare)	
Expansion Diameter (mm)	Recommended Introducer Size (Fr)
12	13
14	13
15	13
16	14
18	14
20	14
22	14
24	14
26	16
28	16
30	16



G-ARMOR Stent® Wire Loop pattern versus first generation CP Stent® pattern supports a significantly improved foreshortening profile.*

Predictably Maintains Stent Lengths Post-Expansion

- Compared with the CP Stent®, even at max dilatation, the G-ARMOR Stent® maintains a greater than 13% longer stent length after expansion allowing you to potentially treat a broader range of patients.*

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%

* Data on file. B. Braun Interventional Systems (2022). CP Stent versus G-ARMOR Stent Foreshortening Data.

G-ARMOR STENT®

Ability to Differentially Flare

- The intentional distribution of larger wire loops at either end of the G-ARMOR Stent confers an intrinsic ability to produce an hour-glass conformation when dilating the stent with compliant balloons.
- Flaring may improve tissue apposition and help manage dissection and pseudoaneurysm.*

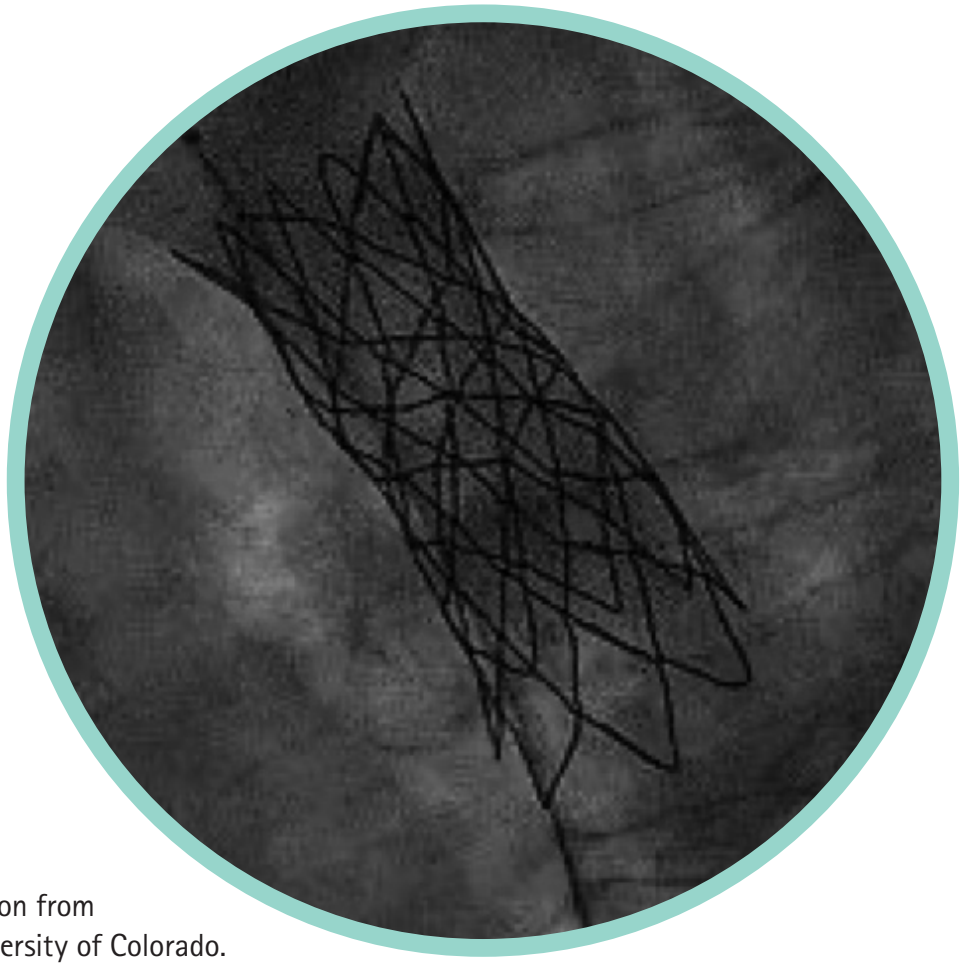


Image used with permission from
Gareth Morgan, MD, University of Colorado.

* Morgan, Gareth. G-ARMOR Stent [Lecture]. 32nd Annual Scientific Meeting of the Japanese Congenital Interventional Cardiology Society. 2021.

ORDERING INFORMATION

G-ARMOR Covered Stent™

Stent Length (cm)	Reference Number	
	8 zig 12-24mm	10 zig 26-30mm
4.6	614815	614811
5.2	614816	614812
5.7	614817	614813
6.3	614818	614814

G-ARMOR Stent® (Bare) (MADE TO ORDER - 6-8 WEEK LEAD)

Stent Length (cm)	Reference Number	
	8 zig 12-24mm	10 zig 26-30mm
4.6	614719	614715
5.2	614720	614716
5.7	614721	614717
6.3	614722	614718

G-ARMOR Mounted Stent™ and G-ARMOR Covered Mounted Stent™ (MADE TO ORDER - 6-8 WEEK LEAD)

Reference Number G-ARMOR Mounted Stent™	Reference Number G-ARMOR Covered Mounted Stent™	Stent Length (cm)	Zig	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Usable Length (cm)	Guide Wire (In)	Rated Burst (ATM)
614767	614723	4.6	8	12	5	110	0.035	7
614768	614724	4.6	8	14	5	110	0.035	6
614769	614725	4.6	8	15	5	110	0.035	5
614770	614726	4.6	8	16	5	110	0.035	5
614771	614727	4.6	8	18	5	110	0.035	4
614772	614728	4.6	8	20	5	110	0.035	4
614773	614729	4.6	8	22	5	110	0.035	3
614774	614730	4.6	8	24	5	110	0.035	3
614775	614731	5.2	8	12	5.5	110	0.035	7
614776	614732	5.2	8	14	5.5	110	0.035	6
614777	614733	5.2	8	15	5.5	110	0.035	5
614778	614734	5.2	8	16	5.5	110	0.035	5
614779	614735	5.2	8	18	5.5	110	0.035	4
614780	614736	5.2	8	20	5.5	110	0.035	4
614781	614737	5.2	8	22	5.5	110	0.035	3
614782	614738	5.2	8	24	5.5	110	0.035	3
614783	614739	5.7	8	12	6	110	0.035	7
614784	614740	5.7	8	14	6	110	0.035	6
614785	614741	5.7	8	15	6	110	0.035	5
614786	614742	5.7	8	16	6	110	0.035	5
614787	614743	5.7	8	18	6	110	0.035	4
614788	614744	5.7	8	20	6	110	0.035	4
614789	614745	5.7	8	22	6	110	0.035	3
614790	614746	5.7	8	24	6	110	0.035	3
614791	614747	6.3	8	12	6.5	110	0.035	7
614792	614748	6.3	8	14	6.5	110	0.035	6
614793	614749	6.3	8	15	6.5	110	0.035	5
614794	614750	6.3	8	16	6.5	110	0.035	5
614795	614751	6.3	8	18	6.5	110	0.035	4
614796	614752	6.3	8	20	6.5	110	0.035	4
614797	614753	6.3	8	22	6.5	110	0.035	3
614798	614754	6.3	8	24	6.5	110	0.035	3
614799	614755	4.6	10	26	5	110	0.035	3
614800	614756	4.6	10	28	5	110	0.035	2
614801	614757	4.6	10	30	5	110	0.035	2
614802	614758	5.2	10	26	5.5	110	0.035	3
614803	614759	5.2	10	28	5.5	110	0.035	2
614804	614760	5.2	10	30	5.5	110	0.035	2
614805	614761	5.7	10	26	6	110	0.035	3
614806	614762	5.7	10	28	6	110	0.035	2
614807	614763	5.7	10	30	6	110	0.035	2
614808	614764	6.3	10	26	6.5	110	0.035	3
614809	614765	6.3	10	28	6.5	110	0.035	2
614810	614766	6.3	10	30	6.5	110	0.035	2

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 have 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.

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

Distributed by:
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Rx Only.

CV-2094 5/22