NuMED
Summary of Safety and Clinical Performance
SSCP – Stents – CoA

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1. Device identification and general information	
Device trade name(s)	NuMED Coarctation of the Aorta (CoA) Stent Family CP Stent Mounted CP Stent
Manufacturer's name and address	NuMED, Inc. 2880 Main Street Hopkinton, NY 12965 USA
Manufacturer's single registration number (SRN)	US-MF-000010948
Basic UDI-DI	CP Stent – 08877141600T2 Mounted CP Stent – 08877141610T5
Medical device nomenclature description / text	EMDN – P070402010102 – METALLIC NON-STAINLESS STEEL CORONARY STENTS
Class of device	III
Year when first certificate (CE) was issued	2004 (CP Stent) 2009 (Mounted CP Stent)
Authorised Representative (AR)	EVOMED, S.L.U. Ctra. Torrejón-Ajalvir Km. 5,2 28864 Ajalvir (Madrid), Spain
AR SRN	ES-AR-000047116
Notified Body	SGS Belgium NV
Notified Body ID number	1639

2. Intended use of the device	
Intended Purpose	Intended to dilate aortic coarctations using percutaneous implantation techniques.
Indications(s) and Target Populations(s)	Coarctation of the Aorta (CoA) Indicated for treatment of 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 adjacent vessel diameter. Stenosis that would present increased risk of vascular damage or disruption; or aneurysm associated with coarctation of the aorta.

	Target Population The devices are used to treat any patients that have an aortic coarctation as long as none of the below listed contraindications and/or limitations are applicable.
Contraindications and/or limitations	Contraindications include: • 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; • 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.

3. Device description	
Description of the device	The stents are balloon expandable and intended for permanent implant. The stents are composed of heat treated 90% platinum / 10% iridium wire that is arranged in a "zig" pattern, laser welded at each joint, and over brazed with 24K gold. 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 percent stent shortening, while the number of rows will determine the unexpanded length of the stent. The Balloon In Balloon (BIB) Stent Placement Catheter is triaxial in construction with two lumens being used to inflate the balloon while one lumen is being used for tracking over a guidewire. The inner balloon is ½ of the outer balloon diameter and 1 cm shorter. The purpose of the double balloon catheter is to apply an incremental inflation for the purpose of dilating a stent. The inner balloon provides initial expansion of the stent and also acts as a tool to hold the stent on the catheter prior to the outer balloon being inflated. The outer balloon is then inflated, providing the remainder of the expansion. There are radiopaque platinum marker bands under the balloon shoulders, to aid during placement. The balloons are designed to inflate to the diameter and length listed on the label at a specific pressure. Thus, it is recommended that the device be used in conjunction with a mechanism to monitor pressure, an inflation device with pressure gauge. The devices are supplied sterile, by ethylene oxide gas, and are intended for single use only.

Reference to previous generation(s) or variants

Device Variants – CP Stent:

REF	Description
CP8Z16	8 Zig 1.6 cm
CP8Z22	8 Zig 2.2 cm
CP8Z28	8 Zig 2.8 cm
CP8Z34	8 Zig 3.4 cm
CP8Z39	8 Zig 3.9 cm
CP8Z45	8 Zig 4.5 cm
CP8Z50	8 Zig 5.0 cm
CP8Z55	8 Zig 5.5 cm
CP8Z60	8 Zig 6.0 cm
CP10Z39	10 Zig 3.9 cm
CP10Z45	10 Zig 4.5 cm
CP10Z50	10 Zig 5.0 cm
CP10Z55	10 Zig 5.5 cm
CP10Z60	10 Zig 6.0 cm

Device Variants – Mounted CP Stent:

REF	Description
MCP001	8 ZIG 1.6 CM 6X1.5////12X2.5X8X8X110X0.035
MCP002	8 ZIG 1.6 CM 7X1.5////14X2.5X8X8X110X0.035
MCP003	8 ZIG 1.6 CM 8X1.5////16X2.5X9X9X110X0.035
MCP004	8 ZIG 2.2 CM 6X1.5////12X2.5X8X8X110X0.035
MCP005	8 ZIG 2.2 CM 7X1.5////14X2.5X8X8X110X0.035
MCP006	8 ZIG 2.2 CM 8X1.5////16X2.5X9X9X110X0.035
MCP007	8 ZIG 2.2 CM 9X1.5////18X2.5X10X9X110X0.035
MCP008	8 ZIG 2.8 CM 7X2////14X3X8X8X110X0.035
MCP009	8 ZIG 2.8 CM 8X2////16X3X9X9X110X0.035
MCP010	8 ZIG 2.8 CM 9X2////18X3X10X9X110X0.035
MCP011	8 ZIG 2.8 CM 10X2////20X3X10X9X110X0.035
MCP012	8 ZIG 3.4 CM 7X2.5////14X3.5X8X8X110X0.035
MCP013	8 ZIG 3.4 CM 8X2.5////16X3.5X9X9X110X0.035
MCP014	8 ZIG 3.4 CM 9X2.5////18X3.5X10X9X110X0.035
MCP015	8 ZIG 3.4 CM 10X2.5////20X3.5X10X9X110X0.035
MCP016	8 ZIG 3.4 CM 11X2.5////22X3.5X11X9X110X0.035
MCP017	8 ZIG 3.9 CM 7X3////14X4X8X8X110X0.035
MCP018	8 ZIG 3.9 CM 8X3////16X4X9X9X110X0.035
MCP019	8 ZIG 3.9 CM 9X3////18X4X10X9X110X0.035
MCP020	8 ZIG 3.9 CM 10X3////20X4X10X9X110X0.035
MCP021	8 ZIG 3.9 CM 11X3////22X4X11X9X110X0.035
MCP022	8 ZIG 3.9 CM 12X3////24X4X11X9X110X0.035
MCP023	8 ZIG 4.5 CM 7X3.5////14X4.5X8X8X110X0.035
MCP024	8 ZIG 4.5 CM 8X3.5////16X4.5X9X9X110X0.035
MCP025	8 ZIG 4.5 CM 9X3.5////18X4.5X10X9X110X0.035
MCP026	8 ZIG 4.5 CM 10X3.5////20X4.5X10X9X110X0.035
MCP027	8 ZIG 4.5 CM 11X3.5////22X4.5X11X9X110X 0.035
MCP028	8 ZIG 4.5 CM 12X3.5////24X4.5X11X9X110X0.035
MCP029	8 ZIG 4.5 CM 7X4////14X5X8X8X110X0.035
MCP030	8 ZIG 4.5 CM 8X4////16X5X9X9X110X0.035
MCP031	8 ZIG 4.5 CM 9X4////18X5X10X9X110X0.035
MCP032	8 ZIG 4.5 CM 10X4////20X5X10X9X110X0.035
MCP033	8 ZIG 4.5 CM 11X4////22X5X11X9X110X0.035
MCP034	8 ZIG 4.5 CM 12X4////24X5X11X9X110X0.035
MCP035	8 ZIG 3.4 CM 6X2.5////12X3.5X8X8X110X0.035
MCP036	8 ZIG 3.9 CM 6X3////12X4X8X8X110X0.035
MCP037	8 ZIG 4.5 CM 6X4////12X5X8X8X110X0.035
MCP038	8 ZIG 2.8 CM 6X2////12X3X8X8X110X0.035
MCP040	10 ZIG 3.9 CM 13X3////26X4X16X11X110X0.035

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Reference to previous generation(s) or variants

REF	Description
MCP041	10 ZIG 3.9 CM 14X3////28X4X16X11X110X0.035
MCP042	10 ZIG 3.9 CM 15X3////30X4X16X11X110X0.035
MCP044	10 ZIG 4.5 CM 13X4////26X5X16X11X110X0.035
MCP045	10 ZIG 4.5 CM 14X4////28X5X16X11X110X0.035
MCP046	10 ZIG 4.5 CM 15X4////30X5X16X11X110X0.035
MCP048	10 ZIG 5.0 CM 13X4.5///26X5.5X16X11X110X0.035
MCP049	10 ZIG 5.0 CM 14X4.5///28X5.5X16X11X110X0.035
MCP050	10 ZIG 5.0 CM 15X4.5///30X5.5X16X11X110X0.035
MCP052	10 ZIG 5.5 CM 13X5////26X6X16X11X110X0.035
MCP053	10 ZIG 5.5 CM 14X5////28X6X16X11X110X0.035
MCP054	10 ZIG 5.5 CM 15X5////30X6X16X11X110X0.035
MCP056	10 ZIG 6.0 CM 13X5////26X6X16X11X110X0.035
MCP057	10 ZIG 6.0 CM 14X5////28X6X16X11X110X0.035
MCP058	10 ZIG 6.0 CM 15X5////30X6X16X11X110X0.035
MCP059	8 ZIG 5.0 CM 6X4.5////12X5.5X8X8X110X0.035
MCP060	8 ZIG 5.0 CM 7X4.5////14X5.5X8X8X110X0.035
MCP061	8 ZIG 5.0 CM 8X4.5////16X5.5X9X9X110X0.035
MCP062	8 ZIG 5.0 CM 9X4.5////18X5.5X10X9X110X0.035
MCP063	8 ZIG 5.0 CM 10X4.5////20X5.5X10X9X110X0.035
MCP064	8 ZIG 5.0 CM 11X4.5////22X5.5X11X9X110X0.035
MCP065	8 ZIG 5.0 CM 12X4.5////24X5.5X11X9X110X0.035
MCP066	8 ZIG 5.5 CM 6X5////12X6X8X8X110X0.035
MCP067	8 ZIG 5.5 CM 7X5////14X6X8X8X110X0.035
MCP068	8 ZIG 5.5 CM 8X5////16X6X9X9X110X0.035
MCP069	8 ZIG 5.5 CM 9X5////18X6X10X9X110X0.035
MCP070	8 ZIG 5.5 CM 10X5////20X6X10X9X110X0.035
MCP071	8 ZIG 5.5 CM 11X5////22X6X11X9X110X0.035
MCP072	8 ZIG 5.5 CM 12X5////24X6X11X9X110X0.035
MCP073	8 ZIG 6.0 CM 6X5////12X6X8X8X110X0.035
MCP074	8 ZIG 6.0 CM 7X5////14X6X8X8X110X0.035
MCP075	8 ZIG 6.0 CM 8X5////16X6X9X9X110X0.035
MCP076	8 ZIG 6.0 CM 9X5////18X6X10X9X110X0.035
MCP077	8 ZIG 6.0 CM 10X5////20X6X10X9X110X0.035
MCP078	8 ZIG 6.0 CM 11X5////22X6X11X9X110X0.035
MCP079	8 ZIG 6.0 CM 12X5////24X6X11X9X110X0.035

Accessories which are intended to be used in combination with the device	All stents are designed to be used with the hemostasis valve tools that are provided with the stents.
Description of any other devices and products which are intended to be used in combination with the device	All stents are designed to be used with delivery catheter, guidewire, introducer, balloon inflation medium, inflation device with pressure gauge, and a stopcock.

4. Risks and Warning	
Residual risks and undesirable effects	All significant risks were considered, mitigated as far as possible (AFAP), and are acceptable in regard to the clinical benefit of the device. The clinical investigations performed on the CP Stent family of devices reported the following side effects: Coarctation of the Aorta Stent Trial (COAST): aortic aneurysm, stent fracture The literature reported the following side effects: acute wall rupture / dissection, aortic aneurysm / pseudoaneurysm, balloon rupture, death, femoral artery dissection / pseudoaneurysm, homograft rupture, femoral / groin hematoma, thrombosis, late lumen loss, cerebrovascular incident, stent displacement, stent fracture, stent migration, and cardiogenic / septic shock. Known and foreseeable clinical risks have been considered in accordance with risk management (RM) procedure AP-346 and through the RM files and mitigated as far as possible (AFAP). **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. Potential complications & adverse effects associated with device use and indication include: • Femoral artery injury • Stent Migration • Stent Fracture • Aortic Rupture/Tear • Hematoma • Thrombosis • Embolization • Death • Endocarditis • Stent Stenosis • Aneurysm / Pseudoaneurysm • Stent Malposition • Sepsis/Infection • Transitory arrhythmia • Bleeding • Cerebrovascular Incident
Warning and Precautions	The following Warnings and Precautions have been identified and are called out in the Instruction for Use: **STENT WARNINGS** • Radiofrequency heating during MRI scans on overlapped, 10 zig Stents has not been evaluated, and is not recommended. • As with any type of implant, infection secondary to contamination of the stent may lead to aortitis, or abscess. • The platinum/iridium stent may migrate from the site of implant. • Over-stretching of the artery may result in rupture or aneurysm formation. • When the stent is crimped onto a balloon delivery catheter, the maximum balloon inflation pressure must not exceed the recommended inflation pressure specified in the manufacturer's instructions. • The inflated diameter of the stent should at least equal the diameter of the intended implant site. • 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. • 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.

MOUNTED STENT WARNINGS

- Radiofrequency heating during MRI scans on overlapped, 10 zig Stents has not been evaluated, and is not recommended.
- As with any type of implant, infection secondary to contamination of the stent may lead to aortitis, or abscess.
- The platinum/iridium stent may migrate from the site of implant.
- Over-stretching of the artery may result in rupture or aneurysm formation.
- The inflated diameter of the stent should at least equal the diameter of the intended implant site.
- 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.

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 markers 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 dilatation 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 except when the procedure has been completed.
- 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.

STENT PRECAUTIONS

- Use of an inflation device with pressure gauge is highly recommended during this procedure.
- Stents are delicate devices. Care should be exercised while handling to help prevent the possibility of breakage.
- 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 instruments. 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.
- 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.

MOUNTED STENT PRECAUTIONS

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- Dilatation procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment.
- Guidewires are delicate instruments. 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, then the balloon, guidewire and the sheath should be removed together 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.

	• The balloons must be completely deflated before retracting into the sheath. • 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.
Other relevant aspects of safety, including a summary of any field safety corrective actions (FSCA including FSN) if applicable	Since commercialization, there has been one recall on the Bare CP Stent in 2003 (#Z-0983-03, completed in 2004) concerning the lack of PMA or 510(k) for the Bare CP Stent. The recall was conducted in the U.S. only. There have not been any Field Safety Corrective Actions or Field Safety Notices on any other version of the Stents.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

Summary of clinical data related to equivalent device, if applicable:

An equivalent device was not used for the clinical evaluation.

Summary of clinical data from conducted investigations of the device, if applicable:

1. **Study name: COAST**

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Prospective, multicenter, single arm interventional, open label study.	To evaluate the intermediate results of CP Stent (Bare and Covered) to treat native and recurrent CoA in selected children, adolescents, and adult.	1	**2**	3	4	5

Suitability	Relevant Data	Grading		
Device	- CP Stents (Bare and Covered) - CP Stent delivered on a BIB (not pre-mounted) - Because of the known risk of aortic wall complications during CoA intervention, NuMED covered CP Stents (CCPs) were made available to study centers for use in the event of aortic wall injury (AWI). Data on patients receiving a CCPS are included in this report for safety outcomes. These patients were then enrolled in the COAST II trial of aortic covered stents (NCT01278303) for subsequent evaluation of efficacy and long-term outcomes.	**D1**	D2	D3
Application	- CoA (native and recurrent)	**A1**	A2	A3
Patient	- Patients with native or recurrent CoA - Sampling: n=105 - Mean age: 16 (range: 8 to 52) years old - Sex: 73M; 32F	**P1**	P2	P3
Report	- High quality	**R1**	R2	R3
	Suitability Grade (Range 4-12)	4		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	- Blood pressure gradient - Coarctation minimum diameter: cardiac catheterization before and after CP Stent placement - Safety	**Yes 1**	No 2
Follow-up	- 12 - 24 months with certain assessments extending to 5 years.	**Yes 1**	No 2
Statistical analysis	- Descriptive statistics are presented as mean ± SD or median (minimum–maximum). Bivariate comparisons of preimplantation and post implantation catheterization data and subsequent blood pressures were performed with the paired t test. Comparison of means or proportions between populations were performed by unpaired t test or Wilcoxon rank-sum test based on distribution and the Fisher exact test, respectively. Multivariable analysis of dichotomous outcome variables was performed with logistic regression. Analysis of time-dependent occurrences was presented graphically with Kaplan-Meier plots and analyzed statistically	**Yes 1**	No 2

		by the log-rank test. Predictors of time-dependent outcomes such as reintervention were obtained from Cox proportional hazards modeling.		
Clinical significance	-	The CP stent is safe and associated with persistent relief of aortic obstruction. Stent fracture and progression of fracture occur but have not resulted in clinically important sequelae. Reintervention is common and related to early and late aortic wall injury and need for re-expansion of small-diameter stents.	**Yes 1**	No 2
		Data Contribution Grade (Range 4-8)	4	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (2) + Suitability (4) + Data Contribution (4) = 10	Disposition and Weighting (select)	**Accepted and Pivotal 9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

Purpose: to provide information that will support labeling of both the CP Stent (Bare and Covered) to treat native and recurrent CoA in selected children, adolescents and adult

Clinical Study Methodology: Single arm interventional study (open label). The COAST is a prospective, multicenter, single-arm clinical study involving 19 pediatric cardiology centers in the United States. The study includes patients with native or recurrent CoA treated by physicians at the participating institutions. A total of 105 patients underwent attempted implantation, with 104 successes.

Reference to the clinical study plan (and amendment) n°: NCT00552812

Investigation Site: 19 pediatric cardiology centers in United States ***Reference to Approved Consent Forms:*** *N/A*	**Ethics Committee Approvals:** Institutional Review Board approvals from all participating institutions ***Reference to Document n°:*** *N/A*	**Regulatory Authority Approvals:** Investigational Device Exemption from US FDA (August 3, 2007) ***Reference to Documents n°:*** G060057

Patient Population: Patients with native or recurrent CoA. A total of 105 patients underwent attempted implantation, median age 16 years (range from 8 to 52 years) and with 69.5% male.

Clinical Study Results: Results held by Sponsor.

Purpose	Criteria	Results
Safety	Adverse events	No serious adverse events reported, 7% of the patients experienced somewhat serious events. Aortic aneurysms (n=6): 5 were successfully treated with covered stent placement, and 1 resolved without intervention. Stent fractures were seen in 2 patients after one year, 11 patients at two years and 12 additional fractures above 2 years.

Reference to the Clinical Study Report n°: NCT00552812

Device Used: Bare CP Stent and BIB catheter; covered stents were available in case of aortic wall injury

Conclusion: The CP stent is safe and associated with persistent relief of aortic obstruction. Stent fracture and progression of fracture occur but have not resulted in clinically important sequelae. Reintervention is common and related to early and late aortic wall injury and need for re-expansion of small-diameter stents.

Clinical Publication: Meadows J, Minahan M, McElhinney DB, McEnaney K, Ringel R. Intermediate Outcomes in the Prospective, Multicenter Coarctation of the Aorta Stent Trial (COAST). Circulation 131, 1656-1664 (2015)

Summary of clinical data from other sources, if applicable:

First Author (Year)	Appraisal/Results
1. Baykan et al. (2018)	**Safety & Performance (safety only)**

Contribution	
S&P	X (safety only)
SOA	

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Control study. Study group was composed of 20 CoA patients who were treated with CP Stent between the dates October 2008 and February 2015, and control group was composed of 20 healthy children with age and sex matched.	To address the presence of hypertension and risk for cardiovascular diseases in patients with CoA who were treated with endovascular stent placement.	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	- CP Stents (Bare and Covered)	**D1**	D2	D3
Application	- CoA	**A1**	A2	A3

Patient	- Patients who had undergone stent placement for CoA compared with control group (healthy children with age and sex matched).
	- Sampling: n=20 CoA and n=20 healthy children
	- Mean age:
	  - CoA group: 14.2 (SD: 3.9) years
	  - Control group: 13.7 (SD: 2.7) years
	- Sex:
	  - CoA group: 16M; 4F
	  - Control group: 15M; 5F
		P1	P2	P3

Report	- High quality	**R1**	R2	R3
	Suitability Grade (Range 4-12)	4		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	- Ambulatory blood pressure	**Yes 1**	No 2
Follow-up	- 6 months and 6 years	**Yes 1**	No 2
Statistical analysis	- Student t-test was used if the two independent group comparisons were normal and the Mann-Whitney U test was used if the normal distribution was not present. Pearson chi-square analysis was performed to determine whether there was a difference in categorical variables between the case and control groups.	**Yes 1**	No 2
Clinical significance	- It was shown that hypertension incidence as demonstrated by ambulatory blood pressure monitorization and risk for cardiovascular diseases as indicated by carotid intima media thickness and pulse wave velocity were higher than those in healthy population even after CoA is corrected. - CoA should be carefully monitored for hypertension, even if it has been completely corrected	**Yes 1**	No 2

	by any method. This study suggests that CoA is a part of generalized vasculopathy rather than being a localized narrowing.		
	Data Contribution Grade (Range 4-8)	4	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (3) + Suitability (4) + Data Contribution (4) = 11	Disposition and Weighting (select)	**Accepted and Pivotal 9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

Relevant S&P Results

Safety data	- Hypertensive:
	  - Daytime: 5% were hypertensive and 20% were pre-hypertensive in the study group compared to 0% in the control group.
	  - Night: 15% were hypertensive and 15% were pre-hypertensive in the study group compared to 0% in the control group.

Performance data	- Mean arterial pressure:
	  - At 24 hours: 88.5 (81-96) mmHg in study group and 83 (80-86) mm Hg in control group
	  - Daytime: 91 (84-99) mmHg in study group and 84 (81-88) mmHg in control group
	  - Night: 78 (76-87) mmHg in study group and 78 (75-81)mmHg in control group

Benefits/claims data	- N/A
Strengths	- N/A
Weaknesses/ Potential bias	- Patients were treated only with "NuMED brand Bare and Covered Stent" types. In the future the authors can do more extensive studies with more cases and different types of stents. - Same methodology (blood pressure monitoring with Holter device) in pre-operative period could not be used because at that time they did not have a blood pressure Holter device.

2. Sohrabi et al. (2014)

Contribution	
S&P	X (safety only)
SOA	

Safety & Performance (safety only)

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Prospective randomized controlled trial.	To evaluate outcomes of treatment with Covered versus Bare NuMED CP Stents.	1	**2**	3	4	5

Suitability	Relevant Data	Grading		
Device	- NuMED CP Stent (Bare and Covered) - BIB	**D1**	D2	D3
Application	- Severe native CoA	**A1**	A2	A3
Patient	- Patients with severe native CoA - Sampling: n=120 (60 CP Stents versus 60 CP Stents, Covered) - Mean age: 23.6±10.99 (range 12 to 58) years - Sex: 79 M; 41 F	**P1**	P2	P3
Report	- High quality.	**R1**	R2	R3
	Suitability Grade (Range 4-12)	4		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	- Procedural success - Reduction in systolic blood pressure gradient - Reduction in mean diameter of coarctation segment - Adverse effects	**Yes 1**	No 2
Follow-up	- 31.1 ± 19.2 months	**Yes 1**	No 2
Statistical analysis	- A p-value <0.05 was considered significant.	**Yes 1**	No 2
Clinical significance	- Implanting CP Stent (Bare) and CP Stent (Covered) have very high success rates with remarkable hemodynamic effects in severe native CoA patients, with no significant complication during the procedure and hospitalization. - Patients undergoing CP Stent (Covered) implantation experienced a non-significantly lower re-coarctation rate and a higher occurrence of pseudoaneurysm formation with respect to CP Stent (Bare) stenting during follow-up. - In both groups, blood pressure was significantly reduced after intervention. - These findings indicate that CoA stenting is a safe procedure.	**Yes 1**	No 2
	Data Contribution Grade (Range 4-8)	4	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (2) + Suitability (4) + Data Contribution (4) = 10	Disposition and Weighting (select)	**Accepted and Pivotal 9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

Relevant S&P Results

Safety data	- Pseudoaneurysms: 0 (CP Stent, Bare) versus 2 (CP Stent, Covered) - Mortality: 1 (CP Stent, Bare) versus 0 (CP Stent, Covered)
Performance data	- Successful placement: successful in all patients - Mean systolic blood pressure gradient reduction: from 54.61 (CP Stent, Bare) and 54.42 (CP Stent, Covered) to 3.47 and 3.36 mmHg respectively; no significant difference between the two types of stent, P<0.001 - Mean diameter of coarctation segment reduction: From 3.34 (CP Stent, Bare) and 3.30 (CP Stent, Covered) to 16.07 and 15.82 mm respectively; no significant difference between the two types of stent, P<0.001 - Recurring coarctation: 4 (CP Stent, Bare) versus 0 (CP Stent, Covered), non-significant
Benefits/claims data	- Reduction in mean systolic blood pressure gradient - Reduction in diameter of coarctation segment
Strengths	- The CP Stent was hand-crimped down onto a balloon-in-balloon catheter (NuMED), which allows a precise and safe stent delivery
Weaknesses/ Potential bias	- Although the first randomized clinical trial in this respect, study was limited in some aspects. First, during follow-up, patients did not undergo 24-hour ambulatory blood pressure monitoring, which could have diagnosed the normotensive state more accurately. Second, evaluation of the blood pressure response during exercise testing could have been more valuable in defining the procedure outcome. -

3. Erdem et al. (2011)

Contribution	
S&P	X (safety only)
SOA	

Safety & Performance (safety only)

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Single arm interventional study.	To present author's institutional experience of endovascular CP Stent implantation in children and adults with native and recurrent CoA.	1	2	3	**4**	5

Suitability	Relevant Data	Grading		
Device	- CP Stent (16 Covered or 31 Bare) – n=47 - BIB (n=29) or single balloon catheter (n=18), Z-med (not subject device)	D1	**D2**	D3
Application	- Patients with native or recurrent CoA	**A1**	A2	A3
Patient	- Patients with native CoA (Group 1); recurrent CoA and/or aneurysm developed after either surgery or balloon angioplasty (Group 2) - Sampling: n=45 (47 CP Stents, Covered or Bare) - Median age: 11 (range: 5-33) years - Sex: 34M; 11F	**P1**	P2	P3
Report	- High quality.	**R1**	R2	R3
	Suitability Grade (Range 4-12)	5		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	- Decrease in invasive and echocardiographic gradients - Increase in lesion diameter - Adverse effects	**Yes 1**	No 2
Follow-up	- 12.1±7.1 months; median 11 month (range 2-29)	**Yes 1**	No 2
Statistical analysis	- A p value <0.05 was considered statistically significant.	**Yes 1**	No 2
Clinical significance	- Early and short- term follow-up results indicate that stent implantation is safe and very effective in reducing coarctation gradient and increasing lesion diameter both in native and recurrent CoA. - Some serious complications do occur and hypertension remains in some patients. - Aortic disruption and stent displacement are potentially catastrophic complications of stenting but implanting a second covered stent can seal the ruptured wall and parking in a safe area or replacement of displaced stent carried by half-inflated balloon could solve the problem.	**Yes 1**	No 2
	Data Contribution Grade (Range 4-8)	4	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (4) + Suitability (5) + Data Contribution (4) = 13	Disposition and Weighting (select)	Accepted and Pivotal 9-12 **Accepted but not Pivotal, 13-21** Excluded, 22-25

Relevant S&P Results

Safety data	- No procedure related death.
	- Two immediate complications relating to stenting:
	  - One an acute wall rupture, successfully managed immediately in the same session with implantation of a second covered stent
	  - One stent was displaced before it was completely opened. It was carried with support of partially inflated balloon and long sheath, and repositioned into the correct place.
	- No femoral arterial complications
	- No difficulty in catheter manipulation.
	- None of the patients required intensive care following the procedure, and all were discharged home the following day except the patient with aortic rupture and after stenting with covered stent this patient was followed two days in intensive care unit.

Performance data	- Considering all cases, a statistically significant decrease in both the invasive and echocardiographic gradients (p<0.001 for both) - Statistically significant increase in lesion diameter (p<0.001) were detected. - Before the procedure, the invasive gradient was significantly higher and the lesion diameter was significantly lower in Group I than in Group II (p=0.002 and p=0.005, respectively). - Percentage of decrease in gradient and increase in diameter was statistically higher in group 1 than in group 2 (p=0.04 and p=0.04). - When the stent was in good position, the balloon was inflated to fix the stent in the coarctation site.
Benefits/claims data	- Increase in luminal/lesion diameter.
Strengths	- CP stent is the one of the most commonly used stent in pediatric cardiology - This stent has excellent radial strength even at larger diameters and also has brilliant visibility on fluoroscopy.

Weaknesses/ Potential bias	- Some limitations have to be noted about this study:
	  - Firstly, there is a need a greater number of patients have undergone stent implantation and their long-term results.
	  - Secondly, population included both children and adult.
	  - Thirdly, this was a single-center report and patients were not compared with surgery or balloon angioplasty alone.
	  - Fourthly, 24-hour ambulatory blood pressure monitoring before stenting was not performed in any patients.
	  - Finally, radiologic imaging for aneurysm was done in limited number of patients after procedure.
	- Conflict of interest: None declared.

4. Moltzer et al. (2010)

Contribution	
S&P	X (safety only)
SOA	

Safety & Performance (safety only)

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Prospective observational study.	To evaluate the intermediate-term outcome of stent implantation for CoA in adults.	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	- CP Stent (Bare and Covered) - BIB	**D1**	D2	D3

Application	- Native CoA and re-coarctation	**A1**	A2	A3
Patient	- Patients with native CoA and re-coarctation - Sampling: n=24 - Mean age: 36 (18-60) years - Sex: 12 M; 12 F	**P1**	P2	P3
Report	- High quality.	**R1**	R2	R3
	Suitability Grade (Range 4-12)	4		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	- Decrease in systolic gradient - Increase in minimum aortic diameter - Adverse effects	**Yes 1**	No 2
Follow-up	- 24 hours post intervention and 33 (8-77) months	**Yes 1**	No 2
Statistical analysis	- All statistical tests were two-sided and a p-value <0.05 was considered statistically significant	**Yes 1**	No 2
Clinical significance	- Stenting in adults results in significant blood pressure gradient decrease and increase in vessel diameter. However, serious complications do occur and hypertension remains in the majority of patients.	**Yes 1**	No 2
	Data Contribution Grade (Range 4-8)	4	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (3) + Suitability (4) + Data Contribution (4) = 11	Disposition and Weighting (select)	**Accepted and Pivotal 9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

Relevant S&P Results

Safety data	- One death due to aorta ruptured. - Two groin hematoma post-op.
Performance data	- Systolic gradient: Decreased to < 10 mmHg in 21 patients, P<0.001 - Minimum aortic diameter: Increased from median 10 (2-17) to 16 (10-28) mm, P<0.001
Benefits/claims data	- Reduced in systolic gradient - Increased in minimum aortic diameter
Strengths	- N/A
Weaknesses/ Potential bias	- Only a small number of patients have undergone stent implantation since the authors started this procedure in 2003. This was a single-center report and patients were not compared with surgery or balloon angioplasty alone. Finally, 24-hour blood pressure monitoring before stenting was not performed in the majority of the patients. Post-stent 24-hour ambulatory blood pressure monitoring is therefore difficult to translate in terms of blood pressure reduction.

5. Agnoletti et al. (2009)

Contribution	
S&P	X (safety only)
SOA	

Safety & Performance (safety only)

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Two arms comparative interventional study.	To compare the CP Stent and the Palmaz stent for treatment of native and postoperative lesions of CHD patients.	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	- CP Stent (Bare & Covered), crimped on BIB - Palmaz stent, crimped on BIB and simple balloons	**D1**	D2	D3
Application	- Patients with CHD (including CoA/re-coarctation, RVOT)	A1	**A2**	A3

Patient	- Patients with CHD (including CoA/re-coarctation, RVOT and other CHD conditions, such as transposition of the great arteries, ventricular septal defect, single ventricle, etc.)
	- Sampling: n= 153
	  - 89 CP Stents (crimped on 77 BIB & 12 other balloons)
	  - 64 Palmaz Stents (crimped on 23 BIB and 41 simple balloons)
	- Mean age:
	  - CP Stents: 15.4 (SD: 9.2) years
	  - Palmaz Stents: 11.6 (SD: 8.1) years
	- Sex: Not reported
		P1	**P2**	P3

Report	- High quality.	**R1**	R2	R3
	Suitability Grade (Range 4-12)	6		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	- Blood pressure gradient reduction - Vessel diameter reduction - Adverse effects	**Yes 1**	No 2
Follow-up	- Not reported.	Yes 1	**No 2**
Statistical analysis	- A P-value less than 0.05 was considered statistically significant for stent group comparison.	**Yes 1**	No 2
Clinical significance	- The use of the CP Stents to treat stenotic lesions of CHD is effective and relatively safe. The overall efficacy of CP Stents for the treatment of stenotic lesions is superior to that of the Palmaz stent. - CP Stents' overall safety is higher than that of the Palmaz stent; but Palmaz stents have a lower profile when inserted.	**Yes 1**	No 2
	Data Contribution Grade (Range 4-8)	5	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (3) + Suitability (6) + Data Contribution (5) = 14	Disposition and Weighting (select)	Accepted and Pivotal 9-12 **Accepted but not Pivotal, 13-21** Excluded, 22-25

Relevant S&P Results

Safety data	- Stent-related complications:
	  - CP Stents (n=89 patients): 4 mild, 1 moderate, 1 severe.
	  - Palmaz (n=64 patients): 10 mild, 2 moderate, 2 severe.
	- Stent migration:
	  - CP Stents: 7.
	  - Palmaz: 4.
	- Non stent related complications:
	  - CP Stents: 1 mild, 2 moderate.
	  - Palmaz: 1 mild, 2 moderate, 5 severe.
	- Urgent surgery:
	  - CP Stents: 2 due to homograft rupture and stent migration.
	  - Palmaz: 1 for aortic dissection.
	- Balloon related complications: Balloon burst
	  - CP Stents: 0.
	  - Palmaz: 7 (3 in BIB, 3 with simple balloons, and 1 on pre-mounted stent).

Performance data	- Blood pressure gradient reduction (P<0.004)
	  - CP: from 45.4 ± 25.7 to 8.7 ± 15.7 mmHg.
	  - Palmaz: from 37.7 ± 28.3 to 12.3 ± 15.1 mmHg.
	- Vessel diameter (P<0.002)
	  - CP: from 7.4 ± 2.6 to 13.3 ± 3.4 mm.
	  - Palmaz: from 5.8 ± 2.7 to 13.3 + 4.5 mm.

Benefits/claims data	- Decreased in blood pressure gradient. - Increased in vessel diameter.
Strengths	- Efficacy of CP Stents was similar to that of Palmaz stent for stenting of the right ventricular outflow, and higher than that of Palmaz for the stenting of aorta, but the difference was not statistically.
Weaknesses/ Potential bias	- Study presented retrospective results obtained in 153 consecutive patients. - CP stents were used for patients weighing more than 15 kg; and thus two populations were different concerning age, weight, indication for stenting; however, none of these differences were related to occurrence of complications. - Subgroup analyses were not performed.

6. Meadows et al. (2015)

Contribution	
S&P	x
SOA	

Safety & Performance

This publication presents the results from the COAST trial for CP Stent (Bare and Covered) to treat native and recurrent CoA in selected children, adolescents and adult (NCT00552812). Please refer information presented in **Table G-1** for safety and performance of the subject devices, Study no. 1.

7. Sasikumar et al. (2020)

Contribution	
S&P	X (safety only)
SOA	x

Safety & Performance (safety only)

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Retrospective study.	To study the early and late outcomes after stenting of native and recurrent CoA with uncovered and covered stents.	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	- CP Stent (Bare and Covered) – "D1" for subject devices - Other devices, including Advanta V12 stent (covered), Andra XL and XXL stents, Palmaz XL	**D1**	D2	D3
Application	- CoA (native and recurrent)	**A1**	A2	A3

Patient	- Patients with CoA (native and recurrent)
	- Sampling: n=45 (20 covered stents, 25 non-covered stents)
	  - Covered stents used were covered 7 CP Stent; 13 Advanta V12 Stent
	  - Non-covered stents used were 17 CP Stent, 6 Andra XL and XXL stents, and 2 Palmaz XL.
	- Mean age: 28±17.5 (range 8 to 65) years. Age per device group was not reported.
	- Sex: 32 M, 13 F. Sex per device group was not reported.
		P1	**P2**	P3

Report	- High quality with deficiencies	R1	**R2**	R3
	Suitability Grade (Range 4-12)	6		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	- Safety	**Yes 1**	No 2
Follow-up	- Covered stent group: 57 months - Non-covered stent group: 35 months	**Yes 1**	No 2
Statistical analysis	- Statistical analysis was done by the Statistical Package for Social Sciences (version 21.0). Quantitative data were presented as mean ± SD or as median and range and qualitative data were presented as frequency (percentages). The categorical parameters were compared by chi-square test, and the continuous variables were compared by Student t test for independent continuous data and Manne Whitney U test for nonparametric data.	**Yes 1**	No 2
Clinical significance	- Not reported specifically for subject devices.	Yes 1	**No 2**
	Data Contribution Grade (Range 4-8)	5	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (3) + Suitability (6) + Data Contribution (5) = 14	Disposition and Weighting (select)	Accepted and Pivotal 9-12 **Accepted but not Pivotal, 13-21** Excluded, 22-25

Relevant S&P Results

Safety data	**Outcomes**	**Covered (n=18)**	**Uncovered (bare metal) (n=8)**

Late lumen loss (no or mild)	2 (Advanta 1, CP 1)	4 (CP 3, Palmaz 1)
Late lumen loss (moderate)	12 (Advanta 7, CP 4, Andra 1)	4 (CP3, Palmaz 1)
Late lumen loss (severe)	4 (Advanta 3, CP 1)	0
Fracture	1 Advanta	0

Performance data	- Not reported specially for subject devices.
Benefits/claims data	- Not reported
Strengths	- Not reported.
Weaknesses/ Potential bias	- Not reported.

State of the Art

Appraisal

Medical condition		Alternatives		Risk/benefit		Side-effects		Equivalence		Surrogate endpoints	
Yes 1	No 2	**Yes 1**	No 2	**Yes 1**	No 2	**Yes 1**	No 2	Yes 1	**No 2**	Yes 1	**No 2**

Overall SOA Appraisal and Disposition

SOA Grade (Range 6-12)	8	Disposition (select)	**Accepted, < 12** Excluded, 12

Relevant SOA Results

SOA data	- Patients in the covered stent group were older and had greater basal pressure gradient. More patients in the covered stent group had residual gradient >10 mm Hg after the procedure. - No mortality or aortic wall injury in either group. - Mean number of anti-hypertensive was 1.38 ± 0.74 in the covered goup and 1+0.7 in the uncovered group - Greater incidence of severe late lumen loss (>30% lumen loss) in the covered stent group on follow-up. According to the authors, this phenomenon was brand specific (Advanta V12 stent). Single strut fracture which was not causing any lumen obstruction was also noted in one Advanta V12 stent. The stents have an open cell stent geometry with consequent less radial strength. - A previous study on Advanta stent implantation in 25 patients did not show any complications related to the stent. However, the median period of follow-up in that study was only 4.9 months and longer follow-up is needed to look for re-coarctation or aneurysm formation. - Another study described 2 patients with Advanta stent implantation who developed in-folding of the proximal edge of the stent on follow-up and both the cases were managed by re-stenting. The authors had a similar proximal stent collapse in a patient who had Advanta stent implantation, which was managed by balloon angioplasty. Though the residual gradient was 5 mm Hg immediately after the balloon angioplasty, the gradient increased to 25mmHg on follow-up and he underwent a repeat balloon angioplasty with good result.

Comments	- Uncovered stents can be safely implanted with minimal risk of aortic wall injury in patients with low risk anatomic features. Covered stent implantation is associated with higher incidence of planned and unplanned re-intervention.

8. Holzer et al. (2021)

Contribution	
S&P	X (safety only)
SOA	x

Safety & Performance (safety only)

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Included in this report are the 5-year follow-up data from patients in these 2 trials and those treated through their Continued Access protocols. Data was prospectively collected during the 2 multi-center studies.	To report the late-term follow-up data and to compare this to earlier follow-up data. For the purpose of this study, follow-up was defined as: - Immediate (1 month), - Early (12 months), - Late (48 or 60 months). To identify possible predictors of late-term outcome post-stent implantation.	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	- CP Stent (Bare and Covered) - 52% received covered stents and 48% received bare stents. - The minimum stent diameter was 14.4mm (interquartile range (IQR), 12.6-16.0mm) with a minimum stent diameter to the aorta at diaphram ratio of 0.87 (IQR, 0.77-1.0).	**D1**	D2	D3
Application	- CoA (native or recurrent) - Native coarctation was present in 49%, postsurgical in 24% and post-catheterization in 27%. - The minimum coarctation diameter was 8.0mm (IQR, 5.4-10.5mm), and median aortic diameter at the diaphragm was 16.0mm (IQR, 14.0-19.0mm).	**A1**	A2	A3
Patient	- All patients enrolled in the COAST or COAST II trials and their Continued Access extensions were included. Patients without late follow-up data were excluded from analysis, except for analyzing the estimated cumulative incidence of stent fractures, aortic wall injury, and reinterventions. - Cohort of 248 patients - COAST: 105 patients enrolled in COAST with 16 Continued Access patients (n=121) - COAST II: 82 participants from COAST II with an additional 45 Continued access patients (n=127). - From the 180 patient cohort, the median age at implant was 17 years (IQR, 13-28 years), the median weight (66.3kg, IQR, 53.8-78.1kg).	**P1**	P2	P3
Report	- High quality report	**R1**	R2	R3
	Suitability Grade (Range 4-12)	4		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	- Parameters used to assess aortic stent outcomes: -Hemodynamic	**Yes 1**	No 2

		-Systemic systolic hypertension -Use of antihypertensive medication -Upper limb to lower limb blood pressure difference of ≥20mm Hg -Reinterventions -Stent fractures -Aortic wall injury - Predictor variables used to assess late-term results: -Demographics -Type of coarctation -Preimplantation clinical data -Baseline characterization data -Type of stent -Poststent catherization data -Postcatheterization data		
	Follow-up	- Follow-up data was collected at 1, 6, 12, 24, 36, 48 and 60 months and included MRI at 12 and 24 months, and fluoroscopy at 12, 24, 48 and 60 months. - 96% of patients returned for 1-month follow-up, 86% for 12-month follow-up, and 63% for 60-month. - A total of 180 patients (73%) had either 48- or 60-month follow-up data. - Out of the 180 patients with late follow-up, 177 (98%) had also immediate and 180 (100%) early follow-up data available for analysis. - Aortic imaging (either MRI, computed tomography, or angiography) was available for 180/180 (100%) at immediate follow-up, 177/180 (98%) at intermediate follow-up, and 41:180 (23%) at late follow-up. Fluoroscopy was available for 180/180 (100%) at immediate follow-up, 178/180 (99%) at intermediate follow-up, and 136/180 (76%) at late follow-up.	**Yes 1**	No 2
	Statistical analysis	- Categorical variables are summarized as frequencies and percentages, and continuous variables as either means and SDs or medians with interquartile range (IQR) as noted. For the entire cohort, the cumulative incidence of stents fractures, aortic wall injury, and reinterventions at immediate, early and late follow-up was estimated using the Kaplan-Meier method. Patients who did not have an outcome event were censored at time. Changes in hemodynamic measures over time were evaluated using tests of trend. For patients with late follow-up, associations between patient and procedure characteristics and 4 binary outcome variables – suboptimal hemodynamic outcome, stent fractur, catheter reintervention, and aortic wall injury – were assessed using Fisher exact test. Characteristics significant at the 0.20 level were considered for inclusion in multivariable logistic regression models. Forward selection was used, and P <0.05 was required for retention in the final model. To assess generalizability, characteristics of patients with and without late follow-up were compared using Fisher exact and Wilcoxon rank sum tests; no significant differences were found. All analytics were performed using SAS software version 9.4.	**Yes 1**	No 2
	Clinical significance	- Coarctation stenting is effective at maintaining obstruction relief up to 60 months postimplant	**Yes 1**	No 2

	with reduction in the number of patients requiring antihypertensive medication. However, an increase in-stent fractures and reinterventions were observed between medium and long-term follow-up. Covered stents appear to confer some protection from the development of stent fractures but do not provide complete protection from late aneurysm formation.		
		Data Contribution Grade (Range 4-8)	4

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (3) + Suitability (4) + Data Contribution (4) = 11	Disposition and Weighting (select)	**Accepted and Pivotal 9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

Relevant S&P Results

Safety data	Aortic Wall Injury: - 13 patients were identified as having aneurysms or pseudo-aneurysms (COAST: 6/121 [5%], COAST II: 7/127 [5.5%]. - No dissections were found. - The cumulative incidence was 1.2% by early and 6.3% by late follow-up. - In 3 patients, the aneurysm was proximal to the implanted stent, in one patient the location was not specified, and in the reminder, the aneurysm was within the borders of the implanted stent. - In 4 of 13 patients, aneurysms were identified on MRI or computed tomography before reintervention, while in 9 patients the aneurysms were diagnosed by angiography during catheterization performed for other reasons such as elective stent re-expansion. - 17 patients had covered stents implanted to treat the aneurysm; 2 did not. - By univariate analysis, coarctation minimum diameter <6mmm was the only factor significantly associated with aortic wall injury (12% versus 2%, P=0.007). - There was a borderline relationship between minimum stent to aortic diameter at the diaphragm <0.7 and aortic wall injury (19% versus 5%, M=0.059). - Aneurysms did not just occur in patients with bare metal stents, but equally in patients who had covered stents implanted. As such, the notion that covered stent implantation confers long-term protection from the development of aneurysm, may not be the case. Data are in contrast with Butera et al.[1] who did show a significant difference in the incidence of aneurysm formation when comparing patients bare versus covered stents, albeit in a much smaller cohort. Also, the median follow-up in that study was significantly longer for those with bare stents compared with covered stents (85 versus 35 months). This is important as the current study demonstrates that the majority of aneurysms were not identified until late follow-up. - Most aneurysms developed within the borders of the stent, including covered stents. One possible explanation is that pressure within the aorta distributes flow between the stent and the aortic wall, eventually leading to aneurysm formation. Another possibility is that the expanded polytetrafluoroethylene became damaged during initial implantation. - Current study did not investigate the benefit of a covered stent to reduce the risk of acute aortic wall injury during

[1] Butera G, Manica JL, Marini D, Piazza L, Chessa M, Filho RI, Sarmento Leite RE, Carminati M. From bare to covered: 15-year single center experience and follow-up in trans-catheter stent implantation for aortic coarctation. Catheter Cardiovasc Interv. 2014 May 1;83(6):953-63. doi: 10.1002/ccd.25404. Epub 2014 Feb 4. PMID: 24459104.

		stent implantation because cases have not been randomly assigned and high-risk patients were excluded for bare stent implantation and received covered stents. Other Adverse Events: - Over the follow-up period, 2 patients had additional adverse events that were captured in the data set. One patient had a self-resolving neurological adverse event (possible transient ischemic attack) 2 weeks after the procedure without any clear relationship to the procedure itself. Another patient developed cardiogenic/sceptic chock 7 months after the procedure. No other serious adverse events were documented in any patients.
	Performance data	Hemodynamic Outcome: - The number of patients with suboptimal hemodynamic outcome was 59% at immediate and early follow-up and decreased to 44% at late follow-up (P=0.001; median age, 21.7 years). - When comparing immediate, to early and late follow-up, there was no significant difference in SBP. Hypertension remained fairly constant at about 20% of patients. - Systolic arm-leg blood pressure gradients did not change significantly between immediate, early and late follow-up (median of -1 to -2mm Hg) with 91% to 95% <20mm Hg, 85% to 89% <15mm Hg, and 77% to 80% <10mm Hg. - There was a significant decrease in use of hypertension medication, from 53% at immediate, to 42% at early, and 29% at late follow-up (P<0.001). - By univariate analysis, none of the predictor variables had a significant association with suboptimal hemodynamic outcome at late follow-up. - No association was found between the ratio of minimum stent diameter to aortic diameter at the diaphragm <0.7, and residual arm-leg SBP gradients >10, 15, or 20mm Hg at late follow-up. Stent Fractures: - There were 50 patients with stent fractures. - The cumulative incidence was 0% by immediate, 2.9% by early, and 24.4% by late follow-up. - There were no stent segment embolization and no complete circumferential or longitudinal stent fractures. - The CP stent fractured in multiple locations leading to loss of stent integrity in only 3 patients. - No patient with stent fracture had a reintervention at immediate or early follow-up, but 12 had reinterventions at late follow-up (estimated incidence 6.0%. - By multivariate analysis, independent predictors of stent fracture by late follow-up were age: < 18 years (odds ratio [OR], 3.33 [95%CI, 1.38-8.03], P=0.008), male sex (OR, 3.11 [95% CI, 1.15-8.47], P=0.026), minimum stent diameter at implantation ≥12 mm (OR, 5.13 [95% CI, 1.38-19.1], P=0.015), and use of a bare metal stent (OR, 3.14 [95%, 1.37-7.20], P=0.007). Reinterventions: - 45 patients required catheter-based reinterventions (n=21 balloon angioplasty, n=24 stent implantation). - The cumulative incidence was 1.6% by immediate, 5.1% by early, and 21.3% by late follow-up. - Where data was available, reasons for intervention included staged re-expansion (n=5), aortic wall injury (n=11), restenosis (n=15). - Stent fractures were noted in 12 patients undergoing reintervention, only one with loss of structural integrity. - By multivariate analysis, independent predictors of reinterventions at late follow-up were: age <18 years (OR, 3.76 [95% CI, 1.10-12.9], P=0.035), coarctation minimum diameter <6mm (OR, 3.47 [95% CO, 1.21-9.98], P=0.021), minimum stent diameter at implantation <12 mm (OR, 4.16 [95% CI, 1.37-12.7], P=0.012); and post-implantation systolic arm-leg BP gradient ≥10 mm Hg (OR, 3.25 [95% CI, 1.13-9.35], P=0.029).

	Native Versus Recurrent Coarctation: - Study did not find significant differences of any outcome variable when comparing native, postsurgical, or postcatheterization coarctation. However, subtle differences in the need for reintervention and presence of aortic wall injuries are noted. - Reintervention incidence was 7% for postsurgical coarctation, 22% and 23% for native and postcatheterization. - Aortic wall injuries were not seen in the postsurgical group compared with 6 to 7% in native and postcatheterization coarctation.
Benefits/claims data	- At late follow-up, freedom from surgical intervention was 100%, catheter reintervention 78.7%, stent fracture 75.6%, and freedom from aortic wall injury 93.7%. - 44% of patients had suboptimal long-term hemodynamic outcomes. - It has documented that hemodynamic results are generally maintained over the follow-up period. Stent fractures, catheterization reinterventions, and aortic wall injuries, all increase in frequency between medium and long-term follow-up. Overed stents appear to confer some protection from the development of stent fractures, but they do not provide complete protection from late aneurysm formation.
Strengths	- The largest study to date with comprehensive follow-up data up to 60 months post-procedure.
Weaknesses/ Potential bias	- Small sample size - Did not have the statistical power to evaluate all parameters contributing to long-term morbidity in these patients, such as aortic wall injury. - Once the COAST studies were closed, it was not permissible to contact centers for additional data regarding stent fractures, indications for reintervention and other clinical data elements. - There were inherent differences between COAST and COAST II enrollment indications and the way some of the data was collected. - While this study defined 48 to 60 months follow-up as long-term, this is still a relatively short time period. - This study only analyzed the outcome of stent implantation for coarctation using CP stents. Ot did not compare the outcome of stent implantation to other treatment modalities, as was done in the Congenital Cardiovascular Interventional Study Consortium Report.[2]

State of the Art
Appraisal

Medical condition		Alternatives		Risk/benefit		Side-effects		Equivalence		Surrogate endpoints	
Yes 1	No 2	**Yes 1**	No 2	**Yes 1**	No 2	**Yes 1**	No 2	Yes 1	**No 2**	**Yes 1**	No 2

Overall SOA Appraisal and Disposition

SOA Grade (Range 6-12)	7	Disposition (select)	**Accepted, < 12** Excluded, 12

[2] Forbes TJ, Kim DW, Du W, Turner DR, Holzer R, Amin Z, Hijazi Z, Ghasemi A, Rome JJ, Nykanen D, Zahn E, Cowley C, Hoyer M, Waight D, Gruenstein D, Javois A, Foerster S, Kreutzer J, Sullivan N, Khan A, Owada C, Hagler D, Lim S, Canter J, Zellers T; CCISC Investigators. Comparison of surgical, stent, and balloon angioplasty treatment of native coarctation of the aorta: an observational study by the CCISC (Congenital Cardiovascular Interventional Study Consortium). J Am Coll Cardiol. 2011 Dec 13;58(25):2664-74. doi: 10.1016/j.jacc.2011.08.053. PMID: 22152954.

	Relevant SOA Results	
	SOA data	CoA: - CoA is repaired during the neonatal period and infancy by surgery. Beyond infancy, percutaneous treatment using either balloon angioplasty or stent implantation are more frequently employed to treat native or recurrent coarctation. - The Cheatham-Platinum (CP) Stent was developed by NuMED (Hopkinton, NY) specifically designed to treat aortic coarctation. It has rounded edges to reduce the incidence of aortic wall injury and can be expanded to 24mm diameter. - Stent implantation, balloon angioplasty, and surgery are all treatment options for coarctation in patients beyond infancy. - Treated coarctation is associated with long-term morbidity irrespective of treatment strategy. COAST Trials: - The FDA pivotal trials COAST (Coarctation of the Aorta Stent Trial; 2007-2016) demonstrated safety and efficacy of the bare CP Stent when used to treat aortic coarctation. Short- and medium-term results have been previously reported (Meadows et al. *(32)*). - The Covered CP Stent is a CP stent covered by a 0.28'' sleeve of 0.005'' thick expanded polytetrafluoroethylene tubing and was available to centers participating in the COAST trial for compassionate and emergency use for aortic wall injury occurring during aortic interventions.
	Comments	Hemodynamic Outcome: - Study corroborates the results from the largest multi-center study of stenting for coarctation from the Congenital Cardiovascular Interventional Study Consortium, which reported 23% systolic hypertension at 12 to 60 months of follow-up, 9% arm-leg blood pressure gradient ≥20 mm Hg, 23% need for antihypertensive medication and the presence of any of these 3 in 37%.[3] Stent Fractures: - Previous studies of the bare metal CP stent documented stent fractures of 2% at 12 months, and 12% at 24 months (Meadows et al. *(32)*). While the design and metallic composition of the CP stent may contribute, stents fractures are not limited to CP stents.[4] Boe et al.[5] reported a 21% fracture rate for Palmaz Genesis XD stents when used for coarctation therapy in children < 20Kg at a mean follow-up of 75 months. - It is unclear whether somatic growth can add additional force and loading conditions to the implanted stent, or whether participation in contact sports might impact the incidence of stent fractures. - Bare metal stents have a significantly higher fracture rate than covered CP stent. Possible explanations could be that the struts of a bare stent become more solidly embedded into the aortic wall, and that the expanded polytetrafluoroethylene covering more equally distributes the radial force to multiple struts or that it reduces the transmission of aortic pulsability to the struts.

[3] Holzer R, Qureshi S, Ghasemi A, Vincent J, Sievert H, Gruenstein D, Weber H, Alday L, Peirone A, Zellers T, Cheatham J, Slack M, Rome J. Stenting of aortic coarctation: acute, intermediate, and long-term results of a prospective multi-institutional registry--Congenital Cardiovascular Interventional Study Consortium (CCISC). Catheter Cardiovasc Interv. 2010 Oct 1;76(4):553-63. doi: 10.1002/ccd.22587. PMID: 20882661.
[4] McElhinney DB, Marshall AC, Schievano S. Fracture of cardiovascular stents in patients with congenital heart disease: theoretical and empirical considerations. Circ Cardiovasc Interv. 2013 Oct 1;6(5):575-85. doi: 10.1161/CIRCINTERVENTIONS.113.000148. PMID: 24129934.
[5] Boe BB, Loccoh E, Stockmaster K, Holzer RJ, Cheatham SL, Cheatham JP, Armstrong A, Berman DP. Median and long-term outcomes of stent implantation for coarctation of the aorta in small patients (<20 kg). [Abstract presented at PICS 2019]. *J Struct Heart Dis. 2018;4:140.*

Reinterventions:
- Previously reported data documented transcatheter reinterventions of about 5% by 24 months follow-up (Meadows et al. *(32)*).
- There is no expert consensus defining when a reintervention should be performed.
- Reinterventions in this patient population are not unexpected and do not represent a poor outcome.

Aortic Wall Injury:
- Aneurysms did not just occur in patients with bare metal stents, but equally in patients who had covered stents implanted. As such, the notion that covered stent implantation confers long-term protection from the development of aneurysm, may not be the case. Data are in contrast with Butera et al.[6] who did show a significant difference in the incidence of aneurysm formation when comparing patients bare versus covered stents, albeit in a much smaller cohort. Also, the median follow-up in that study was significantly longer for those with bare stents compared with covered stents (85 versus 35 months). This is important as the current study demonstrates that the majority of aneurysms were not identified until late follow-up.
- Most aneurysms developed within the borders of the stent, including covered stents. One possible explanation is that pressure within the aorta distributes flow between the stent and the aortic wall, eventually leading to aneurysm formation. Another possibility is that the expanded polytetrafluoroethylene became damaged during initial implantation.
- Current study did not investigate the benefit of a covered stent to reduce the risk of acute aortic wall injury during stent implantation because cases have not been randomly assigned and high-risk patients were excluded for bare stent implantation and received covered stents.

9. Kasar et al. (2022)

Contribution	
S&P	x (S only)
SOA	x

Safety & Performance (Safety only)

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Non-randomized retrospective analysis.	The aim of this study was to follow the procedural results of stenting for CoA in young children and adolescents and evaluate the safety and effectiveness of this procedure for younger patients.	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	- CP covered stent was implanted in 32 (73%) patients and CP uncovered stent in 12 (27%) patients - Unknown whether mounted or manual	**D1**	D2	D3
Application	- Native CoA	**A1**	A2	A3
Patient	- 44 total patients - Patients aged < 18 years who underwent stenting for native CoA between Aug 2010 and Nov 2017 - Patients with re-coarctation were excluded	**P1**	P2	P3

[6] Butera G, Manica JL, Marini D, Piazza L, Chessa M, Filho RI, Sarmento Leite RE, Carminati M. From bare to covered: 15-year single center experience and follow-up in trans-catheter stent implantation for aortic coarctation. Catheter Cardiovasc Interv. 2014 May 1;83(6):953-63. doi: 10.1002/ccd.25404. Epub 2014 Feb 4. PMID: 24459104.

	- Mean age 10.4 years (4.3-18) - 77.2% male - Group I: 10–18 years, adolescent group and Group II: ≤ 9.9 years, pediatric group			
Report	- Suitable for review	**R1**	R2	R3
	Suitability Grade (Range 4-12)	4		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	- Complications.	**Yes 1**	No 2
Follow-up	- Mean follow-up was 23 months (range 2-84 months).	**Yes 1**	No 2
Statistical analysis	- Categorical variables were stated as number (n) and percentage (%), and continuous variables as mean ± standard deviation, median, minimum and maximum values. Categorical data were compared using the Chi-square test or Fisher's Exact test when expected frequencies were <5. In the comparisons of quantitative variables between the 2 groups, the Student's *t* test, -test for paired data and the Mann-Whitney *U*-test were used. A 2-tailed *P* value <0.05 was considered statistically significant.	**Yes 1**	No 2
Clinical significance	- The magnitude of the treatment effect observed was clinically significant.	**Yes 1**	No 2
	Data Contribution Grade (Range 4-8)	4	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (3) + Suitability (4) + Data Contribution (4) = 11	Disposition and Weighting (select)	**Accepted and Pivotal 9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

Relevant S&P Results

Safety data	Complications: - Complications developed in three patients, and all in Group I. Femoral hematoma developed in one patient, balloon rupture occurred during the procedure in one patient, and there was temporary loss of pulse in one patient. All the complications were treated successfully. - In the second case, a 16-year-old girl, the femoral artery pulse was lost. After 24 hours of heparin infusion, the pulse was viewed on color Doppler USG, the heparin treatment was ceased, and the patient was discharged.
Benefits/claims data	- Stent implantation for aortic coarctation in the pediatric age group may provide pleasing results, reducing the coarctation gradient, providing effective dilatation in the lesion area and eliminating hypertension.
Strengths	- N/A
Weaknesses/ Potential bias	- … current stent technology, which requires a larger sheath, raises concerns in the very young age group.

State of the Art

Appraisal

Medical condition		Alternatives		Risk/benefit		Side-effects		Equivalence		Surrogate endpoints	
Yes 1	No 2	**Yes 1**	No 2	**Yes 1**	No 2	**Yes 1**	No 2	Yes 1	**No 2**	Yes 1	**No 2**

Overall SOA Appraisal and Disposition

SOA Grade (Range 6-12)	8	Disposition (select)	**Accepted, < 12** Excluded, 12

Relevant SOA Results

SOA data	CoA: - CoA has been reported in 0.04% of all live births and in 5 to 8% of all patients with CHD. - Surgical repair is the gold standard treatment for CoA in infants and young children. - The aim of this study was to compare and evaluate the data of young pediatric and adolescent patients who underwent balloon-expandable stent implantation because of native aortic coarctation. - The patients were separated into two groups as the adolescent group (Group I: 10‑18 years) and the pediatric group (Group II: ≤ 9.9 years). Group-I comprised of 18 patients and Group-II, 32 patients. Covered stent was implanted to 32 (73%) patients and uncovered stent to 12 (27%) patients. - The procedural success rate was 100%. Following stent implantation, peak systolic gradient decreased significantly in both groups ($P < .0001$) (Group-I: from 35.9 ± 16.6 mm Hg-2.2 ± 3.4 mm Hg, Group II: from 34 ± 13.3 mm Hg-3± 4.09 mm Hg). - Complications developed in three patients, and all in Group I. Femoral hematoma developed in one patient, balloon rupture occurred during the procedure in one patient, and there was temporary loss of pulse in one patient. All the complications were treated successfully. - All the patients were taking anti-hypertensive drugs before intervention and during the mean 23-month follow-up period (range, 2-84 months), hypertension recovered in 35 (80%) patients and drugs were terminated. - Stent implantation for aortic coarctation in the pediatric age group may provide pleasing results, reducing the coarctation gradient, providing effective dilatation in the lesion area and eliminating hypertension.
Comments	- Limitations: Limitations include retrospective design and small population. - Authors have no funding and conflicts of interest to disclose.

10. Sadeghipour et al. (2022)

Contribution	
S&P	x
SOA	x

<u>Safety & Performance</u>
Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Open-label, parallel-group, blinded endpoint randomized pilot clinical trial.	To compare the safety and efficacy of the balloon-expandable stent (BES) and the self-expandable stent (SES) in the endovascular treatment of CoA.	1	**2**	3	4	5

Suitability	Relevant Data	Grading		
Device	- Uncovered CP BES (n=46 patients) - Uncovered nitinol SES (n=46 patients)	**D1**	D2	D3
Application	- Adult patients with de novo native CoA	**A1**	A2	A3
Patient	- 92 eligible patients (32 women, 34.8%) with a median age of 30 years (IQR: 20-36 years) were randomized equally into the two groups - Median age	**P1**	P2	P3

	○ BES: 29.9 years (IQR: 19.5-37.0 years) ○ SES: 28.6 years (IQR: 21.0-33.5 years) - Female ○ BES: 14 (30.4%) ○ SES: 18 (39.1%)			
Report	- Report suitable for review.	**R1**	R2	R3
	Suitability Grade (Range 4-12)	4		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	- Primary outcome was a composite of periprocedural and vascular access complications. - Secondary outcomes were composed of the incidence of aortic recoarctation, thoracic aortic aneurysm/pseudoaneurysm, and residual hypertension at the 12-month follow-up.	**Yes 1**	No 2
Follow-up	- 12-month follow-up period at intervals of one, three, six and 12 months	**Yes 1**	No 2
Statistical analysis	- Data were expressed as mean ± SD or median (IQR) for interval variables and counts (%) for categoric variables. Categoric variables were compared using the chi-square test or the Fisher exact test. Continuous variables were compared between the two groups with the aid of the Student's t-test (or its nonparametric equivalent, the Mann-Whitney U test). Analyses of the study outcomes were based on the binary logistic regression and the odds ratio (OR) as the effect size. The cumulative incidence rate of the primary composite endpoint with its respective 95% CI was reported for each arm. A P value <0.05 was considered significant.	**Yes 1**	No 2
Clinical significance	- The magnitude of the treatment effect observed was clinically significant.	**Yes 1**	No 2
	Data Contribution Grade (Range 4-8)	4	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (2) + Suitability (4) + Data Contribution (4) = 10	Disposition and Weighting (select)	**Accepted and Pivotal 9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

Relevant S&P Results

Overview	- Among 105 patients who were screened between January 2017 and December 2019, 92 eligible patients (32 women [34.8%]) with a median age of 30 years (IQR: 20-36 years) were randomized equally into the BES and SES groups. The composite of procedural and vascular complications occurred in 10.9% of the BES group and 2.2% of the SES group (odds ratio: 0.18; 95% CI: 0.02-1.62; P = 0.20).
Safety data	- The primary composite outcome was observed in five patients (10.9%) in the BES group and one patient (2.2%) in the SES group (OR: 0.18; 95% CI: 0.02-1.62; P = 0.20). Periprocedural complications were observed in three patients (6.5%) in the BES group and one patient (2.2%) in the SES group (OR: 0.31; 95% CI: 0.03-3.18; P = 0.617). - Vascular access complications, consisting of non–flow-limiting femoral artery dissection, femoral artery

	pseudoaneurysm, and retroperitoneal hemorrhage, occurred with an incidence rate of 1.1% in the overall cohort (two patients [4.3%] in the BES group and no patients in the SES group; P = 0.49). - One patient (1.1%) was complicated by aortic pseudoaneurysm formation, which was subsequently treated with aortic stent– graft implantation (one patient [2.2%] in the BES group, P = 0.31).
Performance data	- The procedural success rate was 100%, with no mortality during the 12-month follow-up. The mean catheterization-based postprocedural pressure gradient was 1.4 ± 4.2 mm Hg in the SES group and 1.5 ± 3.2 mm Hg in the BES group (P = 0.52). - Aortic recoarctation was confirmed by cardiac catheterization (pressure gradient >20 mm Hg) in five patients (5.4%) (three patients [6.5%] in the BES group and two patients [4.3%] in the SES group; OR: 0.65; 95% CI: 0.10-4.09; P = 0.64).
Benefits/claims data	- At the one-year follow-up, the median number of antihypertensive medications had dropped from two (IQR: 1-3) to one (IQR: 0-2) in the study population (P < 0.001).
Strengths	- Randomized clinical trial
Weaknesses/ Potential bias	- Limitations: Author-identified limitations include the study may be underpowered, trial was set for 100 patients but reduced to 92 due to shortage of stents, some components of procedural complications were not specifically mentioned in the clinical trial registration website, the severity and clinical impact of vascular access complications varies and may not be comparable, and one year is insufficient for the evaluation of long-term complications.

State of the Art

Appraisal

Medical condition		Alternatives		Risk/benefit		Side-effects		Equivalence		Surrogate endpoints	
Yes 1	No 2	**Yes 1**	No 2	**Yes 1**	No 2	**Yes 1**	No 2	Yes 1	**No 2**	Yes 1	**No 2**

Overall SOA Appraisal and Disposition

SOA Grade (Range 6-12)	8	Disposition (select)	**Accepted, < 12** Excluded, 12

Relevant SOA Results

SOA data	- … increasing the mortality of CoA up to 80% by the time the patient is 50 years old if left untreated. - Generally, surgical repair is considered the gold standard therapy in isolated CoA with acceptable perioperative mortality and long-term outcomes. - Both the BES and the SES were safe and effective in the treatment of native coarctation.
Comments	- Authors reported that they have no relationships relevant to the contents of this paper to disclose.

Safety & Performance

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Three-year follow-up to open-label, parallel-group, blinded endpoint	To compare the safety and efficacy of the balloon-expandable stent (BES) and the self-expandable stent	1	**2**	3	4	5

	randomized pilot clinical trial reported in *(10)*	(SES) in the endovascular treatment of CoA.					

11. Sadeghipour et al. (2024)

Contribution	
S&P	x
SOA	x

Suitability	Relevant Data	Grading		
Device	- Uncovered CP BES (n=35 patients) - Uncovered nitinol SES (n=36 patients)	**D1**	D2	D3
Application	- Adult patients with de novo native CoA	**A1**	A2	A3
Patient	- 71 of 92 patients randomized in initial study participated in the three-year structural follow-up (two passed away (one COVID-19 infection, one car accident), three withdrew from study and 16 declined to participate in follow-up) - 25 women (32.2%) with a median age of 30 years (IQR: 20-35 years)	**P1**	P2	P3
Report	- Report suitable for review; the terms thoracic aortic aneurysmal formation and aortic wall injury applied interchangeably.	R1	**R2**	R3
	Suitability Grade (Range 4-12)	5		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	- The main outcomes assessed were the three-year rates of recoarctation, aortic injuries, and residual hypertension.	**Yes 1**	No 2
Follow-up	- Three-year structural follow-up	**Yes 1**	No 2
Statistical analysis	- Data are presented as n (%) or median (IQR). P-values reported for significance.	**Yes 1**	No 2
Clinical significance	- The magnitude of the treatment effect observed was clinically significant.	**Yes 1**	No 2
	Data Contribution Grade (Range 4-8)	4	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (2) + Suitability (5) + Data Contribution (4) = 11	Disposition and Weighting (select)	**Accepted and Pivotal 9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

Relevant S&P Results

Overview	- Previously, we reported the one-year results of a randomised controlled trial comparing BES and SES in patients with de novo native CoA. *(10)* Herein, we have summarised the three-year follow-up results (IRCT20181022041406N3). - Of 92 patients initially randomised, 71 patients (25 women [32.2%]), with a median age of 30 years (interquartile range 20-35), participated in the three-year structural follow-up (two patients passed away [one COVID-19 infection and one car accident] and the others did not participate in the follow-up).
Safety data	- Aortic wall injuries were detected in six patients (8.5%), all treated conservatively with no further endovascular/surgical intervention needed.
Performance data	- No new recoarctation was detected between the one- and three-year follow-up, and only five patients (with recoartation previously detected during the first year of follow-up) were identified as having recoarctation. Among

	those patients, two cases, both initially randomised into the BES group and treated for recoarctation during the first year, needed reballooning due to significant restenosis during the three-year follow-up. - We followed up 77.1% (71 of 92) of our randomised population with the structural imaging protocol, and recoarctation occurred in 7.0% of the population with no new cases between the one- and three-year follow-up periods. This finding is in contrast with the major investigations focusing on long-term outcomes, in which a higher rate (~20%) of reintervention has been reported. The inclusion of paediatric patients in the mentioned studies might explain the higher rates of reintervention. Recoarctation rates below 10% were reported when limiting their population to adult patients. - A total of 42 out of the 71 patients (59.1%) had residual hypertension, detected more frequently in the BES group, with a trend existing towards a higher median number of antihypertensive drugs during the three-year follow-up. - Holzer et al *(**Error! Reference source not found.**)* and Eriksson et al *(**Error! Reference source not found.**)* reported a downward trend in prolonged hypertension prevalence (42% and 34%, respectively) in patients treated endovascularly. The higher incidence of residual hypertension in the current study might result again from their inclusion of a paediatric population and better blood pressure response in this younger population.
Benefits/claims data	- In this three-year follow-up, both BES and SES exhibited low rates of recoarctation, aortic wall injuries and remodelling, but still, more than half of the studied population suffered from residual hypertension.
Strengths	- Three-year follow-up of randomized clinical trial
Weaknesses/ Potential bias	- Limitations: Author-identified limitations include small sample size, 23% attrition rate, and lacking ambulatory blood pressure monitoring for residual hypertension.

State of the Art
Appraisal

Medical condition		Alternatives		Risk/benefit		Side-effects		Equivalence		Surrogate endpoints	
Yes 1	No 2	**Yes 1**	No 2	**Yes 1**	No 2	**Yes 1**	No 2	Yes 1	**No 2**	Yes 1	**No 2**

Overall SOA Appraisal and Disposition

SOA Grade (Range 6-12)	8	Disposition (select)	**Accepted, < 12** Excluded, 12

Relevant SOA Results

SOA data	- Thoracic aortic aneurysmal formation at three years, all treated conservatively with no further endovascular/surgical therapies ○ BES: 4/35 (11.4%) - SES: 2/36 (5.6%)
Comments	- Funding: Study was financially supported by Rajaie Cardiovascular, Medical and Research Center. - Conflict of interest: Authors reported that they have no conflicts of interest to declare.

12. Schleiger et al. (2023)

Contribution	
S&P	x
SOA	x

Safety & Performance Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Single center retrospective study.	The aim of this study was to analyze long-term results after CoA treatment with bare and covered CP stents in our institution and to derive recommendations for the differential use of these stent types.	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	- 212 patients received treatment with bare (n=71) and covered (n=141) CP stents between September 1999 and July 2021 - Stents were mounted on BIB catheters, not specified as pre-mounted	**D1**	D2	D3
Application	- Native CoA (n=110/212, 51.9%) and recoarctation after primary surgical or interventional treatment (n=102/212, 48.1%)	**A1**	A2	A3
Patient	- Median study patient age was 18.8 years (IQR 11.9; 35.8); median 16.3 years (IQR 10.3-25.9) for Bare CP stent - Median study patient weight 61.3 kg (IQR 43.3; 74.7); median 56.4 kg (IQR 40.0-73.7) or Bare CP stent - 146/212 (68.9%) male; 51/71 (71.8% male) for Bare CP stent	**P1**	P2	P3
Report	- High quality.	**R1**	R2	R3
	Suitability Grade (Range 4-12)	4		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	- Procedural success, survival rate, freedom from re-intervention, peri-procedural and long-term complications were reported.	**Yes 1**	No 2
Follow-up	- Medan follow-up of 7.3 years (IQR: 4.3-12.6)	**Yes 1**	No 2
Statistical analysis	- Patient characteristics expressed as median and IQR. Survival and freedom from re-intervention were assessed using Kaplan-Meier survival analysis. Survival and reintervention rates between groups were compared using the log rank test. Differences between groups were analyzed using the $\chi 2$ test for categorical variables and Wilcoxon rank sum test for continuous variables. Potential risk factors for re-intervention were evaluated with univariate logistic and Cox regression analysis. Time-independent variables were included in a multivariable model using HR. A $p < 0.05$ was considered statistically significant.	**Yes 1**	No 2
Clinical significance	- The magnitude of the treatment effect observed was clinically significant.	**Yes 1**	No 2
	Data Contribution Grade (Range 4-8)	5	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (3) + Suitability (4) + Data Contribution (4) = 11	Disposition and Weighting (select)	**Accepted and Pivotal 9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

	Relevant S&P Results	
	Safety data	- Survival rate: Survival rate was 98.1% after five, and 95.6% after 10 and 15 years, respectively, and did not differ between patients who received bare or covered CP stents (Log Rank p = 0.263). In-hospital mortality occurred in 1/212 patients (0.5%) and late mortality in 8/158 patients (5.1%). Late mortality was not attributable to previous CoA treatment…There was no difference in late mortality according to stent type (p = 0.261). - Mortality – Bare CP stent: o In-hospital: 1/71 (1.4%) – acute aortic rupture led to immediate patient death o Long-term: 5/60 (8.3%), not attributable to CoA treatment - Complications rate – Bare CP stent: o Peri-procedural complications – Bare CP stent (n=71) ▪ Injury/thrombosis of vascular access vessel: 3/71 (4.2%) ▪ Stent dislocation: 2/71 (2.8%) ▪ Aortic dissection/aortic wall rupture: 2/71 (2.8%) o Long-term complications – Bare CP stent ▪ Aneurysm formation: 5/50 (10.0%) ▪ Stent fracture: 10/39 (25.6%)
	Performance data	- Procedural success was achieved in 187/212 (88.2%) patients. - After stent implantation a significant reduction of systolic blood pressure was achieved from a preinterventional median pressure of 145 mmHg (IQR 134; 157) to a postinterventional median pressure of 123 mmHg (IQR 112; 135) (p < 0.001). - In 25 patients the interventional procedure was not considered successful: In 22 of these patients a reduction of the peak systolic pressure ≤10 mmHg was not achieved. o Fifteen of these patients were additionally diagnosed with a hypoplastic aortic arch with a remaining systolic ascending to descending aortic pressure difference >10 mmHg after successful implantation of the CP stent in the CoA region. o In two patients with an unsuccessful procedure the stent migrated into the descending aorta immediately after placement. Both patients underwent subsequent surgical repair after fixation of the stent in the descending aorta by balloon dilatation. o Another patient developed an aortic wall rupture immediately after stent implantation and died during extracorporeal cardiopulmonary resuscitation. - Re-intervention rate: Planned re-interventions were performed in 33/158 patients (20.9%). In 44/158 patients (27.8%), unplanned re-interventions were performed to treat re-stenosis or aortic wall injuries… The probability of freedom from re-intervention in the entire cohort was 81.0% after five, 64.0% after 10 and 62.0% after 15 years, respectively. Re-intervention rate did not differ between patients who received endovascular CoA treatment with bare or covered CP stents (p = 0.50)… Multivariable risk factor analysis revealed previous CoA surgery (HR: 2.0, 95% confidence interval [CI]): 1.1‑3,9, p = 0.029), postdilatation (HR: 2,9, 95% CI: 1.1‑6.3, p = 0.028) and age at intervention (HR: 0.96, 95% CI: 0.94‑0.99, p = 0.002) as independent risk factors for re-intervention. - Antihypertensive medications: Residual arterial hypertension was present in 53/158 patients (33.5%); 23 of these patients were adult and 30 patients pediatric (p = 0.173). Before endovascular treatment with bare or covered CP stent 114 patients received no medical antihypertensive therapy, 44 patients received monotherapy, 30 patients dual

	therapy, and 24 patients triple or quadruple therapy. In 76/158 patients (48.1%) the number of antihypertensive medications did not change during follow-up, whereas in 57/158 patients (36.1%) the number of antihypertensive medications was increased and in 25/158 patients (15.8%) decreased.
Benefits/claims data	- In conclusion, our study documents excellent long-term results after CoA treatment with bare and covered CP stents. In our cohort, mortality, re-intervention and complication rate did not significantly differ between both stent types.
Strengths	- Long-term follow-up (median of 7.3 years, IQR: 4.3-12.6)
Weaknesses/ Potential bias	- Single center design - Retrospective design

State of the Art

Appraisal

Medical condition		Alternatives		Risk/benefit		Side-effects		Equivalence		Surrogate endpoints	
Yes 1	No 2	**Yes 1**	No 2	**Yes 1**	No 2	**Yes 1**	No 2	Yes 1	**No 2**	Yes 1	**No 2**

Overall SOA Appraisal and Disposition

SOA Grade (Range 6-12)	8	Disposition (select)	**Accepted, < 12** Excluded, 12

Relevant SOA Results

SOA data	CoA:
	- CoA comprises 5% to 8% of all congenital heart disease.
	- Mortality – Covered CP stent
	  o In-hospital: 0/141 (0%)
	  o Long-term: 3/98 (3.1%), not attributable to CoA treatment
	  o Aortic dissection/aortic wall rupture: 2/71 (2.8%)
	- Peri-procedural complications – Covered CP stent (n=141)
	  o Injury/thrombosis of vascular access vessel: 6/141 (4.3%)
	  o Bleeding of vascular access vessel: 1/141 (0.7%)
	  o Aortic dissection/aortic wall rupture: 1/141 (0.7%)
	- Long-term complications – Covered CP stent
	  o Aneurysm formation: 9/83 (10.8%)
	  o Stent fracture: 9/69 (13.0%)
	  o Endoleak: 1/98 (1.0%)

Comments	- Author-identified limitations included unequal distribution between subgroups with more patients receiving Covered CP stents due to institutional preference, difference in follow-up duration between sub-groups due to differences in time points of availability and product approval, 54 patients lost to follow-up could not be considered in long-term analysis, the low event rate of major complications (e.g., aortic dissection, stent fracture, aneurysm formation) may limit statistical comparison between groups, incidence of long-term aortic wall complications may be underestimated as re-catheterization or cross-sectional imaging was not available for all patients, non-invasive blood measurement during exercise or 24-hours blood pressure measurements were not available to identify unmasked arterial

		hypertension and the number of antihypertensive medications may be affected by cofounders. - Authors declare no conflict of interest. Open access funding enabled and organized by Projekt DEAL.

An overall summary of the clinical performance and safety:

A comprehensive, systematic, and critical evaluation of the pertinent clinical data and pre-clinical study data in relation to the Bare Stents has been carried out and documented in this report. Based on the results of this evaluation, it is considered that:

a) Conformity with relevant general safety and performance requirements set out in MDR Annex I under the normal conditions of the intended use of the device has been confirmed.
b) Undesirable side-effects and acceptability of the benefit-risk ratio have been evaluated and are acceptable according to the current knowledge/the state of the art in the medical fields concerned and according to available medical alternatives.
c) The information materials supplied by NuMED, and the risk reduction measures are adequate taking into account the intended purpose of the device.
d) Usability aspects have been adequately considered and the Stents including the IFUs, are suitable for the intended users.
e) The claims foreseen in the information materials provided with the Clinical Evaluation Report (CER) are adequate taking into account the intended purpose of the device.
f) The information materials supplied and the RM documentation for the device under evaluation are consistent with the clinical data and pre-clinical study data presented in this CER and with the current knowledge/state of the art.

Overall, it is concluded that the risks associated with the use of the Bare Stents are acceptable when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art; that the intended clinical performances are achieved by the device; and that known and foreseeable risks and undesirable side-effects are considered acceptable when weighed against the benefits from performance achieved by the device.

Ongoing planned post-market clinical follow-up:

The Stent Device Family has been on the market since 2004 in the EU and 1999 in other markets. Over time variants of the Stent Device Family have been introduced to these markets. Since then, the devices are likely to have been used in a variety of patients and populations. The Stents have been subjected to several clinical investigations where efficacy and safety has been demonstrated.

For the original Stent Device Family, a PMCF study is not warranted at this time due to the fact that the long-term safety and clinical performance has been established via device use and ample clinical experience. This experience would likely have identified any rare complications or problems that would become apparent only after widespread device use. Continued PMS activities will provide sufficient data to adequately address clinical risks, and detect emerging risks on the basis of evidence. Additionally, a clinical study was conducted in the US under the COAST clinical trial.

A PMCF study was initiated in 2018 for the additional sizes that were added to the product line, to determine if there were any new complications which were previously not addressed through actual clinical use, or if any new risks are introduced. The target study size was 59 patients, based on a confidence level of 95%. The study was conducted by issuing a form to the treating physician and collecting data. The study is complete and the results are included in the clinical data that is used for the clinical evaluation.

PMCF Activity #1

Literature and media searches are conducted annually in January. This is to review all published data on the devices for information related to safety and performance. This includes a review to determine if the devices continue to be safe and perform as intended in the IFU by reviewing any complaints or emerging clinical risks. The search strategy is based on the device names.

An additional literature search of peer-reviewed scientific publications is performed as part of the update to the CER. This search is a broader search to identify all publications that report on the clinical use of the device or similar devices on the market. It includes searches of device names, indications, and product codes. This search is used to demonstrate the safety and performance of the devices in question within the state of the art, and to determine whether the devices continue to be safe and perform as intended in the IFU by reviewing any complaints or emerging clinical risks.

Post market surveillance includes review of data for both NuMED devices as well as similar competitor products. This includes both a reactive review of NuMED data, as well as, a proactive search to collect data from literature, recall, and vigilance databases. The reactive review is documented in NuMED's monthly and annual Quality Management reviews, and the proactive search is documented in both the annual update of the PSUR document, and the CER when it is updated. All PMS data is reviewed to determine if the risk management file or IFU needs to be updated based on the findings. All device related adverse events are evaluated for determination on vigilance reporting

PMCF Activity #2

The PMS form is a proactive way for NuMED to gather additional information on their products. It is quick way for the physician to communicate both negative and positive things about the individual devices. PMS forms are reviewed upon receipt to determine if a

complaint, corrective action, recalls, FSCA or any other vigilance reporting needs to be initiated. They are also reviewed to determine if any information is provided that would require updates to both the risk management file or IFU. It is also a way to determine if the devices are being used for off-label procedures

6. Possible diagnostic or therapeutic alternatives

Alternative treatments for CoA include surgery or balloon angioplasty.

7. Suggested profile and training for users

The COA Stent Device Family is intended for use by trained cardiology and surgical professionals undertaking stent implantation.

8. Reference to any harmonised standards and CS applied

There are no Common Specifications for this type of device.

The following harmonised standards are followed for this device:

- EN 556-1:2024 – Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" – Part 1: Requirements for terminally sterilized medical devices.
- EN ISO 10993-4:2017 / A1:2025 – Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood – Amendment 1 (ISO10993-4:2021/Amd 1:2025, corrected version 2025-04)
- EN ISO 10993-10: 2023 – Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization
- EN ISO 10993-18: 2020 – Biological Evaluation of Medical Devices – Part 18: Chemical characterization of medical device materials within a risk management process
- EN ISO 10993-23: 2021 – Biological Evaluation of Medical Devices – Part 23: Tests for Irritation
- EN ISO 11135: 2014 / A1:2019 – Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.
- EN ISO 11607-1: 2020 +A1: 2023 – Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for materials, sterile barriers systems and packaging systems
- EN ISO 11607-2: 2020 +A1: 2023 – Packaging for Terminally Sterilized Medical Devices – Part 2: Validation requirements for forming, sealing and assembly processes
- EN ISO 11737-1: 2018 / A1:2021 – Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
- EN ISO 13485: 2016 / A11:2021 – Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 14971: 2019 / A11:2021 – Medical Devices – Application of Risk Management to Medical Devices
- EN ISO 15223-1: 2021 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

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10. Revision History

SSCP revision number	Date Issued	Change Description	Revision validated by Notified Body
00	21 June 2022	Initial implementation	☐ Yes Validation Language: English ☒ No
01	14 July 2023	Updated sections 4, 5, 7, 8, and 9 for CER Update.	☐ Yes Validation Language: English ☒ No
02	19 February 2025	Revised Section 1 to update Basic UDI-DI. Revised Section 2 to update intended purpose. Revised Section 3 to add model variants. Revised Section 4 to update warnings and Section 5 to update clinical literature. Updated Section 8 for harmonized standards and Section 9 for references.	☐ Yes Validation Language: English ☒ No
03	23 June 2026	Updated to Rev 03 of the blank form. Updated EU Rep, harmonized standards listing and PMCF section.	☐ Yes Validation Language: English ☒ No

NuMED
Summary of Safety and Clinical Performance
SSCP – Stents – CoA

Document Revision: 03
Date issued: 23 June 2026

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay person. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions for Use to provide information on the safe use of the device.

1. Device identification and general information	
Device trade name(s)	CP Stent Mounted CP Stent
Manufacturer's name and address	NuMED, Inc. 2880 Main Street Hopkinton, NY 12965 USA
Year when first certificate (CE) was issued	2004 (CP Stent) 2009 (Mounted CP Stent)
Basic UDI-DI	CP Stent – 08877141600T2 Mounted CP Stent – 08877141610T5

2. Intended use of the device	
Intended purpose	The stents are intended to dilate aortic coarctations. An aortic coarctation is a partial blockage or narrowing in the aorta, the body's main blood vessel distributing blood to all parts of the body. This blockage of the aorta makes the heart work harder to pump blood to your body and can weaken the heart muscle. Furthermore, this blockage can cause severe upper body hypertension (high blood pressure), increasing the risk of stroke. This blockage is present from birth.
Indications and intended patient groups	The device is used to treat any patients that have an aortic coarctation as long as none of the below listed contraindications and/or limitations are applicable.
Contraindications and/or limitations	The following patients should NOT receive the stent: • Patients who are too small to allow the stent to pass through their arteries without damaging the artery; • Patients with a stiff aorta that does not get larger with balloon dilation; • Patients with blocked leg arteries making it difficult or unsafe to move the catheter and stent to the narrowed aorta; • Patients with any signs of infection; • Patients with active infection in the heart or blood vessels (endocarditis); • Patients with a known allergy to aspirin, other antiplatelet agents, or heparin; • Pregnancy.

3. Device description	
Description of the device	The stents are balloon expandable and intended to permanently stay in your body. The stents are used for coarctation of the aorta The stents are composed of heat treated 90% platinum / 10% iridium wire that is arranged in a "zig" pattern, laser welded at each joint, and over brazed with 24K gold. The number of rows determines the unexpanded length of the stent. The BIB Stent Placement Catheter is triaxial in construction with two lumens being used to inflate the balloon while one lumen is being used for tracking over a guidewire. The inner balloon is ½ of the outer balloon diameter and 1 cm shorter. The purpose of the double balloon catheter is to apply an incremental inflation for the purpose of dilating a stent. The inner balloon provides initial expansion of the stent and also acts as a tool to hold the stent on the catheter prior to the outer balloon being inflated. The outer balloon is then inflated, providing the remainder of the expansion. There are radiopaque platinum marker bands under the balloon shoulders, to aid during placement. The balloons are designed to inflate to the diameter and length listed on the label at a specific pressure. Thus, it is recommended that the device be used in conjunction with a mechanism to monitor pressure, an inflation device with pressure gauge.
Medicinal Substances	The stents do not contain any medicinal substances.
Mode of Action	The stents are implanted using a thin hollow tube (catheter) with a balloon on the end. Your physician will place the stent on the balloon at the start of your procedure. The catheter with the stent is then placed through the skin, typically into the artery in your upper leg. The balloon and stent are moved to the appropriate position at the narrowed part of your aorta. Once in place, the balloons are inflated to expand the stent. The catheter is then removed from the body and the stent stays in place.
Description of Accessories	All stents are packaged and shipped to the physician with hemostasis valve tools. These tools are hollow tubes that are placed in the valve of the introducer to help the stent move through that valve without any issues. The valve of the introducer is very tight to prevent blood loss during the procedure, so the tools help the stent move through the valve without causing damage to the stent or moving the stent on the catheter. The stent is also used with other accessories not provided by NuMED, including, a delivery catheter to expand the stent (unmounted version only), guidewire, introducer, balloon inflation medium to inflate the balloon, inflation device with pressure gauge, and a stopcock.

4. Risks and Warning	
Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.	
How potential risks have been controlled or managed	The Stent Device Family has been developed in accordance with documented processes to ensure that it is designed, manufactured, packaged, and labelled in accordance with the current state of the art and meets all requirements of the appropriate regulations. Design verification activities were performed and include pre-clinical testing and clinical investigations. A clinical literature review has also been performed on the Stent Device Family. All risks identified during these activities were mitigated as far as possible and are considered acceptable in regards to the clinical benefit of the device. Continued review of all Post Market Surveillance and Post Market Clinical Follow-up Data is performed to identify any additional risks that may be identified after the device was placed on the market.
Remaining risks and undesirable effects	Cardiac catheterization and stent insertion carry certain risks. Potential complications & adverse effects associated with device use and indication include: • Femoral Artery Injury • Stent Migration – movement of the stent away from original implant site • Stent Stenosis – growth of tissue within the stent, leading to return of the blockage • Stent Fracture – break in the frame of the stent • Aneurysm/Pseudoaneurysm – weakening or injury of the aorta wall • Aortic Rupture/Tear – perforation or tearing of the aorta, causing internal bleeding • Stent Malposition – poor position of stent, requiring a 2nd stent • Hematoma – bruising at the site where the device is introduced into the body

	• Sepsis/infection – Infection • Thrombosis – formation or presence of a blood clot • Embolization – passage and lodging of an embolus within the bloodstream • Transitory arrhythmia – Irregular heartbeat • Endocarditis – infection within the stent • Bleeding – at the site of where the device is introduced into the body • Cerebrovascular Incident – stroke • Death
Warning and Precautions	The majority of warnings and precautions listed for the stents pertain to the placement and use of the device in the cath. lab by the physician. MRI Conditional information is applicable to the stents after they are implanted. This information should be used by any MRI technician that is performing an MRI procedure on any patient with a NuMED stent implanted. All patients will be provided with an Implant Card after their procedure. This Implant Card will give the location of where to find the most up to date MRI parameters to be used for patients that have a NuMED stent implanted.
Summary of any field safety corrective actions (FSCA including FSN) if applicable	Since commercialization, there has been one recall on the Bare CP Stent in 2003 (#Z-0983-03, completed in 2004) concerning the lack of PMA or 510(k) for the Bare CP Stent. The recall was conducted in the U.S. only. There have not been any Field Safety Corrective Actions or Field Safety Notices on any other version of the Stents.

5. Summary of clinical evaluation and post-market clinical follow-up	
Clinical background of the device	The NuMED Stent Device Family has been sold globally since 1999. The following data is based on the NuMED CP Stent®. It was tested and found to be safe and effective to widen the narrow part of the aorta related to coarctation of the aorta. A study was conducted with 105 patients weighing more than 77 lbs at the time of implant. Most patients (98%) were treated with one CP Stent®. On average arm systolic blood pressure was 27 mmHg higher than the leg pressure before the procedure. A reduction of a gradient to 15mmHg or less following the procedure suggests that the blockage is reduced effectively. By one month after bare metal stent placement the average leg pressure was 1 mmHg higher than the arm pressure. Two years after implant, 91% of patients had arm blood pressures less than 15 mmHg above their leg blood pressure which suggests that most of the treated aortas did not re-narrow. An overview of complications and additional treatments provided after the stenting procedure is shown below: • Serious complications related to the CP Stent® or implant procedure, such as: injury to the aortic wall and leg artery-vein fistula (an abnormal passageway between the artery and vein), were identified in 1 out of 20 (5%) patients within the first month of implant. • No patients needed surgery to repair the aorta, remove the stent or repair the arterial access site. • 1 out of 20 (5%) patients developed small aneurysms (weakened areas of the aorta) in the area of stent placement in the years following stent therapy, making CT or MRI imaging an important part of follow up care. However, none of the patients who developed aneurysms demonstrated symptoms or required surgery. All were successfully treated with covered stent placement. • Approximately 3 out of 20 (15%) patients required repeat cardiac catheterization for a second dilation of the stent, mostly to keep up with the size of the patient as he/she grew and for some to repair aortic wall injuries as noted above.
The clinical evidence for the CE marking	CE marking is based on data from one clinical study, a review of published literature, and a review of post market surveillance data. Additional pre-clinical testing was performed as part of the development and design of the device. In vitro (on the bench) testing was performed on the devices as part of the Design History File. Biocompatibility testing was also performed on the materials used to manufacture this device to determine if it met the requirements for an implant in the human body. The device passed all tests.

Safety	The clinical data and pre-clinical study data demonstrated that the device performed as intended by NuMED in the clinical setting; the device does not pose unacceptable safety concerns in the clinical setting; and any risks associated with clinical use of the device are acceptable when weighed against the benefits to the patient.

6. Possible diagnostic or therapeutic alternatives	
When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.	
General Description of therapeutic alternatives	**Coarctation of the Aorta** Your cardiologist believes that relief of the blockage is important for your health and safety. There are three ways to relieve the blockage: by surgery, by stent implantation without surgery, or by balloon angioplasty. **Surgical Therapy** Surgical treatment of the blockage is usually performed through an incision on the side of the chest, approaching the aorta by spreading the ribs. The narrowed portion of the aorta is removed and then the aorta is sewn back together. For more complicated coarctation, surgery might be performed from the front of the chest, opening the breast bone and using heart lung bypass. For some patients a benefit of a surgical approach is that the repair can be performed without the use of man-made materials. However, for other (especially adult) patients a man-made tube graft or patch may be needed. Please consult with your surgeon regarding his or her approach. For younger patients, surgery results in a lower need for a second procedure to keep up with growth when compared to balloon or stent therapy. Risks of surgery include: pain from the surgical incision, prolonged fluid drainage from the chest after surgery, chest or wound infection, longer recovery time compared to stent therapy, prolonged postoperative rib discomfort and increased risk of very high blood pressure occurring after immediately after surgery, requiring intravenous therapy in an ICU, compared to stent repair. There is a low risk, probably less than 5%, of developing an aneurysm (weakened areas of the aorta) in the area of surgery in the years following stent therapy, making CT or MRI imaging an important part of follow up care. **Stent Therapy (without surgery)** A stent is an expandable metal tube that is implanted into your aorta to keep it open. Surgery is not required for this procedure. The stent is implanted using a thin hollow tube (catheter) with a balloon on the end. The catheter with stent is inserted through the artery in the upper leg. The balloon and stent are then moved to the appropriate position to the narrowed part of your aorta. Once in place, the balloons are inflated to expand the stent against the aortic wall. The catheter is then removed from the body and the stent remains in place. **Balloon Angioplasty** A specially designed catheter with a tiny balloon is carefully guided through the artery to the blockage, then inflated to widen the opening and increase blood flow to the heart.

7. Suggested profile and training for users
The COA Stent Device Family is intended for use by trained cardiology and surgical professionals undertaking stent implantation.