Mounted

CP Stent™

COARCTATION OF THE AORTA

INSTRUCTIONS FOR USE

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Read all instructions prior to use.

Interventional Systems
B BRAUN

Distributed by:
B. Braun Interventional Systems Inc.
824 Twelfth Avenue
Bethlehem, PA 18018
Customer Service:
TEL: (877) 836-2228
FAX: (610) 849-1334
Technical Support
TEL: (800) 443-8362
Made in U.S.A.

NuMED, Inc.

2880 Main Street
Hopkinton, New York USA 12965
Telephone: (315) 328-4491
Facsimile: (315) 328-4941
Email: info@numedusa.com
Internet: www.numedforchildren.com

INDICATIONS

The Mounted 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.

DESCRIPTION

The CP Stent is balloon expandable and intended for permanent implant. The CP Stent is composed of heat treated 90% platinum and 10% iridium wire that is arranged in laser welded rows with a "zig" pattern. The number of zigs in a row can be varied and will impact the strength of the stent as well as the eventual expanded diameter and percentage of stent shortening, while the number of rows will determine the unexpanded length of the stent.

The NuMED BIB® (Balloon in Balloon) Catheter is a triaxial design catheter. Two lumens are used to inflate the balloon while one lumen is for tracking over a guidewire. The radiopaque platinum marker(s) are placed beneath the "working area" of the balloon. The inner balloon is ½ of the outer balloon diameter and 1 cm shorter. Each balloon inflates to the stated diameter and length at specific pressure. The balloon size is ±10% at Rated Burst Pressure (RBP). The RBP is different for each size. Check the package label for the RBP. It is important that the balloon not be inflated beyond the RBP.

The purpose of the double balloon catheter is to apply an incremental inflation for the purpose of opening a vascular channel using a balloon expandable intravascular stent. The inner balloon provides initial expansion of the stent and also acts as a tool to hold the stent in place while the outer balloon is inflated. The outer balloon is then inflated securing the stent against the vessel wall.

CONTRAINDICATIONS

- 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 of the stent;
- Clinical or biological signs of infection;
- Active endocarditis;
- Known allergy to aspirin, other antiplatelet agents, or heparin;
- Pregnancy.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas. Sterile and non-pyrogenic if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

CP STENT WARNINGS

- 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.
- Excessive force while crimping may weaken welds of the stent.

BIB STENT PLACEMENT WARNINGS

- 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 through the introducer sheath.
- Confirm that the distal end of the introducing 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.
- Use two appropriate size inflation devices with pressure gauges for inflation.
- Do not advance the guidewire, balloon catheter, or any other component if resistance is met, without first determining the cause and taking remedial action.
- This catheter is not recommended for pressure measurement or fluid injection.
- Do not remove the guidewire from the catheter at any time during the procedure.
- This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross-contamination.

PRECAUTIONS

- Use of an inflation device with pressure gauge is highly recommended during this procedure.
- The stent is rigid and may make negotiation through vessels difficult.
- Dilatation procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- Guidewires are delicate devices. Care should be exercised while handling to help prevent the possibility of breakage.
- Careful attention must be paid to the maintenance of tight catheter connections and by aspiration before proceeding to avoid air introduction into the system.
- The inflation diameter of the balloon used during stent delivery should approximate the diameter of the obstructive vessel and the intended implant site.
- Under no circumstances should any portion of the catheter system be advanced against resistance. The cause of the resistance should be identified with fluoroscopy and action taken to remedy the problem.
- If resistance is felt upon removal, the balloon, guidewire, and sheath should be removed as a unit, particularly if balloon rupture or leakage is known or suspected. This may be accomplished by firmly grasping the balloon catheter and sheath as a unit and withdrawing both together, using a gentle twisting motion combined with traction.
- Proper functioning of the catheter depends on its integrity. Care should be used when handling the catheter. Damage may result from kinking, stretching, or forceful wiping of the catheter.

POTENTIAL COMPLICATIONS / ADVERSE EFFECTS

NOTE: Circumferential tear of the delivery balloon catheter prior to complete expansion of the stent may cause the balloon to become tethered to the stent, requiring surgical removal. In case of rupture of an adequately sized balloon after stent expansion, it can be withdrawn and a new balloon catheter exchanged over a guidewire to complete expansion of the stent.

Cardiac catheterization carries certain risks. In addition, potential complications, and related adverse effects associated with implants include, but are not limited to:

- Femoral Artery injury, thrombosis or pseudoaneurysm
- Stent Migration
- Stent Fracture
- Aortic Rupture/Tear
- Hematoma
- Thrombosis/Thromboembolism
- Death
- Endocarditis
- Cell necrosis at the site of implant
- Stent Stenosis
- Aortic Aneurysm/Pseudoaneurysm
- Stent Malposition
- Sepsis/infection
- AV fistula formation
- Transitory arrhythmia
- Bleeding
- Cerebrovascular Incident

MRI SAFETY INFORMATION

Nonclinical testing and modeling has demonstrated that the CP Stent is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3 T
- Maximum spatial gradient magnetic field of 2500 gauss/cm (25 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning (Normal Operating Mode)

Based on nonclinical testing and modeling, under the scan conditions defined above, the CP Stent is expected to produce a maximum in vivo temperature rise of less than 2°C after 15 minutes of continuous scanning.

MR image quality may be compromised if the area of interest is in the same area, or relatively close to the position of the device. In nonclinical testing, the image artifact caused by the device extends approximately 3 mm from the CP Stent when imaged with a spin echo pulse sequence and 6 mm when imaged with a gradient echo pulse sequence and a 3 T MRI System. The lumen of the device was obscured.

The presence of other implants or medical circumstances of the patient may require lower limits on some or all of the above parameters.

CLINICAL STUDY INFORMATION

The COAST clinical study was performed to establish a reasonable assurance of safety and effectiveness of implantation of the Bare CP Stent in the native and/or recurrent coarctation of the aorta in the US. The study was a prospective, multi-center, single-arm clinical study comparing stent treatment of native or recurrent aortic coarctation to a performance goal (PG) derived from surgical treatment. Surgical PGs are derived from retrospective data collection at selected participating centers and from the literature.

1. Clinical Inclusion and Exclusion Criteria

Enrollment in the COAST study was limited to patients who met the following inclusion criteria:

Pre-catheterization Inclusion Criteria:

a. Native or recurrent aortic coarctation
b. Weight 35 kg
c. Noninvasive, arm-leg cuff systolic blood pressure* difference or catheter measured systolic coarctation gradient 20 mmHg
   *Patients receiving antihypertensive therapy can be included in the study. The type and dose of the medication will be recorded and used for comparisons with follow up evaluations.

Catheterization Inclusion Criteria:

a. Coarctation of the aorta, either native or recurrent that is demonstrated, angiographically to involve the aortic isthmus or first segment of the descending aorta
b. Coarctation of the aorta found to be compliant on pre-stent balloon dilation
c. Patency of at least one femoral artery

Patients were not permitted to enroll in the COAST study if they met any of the following exclusion criteria:

Pre-catheterization Exclusion Criteria:

a. Age > 60 years
b. Connective tissue disorders, including Marfan syndrome and other genetic syndromes such as Turner syndrome and Noonan syndrome
c. Inflammatory aortitis
d. Bloodstream infection, including endocarditis

e. Pregnancy
f. Aortic aneurysm
g. Prior stent placemen
h. Adults lacking capacity to consent
i. Foster children and/or wards of the court

Catheterization Exclusion Criteria

a. Angiography that demonstrates aortic coarctation involving a "curved" region of the aorta, the transverse aortic arch, carotid arterial branches or obstruction extending into or beyond the mid-thoracic descending aorta
b. Complete aortic atresia demonstrated angiographically
c. Anatomic location of coarctation judged by operator to preclude safe placement of a stent
d. Coarctation of the aorta found to be non-compliant on pre-stent balloon dilation

2. Follow-up Schedule

All patients were scheduled to return for follow-up examinations at 1 month, 6 months, 12 months, 24 months, and annually to 5 years. Adverse events and complications were recorded at all visits.

3. Clinical Endpoints

With regards to safety, the following criteria were evaluated:

Primary Safety Endpoint #1: Occurrence of any serious or somewhat serious adverse event attributed to the stent or implantation procedure within 30 days of the catheterization procedure.

The following hypothesis was tested using a one-sample, one-sided test of proportions conducted at the 0.05 level of significance:

$$H_0: p \geq 0.18 \text{ vs. } H_A: p < 0.18$$

Primary Safety Endpoint #2: Occurrence of post-procedure paradoxical hypertension.

The following hypothesis was tested using a two-sided, one-sample test of proportions conducted at the 0.05 level of significance:

$$H_0: p = 0.84 \text{ vs. } H_A: p \neq 0.84$$

With regards to effectiveness, the following criteria were evaluated.

***Primary Effectiveness Endpoint #1*:** Reduction in arm-leg systolic blood pressure gradient from pre-dilation to the 12 month post-dilation follow-up.

Assuming that μ represents the true mean gradient reduction among stent patients, the following hypothesis was tested using a one-sample, one-sided t test conducted at the 0.05 level of significance:

$$H_0: \mu \leq 31 \text{ vs } H_A: \mu > 31$$

***Primary Effectiveness Endpoint #2*:** Length of stay in the hospital, measured in days

The following hypothesis was evaluated using a two-sided, one-sample t test conducted at the 0.05 level of significance:

$$H_0: \mu = 3.5 \text{ vs. HA: } \mu \neq 3.5$$

Of the 167 enrolled patients, 102 met the study eligibility criteria and were treated with the Bare CP Stent. 112 patients were evaluated for safety, of which 5 patients crossed-over to the Covered CP Stent therapy. Approximately 107 stents were implanted in 105 patients and these patients were included in the evaluation of effectiveness. Study accountability is detailed in Table 1.

Table 1. COAST Accountability

	Possible N (100%)	1 Month Visit n (%)	12 Month Visit n (%)	24 Month Visit n (%)	3 years n (%)	4 years n (%)	5 years n (%)
Safety Cohort	112	102 (91%)	94 (84%)	90 (80%)	80 (71%)	76 (68%)	73 (65%)
Effectiveness Cohort	105*	100 (95%)	92 (88%)	87 (83%)	77 (73%)	69 (66%)	56 (53%)

*112 patients underwent catheterization and pre-stenting balloon angioplasty, five then received Covered CP Stents and were entered into the COAST II trial where they have been followed since. Two patients did not receive study stents and are followed for safety outcomes only.

Subject Demographics

Table 2 presents subject demographics and baseline characteristics analyzed for the enrolled subjects.

Table 2. COAST Patient Characteristics

Assessment	Number (Percent) or Median (Range)	
	Safety Cohort (n=112)	Efficacy Cohort (n=105)
Gender		
Male	77 (69%)	73 (70%)
Female	35 (31%)	32 (30%)
Age, years	16 (8 to 52)	16 (8 to 52)
NYHA Classification		
I	88 (79%)	82 (78%)
II	22 (20%)	21 (20%)
III	1 (1%)	1 (1%)
IV	1 (1%)	1 (1%)
Primary Indication		
Native Coarctation	65 (58%)	60 (57%)
Recurrent Coarctation	47 (42%)	45 (43%)

The analysis of safety was based on the implanted cohort of 112 COAST patients. The primary safety outcomes are presented in Table 3.

Table 3. Summary of COAST Outcomes and Pre-Specified Safety Endpoints

COAST	Safety Endpoint	Event Rate	P Value (CI)
Primary	Serious or Somewhat Serious Adverse event attributed to the Stent or Implantation procedure within 30 days of the procedure	8.9%	0.006 (4.9%, 14.7%)*
	Post-procedure paradoxical hypertension	7.5%	<0.001 (3.3%, 14.2%)+

*90% Confidence interval
+ 95% Confidence Interval
# confidence interval provided to illustrate the variability only and should not be used to draw any statistical conclusion.

The COAST primary safety endpoints were met with the occurrence of any serious or somewhat serious adverse events within 30 days post procedure being less than the predefined 18%. Post procedural paradoxical

hypertension was observed in 7.5% of patients in the COAST Trial. The COAST primary safety endpoint for the incidence of paradoxical hypertension (< 84%) was met.

The overall incidence and types of adverse events were within expected ranges. Aortic wall injuries were rare and treated appropriately without the need for emergency surgery.
There were no late complications related to device fracture noted, though incidence of stent fracture increased with time for COAST patients. Table 4 provides a summary of the adverse events reported under COAST.

Table 4. Summary of Adverse Events (AEs) for COAST

	Stent Related Events[1] (Rates)	**Stent, Implantation, or Catheterization Related Events[2] (Rates)**	**All Events (Rates)**
Patients with adverse events at 30 days	1 (0.9%)	37 (33.0%)	50 (44.6%)
Serious or somewhat serious events at 30 days	1 (0.9%)	10 (8.9%)	11 (9.8%)
Serious or somewhat serious events at 30 days, excluding stent fracture	1 (0.9%)	10 (8.9%)	11 (9.8%)
Serious event at 30 days	0 (0.0%)	0 (0.0%)	0 (0.0%)
Patients with adverse events at 12 Months	4 (3.6%)	40 (35.7%)	69 (61.6%)
Serious or somewhat serious events at 12 months	4 (3.6%)	13 (11.6%)	16 (14.3%)
Serious or somewhat serious events at 12 months, excluding stent fracture	2 (1.8%)	11 (9.8%)	14 (12.5%)
Serious event at 12 months	0 (0.0%)	0 (0.0%)	0 (0.0%)
Patients with adverse event at 24 Months	13 (11.6%)	47 (42.0%)	73 (65.2%)

[1]Includes events that are due to or possible due to stent, and stent fractures.
[2]Includes events that are due to or possible due to stent, implantation, or catheterization, and stent fractures

Table 5 through 7 document the stent related, implantation related and catheterization procedure related adverse events in the COAST.

Table 5: Stent Related Adverse Events for COAST

	Event	**n (Event Rate)**
COAST (n=112)	Aortic Aneurysm	1 (0.9 %)
	Increased cardiac output, tachycardia/light-headedness	1 (0.9 %)

Table 6: Implantation Related Adverse Events for COAST

	Event	n (Event Rate)
COAST (n=112)	Aortic Aneurysm	2 (1.8 %)
	Back Pain	1 (0.9 %)
	Chest Pain	5 (4.5 %)
	Confined Vascular Tear	3 (2.7 %)
	Groin Pain	4 (3.6 %)
	Intimal tear with vessel irregularity	1 (0.9 %)
	Jailed left subclavian	1 (0.9 %)
	Local hematoma groin	1 (0.9 %)
	Pain	1 (0.9 %)
	Right leg pain	1 (0.9 %)
	Stent malposition	1 (0.9 %)

Table 7: Catheterization Related Adverse Events for COAST

	Event	n (Event Rate)
COAST (n=112)	AV fistula	1 (0.9 %)
	Bleeding	1 (0.9 %)
	Corneal abrasion	1 (0.9 %)
	Decreased pulse	1 (0.9 %)
	Fever	1 (0.9 %)
	Groin pain	1 (0.9 %)
	Local hematoma groin	4 (3.6 %)
	Right inguinal hematoma	1 (0.9 %)

In the COAST trial five patients experienced aortic wall injury, four that occurred prior to hospital discharge and one that occurred by 24 month follow-up. These five events are detailed in Table 8, below.

Table 8: COAST Aortic Wall Injuries by 24 Month Follow-up

Patient	Bare Metal CP Stent Implanted	Type of Injury	Outcome of Event
1	No	Small aneurysm after dilation	Cross-over to Covered CP Stent
2	Yes	Therapeutic and localized tear	Resolved after implantation of Bare Metal CP Stent; tear no longer visible and not noted on further imaging
3	Yes	Contained rupture	Possible minimal aneurysm with no progression during admission; not noted on further imaging
4	Yes	Aneurysm	Implantation of Covered CP Stent
5	No	Acute, rapidly expanding aneurysm after dilation	Cross-over to Covered CP Stent

In COAST, four patients with events underwent catheter reinterventions, representing 3.7% of patients with an event. No surgical interventions were performed. Table 9 provides a summary of these four interventions.

Table 9: COAST Coarctation-Related Reintervention by 24 Months

Approximate Time to Intervention Post-procedure (Months)	Indication for Reintervention	Procedure Performed
11	Planned reintervention to fully expand stent	Redilation of stent, implantation of non-study stent
20	Planned re-expansion of stent	Redilation of stent
14	Aneurysm detected at 12m visit	Therapy for new aortic wall injury - implantation of Covered CP Stent
14	Planned re-expansion of stent, signs of restenosis at coarctation site	Redilation of stent

In COAST, two patients experienced non-coarctation related reinterventions that were documented by the 24 month follow-up. These patients underwent surgical interventions. The time to intervention for one patient was 20 months, at which time the patient had an aortic valve replacement to address progressive and severe left ventricular enlargement and progression of exercise intolerance. The time to intervention for the second patient was approximately two months, when the patient received a mitral valve replacement to address mitral regurgitation.

Stent fracture was increasingly common during follow-up ranging from 12% at 24 months to 36% at 60 months in patients treated with bare metal stents (COAST trial). However, no loss of structural integrity and no complications resulting in patient injury were observed. Table 10 shows the stent fractures in the COAST pivotal cohort.

Table 10: COAST Pivotal Cohort – Safety Data – Adverse Events – Stent Fracture

	Completed 12 Month Fluoroscopy (n=91)[1]	Completed 24 Month Fluoroscopy (n=87)[3]
Percentage of Eligible Subjects Undergoing Fluoroscopy	91/104[2] (88%)	87/103[4] (84%)
Stent Fracture	2 (2.2%)	11 (12.6%)
No loss of structural integrity	2	11
Loss of structural integrity	0	0

[1] Among 104 eligible subjects, excludes: 1 patient lost to follow-up at 1 month, 2 patients lost to follow-up at 6 months, and 3 patients lost to follow-up at 12 months. An additional 7 patients did not undergo fluoroscopy at 12 months.

[2] Cross-over patients treated with Covered CP Stent (5) were followed only through implantation of Bare Metal CP Stent; intent to treat patients (2) were followed only through hospital discharge. One patient withdrew consent prior to the 12 month visit.

[3] Among 103 eligible subjects, excludes: 6 patients previously lost to follow-up, and 5 patients lost to follow-up at 24 months. An additional 5 patients did not undergo fluoroscopy at 24 months.

[4] In addition to cross-over patients treated with Covered CP Stent, intent to treat patients, and 1 patient who withdrew consent prior to the 12 month follow-up, 1 patient was noted to have an aneurysm at the 12 month visit and was treated using a Covered CP Stent; this patient is no longer followed for COAST and is currently enrolled in COAST II.

The analysis of effectiveness was based on the 105 COAST patients receiving bare metal CP stents. The key effectiveness outcomes are presented in Tables 11 through 12. Although the COAST primary effectiveness for blood pressure gradient reduction was not met, the observed blood pressure gradients were clinically meaningful. Failure to meet the endpoint was a function of the endpoint chosen rather than a failure to achieve reduction of the underlying gradient. From a clinical perspective, relief of systolic blood pressure gradient was complete and sustained.

Table 11. Summary of Late Outcomes and Major Pre-Specified Effectiveness Study Endpoints

COAST	Effectiveness Endpoint	Event Rate	P Value (CI)
Primary	Mean Reduction in Systolic Blood Pressure Difference, Pre-Dilation to the 12 Month Post-Dilation Follow-Up	30 ±22mmHg	0.64 (26mmHg, 34mmHg)*
	Length of Stay in Hospital	1.1±0.3 days	<0.001 (1.0 days, 1.1 days)+

*90% Confidence interval
+ 95% Confidence Interval
# confidence interval provided to illustrate the variability only and should not be used to draw any statistical conclusion.

Table 12. COAST Pivotal Cohort - Systolic Blood Pressure

	Number (Percent) or Median (Range) And Mean ± Standard Deviation		
	Completed 1 Month Follow-up (n=100)[1]	Completed 12 Month Follow-up (n=92)[2]	Completed 24 Month Follow-up (n=87)[3]
Upper Extremity Systolic Blood Pressure (mmHg)			
Median (range)	118 (83 to 148)	122 (82 to 148)	121 (87 to 175)
Mean ± standard deviation	120 ± 12	123 ± 12	122 ± 14
Lower Extremity Systolic Blood Pressure (mmHg)			
Median (range)	119 (91 to 163)	122 (89 to 180)	123 (84 to 172)
Mean ± standard deviation	122 ± 15	123 ± 15	125 ± 16
Systolic Blood Pressure Difference (mmHg)			
Median (range)	-1 (-45 to 32)	-1 (-37 to 40)	-4 (-46 to 43)
Mean ± standard deviation	-2 ± 13	-1 ± 15	-3 ± 15
Reduction in Systolic Blood Pressure Difference Pre-Dilation (n=99[4], 91[5])	31 ± 18	30 ± 22[6]	33 ± 20

[1] Among 104 eligible subjects, excludes: 1 patient lost to follow-up at 1 month. An additional 3 patients missed the 1 month visit.

[2] Among 104 eligible subjects, excludes: 1 patient previously lost to follow-up, 2 patients lost to follow-up at 6 months, and 3 patients lost to follow-up at 12 months. An additional 6 patients missed the 12 month visit.

[3] Among 101 eligible subjects, excludes: 6 patients previously lost to follow-up, and 5 patients lost to follow-up at 24 months. An additional 3 patients missed the 24 month visit.

[4] One patient does not have 1 month systolic blood pressure difference due to missing lower extremity pressure.

[5] One patient does not have 12 month systolic blood pressure difference due to missing lower extremity pressure.

[6] Primary effectiveness outcome.

Procedural Data

A summary of procedural data of those enrolled patients who underwent cardiac catheterization for the purpose of Coarctation of the Aorta is provided in Table 13.

Table 13: COAST Pivotal Cohort – Procedural Data

	Number (Percent)
	Treated with Bare Metal CP Stent, or Meeting Study Eligibility Criteria but Not Treated with Bare Metal CP Stent (n=107)[1]
Bare Metal CP Stent Implanted	105 (98%)
Second Bare Metal CP Stent Implanted (n=105)	2 (2%)

[1] Includes: Patients treated with Bare Metal CP Stent meeting study eligibility criteria (102), patients treated with Bare Metal CP Stent not meeting study eligibility criteria (3), patients meeting study eligibility but not treated with Bare Metal CP Stent (2).

INSTRUCTIONS FOR USE:

Select Stent Size

1. Measure the length of the target stricture to determine the length of stent required. Size the stent length to extend slightly proximal and distal to the stricture.
2. The appropriate stent length should be selected based on covering the entire obstructed segment with a single stent.
   Note: Should more than one stent be required, place the stent most distal from the puncture site first, followed by placement of the proximal stent in tandem.
3. Measure the diameter of the reference stricture and vessel proximal and distal to the target lesion to determine the appropriate size stent and delivery system.

Preparation of Stent Delivery System

- Visually inspect the balloon/stent assembly to assure proper placement of the stent.

Stent Deployment

1. **Use of the tools supplied with the stent is necessary to defeat the hemostasis valve without damaging the stent or covering. Refer to insert IFU-CPCE. Once the stent is past the hemostasis valve, the tool must be pulled out of the valve.**
2. The system is advanced through the long delivery sheath and over the stiff guidewire into the desired location for implant.
3. After correct positioning of the stent, pull back on the sheath to expose the stent. Confirm proper stent position by a small injection of contrast through the sidearm of sheath or through a second catheter.
4. Expand the stent initially by inflating the inner balloon until it is fully expanded. One may "reposition" the stent at this point by moving the BIB catheter. The unexpanded outer balloon and expanded inner balloon hold the stent tightly against the BIB catheter. DO NOT deflate the inner balloon before expansion of the outer balloon. This could cause the stent to slip off the balloon catheter.
5. Confirm positioning and inflate the outer balloon to rated diameter. Do not exceed the rated burst pressure.

Delivery System Withdrawal

1. Once the stent is expanded, deflate both balloons completely and rotate to insure the stent is free and properly deployed. If there is a residual waist in the stent, expand only the outer balloon again, making sure not to exceed the rated burst pressure.
2. Remove the balloon catheter and confirm the result with angiography.

NOTE: Diameter of the stent may be increased after placement by expanding with a larger diameter balloon. Do not exceed the maximum recommended expanded stent diameter of 24mm.

RETURN OF EXPLANTED DEVICE:

NuMED, Inc. is interested in obtaining recovered CP Stents. Place the explanted device in a container or vial immediately after excision. For further instructions on the return of an explanted device, contact the RA Manager, NuMED, Inc. 2880 Main Street, Hopkinton, New York, 12965. Phone number: 315-328-4491.

WARNING:

NuMED stents are placed in the extremely hostile environment of the human body. Stents may fail to function for a variety of causes including, but not limited to, medical complications or failure of stent by fracture and embolization. In addition, despite the exercise of all due care in design, component selection, manufacture, and testing prior to sale, stents may be easily damaged before, during, or after insertion by improper handling, crimping or other intervening acts. Metal stents placed where there are extrinsic forces of compression, i.e. right ventricular outflow tract, are especially prone to fatigue fracture and embolization and should be avoided.

WARRANTY AND LIMITATIONS

Stents and accessories are sold in an 'as is' condition. The entire risk as to the quality and performance of the stent is with the buyer. NuMED disclaims all warranties, expressed or implied, with respect to catheters and accessories, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. NuMED shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any catheter or accessory or caused by any defect, failure, or malfunction of any catheter or accessory, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind NuMED to any representation or warranty with respect to catheters and accessories.

CP Stent™ Foreshortening Chart

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

CP Stent™ Balloon Sizing Chart

	Stent ID (mm)							
Inner Balloon Pressure (atm)	**12mm Diameter RBP = 7.0**	**14mm Diameter RBP = 6.0**	**15mm Diameter RBP = 5.0**	**16mm Diameter RBP = 5.0**	**18mm Diameter RBP = 4.0**	**20mm Diameter RBP = 4.0**	**22mm Diameter RBP = 3.0**	**24mm Diameter RBP = 3.0**
1	2.75	3.22	3.49	3.75	3.94	4.02	4.20	4.28
2	2.85	3.32	3.59	3.85	4.36	4.13	4.33	4.50
3	5.85	6.91	6.89	7.79	8.54	9.20	10.16	10.57
4	6.12	7.00	7.02	7.95	8.71	9.63	10.40	11.08
4.5							**10.84**	**11.94**
5	**6.20**	**7.08**	**7.10**	**8.04**	**8.91**	**10.00**		
Outer Balloon Pressure (atm)								
1	10.73	13.08	13.45	14.87	16.85	17.91	20.52	22.79
2	10.86	13.27	14.16	15.10	17.06	18.38	21.46	23.95
3	11.15	13.50	14.55	15.68	17.64	19.42	**21.98**	**24.68**
4	11.33	13.68	14.88	15.93	**18.06**	**20.07**		
5	11.62	13.87	**15.06**	**16.19**				
6	11.80	**13.98**						
7	**12.04**							

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

The figures in bold face represent the stent ID @ Rated Burst Pressure.

FOR ALL NUMED CATHETERS AN INFLATION DEVICE WITH PRESSURE GAUGE SHOULD BE USED.

BIB DELIVERY CATHETER BALLOON DIAMETER AND INTRODUCER 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**

This page intentionally left blank.

This page intentionally left blank.

Description of Graphical Symbols:

USE BY

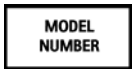
CONSULT INSTRUCTIONS FOR USE

REF

CATALOGUE NUMBER

MANUFACTURER

MR CONDITIONAL



MODEL NUMBER

BATCH CODE

STERILIZED USING ETHYLENE OXIDE

DO NOT REUSE

KEEP AWAY FROM SUNLIGHT

TEMPERATURE LIMITATION