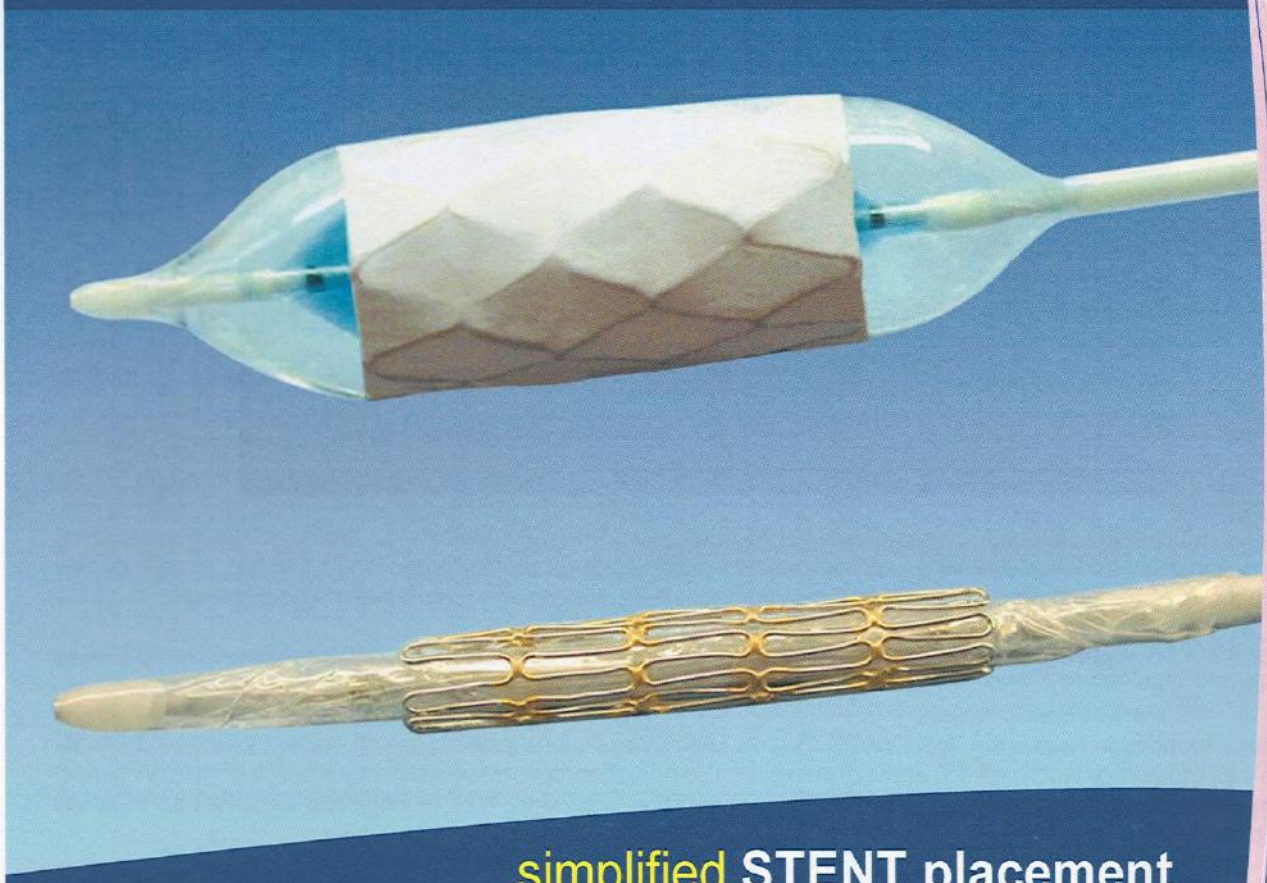
NuMED

For Children



simplified **STENT placement**

BIB Stent Placement **catheter - 3**

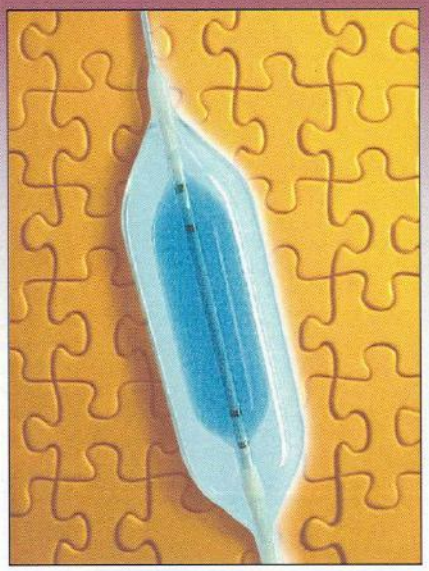
Bare & Covered CP Stent - 4

Mounted Bare & Covered CP Stent - 5

BIB® Stent Placement catheter* for vessels over 8.0 mm in diameter

Outer Balloon Specifications

Balloon Diameter (MM)	Balloon Length (CM)	Introducer Size (FR)	Shaft Size (FR)	Usable Length (CM)	Guide Wire (Inches)	Rated Burst (ATM)	Catalog No.
12.0	2.5	8	8	110	0.035	7	BB003
12.0	3.0	8	8	110	0.035	7	BB006
12.0	3.5	8	8	110	0.035	7	BB009
12.0	4.0	8	8	110	0.035	7	BB033
12.0	4.5	8	8	110	0.035	7	BB037
12.0	5.0	8	8	110	0.035	7	BB034
12.0	5.5	8	8	110	0.035	7	BB051
14.0	2.5	8	8	110	0.035	6	BB022
14.0	3.0	8	8	110	0.035	6	BB052
14.0	3.5	8	8	110	0.035	6	BB025
14.0	4.0	8	8	110	0.035	6	BB038
14.0	4.5	8	8	110	0.035	6	BB035
14.0	5.0	8	8	110	0.035	6	BB039
14.0	5.5	8	8	110	0.035	6	BB053
15.0	2.5	9	9	110	0.035	5	BB054
15.0	3.0	9	9	110	0.035	5	BB055
15.0	3.5	9	9	110	0.035	5	BB056
15.0	4.0	9	9	110	0.035	5	BB057
15.0	4.5	9	9	110	0.035	5	BB058
15.0	5.0	9	9	110	0.035	5	BB059
15.0	5.5	9	9	110	0.035	5	BB060
16.0	2.5	9	9	110	0.035	5	BB023
16.0	3.0	9	9	110	0.035	5	BB010
16.0	3.5	9	9	110	0.035	5	BB026
16.0	4.0	9	9	110	0.035	5	BB013
16.0	4.5	9	9	110	0.035	5	BB016
16.0	5.0	9	9	110	0.035	5	BB028
16.0	5.5	9	9	110	0.035	5	BB019
18.0	2.5	10	9	110	0.035	4	BB024
18.0	3.0	10	9	110	0.035	4	BB040
18.0	3.5	10	9	110	0.035	4	BB027
18.0	4.0	10	9	110	0.035	4	BB041
18.0	4.5	10	9	110	0.035	4	BB029
18.0	5.0	10	9	110	0.035	4	BB030
18.0	5.5	10	9	110	0.035	4	BB031
20.0	3.0	10	9	110	0.035	4	BB011
20.0	3.5	10	9	110	0.035	4	BB042
20.0	4.0	10	9	110	0.035	4	BB014
20.0	4.5	10	9	110	0.035	4	BB017
20.0	5.0	10	9	110	0.035	4	BB032
20.0	5.5	10	9	110	0.035	4	BB020
22.0	3.0	11	9	110	0.035	3	BB061
22.0	3.5	11	9	110	0.035	3	BB062
22.0	4.0	11	9	110	0.035	3	BB063
22.0	4.5	11	9	110	0.035	3	BB064
22.0	5.0	11	9	110	0.035	3	BB065
22.0	5.5	11	9	110	0.035	3	BB066
24.0	3.0	11	9	110	0.035	3	BB012
24.0	3.5	11	9	110	0.035	3	BB067
24.0	4.0	11	9	110	0.035	3	BB015
24.0	4.5	11	9	110	0.035	3	BB018
24.0	5.0	11	9	110	0.035	3	BB036
24.0	5.5	11	9	110	0.035	3	BB021



All Catheters have:

An inner balloon 1/2 of the balloon diameter of the outer balloon. i.e. BB010 has an 8.0 mm inner balloon.

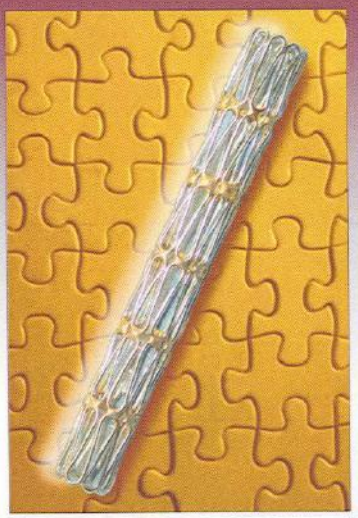
An inner balloon that is 1.0 cm shorter than the outer balloon. i.e. BB010 has an inner balloon that is 2.0 cm long.

An inner balloon with a rated burst pressure of 4.5 to 5.0 atmospheres. Four image bands that match the functional length of each balloon.

A length of 110 cm.

All Catheters are for use with a 0.035" wire.

*** NOT FOR SALE IN THE U.S.A.**



CP STENT™

Bare and Covered Stent*

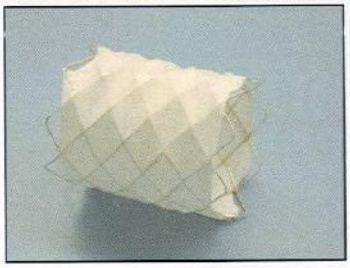
Stent Characteristics

The **CP Stent™** is composed of 0.013" platinum/iridium wire that is arranged in a "zig" pattern, laser welded at each joint and over brazed with 24K gold. It allows expansion from 12.0 mm to 24.0 mm. The **Covered CP Stent™** is comprised of the Bare CP Stent that is covered with an expandable sleeve of ePTFE.

Bare Stent

Indicated for implantation in the native and/or recurrent coarctation of the aorta on patients with the following clinical conditions:

- Stenosis of the aorta resulting in significant anatomic narrowing as determined by angiography or non-invasive imaging, i.e. echocardiography, magnetic resonance imaging (MRI), CT Scan;
- Stenosis of the aorta resulting in hemodynamic alterations, resulting in systolic pressure gradient, systemic hypertension or altered left ventricular function;
- Stenosis of the aorta where balloon angioplasty is ineffective or contraindicated;
- Stenosis diameter >20% of the adjacent vessel diameter.



Covered Stent

Indicated for implantation in the native and/or recurrent coarctation of the aorta on patients with the following clinical conditions:

- Stenosis of the aorta resulting in significant anatomic narrowing as determined by angiography or non-invasive imaging, i.e. echocardiography, magnetic resonance imaging (MRI), CT Scan;
- Stenosis of the aorta resulting in hemodynamic alterations, resulting in systolic pressure gradient, systemic hypertension or altered left ventricular function;
- Stenosis of the aorta where balloon angioplasty is ineffective or contraindicated;
- Stenosis diameter <20% of the adjacent vessel diameter;
- Stenosis that would present increased risk of vascular damage or disruption;
- Aneurysm associated with coarctation of the aorta.

NuMED recommends using the BIB Stent Placement

CP Stent™ Specifications

Stent Length (CM)	Configuration (Number of Zigs)	Platinum Wire (Inches)	Bare Stent Catalog No.	Covered Stent Catalog No.
1.6	8	0.013	CP8Z16	CVRDCP8Z16
2.2	8	0.013	CP8Z22	CVRDCP8Z22
2.8	8	0.013	CP8Z28	CVRDCP8Z28
3.4	8	0.013	CP8Z34	CVRDCP8Z34
3.9	8	0.013	CP8Z39	CVRDCP8Z39
4.5	8	0.013	CP8Z45	CVRDCP8Z45

INFLATED BALLOON DIAMETER	CP8Z16 (LENGTH AFTER EXPANSION) (%SHORTENING)	CP8Z22 (LENGTH AFTER EXPANSION) (%SHORTENING)	CP8Z28 (LENGTH AFTER EXPANSION) (%SHORTENING)	CP8Z34 (LENGTH AFTER EXPANSION) (%SHORTENING)	CP8Z39 (LENGTH AFTER EXPANSION) (%SHORTENING)	CP8Z45 (LENGTH AFTER EXPANSION) (%SHORTENING)
12mm	1.61cm (2.8%)	2.18cm (0.8%)	2.62cm (4.4%)	3.23cm (3.1%)	3.72cm (1.9%)	4.17cm (3.8%)
14mm	1.54cm (6.5%)	2.08cm (5.4%)	2.56cm (6.8%)	3.15cm (5.4%)	3.66cm (3.6%)	3.97cm (8.4%)
15mm	1.51cm (8.5%)	2.02cm (7.9%)	2.51cm (8.6%)	3.10cm (7.0%)	3.54cm (6.6%)	3.94cm (9.2%)
16mm	1.48cm (10.6%)	1.98cm (10.1%)	2.45cm (10.7%)	3.00cm (9.8%)	3.48cm (8.2%)	3.84cm (11.4%)
18mm	1.43cm (13.7%)	1.89cm (14.0%)	2.38cm (13.3%)	2.88cm (13.5%)	3.20cm (15.6%)	3.71cm (14.5%)
20mm	1.32cm (20.0%)	1.80cm (17.9%)	2.30cm (16.3%)	2.63cm (20.9%)	2.96cm (21.9%)	3.27cm (24.7%)
22mm	1.23cm (25.4%)	1.67cm (23.9%)	2.09cm (24.0%)	2.46cm (26.0%)	2.85cm (25.0%)	3.15cm (27.3%)
24mm	1.05cm (36.4%)	1.46cm (33.8%)	1.91cm (30.3%)	2.07cm (37.9%)	2.27cm (40.1%)	2.83cm (34.9%)

BIB DELIVERY CATHETER BALLOON DIA. AND INTRO. SIZE	REQUIRED INTRODUCER WITH BARE CP STENT	REQUIRED INTRODUCER WITH COVERED CP STENT
12MM (8F)	10F	12F
14MM (8F)	10F	12F
15MM (9F)	11F	12F
16MM (9F)	11F	12F
18MM (10F)	11F	14F
20MM (10F)	12F	14F
22MM (11F)	12F	14F
24MM (11F)	12F	14F

*** NOT FOR SALE IN THE U.S.A.**

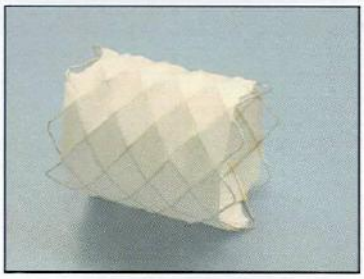
MOUNTED CP STENT™

Mounted CP Stent

The **Mounted CP Stent™** consists of a **bare CP Stent™** pre-mounted on a **BIB Catheter**. This system allows the physician the flexibility of using the pre-mounted complete system and will save the time required to mount the stent on the catheter. The **CP Stent™** is composed of 0.013" platinum/iridium wire that is arranged in a "zig" pattern, laser welded at each joint and then over brazed with 24K gold. It allows expansion from 12.0mm to 24.0mm. The **CP Stent™** is pre-mounted on a BIB (balloon in balloon) catheter.

The **Mounted CP Stent™** is indicated for implantation in the native and/or recurrent coarctation of the aorta on patients with the following clinical conditions:

- Stenosis of the aorta resulting in significant anatomic narrowing as determined by angiography or non-invasive imaging, i.e. echocardiography, magnetic resonance imaging (MRI), CT Scan;
- Stenosis of the aorta resulting in hemodynamic alterations, resulting in systolic pressure gradient, systemic hypertension or altered left ventricular function;
- Stenosis of the aorta where balloon angioplasty is ineffective or contraindicated;
- Stenosis diameter >20% of the adjacent vessel diameter.



Covered Mounted CP Stent

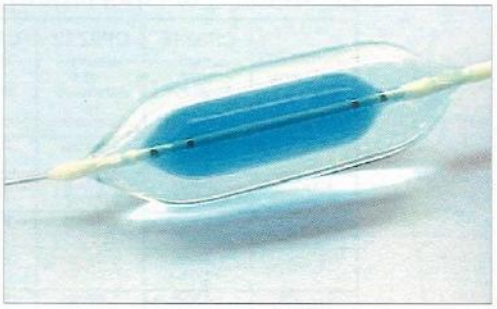
The **Covered Mounted CP Stent™** consists of a **Covered CP Stent™** pre-mounted on a **BIB Catheter**. This system allows the physician the flexibility of using the pre-mounted complete system and will save the time required to mount the stent on the catheter. This may be critical in some cases of aneurysmal repair or in cases where vascular damage has occurred. The **Covered CP Stent™** is comprised of the bare **CP Stent™** that is covered with an expandable sleeve of ePTFE.

The **Covered Mounted CP Stent™** is indicated for implantation in the native and/or recurrent coarctation of the aorta on patients with the following clinical conditions:

- Stenosis of the aorta resulting in significant anatomic narrowing as determined by angiography or non-invasive imaging, i.e. echocardiography, magnetic resonance imaging (MRI), CT Scan;
- Stenosis of the aorta resulting in hemodynamic alterations, resulting in systolic pressure gradient, systemic hypertension or altered left ventricular function;
- Stenosis of the aorta where balloon angioplasty is ineffective or contraindicated;
- Stenosis diameter <20% of the adjacent vessel diameter;
- Stenosis that would present increased risk of vascular damage or disruption;
- Aneurysm associated with coarctation of the aorta.

BIB Stent Placement Catheter

The **BIB Catheter** allows for the controlled expansion of the **CP Stent™** by utilizing an incremental expansion of the stent. The inner balloon of the **BIB Catheter** is ½ the diameter of the outer balloon and is 1.0cm shorter in length. When the inner balloon is inflated, the stent expansion begins from the center of the stent. The stent is firmly gripped on to the balloon to allow for fine positioning before the final expansion by inflating the outer balloon. All **BIB Catheters** are 110cm in length and utilize a 0.035" guidewire.



Both products are the same units that have been previously for sale in the EU. NuMED has received approval to market the system consisting of the stent and delivery catheter.

*** NOT FOR SALE IN THE U.S.A.**

Mounted CP Stent™ Specifications

Stent Length (CM)	Configu-ration (Number of Zigs)	Platinum Wire (Inches)	Outer Balloon Diameter (MM)	Outer Balloon Length (CM)	Shaft Size (FR)	Usable Length (CM)	Guide Wire (Inches)	Rated Burst (ATM)	Mounted CP Stent Cat. No.	Covered Mounted CP Stent Cat. No.
1.6	8	0.013	12.0	2.5	8	110	0.035	7	MCP001	CMCP001
1.6	8	0.013	14.0	2.5	8	110	0.035	6	MCP002	CMCP002
1.6	8	0.013	16.0	2.5	9	110	0.035	5	MCP003	CMCP003
2.2	8	0.013	12.0	2.5	8	110	0.035	7	MCP004	CMCP004
2.2	8	0.013	14.0	2.5	8	110	0.035	6	MCP005	CMCP005
2.2	8	0.013	16.0	2.5	9	110	0.035	5	MCP006	CMCP006
2.2	8	0.013	18.0	2.5	9	110	0.035	4	MCP007	CMCP007
2.8	8	0.013	12.0	3.0	8	110	0.035	7	MCP038	CMCP038
2.8	8	0.013	14.0	3.0	8	110	0.035	6	MCP008	CMCP008
2.8	8	0.013	16.0	3.0	9	110	0.035	5	MCP009	CMCP009
2.8	8	0.013	18.0	3.0	9	110	0.035	4	MCP010	CMCP010
2.8	8	0.013	20.0	3.0	9	110	0.035	4	MCP011	CMCP011
3.4	8	0.013	12.0	3.5	8	110	0.035	7	MCP035	CMCP035
3.4	8	0.013	14.0	3.5	8	110	0.035	6	MCP012	CMCP012
3.4	8	0.013	16.0	3.5	9	110	0.035	5	MCP013	CMCP013
3.4	8	0.013	18.0	3.5	9	110	0.035	4	MCP014	CMCP014
3.4	8	0.013	20.0	3.5	9	110	0.035	4	MCP015	CMCP015
3.4	8	0.013	22.0	3.5	9	110	0.035	3	MCP016	CMCP016
3.9	8	0.013	12.0	4.0	8	110	0.035	7	MCP036	CMCP036
3.9	8	0.013	14.0	4.0	8	110	0.035	6	MCP017	CMCP017
3.9	8	0.013	16.0	4.0	9	110	0.035	5	MCP018	CMCP018
3.9	8	0.013	18.0	4.0	9	110	0.035	4	MCP019	CMCP019
3.9	8	0.013	20.0	4.0	9	110	0.035	4	MCP020	CMCP020
3.9	8	0.013	22.0	4.0	9	110	0.035	3	MCP021	CMCP021
3.9	8	0.013	24.0	4.0	9	110	0.035	3	MCP022	CMCP022
4.5	8	0.013	12.0	5.0	8	110	0.035	7	MCP037	CMCP037
4.5	8	0.013	14.0	4.5	8	110	0.035	6	MCP023	CMCP023
4.5	8	0.013	16.0	4.5	9	110	0.035	5	MCP024	CMCP024
4.5	8	0.013	18.0	4.5	9	110	0.035	4	MCP025	CMCP025
4.5	8	0.013	20.0	4.5	9	110	0.035	4	MCP026	CMCP026
4.5	8	0.013	22.0	4.5	9	110	0.035	3	MCP027	CMCP027
4.5	8	0.013	24.0	4.5	9	110	0.035	3	MCP028	CMCP028
4.5	8	0.013	14.0	5.0	8	110	0.035	6	MCP029	CMCP029
4.5	8	0.013	16.0	5.0	9	110	0.035	5	MCP030	CMCP030
4.5	8	0.013	18.0	5.0	9	110	0.035	4	MCP031	CMCP031
4.5	8	0.013	20.0	5.0	9	110	0.035	4	MCP032	CMCP032
4.5	8	0.013	22.0	5.0	9	110	0.035	3	MCP033	CMCP033
4.5	8	0.013	24.0	5.0	9	110	0.035	3	MCP034	CMCP034

CP Stent™ Foreshortening Chart

INFLATED BALLOON DIAMETER	CP8Z16 (LENGTH AFTER EXPANSION) (% SHORTENING)	CP8Z22 (LENGTH AFTER EXPANSION) (% SHORTENING)	CP8Z28 (LENGTH AFTER EXPANSION) (% SHORTENING)	CP8Z34 (LENGTH AFTER EXPANSION) (% SHORTENING)	CP8Z39 (LENGTH AFTER EXPANSION) (% SHORTENING)	CP8Z45 (LENGTH AFTER EXPANSION) (% SHORTENING)
12mm	1.61cm (2.8%)	2.18cm (0.8%)	2.62cm (4.4%)	3.23cm (3.1%)	3.72cm (1.9%)	4.17cm (3.8%)
14mm	1.54cm (6.5%)	2.08cm (5.4%)	2.56cm (6.8%)	3.15cm (5.4%)	3.66cm (3.6%)	3.97cm (8.4%)
15mm	1.51cm (8.5%)	2.02cm (7.9%)	2.51cm (8.6%)	3.10cm (7.0%)	3.54cm (6.6%)	3.94cm (9.2%)
16mm	1.48cm (10.6%)	1.98cm (10.1%)	2.45cm (10.7%)	3.00cm (9.8%)	3.48cm (8.2%)	3.84cm (11.4%)
18mm	1.43cm (13.7%)	1.89cm (14.0%)	2.38cm (13.3%)	2.88cm (13.5%)	3.20cm (15.6%)	3.71cm (14.5%)
20mm	1.32cm (20.0%)	1.80cm (17.9%)	2.30cm (16.3%)	2.63cm (20.9%)	2.96cm (21.9%)	3.27cm (24.7%)
22mm	1.23cm (25.4%)	1.67cm (23.9%)	2.09cm (24.0%)	2.46cm (26.0%)	2.85cm (25.0%)	3.15cm (27.3%)
24mm	1.05cm (36.4%)	1.46cm (33.8%)	1.91cm (30.3%)	2.07cm (37.9%)	2.27cm (40.1%)	2.83cm (34.9%)

* NOT FOR SALE IN THE U.S.A.

BIB DELIVERY CATHETER BALLOON DIAMETER AND INTRODUCER SIZE	REQUIRED INTRO-DUCER WITH BARE CP STENT	REQUIRED INTRO-DUCER WITH COVERED CP STENT
12MM (8F)	10F	12F
14MM (8F)	10F	12F
15MM (9F)	11F	12F
16MM (9F)	11F	12F
18MM (10F)	11F	14F
20MM (10F)	12F	14F
22MM (11F)	12F	14F
24MM (11F)	12F	14F