Interventional Systems
B|BRAUN
SHARING EXPERTISE

CV-2069 8/21

LATEX Not made with natural rubber latex

DEHP Not made with DEHP

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NuMED

Interventional Systems
B|BRAUN
SHARING EXPERTISE

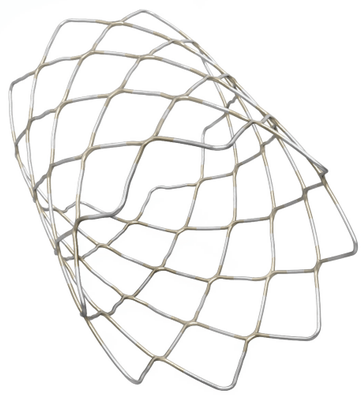
CP STENT® PORTFOLIO

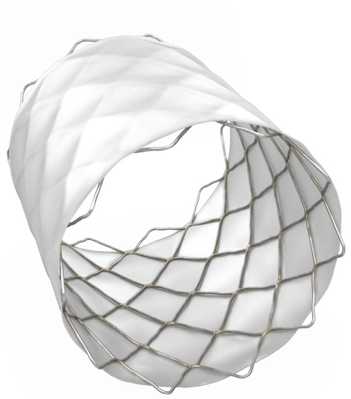
For Treatment of Coarctation of the Aorta and Right Ventricular Outflow Tract Conduit Disruption

CP STENT® PORTFOLIO

CP Stent®

- Large diameter, balloon expandable stent
- Composed of platinum-iridium wire arranged in either an 8 or 10 “zig” pattern
- Available bare or covered with an expandable sleeve of ePTFE
- 12mm–30mm stent diameters
- 1.6cm–6.0cm stent lengths





BIB® Catheter

- Balloon in Balloon (BIB) catheter for CP Stent placement
- Allows for controlled and incremental stent expansion
- Inner balloon acts as a tool to hold the stent in place while outer balloon is inflated
- Four image bands to define the working length of the inner and outer balloon

Pre-mounted CP Stent®

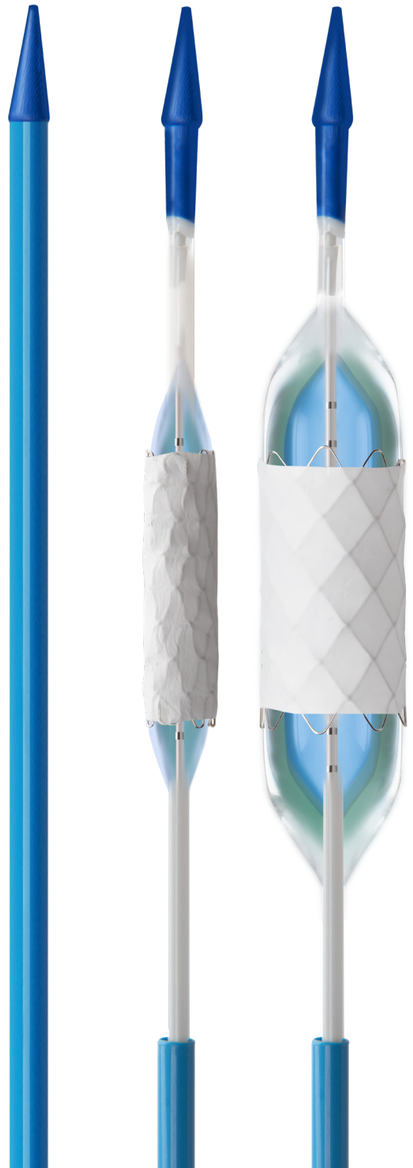
- CP Stent pre-mounted on a BIB catheter
- Eliminates the need to hand crimp the stent on a catheter
- Available bare and covered in 8 zig and 10 zig configurations

D’VILL™ Introducer

- Long length hemostasis introducer
- Braided sheath for optimal kink-resistance
- Compatible with CP Stent and BIB Catheters requiring a 12Fr or 14Fr introducer
- Available in 30cm, 65cm and 85cm lengths

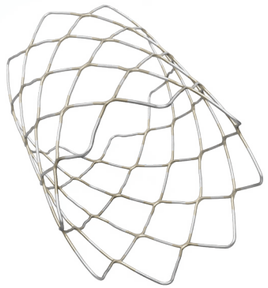
NuDEL™ CP Stent® Delivery System

- Integrated sheath eliminates the need for a separate introducer and protects the stent during delivery
- Pre-loaded system eliminates the need to hand crimp or load the mounted stent into an introducer
- Soft, atraumatic, tapered catheter tip allows for safe tracking through the vasculature



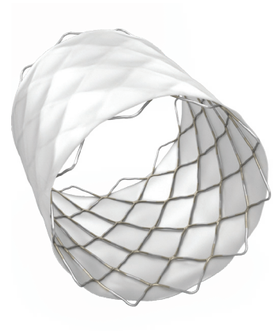
ORDERING INFORMATION

CP Stent® (Bare)



Stent length (cm)	Reference Number: 8 zig 12mm - 24mm	Reference Number: 10 zig 26mm - 30mm	Expansion Diameter (mm)	Recommended Introducer Size (Fr)
1.6	614300	N/A	12	10
2.2	614301	N/A	14	10
2.8	614302	N/A	15	11
3.4	614303	N/A	16	11
3.9	614304	614470	18	12
4.5	614305	614471	20	12
5.0	614511	614472	22	12
5.5	614512	614473	24	12
6.0	614513	614474	26	16
			28	16
			30	16

Covered CP Stent™



Stent Length (cm)	Reference Number: 8 zig 12mm - 24mm	Reference Number: 10 zig 26mm - 30mm	Expansion Diameter (mm)	Recommended Introducer Size (Fr)
1.6	614306	N/A	12	12
2.2	614307	N/A	14	12
2.8	614308	N/A	15	12
3.4	614309	N/A	16	12
3.9	614310	614510	18	14
4.5	614311	614476	20	14
5.0	614514	614477	22	14
5.5	614515	614478	24	14
6.0	614516	614479	26	16
			28	18
			30	18

CLINICAL EVIDENCE

- **Coarctation Of the Aorta Stent Trial (COAST) – Clinical Trial: 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) – Clinical Trial: NCT01278303**
  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) – Clinical Trial: 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).

ORDERING INFORMATION

INNER BALLOON IS 1/2 THE DIAMETER OF THE OUTER BALLOON

INNER BALLOON IS 1CM SHORTER THAN THE OUTER BALLOON

BIB® (Balloon in Balloon) CP Stent® Placement Catheter

Reference Number	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Outer Rated Burst Pressure (atm)	Inner Balloon Diameter (mm)	Inner Balloon Length (cm)	Inner Rated Burst Pressure (atm)	Intro Size (Fr)	Shaft Size (Fr)
614402	12.0	2.5	7.0	6.0	1.5	5.0	8.0	8.0
614403	12.0	3.0	7.0	6.0	2.0	5.0	8.0	8.0
614404	12.0	3.5	7.0	6.0	2.5	5.0	8.0	8.0
614405	12.0	4.0	7.0	6.0	3.0	5.0	8.0	8.0
614406	12.0	4.5	7.0	6.0	3.5	5.0	8.0	8.0
614407	12.0	5.0	7.0	6.0	4.0	5.0	8.0	8.0
614408	12.0	5.5	7.0	6.0	4.5	5.0	8.0	8.0
614409	14.0	2.5	6.0	7.0	1.5	5.0	8.0	8.0
614410	14.0	3.0	6.0	7.0	2.0	5.0	8.0	8.0
614411	14.0	3.5	6.0	7.0	2.5	5.0	8.0	8.0
614412	14.0	4.0	6.0	7.0	3.0	5.0	8.0	8.0
614413	14.0	4.5	6.0	7.0	3.5	5.0	8.0	8.0
614414	14.0	5.0	6.0	7.0	4.0	5.0	8.0	8.0
614415	14.0	5.5	6.0	7.0	4.5	5.0	8.0	8.0
614416	15.0	2.5	5.0	7.0	1.5	5.0	9.0	9.0
614417	15.0	3.0	5.0	7.0	2.0	5.0	9.0	9.0
614418	15.0	3.5	5.0	7.0	2.5	5.0	9.0	9.0
614419	15.0	4.0	5.0	7.0	3.0	5.0	9.0	9.0
614458	15.0	4.5	5.0	7.0	3.5	5.0	9.0	9.0
614421	15.0	5.0	5.0	7.0	4.0	5.0	9.0	9.0
614422	15.0	5.5	5.0	7.0	4.5	5.0	9.0	9.0
614423	16.0	2.5	5.0	8.0	1.5	5.0	9.0	9.0
614424	16.0	3.0	5.0	8.0	2.0	5.0	9.0	9.0
614425	16.0	3.5	5.0	8.0	2.5	5.0	9.0	9.0
614426	16.0	4.0	5.0	8.0	3.0	5.0	9.0	9.0
614427	16.0	4.5	5.0	8.0	3.5	5.0	9.0	9.0
614428	16.0	5.0	5.0	8.0	4.0	5.0	9.0	9.0
614429	16.0	5.5	5.0	8.0	4.5	5.0	9.0	9.0
614627	16.0	6.0	5.0	8.0	5.0	5.0	9.0	9.0
614628	16.0	6.5	5.0	8.0	5.5	5.0	9.0	9.0
614430	18.0	2.5	4.0	9.0	1.5	5.0	10.0	9.0
614431	18.0	3.0	4.0	9.0	2.0	5.0	10.0	9.0
614432	18.0	3.5	4.0	9.0	2.5	5.0	10.0	9.0
614433	18.0	4.0	4.0	9.0	3.0	5.0	10.0	9.0
614434	18.0	4.5	4.0	9.0	3.5	5.0	10.0	9.0
614435	18.0	5.0	4.0	9.0	4.0	5.0	10.0	9.0
614436	18.0	5.5	4.0	9.0	4.5	5.0	10.0	9.0
614629	18.0	6.0	4.0	9.0	5.0	5.0	10.0	9.0
614630	18.0	6.5	4.0	9.0	5.5	5.0	10.0	9.0
614437	20.0	3.0	4.0	10.0	2.0	5.0	10.0	9.0
614438	20.0	3.5	4.0	10.0	2.5	5.0	10.0	9.0
614439	20.0	4.0	4.0	10.0	3.0	5.0	10.0	9.0
614440	20.0	4.5	4.0	10.0	3.5	5.0	10.0	9.0
614441	20.0	5.0	4.0	10.0	4.0	5.0	10.0	9.0
614442	20.0	5.5	4.0	10.0	4.5	5.0	10.0	9.0
614631	20.0	6.0	4.0	10.0	5.0	5.0	10.0	9.0
614632	20.0	6.5	4.0	10.0	5.5	5.0	10.0	9.0
614443	22.0	3.0	3.0	11.0	2.0	4.5	11.0	9.0
614444	22.0	3.5	3.0	11.0	2.5	4.5	11.0	9.0
614445	22.0	4.0	3.0	11.0	3.0	4.5	11.0	9.0
614446	22.0	4.5	3.0	11.0	3.5	4.5	11.0	9.0
614447	22.0	5.0	3.0	11.0	4.0	4.5	11.0	9.0
614448	22.0	5.5	3.0	11.0	4.5	4.5	11.0	9.0
614633	22.0	6.0	3.0	11.0	5.0	4.5	11.0	9.0
614634	22.0	6.5	3.0	11.0	5.5	4.5	11.0	9.0

All BIB catheters have a usable length of 110cm and 0.035" guidewire compatibility.

BIB® (Balloon in Balloon) CP Stent® Placement Catheter *(continued)*

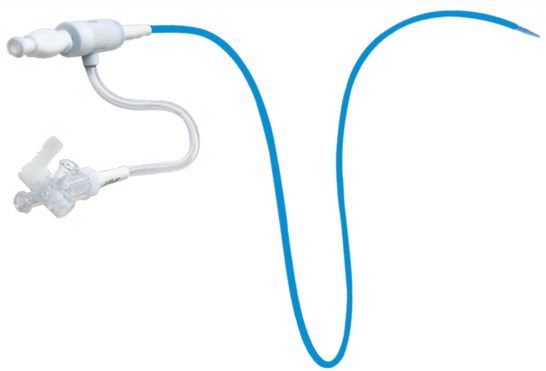
Reference Number	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Outer Rated Burst Pressure (atm)	Inner Balloon Diameter (mm)	Inner Balloon Length (cm)	Inner Rated Burst Pressure (atm)	Intro Size (Fr)	Shaft Size (Fr)
614449	24.0	3.0	3.0	12.0	2.0	4.5	11.0	9.0
614450	24.0	3.5	3.0	12.0	2.5	4.5	11.0	9.0
614451	24.0	4.0	3.0	12.0	3.0	4.5	11.0	9.0
614452	24.0	4.5	3.0	12.0	3.5	4.5	11.0	9.0
614453	24.0	5.0	3.0	12.0	4.0	4.5	11.0	9.0
614454	24.0	5.5	3.0	12.0	4.5	4.5	11.0	9.0
614469	24.0	6.0	3.0	12.0	5.0	4.5	11.0	9.0
614635	24.0	6.5	3.0	12.0	5.5	4.5	11.0	9.0
614459	26.0	4.0	3.0	13.0	3.0	4.0	16.0	11.0
614460	26.0	5.0	3.0	13.0	4.0	4.0	16.0	11.0
614461	26.0	6.0	3.0	13.0	5.0	4.0	16.0	11.0
614636	26.0	6.5	3.0	13.0	5.5	4.0	16.0	11.0
614462	28.0	4.0	2.0	14.0	3.0	4.0	16.0	11.0
614463	28.0	5.0	2.0	14.0	4.0	4.0	16.0	11.0
614464	28.0	6.0	2.0	14.0	5.0	4.0	16.0	11.0
614637	28.0	6.5	2.0	14.0	5.5	4.0	16.0	11.0
614465	30.0	4.0	2.0	15.0	3.0	4.0	16.0	11.0
614466	30.0	5.0	2.0	15.0	4.0	4.0	16.0	11.0
614467	30.0	6.0	2.0	15.0	5.0	4.0	16.0	11.0
614638	30.0	6.5	2.0	15.0	5.5	4.0	16.0	11.0

All BIB catheters have a usable length of 110cm and 0.035" guidewire compatibility.

D'VILL™ Introducer

Reference Number	Sheath Size (Fr)	Usable Length (cm)	Guidewire Compatibility (in)
612841	12	30	0.035
612846	12	65	0.035
612844	12	85	0.035
612842	14	30	0.035
612847	14	65	0.035
612845	14	85	0.035

Each D'VILL set includes (1) one sheath and (1) one dilator.



Covered Mounted CP Stent™

Reference Number	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Outer Rated Burst Pressure (atm)	Inner Balloon Diameter (mm)	Inner Balloon Length (cm)	Inner Rated Burst Pressure (atm)	Stent Configuration (number of zigs)	Profile (Fr)	Stent Length (cm)
614387	12	3.0	7.0	6	2.0	5.0	8	12	2.8
614552	12	6.0	7.0	6	5.0	5.0	8	12	6.0
614357	14	3.0	6.0	7	2.0	5.0	8	12	2.8
614361	14	3.5	6.0	7	2.5	5.0	8	12	3.4
614366	14	4.0	6.0	7	3.0	5.0	8	12	3.9
614553	14	6.0	6.0	7	5.0	5.0	8	12	6.0
614358	16	3.0	5.0	8	2.0	5.0	8	12	2.8
614362	16	3.5	5.0	8	2.5	5.0	8	12	3.4
614367	16	4.0	5.0	8	3.0	5.0	8	12	3.9
614373	16	4.5	5.0	8	3.5	5.0	8	12	4.5
614554	16	6.0	5.0	8	5.0	5.0	8	12	6.0
614359	18	3.0	4.0	9	2.0	5.0	8	14	2.8
614363	18	3.5	4.0	9	2.5	5.0	8	14	3.4
614368	18	4.0	4.0	9	3.0	5.0	8	14	3.9
614374	18	4.5	4.0	9	3.5	5.0	8	14	4.5
614555	18	6.0	4.0	9	5.0	5.0	8	14	6.0
614369	20	4.0	4.0	10	3.0	5.0	8	14	3.9
614375	20	4.5	4.0	10	3.5	5.0	8	14	4.5
614556	20	6.0	4.0	10	5.0	5.0	8	14	6.0
614370	22	4.0	3.0	11	3.0	4.5	8	14	3.9
614382	22	5.0	3.0	11	4.0	4.5	8	14	4.5
614557	22	6.0	3.0	11	5.0	4.5	8	14	6.0
614371	24	4.0	3.0	12	3.0	4.5	8	14	3.9
614383	24	5.0	3.0	12	4.0	4.5	8	14	4.5
614498	26	5.0	3.0	13	4.0	4.0	10	16	4.5
614501	26	5.5	3.0	13	4.5	4.0	10	16	5.0
614507	26	6.0	3.0	13	5.0	4.0	10	16	6.0
614499	28	5.0	2.0	14	4.0	4.0	10	18	4.5
614502	28	5.5	2.0	14	4.5	4.0	10	18	5.0
614497	30	4.0	2.0	15	3.0	4.0	10	18	3.9
614500	30	5.0	2.0	15	4.0	4.0	10	18	4.5
614503	30	5.5	2.0	15	4.5	4.0	10	18	5.0
614509	30	6.0	2.0	15	5.0	4.0	10	18	6.0

All Covered Mounted CP Stent Configurations have a usable length of 110cm and 0.035" guidewire compatibility.

ORDERING INFORMATION

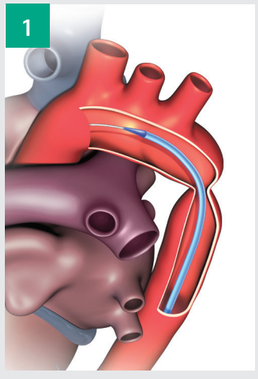
NuDEL™ All-In-One CP Stent® Delivery System

Reference Number	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Outer Rated Burst Pressure (atm)	Inner Balloon Diameter (mm)	Inner Balloon Length (cm)	Inner Rated Burst Pressure (atm)	Stent Configuration (number of zigs)	Profile* (Fr)	Stent Length (cm)
614571	14	3.5	6.0	7	2.5	5.0	8	12	3.4
614576	14	4.0	6.0	7	3.0	5.0	8	12	3.9
614568	16	3.0	5.0	8	2.0	5.0	8	12	2.8
614572	16	3.5	5.0	8	2.5	5.0	8	12	3.4
614577	16	4.0	5.0	8	3.0	5.0	8	12	3.9
614569	18	3.0	4.0	9	2.0	5.0	8	14	2.8
614573	18	3.5	4.0	9	2.5	5.0	8	14	3.4
614578	18	4.0	4.0	9	3.0	5.0	8	14	3.9
614588	20	3.0	4.0	10	2.0	5.0	8	14	2.8
614574	20	3.5	4.0	10	2.5	5.0	8	14	3.4
614579	20	4.0	4.0	10	3.0	5.0	8	14	3.9
614585	20	5.0	4.0	10	4.0	5.0	8	14	4.5
614580	22	4.0	3.0	11	3.0	4.5	8	14	3.9
614586	22	5.0	3.0	11	4.0	4.5	8	14	4.5
614581	24	4.0	3.0	12	3.0	4.5	8	14	3.9
614587	24	5.0	3.0	12	4.0	4.5	8	14	4.5

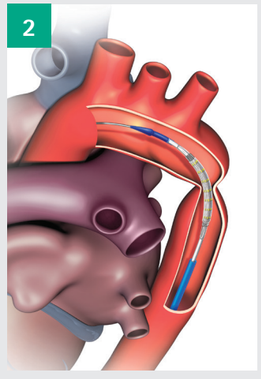
All NuDEL configurations have a usable length of 100cm and 0.035" guidewire compatibility.

**The NuDEL Profile is defined as the inner diameter of the integrated delivery sheath. The outer diameters of the 12F and 14F systems are 4.80mm and 5.61mm respectively.*

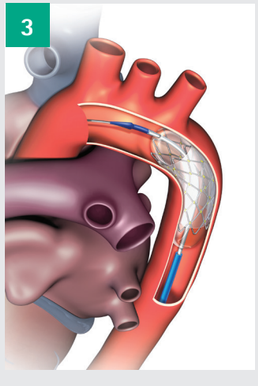
Four-Step Deployment Process



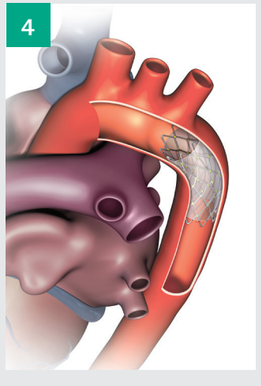
Step 1
The guidewire is advanced to the target area, followed by the NuDEL System.



Step 2
The sheath is retracted, exposing the Covered CP Stent prior to expansion.



Step 3
Controlled stent expansion by inflation of the inner and outer balloon.



Step 4
Covered CP Stent is implanted.

MADE TO ORDER

6-8 WEEK LEAD TIME*

BIB® (Balloon in Balloon) CP Stent® Placement Catheter

Reference Number	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Outer Rated Burst Pressure (atm)	Inner Balloon Diameter (mm)	Inner Balloon Length (cm)	Inner Rated Burst Pressure (atm)	Intro Size (Fr)	Shaft Size (Fr)
614621	12.0	6.0	7.0	6.0	5.0	5.0	8.0	8.0
614622	12.0	6.5	7.0	6.0	5.5	5.0	8.0	8.0
614623	14.0	6.0	6.0	7.0	5.0	5.0	8.0	8.0
614624	14.0	6.5	6.0	7.0	5.5	5.0	8.0	8.0
614625	15.0	6.0	5.0	7.0	5.0	5.0	9.0	9.0
614626	15.0	6.5	5.0	7.0	5.5	5.0	9.0	9.0

All BIB catheters have a usable length of 110cm and 0.035" guidewire compatibility

Covered Mounted CP Stent™

Reference Number	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Outer Rated Burst Pressure (atm)	Inner Balloon Diameter (mm)	Inner Balloon Length (cm)	Inner Rated Burst Pressure (atm)	Stent Configuration (number of zigs)	Profile (Fr)	Stent Length (cm)
614350	12	2.5	7.0	6	1.5	5.0	8	12	1.6
614353	12	2.5	7.0	6	1.5	5.0	8	12	2.2
614384	12	3.5	7.0	6	2.5	5.0	8	12	3.4
614385	12	4.0	7.0	6	3.0	5.0	8	12	3.9
614386	12	5.0	7.0	6	4.0	5.0	8	12	4.5
614538	12	5.5	7.0	6	4.5	5.0	8	12	5.0
614545	12	6.0	7.0	6	5.0	5.0	8	12	5.5
614457	14	2.5	6.0	7	1.5	5.0	8	12	1.6
614354	14	2.5	6.0	7	1.5	5.0	8	12	2.2
614372	14	4.5	6.0	7	3.5	5.0	8	12	4.5
614378	14	5.0	6.0	7	4.0	5.0	8	12	4.5
614539	14	5.5	6.0	7	4.5	5.0	8	12	5.0
614546	14	6.0	6.0	7	5.0	5.0	8	12	5.5
614352	16	2.5	5.0	8	1.5	5.0	8	12	1.6
614355	16	2.5	5.0	8	1.5	5.0	8	12	2.2
614379	16	5.0	5.0	8	4.0	5.0	8	12	4.5
614540	16	5.5	5.0	8	4.5	5.0	8	12	5.0
614547	16	6.0	5.0	8	5.0	5.0	8	12	5.5
614356	18	2.5	4.0	9	1.5	5.0	8	14	2.2
614380	18	5.0	4.0	9	4.0	5.0	8	14	4.5
614541	18	5.5	4.0	9	4.5	5.0	8	14	5.0
614548	18	6.0	4.0	9	5.0	5.0	8	14	5.5
614360	20	3.0	4.0	10	2.0	5.0	8	14	2.8
614364	20	3.5	4.0	10	2.5	5.0	8	14	3.4
614381	20	5.0	4.0	10	4.0	5.0	8	14	4.5
614542	20	5.5	4.0	10	4.5	5.0	8	14	5.0
614549	20	6.0	4.0	10	5.0	5.0	8	14	5.5
614365	22	3.5	3.0	11	2.5	4.5	8	14	3.4
614376	22	4.5	3.0	11	3.5	4.5	8	14	4.5
614543	22	5.5	3.0	11	4.5	4.5	8	14	5.0
614559	22	6.0	3.0	11	5.0	4.5	8	14	5.5
614377	24	4.5	3.0	12	3.5	4.5	8	14	4.5
614544	24	5.5	3.0	12	4.5	4.5	8	14	5.0
614551	24	6.0	3.0	12	5.0	4.5	8	14	5.5
614558	24	6.0	3.0	12	5.0	4.5	8	14	6.0
614495	26	4.0	3.0	13	3.0	4.0	10	16	3.9
614504	26	6.0	3.0	13	5.0	4.0	10	16	5.5
614496	28	4.0	2.0	14	3.0	4.0	10	18	3.9
614505	28	6.0	2.0	14	5.0	4.0	10	18	5.5
614508	28	6.0	2.0	14	5.0	4.0	10	18	6.0
614506	30	6.0	2.0	15	5.0	4.0	10	18	5.5

All Mounted CP Stent Configurations have a usable length of 110cm and 0.035" guidewire compatibility.

**Lead times are estimated. Please contact your local B. Braun Interventional Systems Medical Device Specialist or Customer Support Representative to confirm availability and delivery.*

MADE TO ORDER

6-8 WEEK LEAD TIME*

NuDEL™ All-in-One CP Stent® Delivery System

Reference Number	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Outer Rated Burst Pressure (atm)	Inner Balloon Diameter (mm)	Inner Balloon Length (cm)	Inner Rated Burst Pressure (atm)	Stent Configuration (number of zigs)	Profile (Fr)	Stent Length (cm)
614560	12	2.5	7.0	6	1.5	5.0	8	12	1.6
614563	12	2.5	7.0	6	1.5	5.0	8	12	2.2
614561	14	2.5	6.0	7	1.5	5.0	8	12	1.6
614564	14	2.5	6.0	7	1.5	5.0	8	12	2.2
614567	14	3.0	6.0	7	2.0	5.0	8	12	2.8
614582	14	5.0	6.0	7	4.0	5.0	8	12	4.5
614562	16	2.5	5.0	8	1.5	5.0	8	12	1.6
614565	16	2.5	5.0	8	1.5	5.0	8	12	2.2
614583	16	5.0	5.0	8	4.0	5.0	8	12	4.5
614566	18	2.5	4.0	9	1.5	5.0	8	14	2.2
614584	18	5.0	4.0	9	4.0	5.0	8	14	4.5
614575	22	3.5	3.0	11	2.5	4.5	8	14	3.4

All NuDEL configurations have a usable length of 100cm and 0.035" guidewire compatibility.

The NuDEL Profile is defined as the inner diameter of the integrated delivery sheath. The outer diameters of the 12F and 14F systems are 4.80mm and 5.61mm respectively.

Mounted CP Stent™ (Bare)

Reference Number	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Outer Rated Burst Pressure (atm)	Inner Balloon Diameter (mm)	Inner Balloon Length (cm)	Inner Rated Burst Pressure (atm)	Stent Configuration (number of zigs)	Profile (Fr)	Stent Length (cm)
614312	12	2.5	7.0	6	1.5	5.0	8	10	1.6
614315	12	2.5	7.0	6	1.5	5.0	8	10	2.2
614349	12	3.0	7.0	6	2.0	5.0	8	10	2.8
614346	12	3.5	7.0	6	2.5	5.0	8	10	3.4
614347	12	4.0	7.0	6	3.0	5.0	8	10	3.9
614348	12	5.0	7.0	6	4.0	5.0	8	10	4.5
614517	12	5.5	7.0	6	4.5	5.0	8	10	5.0
614524	12	6.0	7.0	6	5.0	5.0	8	10	5.5
614531	12	6.0	7.0	6	5.0	5.0	8	10	6.0
614313	14	2.5	6.0	7	1.5	5.0	8	10	1.6
614316	14	2.5	6.0	7	1.5	5.0	8	10	2.2
614319	14	3.0	6.0	7	2.0	5.0	8	10	2.8
614323	14	3.5	6.0	7	2.5	5.0	8	10	3.4
614328	14	4.0	6.0	7	3.0	5.0	8	10	3.9
614334	14	4.5	6.0	7	3.5	5.0	8	10	4.5
614340	14	5.0	6.0	7	4.0	5.0	8	10	4.5
614518	14	5.5	6.0	7	4.5	5.0	8	10	5.0
614525	14	6.0	6.0	7	5.0	5.0	8	10	5.5
614532	14	6.0	6.0	7	5.0	5.0	8	10	6.0
614314	16	2.5	5.0	8	1.5	5.0	8	11	1.6
614317	16	2.5	5.0	8	1.5	5.0	8	11	2.2
614320	16	3.0	5.0	8	2.0	5.0	8	11	2.8
614324	16	3.5	5.0	8	2.5	5.0	8	11	3.4
614329	16	4.0	5.0	8	3.0	5.0	8	11	3.9
614335	16	4.5	5.0	8	3.5	5.0	8	11	4.5
614341	16	5.0	5.0	8	4.0	5.0	8	11	4.5
614519	16	5.5	5.0	8	4.5	5.0	8	11	5.0
614526	16	6.0	5.0	8	5.0	5.0	8	11	5.5
614533	16	6.0	5.0	8	5.0	5.0	8	11	6.0
614318	18	2.5	4.0	9	1.5	5.0	8	11	2.2
614321	18	3.0	4.0	9	2.0	5.0	8	11	2.8
614325	18	3.5	4.0	9	2.5	5.0	8	11	3.4
614330	18	4.0	4.0	9	3.0	5.0	8	11	3.9

All Covered Mounted CP Stent Configurations have a usable length of 110cm and 0.035" guidewire compatibility.

**Lead times are estimated. Please contact your local B. Braun Interventional Systems Medical Device Specialist or Customer Support Representative to confirm availability and delivery.*

MADE TO ORDER

6-8 WEEK LEAD TIME*

Mounted CP Stent™ (Bare) *(continued)*

Reference Number	Outer Balloon Diameter (mm)	Outer Balloon Length (cm)	Outer Rated Burst Pressure (atm)	Inner Balloon Diameter (mm)	Inner Balloon Length (cm)	Inner Rated Burst Pressure (atm)	Stent Configuration (number of zigs)	Profile (Fr)	Stent Length (cm)
614336	18	4.5	4.0	9	3.5	5.0	8	11	4.5
614342	18	5.0	4.0	9	4.0	5.0	8	11	4.5
614520	18	5.5	4.0	9	4.5	5.0	8	11	5.0
614527	18	6.0	4.0	9	5.0	5.0	8	11	5.5
614534	18	6.0	4.0	9	5.0	5.0	8	11	6.0
614322	20	3.0	4.0	10	2.0	5.0	8	12	2.8
614326	20	3.5	4.0	10	2.5	5.0	8	12	3.4
614331	20	4.0	4.0	10	3.0	5.0	8	12	3.9
614337	20	4.5	4.0	10	3.5	5.0	8	12	4.5
614343	20	5.0	4.0	10	4.0	5.0	8	12	4.5
614521	20	5.5	4.0	10	4.5	5.0	8	12	5.0
614528	20	6.0	4.0	10	5.0	5.0	8	12	5.5
614535	20	6.0	4.0	10	5.0	5.0	8	12	6.0
614327	22	3.5	3.0	11	2.5	4.5	8	12	3.4
614332	22	4.0	3.0	11	3.0	4.5	8	12	3.9
614338	22	4.5	3.0	11	3.5	4.5	8	12	4.5
614344	22	5.0	3.0	11	4.0	4.5	8	12	4.5
614522	22	5.5	3.0	11	4.5	4.5	8	12	5.0
614529	22	6.0	3.0	11	5.0	4.5	8	12	5.5
614536	22	6.0	3.0	11	5.0	4.5	8	12	6.0
614333	24	4.0	3.0	12	3.0	4.5	8	12	3.9
614339	24	4.5	3.0	12	3.5	4.5	8	12	4.5
614345	24	5.0	3.0	12	4.0	4.5	8	12	4.5
614523	24	5.5	3.0	12	4.5	4.5	8	12	5.0
614530	24	6.0	3.0	12	5.0	4.5	8	12	5.5
614537	24	6.0	3.0	12	5.0	4.5	8	12	6.0
614480	26	4.0	3.0	13	3.0	4.0	10	16	3.9
614483	26	5.0	3.0	13	4.0	4.0	10	16	4.5
614486	26	5.5	3.0	13	4.5	4.0	10	16	5.0
614489	26	6.0	3.0	13	5.0	4.0	10	16	5.5
614492	26	6.0	3.0	13	5.0	4.0	10	16	6.0
614481	28	4.0	2.0	14	3.0	4.0	10	16	3.9
614484	28	5.0	2.0	14	4.0	4.0	10	16	4.5
614487	28	5.5	2.0	14	4.5	4.0	10	16	5.0
614490	28	6.0	2.0	14	5.0	4.0	10	16	5.5
614493	28	6.0	2.0	14	5.0	4.0	10	16	6.0
614482	30	4.0	2.0	15	3.0	4.0	10	16	3.9
614485	30	5.0	2.0	15	4.0	4.0	10	16	4.5
614488	30	5.5	2.0	15	4.5	4.0	10	16	5.0
614491	30	6.0	2.0	15	5.0	4.0	10	16	5.5
614494	30	6.0	2.0	15	5.0	4.0	10	16	6.0

All Covered Mounted CP Stent Configurations have a usable length of 110cm and 0.035" guidewire compatibility.

**Lead times are estimated. Please contact your local B. Braun Interventional Systems Medical Device Specialist or Customer Support Representative to confirm availability and delivery.*

CP Stent® Balloon Sizing Chart

INNER BALLOON	8 zig Stent Configuration								10 zig Stent Configuration		
Balloon Pressure (atm)	12mm Diameter	14mm Diameter	15mm Diameter	16mm Diameter	18mm Diameter	20mm Diameter	22mm Diameter	24mm Diameter	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	8 zig Stent Configuration								10 zig Stent Configuration		
Balloon Pressure (atm)	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
1.0	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.

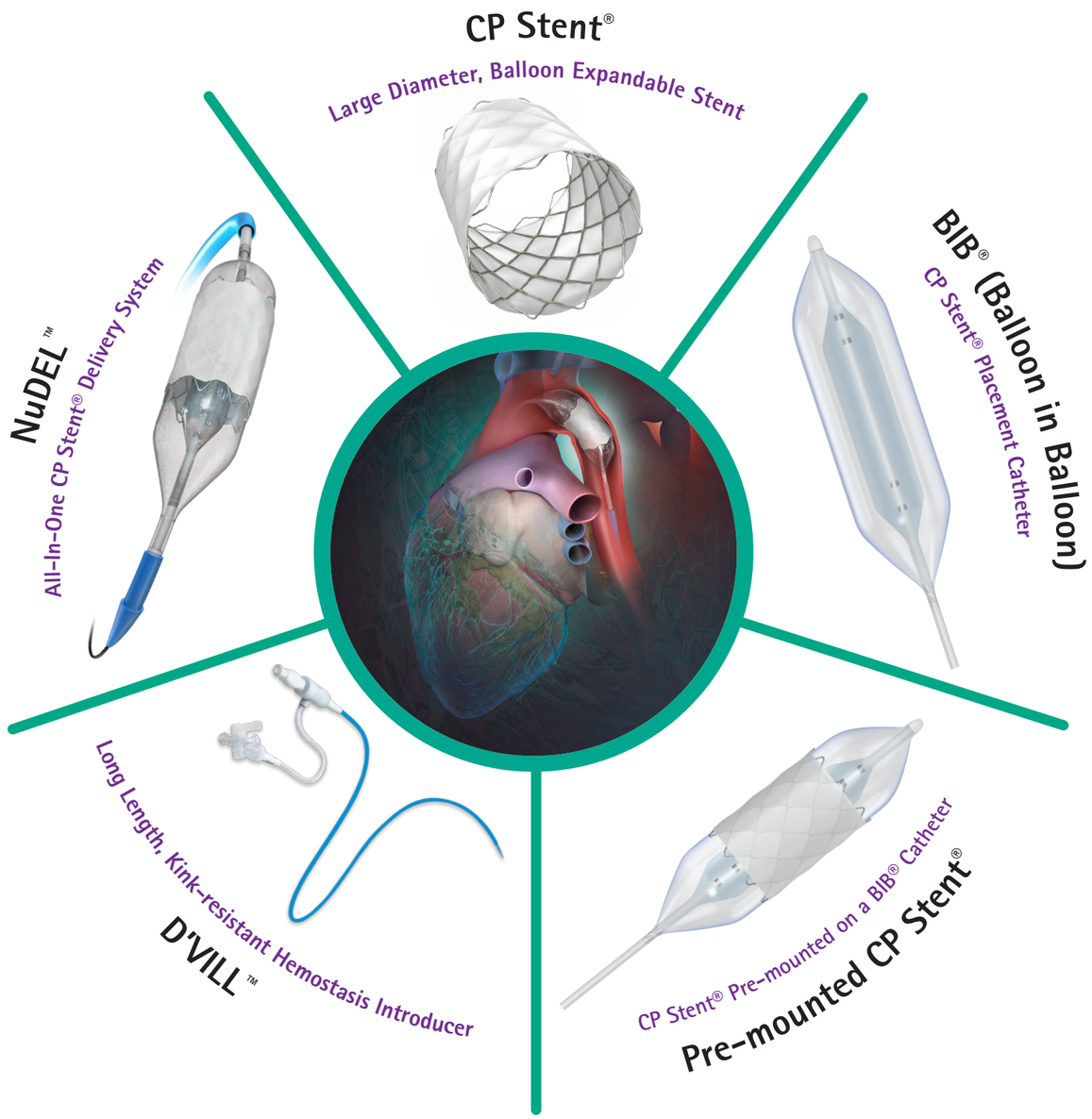
This data is based on testing performed using the BIB® Stent Placement Catheter.

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	N/A	N/A	N/A	N/A	3.17 (18.33%)	3.44 (22.09%)	4.10 (17.34%)	4.24 (23.32%)	4.85 (20.20%)
	28	N/A	N/A	N/A	N/A	2.96 (23.68%)	3.24 (26.75%)	3.71 (25.11%)	4.00 (27.58%)	4.39 (27.87%)
	30	N/A	N/A	N/A	N/A	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

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.



INDICATIONS

CP Stent® and Covered CP Stent™
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.

BIB®
The BIB® Catheter is indicated for CP Stent®/Covered CP Stent™ placement in vessels over 8mm in diameter.

D'VILL™
The D'VILL™ Introducer is recommended for introduction of balloons, catheters, and other diagnostic and interventional devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

NuDEL™
The NuDEL 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 NuDEL 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:** Administer appropriate anticoagulation therapy to reduce potential thrombosis. If the patient is not appropriately anticoagulated, thrombus formation may occur. The sheath must be flushed with heparinized saline via the proximal side port prior to introducing the delivery system into the body. The inflated diameter of the stent should at least equal the diameter of the intended implant site. Excessive handling and manipulation of the covering while crimping the stent may cause the covering to tear off of the stent. Retracting the covered stent back into the sheath may cause the covering to catch and tear off of the stent. Do not exceed the RBP. An inflation device with pressure gauge is recommended to monitor pressure. Pressure in excess of the RBP can cause balloon rupture and potential inability to withdraw the catheter into the sheath. Confirm that the distal end of the introducer sheath is at least 2.5cm back from the most proximal image band before inflating the outer balloon. Failure to do so may stretch the outer tubing and severely hinder balloon deflation. Exercise caution when handling the stent to prevent breakage. The NuDEL system, especially at the stent, is rigid and may make negotiation through vessels difficult. The inflation diameter of the balloon used during stent delivery should approximate the diameter of the obstructive vessel and the intended implant site. If resistance is encountered upon removal, the whole system (balloon, guidewire and sheath) should be removed as a single unit, particularly if balloon rupture or leakage is known or suspected. **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. The platinum/iridium stent may migrate from the site of the implant. 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 (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.

Refer to the IFUs for a complete listing of indications, contraindications, warnings and precautions. www.bisusa.com

Notes: