NuMED
Summary of Safety and Clinical Performance
SSCP – Sizing

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 Sizing Family PTS PTS-X
Model Number	NuMED Sizing Family – Model 1200 PTS – Model 360 PTS-X – Model 360X
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	08877141200SE
Medical device nomenclature description / text	EMDN – C0104020103 - VASCULAR OCCLUSION CATHETERS
Class of device	III
Year when first certificate (CE) was issued	2001 – PTS 2004 – PTS-X
Authorised Representative (AR)	G. van Wageningen B.V. Hallenweg 40, 5683 CT Best, The Netherlands
AR SRN	NL-AR-000010437
Notified Body	SGS Belgium NV
Notified Body ID Number	1639

2. Intended Use of the Device	
Indications for use	Intended Use The PTS Catheters are intended for use as a visual aid while measuring a cardiovascular defect using Transesophageal Echocardiogram (TEE) and fluoroscopy. Indication Recommended for use in those patients with cardiovascular defects wherein accurate measurement of the defect is important to select the appropriately sized occluder device.
Contraindications and/or limitations	There are no contraindications listed for this device and indication.

3. Device Description	
Description of the Device	The Sizing Catheters are coaxially designed with a balloon mounted on the distal tip. The device is inserted in the vessel percutaneously using the standard Seldinger technique over a 0.035 inch guidewire. The inner and outer shaft of the PTS Catheter is polyamide tubing. The outer tubing of the PTS-X is polymeric tubing and the inner shaft is a multilayer extrusion of polyamide (Vestamid PA12) surrounding a braid of 304 LV stainless steel (SS). The catheter body and balloon are DiEthylHexyl Phthalate (DEHP)-free and Latex-free. The catheter features a proximal end bifurcate with two distinct luminal passages. The inflation lumen terminates into a distally mounted balloon. The balloons are non-compliant thermoplastic elastomer. It is designed to insert through the smallest possible introduction sleeve. The through lumen terminates at the tip of the catheter and will accept the passage of the appropriate guidewire. There are two platinum iridium marker bands under the shoulders of the balloon and there are two additional radiopaque platinum marker bands spaced at 10 mm (as measured from leading edge to leading edge). These bands are located at the balloon center and are used as a distance reference. The PTS-X 1 cm balloon length will only have the two image bands at the balloon center. The PTS catheter is white and the balloon material is clear. The PTS-X is identical with the exception of the inner tubing, which is blue. All bonds are achieved via heating. The catheters are double packed in two heat sealed Tyvek pouches and sterilized by ethylene oxide (EtO) gas. Shelf-life has been established to be five years.
Reference to previous generation(s) or variants	N/A
Accessories which are intended to be used in combination with the device	Guidewire, introducer, balloon inflation medium, inflation device with pressure gauge, and stopcock.
Description of any other devices and products which are intended to be used in combination with the device	N/A

4. Risks and Warning	
Residual risks and undesirable effects	Side-effects reported in the literature are inherent and common to all percutaneous sizing procedures and/or intravascular catheter procedures and are not specifically associated with the Sizing Catheter. All risks identified in the clinical literature as well as the risks detected from the Post Market Surveillance or from clinical data have been considered by the risk management process. All significant risks were considered, mitigated as far as possible (AFAP), and are acceptable in regard to the clinical benefit of the device. **POTENTIAL COMPLICATIONS** Potential balloon separation following balloon rupture or abuse and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces. **NOTE:** There have been infrequent reports of larger diameter balloons bursting circumferentially, possibly due to a combination of tight focal strictures in large vessels. In any instance of a balloon rupture while in use, it is recommended that a sheath be placed over the ruptured balloon prior to withdrawal through the entry site. This can be accomplished by cutting off the proximal end of the catheter and slipping an appropriately sized sheath over the catheter into the entry site. For specific technique, refer to:

	Tegtmeyer, Charles J., M.D. & Bezirdijan Diran R., M.D. "Removing the Stuck, Ruptured Angioplasty Balloon Catheter." Radiology, Volume 139, 231-232, April 1981. Potential complications & adverse effects associated with device use and indication include: • Trauma / Overstretching of the Septum • Device Erosion • Device Embolization • Air Embolism • Access Site Complications
Warning and Precautions	The following Warnings and Precautions have been identified and are called out in the Instruction for Use: **WARNINGS** • CAUTION: 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. • Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon. • 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. • This device is intended for single use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of cross- contamination. **PRECAUTIONS** • One should always select a diameter larger than the unstretched defect diameter, i.e., TEE ASD size 12mm - select 20 or 25 mm PTS. • Caution should be used when inflating the balloon, over inflation can cause trauma and overstretching of the septum. • Sizing procedures should be conducted under fluoroscopic guidance with appropriate x-ray equipment. (PTS-X only). • Sizing procedures should be conducted under fluoroscopic/MRI guidance with appropriate x-ray equipment. (PTS only) • 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 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/MRI 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. • Before removing catheter from sheath it is very important that the balloon is completely deflated. • 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	There have not been any Field Safety Corrective Actions or Field Safety Notices on the PTS Catheter. Since commercialization, there has been (1) FSCA / FSN on the PTS-X Catheter (2023), concerning labeling. A total of (10) devices were distributed in Italy only, and is now closed.

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

Summary of clinical data related to equivalent device:

NuMED has elected not to use the clinical data from an equivalent (clinical, technical, and biological characteristics) device(s). In the event there are devices considered equivalent, their data will be considered as similar devices.

Summary of clinical data from conducted investigations of the device :

NuMED has not conducted any clinical investigations on the Sizing Catheters.

Summary of clinical data from other sources:

1. Krizanic et al. (2008)

Safety & Performance
Objective: Investigation of the usefulness feasibility and safety of the Occlutech Figulla® single layer-PFO occlude N for closure of PFO.
Method: Open, prospective, nonrandomized multicenter clinical study
Follow-up: Up to 180 days after procedure
Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Open, prospective, nonrandomized multicenter clinical study	Treatment Benefit, Treatment Harms (Common)	1	2	**3**	4	5

Suitability	**Relevant Data**	**Grading**		
Device	25 mm PTS NuMED Inc. to determine the size and the anatomy of the defect	**D1**	D2	D3
Application	The right femoral vein was punctured under local anesthesia and a soft-tipped 0.035'' wire was inserted and advanced through the PFO, and finally positioned within a left-sided pulmonary vein. PTS balloon sizing was used to determine the size and anatomy of the defect before implementation of PFO-occluder device. Under fluoroscopy and TEE.	**A1**	A2	A3
Patient	P1 (37 patients with PFO; mean age 57 yo (18-80); M 18, F 17)	**P1**	P2	P3
Report	The article contains sufficient information to be able to undertake a rational and objective assessment.	**R1**	R2	R3
	Suitability Grade (Range 4-12)	**5**		

Data Contribution	**Relevant Data**	**Grading**	
Outcomes/Endpoints	The reported outcome measures (implantation success/complications) indirectly reflect the intended performance of the device.	**Yes 1**	No 2
Follow-up	The duration of follow-up (up to 180 days after the procedure) is long enough to assess whether duration of treatment benefits/harms and identify complications.	**Yes 1**	No 2
Statistical analysis	No statistical analysis of the data has been provided.	Yes 1	**No 2**
Clinical significance	The magnitude of the treatment benefit observed was clinically significant (implantation success).	**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 (5) + Data Contribution (5) = **13**	Disposition and Weighting (select)	Accepted and Pivotal 9-12 Accepted but not Pivotal, **13-21** Excluded, 22-25

Population: patients with PFO (7.8 ±2.5 mm defect size mean) All patients suffered from cryptogenic stroke (the origin remains unknown).

Sampling: n= 36

Mean Age: 50 years old (yo) (18 – 80)

Sex:
M – 18
F – 17

Relevant S&P Results

Criteria	Results	P value
Safety data	Perioperatively: No major in-hospital-AE or complications thromboembolism, occlude dislodgement, infection or myocardial infarction.	N/A
	Comparison to Amplatzer® PFO occluder device: See Table 1 below	N/A
Performance data – After implantation	One patient had transient atrial fibrillation, which terminated medically after 12 h.	N/A
Performance data – 60 days after procedure	TEE studies in the remaining 35 patients (one patient was unwilling to further participate) showed a residual shunt in 8.6% (3/35) and a left-to-right shunt in 2.6% (1/35) of patients	N/A
Performance data – 180 days after procedure	One patient with severe arteriosclerotic heart disease and aortic carotic stenosis revealed a stroke without evidence of cardioembolic origin or devices thrombosis. Complete closure was achieved in 88.2% of the cases (30/34).	N/A
Comparison to Amplatzer® PFO occluder device	Table 1 Comparison Amplatzer vs Figulla PFO Occluder N No. / Amplatzer PFO occluder $n = 69$ / Figulla PFO occluder $n = 36$ Implantation success: 100% / 100% Periinterventional Complications: / 1 (a) minor, n %: 1 (1.5%) / 1 Atrial fibrillation Trans. ST-elevation: 1 (1.5%) / 1 Grain bleeding (b) major, n %: 0 / 0 TIA: 0 / 0 Devicedislodgement: 0 / 0 Pericardial effusion: 0 / 0 Arrosion of aorta: 0 / 0 Death: 0 / 0	N/A
Benefits/claims data	Authors mentioned that they routinely used the sizing balloon for definition of the defect size. TEE studies could not exactly determine the defect size. Implantation by monitoring with ICE is an alternative method which was not routinely used. They generally recommend ICE or TEE monitoring during the procedure in the clinical study. For general use both methods are optional. Balloon assessment of PFOs enhances the understanding of their morphology and aids in the identification of long tunnels. De-tunnelisation using the same balloon facilitates the uncomplicated trancatheter closure of long tunnel PFOs in most patients.	N/A
Strengths	Comparison of results with a reference device (Amplatzer PFO occlude (n = 69)).	N/A
Weaknesses/ Potential bias	Low number of subjects included. Study does not directly assess safety and performance of the sizing balloon but was designed for assessment of the PFO occlude device.	N/A

State of the Art

N/A – Articles does not contribute to SOA.

Conclusions of the authors: The novel Occlutech Figulla® PFO N single layer device appears to be safe, feasible and useful for PFO closure despite a 50% reduction of the meshwire, no distal hub and an improved flexibility of the left atrial disc.

Device used: 25 mm NuMED Inc. to determine the size and the anatomy of the defect; the correct position of the PFO-occluder was confirmed by means of fluoroscopy and TEE

2. Kutty et al. (2008)

Safety & Performance

Objective: Presentation of the results of investigations performed to determine causes of significant recurrent focal neurologic events (FNEs) in patients from a center who underwent transcatheter PFO closure over a period of 5.5 years (From March 2000 to September 2005)

Method: Retrospective clinical study

Follow-up: mean of 2.1 years (1 month to 7.1 years) for a total of 438 patient-years after closure (199/216 patients with follow-up information)

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Retrospective clinical study	Treatment Benefit, Treatment Harms (Common)	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	PTS Sizing balloon NuMED Inc.;	**D1**	D2	D3
Application	A complete right-sided hemodynamic catheterization and right atrial angiography was performed to assess the anatomy of the PFO. A guidewire was positioned in the left upper pulmonary vein through a venous catheter advanced through the PFO. PTS Sizing balloon was advanced over the guidewire and incompletely inflated (<1 atm) until a distinct indentation in the balloon and elimination of any shunting by color Doppler was identified. The balloon was not inflated fully to avoid the possibility of inadvertently enlarging the defect. The diameter of the indentation was measured angiography and by echocardiography. Under general anesthesia and TEE and since 2001 ICE and conscious sedation.	**A1**	A2	A3
Patient	216 patients with PFO; 50 yo (19 – 77); M 107/F 109	**P1**	P2	P3
Report	The article contains sufficient information to be able to undertake a rational and objective assessment.	**R1**	R2	R3
	Suitability Grade (Range 4-12)	**5**		

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	The reported outcome measures (implantation success/complications) indirectly reflect the intended performance of the device.	**Yes 1**	No 2
Follow-up	The duration of follow-up (mean 2.1 years) is appropriate to assess whether duration of treatment benefits/harms and identify complications.	**Yes 1**	No 2
Statistical analysis	Statistical analysis of the data has been provided for safety data and is appropriate.	**Yes 1**	No 2
Clinical significance	The magnitude of the treatment benefit observed was clinically significant (implantation success).	**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 (5) + Data Contribution (4) = **12**	Disposition and Weighting (select)	Accepted and Pivotal **9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

Relevant S&P Results:

Criteria	**Results**	**P value**
Safety data - Main results	Twenty patients had a focal neurologic event (FNE) 0.1 month to 40.2 months after PFO closure over 438 person-years of follow-up (mean 2.1 years, range 1 month to 7.1 years). There were 4 recurrent strokes, 2 likely directly device related. Ten patients had	N/A

Population: patients with PFO (11 mm (4 – 24) stretch diameter)

Sampling: n= 216

Mean Age: 50 yo (19 – 77)

Sex: M – 107 F – 109

	transient ischemic attack (TIA) and 6 patients had clear evidence of pathology unrelated to the device.	
Safety data - Event rate for recurrent strokes	0.91% per year or 9.1 per 1,000 person-years (95% CI for difference 3.4 to 24.3)	N/A
Safety data - Combined event-rate for stroke/transient ischemic attack (TIA)	3.42% per year or 34.2 per 1,000 person-years (95% CI for difference 20.7 to 56.8)	N/A
Safety data - Comparison with other studies	The recurrent stroke rate found in this study after CardioSEAL occlusion of PFO is comparable to rates from studies that evaluated recurrence of stroke and TIA in patients with PFO and cryptogenic stroke placed on various regimen of medical prophylaxis.	N/A
Performance data - Successful implantation	100%	N/A
Benefits/claims data	None	N/A
Strengths	High number of subjects included (216) FU of 2.1 years (mean).	N/A
Weaknesses/ Potential bias	Study does not directly assess safety and performance of the sizing balloon but was designed for assessment of the PFO occlude device.	N/A

State of the Art
N/A – Articles does not contribute to SOA.

Conclusions of the authors: In conclusion, transcatheter PFO occlusion can be accomplished as an outpatient procedure with minimal immediate morbidity. Patients may have multiple possible causes of recurrent FNE. Recurrence rate of cryptogenic FNE compares favorably with reports of medical management. Analysis of results from ongoing randomized trials of transcatheter PFO closure versus medical management may improve our ability to select the best treatment for individual patients

Device used: Sizing balloon NuMED Inc.; advanced over the guidewire and incompletely inflated (<1 atm) until a distinct indentation in the balloon and elimination of any shunting by color Doppler was identified. The balloon was not inflated fully to avoid the possibility of inadvertently enlarging the defect. The diameter of the indentation was measured angiography and by echocardiography.

3. Gaspardone et al. (2020)

Safety & Performance
Objective: This study sought to assess PFO anatomy by TEE in patients undergoing percutaneous suture-mediated PFO closure to identify predictors of post-procedural residual atrial right-to-left shunt (RLS).
Method: Retrospective study
Follow-up: 12 months or later if needed

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Retrospective study	Treatment Benefit, Treatment Harms (Common)	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	PTS-X NuMED Inc. to determine the size and the anatomy of the defect	**D1**	D2	D3
Application	Placement in the superior pulmonary vein; TEE monitoring in 27 patients (in the remaining patients the procedure was carried out in local anesthesia without TEE or intracardiac echo monitoring)	**A1**	A2	A3
Patient	230 consecutive patients underwent percutaneous suture-mediated PFO closure; mean 46 ± 13, range 15 to 76); M:84/F:146	**P1**	P2	P3
Report	The article contain sufficient information to be able to undertake a rational and objective assessment.	**R1**	R2	R3
Suitability Grade (Range 4-12)		**5**		

Population: 230 consecutive patients underwent percutaneous suture-mediated PFO closure

Sampling: n= N/A

Mean Age: mean 46 ± 13, range 15 to 76)

Sex:
M – 84
F – 146

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	The reported outcome measures (closure (RLS grade)/complications) indirectly reflect the intended performance of the device.	**Yes 1**	No 2
Follow-up	The duration of follow-up (up to 12 months after the procedure) is acceptable to assess whether duration of treatment benefits/harms and identify complications.	**Yes 1**	No 2
Statistical analysis	Statistical analysis of the data has been provided.	**Yes 1**	No 2
Clinical significance	The magnitude of the treatment benefit observed was clinically significant (closure grade).	**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 (5) + Data Contribution (4) = **12**	Disposition and Weighting (select)	**Accepted and Pivotal 9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

Relevant S&P Results

Criteria	**Results**	**P value**
Safety data	No procedural complications.	N/A
Performance data	At maximum follow-up, TTE evaluation showed a complete closure (RLS grade 0) in 142 (62%) patients and an effective closure (RLS ≤ 1grade) in 193 (84%) patients.	N/A
Benefits/claims data	None	N/A
Strengths	Large population studied (230)	N/A
Weaknesses/ Potential bias	Retrospective analysis with obvious intrinsic limitation and potentially leads to biases. The study is focused on the assessment of the safety and performance of the PFO occlude device and not of the NuMED, Inc. sizing balloon.	N/A

State of the Art
N/A – Articles does not contribute to SOA.

Conclusions of the authors: Percutaneous suture-mediated PFO closure is feasible in the majority of septal anatomies; however, PFO >5 mm in width and spontaneous large RLS are less likely to be closed with 1 stitch only.

Device used: PTS-X NuMED, Inc. for contrast-enhanced sizing-balloon PFO anatomy assessment; TEE monitoring in 27 patients (in the remaining patients the procedure was carried out in local anesthesia without TEE or intracardiac echo monitoring).

4. Karagiannni et al. (2020)

Safety & Performance
Objective: This study aimed to investigate the risk factors for recurrent cryptogenic cerebrovascular events (rCVEs) after closure of PFO during long-term follow-up.
Method: Retrospective study
Follow-up: 8.4 (± 2) years from PFO closure
Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Retrospective study	Treatment Benefit, Treatment Harms (Common)	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	The size and anatomy of the PFO were determined by gentle inflation of a compliant-sized balloon PTS NuMED, Inc. until a waist was apparent.	**D1**	D2	D3

Population: 282 consecutive patients underwent percutaneous PFO closure

Sampling: n= N/A

Mean Age: mean 48 ± 11.7, range not reported

Sex:

Application	PFO closure was performed in a catheterization laboratory under general anesthesia with fluoroscopy and TEE imaging.	**A1**	A2	A3	M – 176 F – 106
Patient	282 consecutive patients underwent percutaneous PFO closure; mean 48 ± 11.7, range not reported; M: 176/F: 106.	**P1**	P2	P3	
Report	The article contains sufficient information to be able to undertake a rational and objective assessment.	**R1**	R2	R3	
	Suitability Grade (Range 4-12)	**5**			

Data Contribution	Relevant Data	Grading	
Outcomes/Endpoints	The reported outcome measures (closure (RLS grade)/complications) indirectly reflect the intended performance of the device.	**Yes 1**	No 2
Follow-up	Long-term duration of follow-up (up to 8.4 years from PFO closure) to assess whether duration of treatment benefits/harms and identify complications.	**Yes 1**	No 2
Statistical analysis	Statistical analysis of the data has been provided.	**Yes 1**	No 2
Clinical significance	The magnitude of the treatment benefit observed was clinically significant (closure grade).	**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 (5) + Data Contribution (4) = **12**	Disposition and Weighting (select)	**Accepted and Pivotal 9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

Relevant S&P Results

Criteria	Results	P value
Safety data – Complications (0 – 6 months)	Intra-operative complications: - Temporary ST-elevation: 4 (1.4%) - Thrombus on catheter during operation: 4 (1.4%) - Device thrombus: 1 (0.7%) - Pericardial effusion: 1 (0.7%) Complications post-operative: - Major bleeding: 0 - Minor bleeding: 5 (1.8%) - Stroke first 48 hours: 1 (0.4%) - Device dislocation: 5 (1.8%)	N/A
Performance data – rCVEs after PFO closure	14 (5%) out of the 282 consecutive patients who underwent PFO closure suffered from rCVEs during a mean FU of 8.4 years (1.7 rCVEs per 1000 patient-years).	N/A
Benefits/claims data	None	N/A
Strengths	Large population studied (282); long-term FU (8.4 years)	N/A
Weaknesses/ Potential bias	Retrospective analysis with obvious intrinsic limitation and potentially leads to biases. The study is focused on the assessment of the safety and performance of the PFO occluder device and not of the NuMED, Inc. sizing balloon.	N/A

State of the Art

N/A – Articles does not contribute to SOA.

Conclusions of the authors: This study indicates that residual shunting and choice of the device may be the major reasons for rCVEs.

Device used: PTS NuMED, Inc. used to determine the size and anatomy of the PFO; general anesthesia; fluoroscopy and TEE imaging.

5. Stapleton et al. (2020)

Safety & Performance

Objective: Describe experience utilizing long Gore DrySeal (GDS) sheaths (WL Gore and Associates, Flagstaff, AZ) to protect the tricuspid valve during advancement of the Commander delivery system for deployment of the SAPIEN 3 valve in the pulmonary position.

Method: Retrospective review

Follow-up: post-procedural

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Retrospective study	Treatment Benefit, Treatment Harms (Common)	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	30 or 40mm diameter PTS-X sizing balloon NuMED, Inc. inflated in the right ventricular outflow tract (RVOT) to determine the minimum diameter of the location that could be used as a landing zone.	**D1**	D2	D3
Application	Internal jugular or femoral vein	**A1**	A2	A3
Patient	48 patients; mean age between 23.2 and 25.9; 24 males	**P1**	P2	P3
Report	The article contains sufficient information to be able to undertake a rational and objective assessment.	**R1**	R2	R3
	Suitability Grade (Range 4-12)	**5**		

Data Contribution	Relevant Data	Grading	
Outcomes/ Endpoints	The reported outcome measures (procedural success) indirectly reflect the intended performance of the device.	**Yes 1**	No 2
Follow-up	The duration of follow-up (post-procedural) seems acceptable to assess whether duration of treatment benefits/harms and identify complications.	**Yes 1**	No 2
Statistical analysis	Statistical analysis of the data has been provided.	**Yes 1**	No 2
Clinical significance	The magnitude of the treatment benefit observed was clinically significant (procedural success).	**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 (5) + Data Contribution (4) = **12**	Disposition and Weighting (select)	**Accepted and Pivotal 9-12** Accepted but not Pivotal, 13-21 Excluded, 22-25

Relevant S&P Results

Criteria	**Results**	**P value**
Safety data –	Severe tricuspid injury occurred in 2/25 (8%) of Group I patients and 0/23 of Group II patients; the mechanism of injury may be attributed to navigating the stiff delivery system through complex curves from the right atrium, through the tricuspid valve, right ventricle and into RVOT. Approach to valve delivery was modified to decrease risk after two patients developed tricuspid valve injury. There were no vascular access or procedural complications.	N/A
Performance data – Severe tricuspid valve injury	Group I: 2/25 (8%) vs. Group II: 0/23	N/A
Benefits/claims data	None	N/A
Strengths	Comparative study	N/A
Weaknesses/ Potential bias	Retrospective analysis with obvious intrinsic limitation and potentially leads to biases. The study is focused on the assessment of the safety and	N/A

Population: 48 patients underwent transcatheter placement of a SAPIEN valve in the pulmonary position

Sampling: Group I (without using a long delivery sheath): n=25
Group I (with): n=23

Mean Age:
Group I: mean 25.9 ± 15.5, range not reported
Group II: mean 23.2 ± 16.5, range not reported

Sex:
Group I: M: 15 (60%)
Group II: M: 9 (39%)

	performance of the Gore sheath and not of the NuMED, Inc. sizing balloon.	

State of the Art
N/A – Articles does not contribute to SOA.

Conclusions of the authors: Use of a long GDS may protect the tricuspid valve from injury during implantation of the S3 valve in the pulmonary position, and is technically feasible in smaller patients.

Device used: 30 or 40mm diameter PTS-X sizing balloon NuMED, Inc. inflated in the RVOT to determine the minimum diameter of the location that could be used as a landing zone.

6. Durong pisitkul et al. (2022)

Safety & Performance (only contributes to safety due to quantity of patients (n=1) and clinical application)
Objective: Report the first successful transcatheter closure of an inferior sinus venosus defect with bare and covered stents and the rerouting of a partial anomalous pulmonary vein drainage into the left atrium to avoid occlusion of the hepatic veins.
Method: Case report
Follow-up: One month

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Case report	Treatment Benefit, Treatment Harms (Common)	1	2	3	**4**	5

Suitability	Relevant Data	Grading		
Device	30mm PTS-X balloon (NuMED)	**D1**	D2	D3
Application	PTS-X balloon to generate a 1 atm pressure for sizing	**A1**	A2	A3
Patient	Inferior sinus venosus defect (less common than superior venous defect)	**P1**	P2	P3
Report	Case report thereby article contain limited information to be able to undertake a rational and objective assessment.	R1	**R2**	R3
	Suitability Grade (Range 4-12)	**5**		

Data Contribution	Relevant Data	Grading	
Outcomes/ Endpoints	The reported outcome measures (implantation success/complications) indirectly reflect the intended performance of the device.	**Yes 1**	No 2
Follow-up	The duration of follow-up (one month) provides limited ability to assess long-term of treatment benefits/harms and identify complications.	Yes 1	**No 2**
Statistical analysis	No statistical analysis of the data has been provided.	Yes 1	**No 2**
Clinical significance	The magnitude of the treatment benefit observed was clinically significant (implantation success).	**Yes 1**	No 2
	Data Contribution Grade (Range 4-8)	**6**	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (4) + Suitability (5) + Data Contribution (6) = **15**	Disposition and Weighting (select)	Accepted and Pivotal 9-12 **Accepted but not Pivotal, 13-21** Excluded, 22-25

Relevant S&P Results:

Criteria	Results	P value
Safety data - Main results	We report the first successful transcatheter closure of an inferior sinus venosus defect with bare and covered stents and the rerouting of a partial anomalous pulmonary vein drainage into the left atrium to avoid occlusion of the hepatic veins.	N/A
Safety data – Intra- and post-procedural events	Intraprocedural covered stent migration managed by overlapping bare stents; suspected thrombus on inferior vena cava treated with anticoagulant, not present at one month follow-up.	N/A

Population: patient with inferior sinus venosus defect resulting in partial anomalous pulmonary vein drainage

Sampling: n=1

Mean Age: 29 years

Sex:
M - 0
F - 1

Benefits/claims data	None	N/A
Strengths	First of kind case report. Transcatheter closure of an inferior sinus venosus defect with partial anomalous pulmonary vein drainage using bare and covered stents in the inferior vena cava was demonstrated as feasible.	N/A
Weaknesses/ Potential bias	Single patient case study; study in a larger patient population with longer-term follow-up is needed to assess efficacy and safety of this technique.	N/A

State of the Art
N/A – Articles does not contribute to SOA.

Conclusions of the authors: Transcatheter closure of an inferior sinus venosus defect with partial anomalous pulmonary vein drainage using bare and covered stents in the inferior vena cava was shown to be feasible. Careful patient selection and intensive assessment of pulmonary and hepatic vein anatomy before and during the procedure were necessary to achieve a successful outcome.

Device used: 30mm PTS-X balloon (NuMED)

7. Hornung et al. (2021)

Safety & Performance (only contributes to safety due to clinical application)
Objective: To investigate subtle functional parameters by invasive measurements with a pressure–volume conductance system (under baseline conditions and under dobutamine application) as well as by noninvasive examinations with cardiac MRI.
Method: Prospective, nonrandomized, monocentric
Follow-up: Not applicable; mean age at repair 1.1 ± 0.8 (0.6-3.4) years; follow-up studies not possible because arterial switch correction is treatment of choice

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Nonrandomized	Treatment Benefit, Treatment Harms (Common)	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	PTS Sizing Balloon, Fa Numed Inc.; size: 20–25mm	**D1**	D2	D3
Application	Preload reduction was achieved by inflation of a balloon catheter in the inferior caval vein	A1	A2	**A3**
Patient	D-transposition of great arteries after atrial switch surgery, indication for invasive hemodynamic evaluation by routine cardiac catheterization	P1	P2	**P3**
Report	The article contains sufficient information to be able to undertake a rational and objective assessment.	**R1**	R2	R3
	Suitability Grade (Range 4-12)	**8**		

Data Contribution	Relevant Data	Grading	
Outcomes/ Endpoints	The reported outcome measures (conductance analysis) indirectly reflect the intended performance of the device.	**Yes 1**	No 2
Follow-up	Study seeking functional parameters of assessment; follow-up not applicable.	Yes 1	**No 2**
Statistical analysis	Statistical analysis of the data has been provided.	Yes 1	**No 2**
Clinical significance	The magnitude of the treatment benefit observed was clinically significant (conductance analysis).	**Yes 1**	No 2
	Data Contribution Grade (Range 4-8)	**6**	

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (3) + Suitability (8) + Data Contribution (6) = **17**	Disposition and Weighting (select)	Accepted and Pivotal 9-12 **Accepted but not Pivotal, 13-21** Excluded, 22-25

Population: patients with D-transposition of great arteries after atrial switch surgery and indication for invasive hemodynamic evaluation by routine cardiac catheterization

Sampling: n=16

Mean Age: 28.2 ± 7.3 years (range 22-50 years)

Sex:
M – 13
F – 3

Relevant S&P Results:

Criteria	Results	P value
Safety data - Main results	No safety data reported.	N/A
Benefits/claims data	None	N/A
Strengths	Conductance analysis revealed intraventricular and predominantly diastolic right ventricular dyssynchrony. To be determined if independent process or precursor of contractility loss.	N/A
Weaknesses/ Potential bias	Author-identified limitations include patients with severe heart failure were excluded, no interobserver variability, single-center cross-sectional study with limited number of eligible patients, follow-up studies no longer possible because arterial switch correction is treatment of choice, conductance data for systemic right ventricle are limited, and inflw tract may not be sufficiently represented in conductance data due to arterial approach.	N/A

State of the Art
N/A – Articles does not contribute to SOA.

Conclusions of the authors: Conductance indices as well as the cardiac MRI-derived strain parameters showed overall reduced values, but a significant relationship was not present.

Device used: PTS Sizing Balloon, Fa Numed Inc.; size: 20–25mm

8. Kim et al. (2022)

Safety & Performance (only contributes to safety due to quantity of patients (n=1) and clinical application)
Objective: Describe a case of creating a fenestration in the Fontan conduit using an NRG radiofrequency transeptal needle
(NRG-E-HF-71-C0; Baylis Medical Inc, Quebec, Canada) followed by implantation of a 20-mm 535 Formula stent pre-mounted on a 10-mm balloon (Cook Medical, Bloomington, Indiana).
Method: Case report
Follow-up: 18 months

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Case report	Treatment Benefit, Treatment Harms (Common)	1	2	3	**4**	5

Suitability	Relevant Data	Grading		
Device	2.5 x 3-cm PTS-X Balloon (NuMed, Boca Raton, Florida)	**D1**	D2	D3
Application	Introduced and inflated to flare the distal and proximal ends (of the stent)	A1	A2	**A3**
Patient	Recurrent plastic bronchitis on optimal medical therapy, history of hypoplastic left-heart syndrome and previous Fontan completion with a lateral tunnel	P1	P2	**P3**
Report	Case report thereby article contain limited information to be able to undertake a rational and objective assessment.	R1	**R2**	R3
	Suitability Grade (Range 4-12)	**9**		

Data Contribution	Relevant Data	Grading	
Outcomes/ Endpoints	The reported outcome measures (technical success/recurrence) indirectly reflect the intended performance of the device.	**Yes 1**	No 2
Follow-up	The duration of follow-up (18 months) seems acceptable to assess whether duration of treatment benefits/harms and identify complications.	**Yes 1**	No 2
Statistical analysis	No statistical analysis of the data has been provided.	Yes 1	**No 2**
Clinical significance	The magnitude of the treatment benefit observed was clinically significant (recurrence).	**Yes 1**	No 2
	Data Contribution Grade (Range 4-8)	**5**	

Population: patient with recurrent plastic bronchitis on optimal medical therapy, history of hypoplastic left-heart syndrome and previous Fontan completion with a lateral tunnel at the age 4 years

Sampling: n=1

Mean Age: 16 years

Sex:
M - 1
F - 0

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (4) + Suitability (9) + Data Contribution (5) = **18**	Disposition and Weighting (select)	Accepted and Pivotal 9-12 **Accepted but not Pivotal, 13-21** Excluded, 22-25

Relevant S&P Results:

Criteria	Results	P value
Safety data - Main results	No further recurrence of the plastic bronchitis at 18-month follow-up; patient was successfully weaned off oral and inhaled steroids over time.	N/A
Benefits/claims data	None	N/A
Strengths	By using radiofrequency needles, can perforate the Fontan prosthesis with less force and greater control.	N/A
Weaknesses/ Potential bias	Single patient case study.	N/A

State of the Art
N/A – Articles does not contribute to SOA.

Conclusions of the authors: For a prosthetic Fontan conduit, creating a fenestration and stenting can be facilitated by a combination of RF needle puncture followed by placement of a balloon expandable stent.

Device used: 2.5 x 3-cm PTS-X Balloon (NuMed, Boca Raton, Florida)

9. Haddad et al. (2022)

Safety & Performance (only contributes to safety due to quantity of patients (n=1) and clinical application)
Objective: Report the first human implantation of a single custom-made longer Optimus-CVS® to effectively treat superior sinus venosus atrial septal defect and partial anomalous pulmonary venous return in an adult patient.
Method: Case report
Follow-up: One month

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Case report	Treatment Benefit, Treatment Harms (Common)	1	2	3	**4**	5

Suitability	Relevant Data	Grading		
Device	30-mm/3-cm PTS sizing balloon catheter (NuMED, Inc.)	**D1**	D2	D3
Application	Balloon interrogation of the cavoatrial junction was performed	A1	**A2**	A3
Patient	Diagnosed with left-to-right sinus venosus atrial septal defect, PFO on ultrasound, and anomalous drainage of the right pulmonary veins into the superior vena cava on cross-sectional cardiac computed tomography angiogram	**P1**	P2	P3
Report	Case report thereby article contain limited information to be able to undertake a rational and objective assessment.	R1	**R2**	R3
	Suitability Grade (Range 4-12)	**6**		

Data Contribution	Relevant Data	Grading	
Outcomes/ Endpoints	The reported outcome measures (technical success/outcome) indirectly reflect the intended performance of the device.	**Yes 1**	No 2
Follow-up	The duration of follow-up (1 month) seems acceptable to assess whether duration of treatment benefits/harms and identify complications.	**Yes 1**	No 2
Statistical analysis	No statistical analysis of the data has been provided.	Yes 1	**No 2**
Clinical significance	The magnitude of the treatment benefit observed was clinically significant (sinus rhythm).	**Yes 1**	No 2
	Data Contribution Grade (Range 4-8)	**5**	

Population: patient diagnosed with left-to-right sinus venosus atrial septal defect, PFO on ultrasound, and anomalous drainage of the right pulmonary veins into the superior vena cava on cross-sectional cardiac computed tomography angiogram

Sampling: n=1

Mean Age: 70 years

Sex:
M - 1
F - 0

Overall S&P Appraisal, Disposition and Weighting

S&P Grade (Range 9-25)	LOE (4) + Suitability (6) + Data Contribution (5) = **15**	Disposition and Weighting (select)	Accepted and Pivotal 9-12 **Accepted but not Pivotal, 13-21** Excluded, 22-25

Relevant S&P Results:

Criteria	Results	P value
Safety data - Main results	Discharge electrocardiogram showed sinus rhythm; one-month follow-up showed excellent outcomes as confirmed on control computed tomography angiogram.	N/A
Benefits/claims data	None	N/A
Strengths	Used a single custom-made long version of stent rather than interlocking two or more stents to avoid unnecessary manipulations.	N/A
Weaknesses/ Potential bias	Single patient case study.	N/A

State of the Art

N/A – Articles does not contribute to SOA.

Conclusions of the authors: Authors present early evidence of the feasibility of percutaneous correction of superior sinus venosus atrial septal defect with partial anomalous pulmonary venous return using the 100-mm long Optimus-CVS® XXL stent in a selected adult patient.

Device used: 30-mm/3-cm PTS sizing balloon catheter (NuMED, Inc.)

10. Haddad et al. (2022)

Safety & Performance (only contributes to safety due to clinical application)

Objective: Report the first human implantation of a single custom-made longer Optimus-CVS® to effectively treat superior sinus venosus atrial septal defect and partial anomalous pulmonary venous return in an adult patient.

Method: From June 2020 to November 2020, 15 congenital heart patients with dysfunctional RVOTs and target transcatheter pulmonary valve replacement diameter ≥23 mm received Optimus-XXL stents before proceeding to transcatheter pulmonary valve replacement using Edwards SAPIENTM valve. Standard safety and outcomes were prospectively assessed.

Follow-up: 4.5 months (median)

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Non-randomized, prospective	Treatment Benefit, Treatment Harms (Common)	1	2	**3**	4	5

Suitability	Relevant Data	Grading		
Device	40 mm large PTS sizing balloon catheter (NuMED, Inc.)	**D1**	D2	D3
Application	Balloon interrogation of large conduit-free RVOTs	**A1**	A2	A3
Patient	Congenital heart patients with dysfunctional RVOTs and target transcatheter pulmonary valve replacement diameter ≥23 mm; median age 25.8 years	P1	**P2**	P3
Report	The article contains sufficient information to be able to undertake a rational and objective assessment.	**R1**	R2	R3
	Suitability Grade (Range 4-12)	**5**		

Data Contribution	Relevant Data	Grading	
Outcomes/ Endpoints	The reported outcome measures (technical success/procedure incidents, complications) indirectly reflect the intended performance of the device.	**Yes 1**	No 2
Follow-up	The duration of follow-up (4.5 months, median) seems acceptable to assess whether duration of treatment benefits/harms and identify complications.	**Yes 1**	No 2
Statistical analysis	No statistical analysis of the data has been provided.	Yes 1	**No 2**

Population: congenital heart patients with dysfunctional RVOTs and target transcatheter pulmonary valve replacement diameter ≥23 mm

Sampling: n=15 patients

Mean Age: 25.8 years (median)

Sex:
M - 8
F - 7

Clinical significance	The magnitude of the treatment benefit observed was clinically significant (valve function).	**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 (5) + Data Contribution (5) = **13**	Disposition and Weighting (select)	Accepted and Pivotal 9-12 **Accepted but not Pivotal, 13-21** Excluded, 22-25

Relevant S&P Results:

Criteria	Results	P value
Safety data - Intraprocedural	Intraprocedural incidents/complications consisted of stent suboptimal expansion, stent slipping from Altosa-XL Gemini balloon inside sheath during delivery, stent slipping off BIB into RVOT during uncovering, and conduit rupture; none were attributed to the PTS catheter.	N/A
Safety data – Follow/up	During a median follow-up of 4.5 months (range, 3-7 months), no valvular dysfunction or rapid increase of valvular gradient or paravalvular leak was noted.	N/A
Benefits/claims data	None	N/A
Strengths	Safety and efficacy were proven across a wide spectrum of patient sizes and anatomical variations; first 15 successful implantations of Optimus-XXL stents to secure large dysfunctional RVOTs prior to transcatheter pulmonary valve replacement (procedural success).	N/A
Weaknesses/ Potential bias	Thin struts of the Optimus stent can be a disadvantage when size reduction of the landing zone is required.	N/A

State of the Art
N/A – Articles does not contribute to SOA.

Conclusions of the authors: Authors report the first implantations of Optimus-XXL stents in dysfunctional RVOTs with excellent preliminary results. Optimus-XXL should be considered as a valuable adjunct in the armamentarium for routine and complex transcatheter pulmonary valve replacement procedures.

Device used: 40 mm large PTS sizing balloon catheter (NuMED, Inc., Hopkinton, NY, USA)

11. Góreczny et al. (2024)

Safety & Performance (only contributes to safety due to quantity of patients (n=2) and clinical application)
Objective: Present the first Polish experience with the Venus P-valve (Venus MedTech) in two pediatric patients.
Method: Case report
Follow-up: 2 weeks

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Case report	Treatment Benefit, Treatment Harms (Common)	1	2	3	**4**	5

Suitability	Relevant Data	Grading		
Device	40 mm PTS-X sizing balloon (NuMed)	**D1**	D2	D3
Application	Check the size and distensibility of the outflow tract; adaptation of the distal flare of the percutaneous pulmonary valve	A1	**A2**	A3
Patient	Born with tetralogy of Fallot with unusual coronary artery anatomy, prior history of surgical repair, progressive pulmonary regurgitation; mean age 17.5 years	**P1**	P2	P3
Report	Case report thereby article contain limited information to be able to undertake a rational and objective assessment.	R1	**R2**	R3
	Suitability Grade (Range 4-12)	**6**		

Population: patients born with tetralogy of Fallot with unusual coronary artery anatomy, underwent surgical repair with a monocusp pulmonary homograft, and presented with progressive pulmonary regurgitation

Sampling: n=2 patients

Data Contribution	Relevant Data	Grading	
Outcomes/ Endpoints	The reported outcome measures (technical success/echocardiogram and ECG-Holter monitoring) indirectly reflect the intended performance of the device.	**Yes 1**	No 2
Follow-up	The duration of follow-up (pre-discharge, six months) seems acceptable to assess whether duration of treatment benefits/harms and identify complications.	**Yes 1**	No 2
Statistical analysis	No statistical analysis of the data has been provided.	Yes 1	**No 2**
Clinical significance	The magnitude of the treatment benefit observed was clinically significant (valve function, arrhythmia).	**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 (4) + Suitability (6) + Data Contribution (5) = **15**	Disposition and Weighting (select)	Accepted and Pivotal 9-12 **Accepted but not Pivotal, 13-21** Excluded, 22-25

Relevant S&P Results:

Criteria	Results	P value
Safety data – Intra-procedural	10 year-old female: Control angiogram confirmed proper position and function of valve and excluded coronary artery compression. 17 year-old male: P-valve shifted below the bifurcation to the middle of the outflow tract during uncovering, but was recovered and redeployed which narrowed the distal flare of the valve. Final angiogram confirmed full expansion of the valve with unobstructed flow to the pulmonary arteries and a trace of regurgitation.	N/A
Safety data – Follow-up	10 year-old female: Pre-discharge and six-month follow-up echocardiograms showed good function of the valve with trivial central regurgitation; ECG-Holter monitoring showed no arrhythmia. 17 year-old male: Pre-discharge and follow-up echocardiograms confirmed good valve function; ECG-Holter monitoring showed a slow irregular sinus rhythm.	N/A
Benefits/claims data	None	N/A
Strengths	First Polish experience with the Venus P-valve (Venus MedTech) in two pediatric patients.	N/A
Weaknesses/ Potential bias	None reported	N/A

State of the Art
N/A – Articles does not contribute to SOA.

Conclusions of the authors: None

Device used: 40 mm PTS-X sizing balloon (NuMed)

Mean Age: 13.5 years

Sex: M - 1 F - 1

12. Morgan et al. (2022)

Safety & Performance (only contributes to safety due to quantity of patients (n=2) and clinical application)
Objective: Present the first clinical experience with a new hybrid cell structure covered stent, designed for congenital heart disease applications.
Method: Case report
Follow-up: 2 weeks

Appraisal

Level of Evidence	Study Method/Design	Question Applied	Oxford LOE 2011				
	Case report	Treatment Benefit, Treatment Harms (Common)	1	2	3	**4**	5

Population: patients diagnosed with a superior sinus venous defect

Sampling: n=2 patients

Mean Age:

Suitability	Relevant Data	Grading		
Device	30mm diameter PTS sizing balloon (Numed Inc.)	**D1**	D2	D3
Application	Balloon interrogation over an externalized guide wire rail from right femoral vein to right internal jugular was first performed with a compliant 30mm diameter PTS sizing balloon (Numed Inc.)	**A1**	A2	A3
Patient	Patients with a superior sinus venous defect; mean age 38 years	**P1**	P2	P3
Report	Case report thereby article contain limited information to be able to undertake a rational and objective assessment.	R1	**R2**	R3
	Suitability Grade (Range 4-12)	**5**		

38 years

Sex:
M - 1
F - 1

Data Contribution	Relevant Data	Grading	
Outcomes/ Endpoints	The reported outcome measures (technical success) indirectly reflect the intended performance of the device.	**Yes 1**	No 2
Follow-up	The duration of follow-up (post-procedure, two weeks) seems acceptable to assess whether duration of treatment benefits/harms and identify complications.	**Yes 1**	No 2
Statistical analysis	No statistical analysis of the data has been provided.	Yes 1	**No 2**
Clinical significance	The magnitude of the treatment benefit observed was clinically significant (no evidence of pulmonary vein or superior vena cava stenosis, complete stent stability).	**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 (4) + Suitability (5) + 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:

Criteria	**Results**	**P value**
Safety data – Post-procedural	Hemodynamic, angiographic, and echocardiographic parameters at the end of the procedures suggested a minimal left-right shunt with no evidence of pulmonary vein stenosis, or superior vena cava stenosis and complete stability of the stents.	N/A
Safety data – Follow/up	Follow-up at two weeks including a negative bubble study was equally satisfactory. The clinical result in all cases was excellent with no obstruction to pulmonary venous return and no visible left-right shunt on the transthoracic echo on 24 hours and two week follow-up for the patient with sinus venosus defects.	N/A
Benefits/claims data	None	N/A
Strengths	First-in-human description of G-ARMOR stent.	N/A
Weaknesses/ Potential bias	Dr. Morgan is a consultant for NuMED Inc.	N/A

State of the Art
N/A – Articles does not contribute to SOA.

Conclusions of the authors: These are the first uses of this stent in human subjects. The design is specifically aimed toward procedures where stent shortening is undesirable.

Device used: 30mm diameter PTS sizing balloon (Numed Inc.)

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 PTS and PTS-X Catheters has been carried out and documented in accordance with MEDDEV 2.7/1 Rev 4. Based on the results of the 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 PTS and PTS-X Catheters, including the IFU, are suitable for the intended users.
e) The claims foreseen in the information materials provided with the 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 the CER and with the current knowledge/state of the art.

Overall, it is concluded that the risks associated with the use of the PTS and PTS-X Catheters 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 Sizing PMCF plan will describe the continuous process by which data concerning the Sizing devices will be collected and the clinical evaluation will be updated. The PMCF plan has been drawn up in accordance with Annex XIV Part B and is located in the Sizing Technical File. Results of activities conducted per the PMCF Plan will be documented in a PMCF Evaluation Report in accordance with MDR Annex XIV, Part B. The PMCF Evaluation Report will be updated regularly and incorporated into the clinical evaluation by reference.

Previous PMCF studies conducted on the Sizing Catheters included a Post Market Clinical Follow-up Study: PMCF-360/360X PTS & PTS-X Catheters – 110cm Useable Length (PMCF-360/360X) completed under the MDD. The objective of this study was to capture data on the 110cm useable length PTS & PTS-X catheters in actual practice, by collection of clinical data from treating physicians, using a data collection form. The study concluded in 2022, after collection of the established sample size. Based on the PMCF study findings, NuMED concluded the long-term safety and clinical performance of these devices has been well established via substantial clinical evidence demonstrated during the study. The Sizing Catheters have been determined to be safe and effective when used as indicated, at all useable lengths. No changes are required to the risk analysis or the instructions for use were required.

6. Possible diagnostic or therapeutic alternatives

Alternatives to the use of sizing balloons would be to not use them; in this case, the size of the defect would only be estimated based on diagnostic and pre-procedure imaging. It was reported by the ASE Guideline (2015) that some operators might not perform balloon sizing because of the dimensions of the effect (small defect). Not sizing the cardiac defect before transcatheter closure would be inconsistent with ASE recommendations and standard-of-care.

Alternatives to the use of transcatheter cardiac occluder devices to which sizing balloons are associated would be to not proceed with a therapeutic intervention and establish a continuous follow-up or to provide medical treatments with dedicated drugs or to proceed with an open surgery of the heart. AHA/ACC and ESC Guidelines offers recommendations and algorithms on how to proceed based on the patient's medical history and disease conditions. However, it is generally accepted that compared to open surgery a percutaneous approach offers a shorter hospital length of stay and a faster recovery, with similar long-term outcomes.

7. Suggested profile and training for users

Users of percutaneous sizing balloons are qualified cardiac surgeons trained to the stop-flow technique.

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 ISO 10993-10: 2023 – Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization
- EN ISO 10993-18: 2020 / A1:2022 – 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

9. References

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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	18 November 2022	Update due to new CER. Change in warnings to separate the one warning for PTS and PTS-X due to MRI, update for PMCF Study completion	☐ Yes Validation Language: English ☒ No
02	03 August 2023	Updated - **Ongoing planned post-market clinical follow-up** – section to change the word in the first sentence from ongoing to completed. Updated Section 8 for the additional harmonized standards.	☐ Yes Validation Language: English ☒ No
03	19 July 2024	Revised sections 2 – 5, 8 and 9 due to the updated CER and revised PMCF Plan.	☐ Yes Validation Language: English ☒ No