Covered 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.

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B BRAUN

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INDICATIONS

The Covered Mounted 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 aortic 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

DESCRIPTION

The Covered CP Stent is balloon expandable and intended for permanent implant. The Covered 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 Covered CP Stent has an ePTFE covering attached to the stent framework. This covering acts as a fluid barrier creating a fluid tight conduit through the stent length.

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.
- 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 valve tool and introducer. This could cause the covering to tear off of 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.

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

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

COAST II was performed to establish a reasonable assurance of safety and effectiveness of implantation of the Covered 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 that evaluates the Covered CP Stent for treatment of coarctation of the aorta. For effectiveness, each patient serves as his or her own control. For safety, a performance goal was derived from surgical literature.

82 patients were included in the COAST II cohort at 19 investigational sites.

1. Clinical Inclusion and Exclusion Criteria

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

   Native or recurrent aortic coarctation*associated with one or more of the following:
   1. Acute or chronic aortic wall injury**
   2. Nearly atretic descending aorta to 3 mm or less in diameter.

3. Genetic Syndromes associated with aortic wall weakening. Individuals with genetic syndromes such as Marfan Syndrome, Turner's Syndrome or familial bicuspid aortic valve and ascending aortic aneurysm.
4. Advanced age. Men and woman aged 60 years or older.

** The significance of aortic obstruction is left to the judgment of the participating investigator. Indications might include mild resting aortic obstruction associated with:*

- *Exercise related upper extremity hypertension;*
- *Severe coarctation with multiple and/or large arterial collaterals;*
- *Single ventricle physiology*
- *Left ventricular dysfunction*
- *Ascending aortic aneurysm*

********Aortic wall injury might include:*

- *Descending aortic aneurysm*
- *Descending aortic pseudo-aneurysm*
- *Contained aortic wall rupture*
- *Non-contained rupture of the aortic wall*

Patients were <u>not</u> permitted to enroll in the COAST II study if they met any of the following exclusion criteria:

a. Patient size too small for safe delivery of the device. The absolute lower limit for inclusion under this protocol is 20 kg. However, serious femoral artery injury can occur in small patients, particularly those in the 20-30 kg range and this risk must be reviewed in detail with parents or guardians of children in this weight range.
b. Planned deployment diameter less than 10 mm or greater than 22 mm
c. Location requiring covered stent placement across a carotid artery*
d. Adults lacking capacity to consent
e. Pregnancy

**crossing or covering of a subclavian artery is acceptable in certain situations, but only after alternative treatments have been considered.*

2. <u>Follow-up Schedule</u>

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

3. <u>Clinical Endpoints</u>

With regards to safety, the following criteria were evaluated.

***Primary Safety Endpoint*:** 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: $p \geq 0.18$ vs. H_A: $p < 0.18$

***Secondary Safety Endpoint*:** Proportion of patients experiencing any of the following adverse events related to the device or implant procedure post 1 year

- Underlying cardiac or non-cardiac disease, aortic wall injury, new aortic aneurysm formation within region of device, stent misplacement, malposition, stent fracture, aortic wall aneurysms, or restenosis requiring reintervention.

With regards to effectiveness, the following criteria were evaluated.

***Primary Effectiveness Endpoint #1*:** Improvement of aortic wall injury and/or aortic arch obstruction by a median increase of at least one grade from pre-implantation baseline to 12 month follow-up using the Severity of Illness Scale(based on upper extremity (UE) systolic BP, UE to lower extremity (LE) systolic BP, and aortic wall injury).

The following hypothesis was tested using a one-sided Wilcoxon signed-rank test conducted at the 0.025 level of significance:

H_0: median change in grade ≤ 0 vs. H_A: median change in grade > 0

Primary Effectiveness Endpoint #2: Aortic wall injury and aortic arch obstruction at Grade 4 or above at the 12 month follow-up, based on the Severity of Illness Scale, with no clinical worsening.

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

H_0: $p \leq 0.70$ vs. H_A: $p > 0.70$

Secondary Effectiveness Endpoints:

- Reduction of arm-leg systolic blood pressure gradients to less than 20mmHg and less than 15 mmHg.
- Reduction of upper extremity blood pressure at 1 year compared to baseline
- Repair of wall defect with <10% residual endoleak on MRI or CT in patients with aortic wall injury
- Hospital length of stay compared to length of stay for surgical repair of aortic coarctation.

82 patients were enrolled in COAST II and study accountability is detailed in Table 1.

Table 1: COAST II Accountability

COAST II Patients	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	82	82 (100%)	69 (84%)	67 (81.7%)	55 (67.1%)	38 (46.3%)	22 (26.8%)
Effectiveness Cohort	82	82 (100%)	68 (83%)	66 (80.5%)	54 (65.8%)	37 (45.1%)	21 (25.6%)

Subject Demographics

Table 2 presents subject demographics and baseline characteristics analyzed for the enrolled subjects. The study population consisted of 52 male and 30 female subjects with a mean age of 18 (range 6 to 67 years).

Table 2: COAST II Pivotal Cohort – Patient Characteristics

Assessment	Number (Percent) or Median (Range)		
	Prospective (n=29)	Legacy (n=53)	Total (n=82)
Gender			
Male	21 (72%)	31 (58%)	52 (63%)
Female	8 (28%)	22 (42%)	30 (37%)
Age, years	20 (6 to 67)	17 (6 to 66)	18 (6 to 67)
Primary Indication			
Repair of aortic wall injury	15 (52%)	34 (64%)	49 (60%)
Prevention of aortic wall injury[1]	14 (48%)	19 (36%)	33 (40%)

[1] Includes 1 patient classified as not having pre-existing aortic wall injury, who was noted to have a small, localized intimal tear with a diameter of < ¼ the aortic diameter.

The analysis of safety was based on the implanted cohort of 82 COAST II patients completing their implant procedures. The primary safety outcomes are presented in Table 3.

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

COAST II	**Safety Endpoint**	**Event Rate**	**P Value (CI)**
Primary	Serious or Somewhat Serious Adverse Events Attributed to the Stent, Implantation or Catheterization within 30 days of the procedure (includes data from COAST combined with COAST II)	8.2%	<0.001 (5.2%, 12.3%)*
Secondary	Proportion of patients experiencing any AEs related to the device or implant procedure post 1 year (among 74 patients followed for at least 1 year)	6.8%	N/A (2.2%, 15.1%)[+#]

*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 II primary safety endpoints were met with the occurrence of any serious or somewhat serious adverse event within 30 days post procedure being less than the predefined 18%. 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. The results are durable out to 60 months for each study and re-coarctation was treated by transcatheter means when it occurred. Table 4 provides a summary of the adverse events reported under COAST II.

Table 4: Summary of Adverse Events (AEs) for COAST II

	Stent Related Events[1] (Rates)	Stent, Implantation, or Catheterization Related Events[2] (Rates)	All Events (Rates)
Patients with adverse events at 30 days	2 (2.4%)	27 (32.9%)	42 (51.2%)
• Serious or somewhat serious events at 30 days	1 (1.2%)	6 (7.3%)	7 (8.5%)
• Serious or somewhat serious events at 30 days, excluding stent fracture	1 (1.2%)	6 (7.3%)	7 (8.5%)
• Serious event at 30 days	0 (0.0%)	1 (1.2%)	1 (1.2%)
Patients with adverse events at 12 Months	4 (4.9%)	30 (36.6%)	58 (70.7%)
Serious or somewhat serious events at 12 months	3 (3.7%)	7 (8.5%)	14 (17.1%)
Serious or somewhat serious events at 12 months, excluding stent fracture	3 (3.7%)	7 (8.5%)	14 (17.1%)
Serious event at 12 months	1 (1.2%)	1 (1.2%)	4 (4.9%)
Patients with adverse event at 24 Months	5 (6.1%)	31 (37.8%)	60 (73.2%)

[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 presents incidence of stent fractures. There were no stent fractures detected at 12 month fluoroscopy. One stent fracture was detected at 24 month fluoroscopy. There was no loss of structural integrity in the detected fracture.

Table 5: COAST II Pivotal Cohort – Safety Data – Adverse Events – Stent Fracture

	Completed 12 Month Fluoroscopy (n=69)[1]	Completed 24 Month Fluoroscopy (n=65)[2]
Percentage of Eligible Subjects Undergoing Fluoroscopy	69/81[2] (85%)	65/80[4] (81%)
Stent Fracture	0 (0.0%)	1 (1.5%)
No loss of structural integrity	0	1
Loss of structural integrity	0	0

[1] Among 81 eligible subjects, excludes: 3 patients lost to follow-up at 6 and 4 patients lost to follow-up at 12 months. An additional 5 patients did not undergo fluoroscopy at 12 months.

[2] One patient died prior to 12 month follow-up.

[3] Among 80 eligible subjects, excludes: 7 patients previously lost to follow-up, and 2 patients lost to follow-up at 24 months. An additional 6 patients did not undergo fluoroscopy at 24 months.

[4] In addition to 1 patient who died prior to 12 month follow-up, 1 patient withdrew consent prior to 24 month visit.

Tables 6 through 8 document the stent related, implantation related and catheterization procedure related adverse events in the COAST II trial.

Table 6: Stent Related Adverse Events for COAST II

	Event	n (Event Rate)
COAST II (n =82)	Aortic Aneurysm	2 (2.4 %)
	Asymmetric Stent Shortening	1 (1.2 %)
	Left arm numbness and weakness	1 (1.2 %)

Table 7: Implantation Related Adverse Events for COAST II

	Event	n (Event Rate)
COAST II (n =82)	Aneurysmal formation	1 (1.2 %)
	Chest pain	4 (4.9 %)
	Chest and back pain	1 (1.2 %)
	Easy bruising on aspirin	1 (1.2 %)
	Increased bruising	1 (1.2 %)
	Right groin pain	1 (1.2 %)
	Stent malposition	2 (2.4 %)
	Wound bleeding	1 (1.2 %)

Table 8: Catheterization Related Adverse Events for COAST II

	Event	n (Event Rate)
COAST II (n =82)	Aneurysm	1 (1.2 %)
	Atrial arrhythmia	1 (1.2 %)
	Brachial plexus injury	1 (1.2 %)
	Contact skin rash	1 (1.2 %)
	Corneal abrasion	1 (1.2 %)
	Discomfort right eye	1 (1.2 %)
	Dissection of iliac artery	1 (1.2 %)
	Ecchymosis/groin tenderness	1 (1.2 %)
	Femoral artery occlusion	1 (1.2 %)
	Local hematoma groin	2 (2.4 %)
	Localized groin bruising	1 (1.2 %)
	Minimal bleeding/cough	1 (1.2 %)
	Neck swelling	1 (1.2 %)
	Pulsatile bleeding	1 (1.2 %)
	Right iliac dissection/pulse loss	1 (1.2 %)
	Superficial infection of groin	1 (1.2 %)
	Wide complex non-sustained tachycardia	1 (1.2 %)

There were five patients that crossed over from COAST to COAST II. One patient crossed over due to a small aneurysm after dilation, two patients due to a near atretic aorta, one patient due to localized intimal tear after dilation and one patient due to an acute, rapidly expanding aneurysm after dilation. In the COAST II trial two patients experienced two events, representing 2.4% of patients, and both events were resolved using a second Covered CP stent to fully occlude the aneurysm developed with no permanent damage. In the COAST II trial, three patients experienced aortic wall injuries by the 24 month follow-up. These injuries are detailed in Table 9, below.

Table 9: COAST II Aortic Wall Injuries by 24 Month Follow-up

Date of Catheterization	Date of MRI	Injury Detected	Intervention
11/11/2009	11/16/2011[1]	Neo-intimal proliferation	Therapy for new aortic wall injury – implantation of Covered CP Stent
2/23/2010	3/31/2011[1]	Small aneurysm at 12 m visit	Therapy for new aortic wall injury – implantation of Covered CP Stent
4/15/2010	5/12/2011	Small aneurysm at 12 m visit	New Covered CP Stent implanted to occlude aneurysm

[1]Aortic wall injury not confirmed by MRI at follow-up visit. Confirmed during reintervention.

In COAST II, six patients experienced coarctation-related events, representing 7.3% of patients with events. These patients underwent catheter reinterventions. No surgical interventions were completed. Table 10 provides a summary of these interventions.

Table 10: COAST II Coarctation-Related Reintervention by 24 months

Approximate Time to Intervention Post-procedure (Months)	Indication for Reintervention	Procedure Performed
7	Persistent hypertension and gradient across aortic arch	Radiation of stent
7	Planned re-expansion of stent	Radiation of stent
9	Planned re-expansion of stent	Radiation of stent
25	Increased gradient with somatic growth; neo-intimal proliferation detected in cath lab	Therapy for new aortic wall injury - implantation of Covered CP Stent
14	Aneurysm detected by MRI at 12 m visit[1]	Therapy for new aortic wall injury - implantation of Covered CP Stent
13	Aneurysm detected by MRI at 12 m visit1	Therapy for new aortic wall injury - implantation of Covered CP Stent

[1.] Presence of aneurysm in this patient was not confirmed by core laboratory review of the MRI

In COAST II, two patients experienced non-coarctation related reinterventions that were documented by the 24 month follow-up, representing 2.4% of the patients with events. These patients underwent catheter reinterventions. The time to intervention for one patient was four months, when the patient received a coronary angiogram and graft angiogram to address symptoms of angina. The time to intervention for the second patient was 26 months when the Melody valve was implanted to address a high right ventricle to pulmonary artery conduit gradient. The incidence of stent fracture for covered CP stents (COAST II) was much lower and was not observed to substantially increase over time. Also, relief from blood pressure gradient was maintained through 60 month follow-up and re-intervention was rare. When needed, this was accomplished using transcatheter interventions.

The key effectiveness outcomes of COAST II are shown in Table 11 through 12.

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

	Effectiveness Endpoint	Event Rate	P Value (CI)
COAST II ***Primary***	Severity of Illness Scale Grade 4 or 5 with No Clinical Worsening at 12 Month Follow-up	80%	0.048 (70.1%, 87%)*
COAST II ***Secondary***	Proportion of patients with arm-leg systolic blood pressure differences less than 20mmHg and less than 15 mmHg at 12 month follow-up, compared to baseline	87% (up from 46% at baseline) 79% (up from 38% at baseline)	p<0.001 (76%, 94%)[+] p<0.001 (68%, 88%)[+]
	Reduction of upper extremity blood pressure at 1 year compared to baseline	12 ±20mmHg	N/A (7mmHg, 17mmHg)[+#]
	Complete repair of aortic wall defect with first Covered CP Stent (no residual endoleak during the catheterization procedure	47 of 49 (96%) of patients treated for an aortic wall injury	N/A
	Proportion of patients with effective treatment of AWI with no residual aneurysm seen on MRI scanning	37 of 39 (95%) patients treated for an aortic wall injury 1/39 (2.5%) with a small aneurysm and one patient's MRI could not be evaluated by core lab	N/A
	Hospital length of stay compared to length of stay for surgical repair of aortic coarctation	1.2 ± 0.9 days	<0.001 (1.0 days, 1.4 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 II Pivotal Cohort – Systolic Blood Pressure

	Number (Percent) or Median (Range) And Mean ± Standard Deviation	
	Completed 12 Month Follow-up (n=68)[1]	Completed 24 Month Follow-up (n=66)[2]
Upper Extremity Systolic Blood Pressure (mmHg)		
Median (range)	123 (98 to 166)	126 (96 to 158)
Mean ± standard deviation	125 ± 14	126 ± 13
Lower Extremity Systolic Blood Pressure (mmHg)		
Median (range)	121 (90 to 199)	124 (86 to 156)
Mean ± standard deviation	124 ± 21	125 ± 16
Systolic Blood Pressure Difference (mmHg)		
Median (range)	2 (-48 to 38)	0 (-35 to 62)
Mean ± standard deviation	1 ± 16	1 ± 17
Systolic Blood Pressure Difference		
< 10 mmHg	46 (68%)	52 (79%)
< 15 mmHg	54 (79%)	56 (85%)
< 20 mmHg	59 (87%)	60 (91%)

[1] Among 81 eligible subjects, excludes: 3 patients lost to follow-up at 6 and 4 patients lost to follow-up at 12 months. An additional 6 patients missed the 12 month visit.

[2] Among 80 eligible subjects, excludes: 7 patients previously lost to follow-up, and 2 patients lost to follow-up at 24 months. An additional 5 patients missed the 24 month visit.

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 II Pivotal Cohort – Procedural Data

	Number (Percent)
	Total (n=82)
Covered CP Stent Implanted	82 (100%)
Second Covered CP Stent Implanted	9 (11%)
Third Covered CP Stent Implanted	2 (2%)
Patient Free of Explant 24 hours after Procedure	82 (100%)

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

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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