

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	n and General Information
Device trade name(s)	<u>NuMED Sizing Family</u> PTS PTS-X
Model Number	<u>NuMED Sizing Family – Model 1200</u> 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 l	Device
	Intended Use The PTS Catheters are intended for use as a visual aid while measuring a cardiovascular defect using Transesophageal Echocardiogram (TEE) and fluoroscopy.
Indications for use	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	
	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.
Description of the Device	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	
	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.
D	All significant risks were considered, mitigated as far as possible (AFAP), and are acceptable in regard to the clinical benefit of the device.
Residual risks and undesirable effects	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 <u>any</u> 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:

NuMED	NuMED Summary of Safety and Clinical Performance
	SSCP – Sizing
	Tegtmeyer, Charles J., M.D. & Bezirdijan Diran R., M.D. "Removing the Stuck, Ruptured Angioplasty Balloon Catheter." <u>Radiology</u> , 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
	The following Warnings and Precautions have been identified and are called out in the Instruction for
	Use: WADNINGS
	 <u>WARNINGS</u> 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.
Warning and Precautions	• 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.
	 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	There have not been any Field Safety Corrective Actions or Field Safety Notices on the PTS Catheter.
safety corrective actions (FSCA including FSN) if applicable	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.



NuMED Summary of Safety and Clinical Performance SSCP – Sizing

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:

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

Apprai	sal
Level	of

Level of Evidence Study Method/Design Question Applied Oxford LOE Open, prospective, nonrandomized multicenter clinical study Treatment Benefit, Treatment Harms (Common) 1 2 3 4	1 ppi albai							
nonrandomized multicenter (Common)		Study Method/Design	Question Applied	-		I LC	Έ	
ennieur study				1	2	3	4	5

Suitability	Relevant Data	Gra	ding		patients PFO (7
Device	25 mm PTS NuMED Inc. to determine the size and the anatomy of the defect	D1	D2	D3	±2.5 m defect s
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	mean) All pat suffere from cryptog stroke
Patient	P1 (37 patients with PFO; mean age 57 yo (18-80); M 18, F 17)	P1	P2	P3	origin remain
Report	The article contains sufficient information to be able to undertake a rational and objective assessment.	R1	R2	R3	unknov
	Suitability Grade (Range 4-12)		5		Sampl n= 36
Data Contribution	Relevant Data		Gradin		Mean 50 yea

(yo) (18

80)

Sex: M - 18F - 17

Data Contribution	Relevant Data			Gra	aing
Outcomes/Endpoints	The reported outcome m	easures (implantation		Yes 1	No 2
	success/complications) i	ndirectly reflect the int	tended		
	performance of the devie	ce.			
Follow-up	The duration of follow-u	p (up to 180 days after	r the procedure)	Yes 1	No 2
	is long enough to assess	whether duration of tre	eatment		
	benefits/harms and ident	tify complications.			
Statistical analysis	No statistical analysis of	the data has been prov	vided.	Yes 1	No 2
Clinical significance	The magnitude of the tre	eatment benefit observe	ed was clinically	Yes 1	No 2
-	significant (implantation	success).	-		
		Data Contribution G	rade (Range 4-8)		5
Overall S&P Apprais	al, Disposition and Weightin				
S&P Grade	LOE (3) + Suitability (5) +	Disposition and	Accepted and P		
(Range 9-25)	Data Contribution $(5) = 13$	Weighting (select)	Accepted but no	ot Pivotal,	13-21
			Excluded, 22-2	5	

FCD-1137



Criteria	Results			P value
Safety data	Perioperatively:			N/A
	No major in-hospital-Al			
	occlude dislodgement, in			
	Comparison to Amplatz	er® PFO occluder dev	ice: See Table 1	N/A
	below			
Performance data – After	One patient had transien	t atrial fibrillation, wh	ich terminated	N/A
implantation	medically after 12 h.			
Performance data – 60	TEE studies in the rema			N/A
days after procedure	to further participate) sh		in 8.6% (3/35) and a	
	left-to-right shunt in 2.6			
Performance data – 180	One patient with severe			N/A
days after procedure	carotic stenosis revealed		ence of	
	cardioembolic origin or		(20/24)	
Companies to	Complete closure was a Table 1 Comparison An			N/A
Comparison to Amplatzer® PFO occluder	Table I Comparison An	iplatzer vs Figulia PFC	J Occluder N	IN/A
device	No.	Amplatzer PFO	Figulla PFO	
device		occluder $n = 69$	occluder $n = 36$	
	Implantation success	100%	100%	
	Periinterventional		1	
	Complications (a) minor, n %	1 (1.5%)	1 Atrial fibrillation	
	Trans. ST-elevation	1 (1.5%)	1 Grain bleeding	
	(b) major, <i>n</i> %	0	0	
	TIA	0	0	
	Devicedislodgement	0	0	
	Pericardial effusion	0	0	
	Arrosion of aorta Death	0	0	
	Death	U	0	
Benefits/claims data	Authors mentioned that	they routinely used the	e sizing balloon for	N/A
	definition of the defect s			
	determine the defect size			
	an alternative method w			
	recommend ICE or TEE	E monitoring during the	e procedure in the	
	clinical study. For gener	al use both methods a	re optional. Balloon	
	assessment of PFOs enh	ances the understanding	ng of their	
	morphology and aids in			
	tunnelisation using the s			
	trancatheter closure of le			
Strengths	Comparison of results w	ith a reference device	(Amplatzer PFO	N/A
	occlude ($n = 69$)).			
Weaknesses/	Low number of subjects			N/A
Potential bias	Study does not directly a			
	balloon but was designe	d for assessment of the	e PFO occlude	
	device.			1

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

					r = 512 mg					1
		ntation of the events (FNEs)) in patients from	m a cent	s performed to determiter who underwent tran					
			-	2003)						
	Method: Retrosp		-				(10			
	with follow-up ir		(1 month to 7.1	years) 1	for a total of 438 patier	it-years after clos	ure (19	9/216 j	patients	
	Appraisal				<u> </u>				-	
	Level of Evidence	Study Me	ethod/Design		Question Applied		201	ord LO	ЭЕ	
	Lindence	Retrospe	ctive clinical stu		Treatment Benefit, Tre (Common)	eatment Harms		2 3	4 5	
	Suitability	Relevant	Data					Gradin	σ	
	Device		ng balloon NuM	/ED Inc	· ·		D1	D2	D3	
	Application				namic catheterization a	nd right atrial	A1	A2	A3	
	pp. monton	angiograj guidewir venous ca PTS Sizir incomple balloon a	phy was perform e was positioned atheter advanced ng balloon was ttely inflated (<2 nd elimination of	med to a d in the d throug advance 1 atm) u of any s	ssess the anatomy of the left upper pulmonary we gh the PFO. and over the guidewire a until a distinct indentation hunting by color Dopp	ne PFO. A yein through a and on in the yler was				Population : patients with
		of inadve was meas Under ge sedation.	ertently enlargin sured angiograp neral anesthesia	ng the de ohy and l a and TH	inflated fully to avoid t efect. The diameter of t by echocardiography. EE and since 2001 ICE	he indentation				PFO (11 mm (4 – 24) stretch diameter)
2. Kutty	Patient	216 patie	nts with PFO; 5	50 yo (1	9 – 77); M 107/F 109		P1	P2	P3	Sampling:
et al. (2008)	Report		le contains suffi and objective as		formation to be able to nt.	o undertake a	R1	R2	R3	n= 216
					Suitability Gra	de (Range 4-12)		5		Mean Age: 50 yo
	2		n					<u>a</u> 11		(19 – 77)
	Data Contribution	Relevant	Data					Gradin	g	G
	Outcomes/Endp oints				(implantation success/ erformance of the device		Yes 1	1 1	No 2	Sex: M – 107 F – 109
	Follow-up	whether of	duration of treat		n 2.1 years) is appropri enefits/harms and ident		Yes 1	1 1	No 2	
	Statistical	complica Statistica	uons. Lanalysis of the	a data be	as been provided for sa	fety data and is	Vec 1	י ו	No 2	
	analysis	appropria		o data Ilè	as oven provided for sa	icry data allu 18	1051		10 2	
	Clinical significance	The mag			benefit observed was c s).	linically	Yes 1	1 1	No 2	
					Data Contribution Gr	ade (Range 4-8)		4		
	Overall S&P Ap									
	S&P Grade (Range 9-25)	LOE (3) + St + Data Contrib	uitability (5) ution $(4) = 12$	Dispo (select	sition and Weighting t)	Accepted and P Accepted but no Excluded, 22-2.	ot Pivo		21	
	Relevant S&P R	esults.				L				
	Criteria	asuns.	Results					P va	lue	
	Safety data - M	ain results	Twenty patien 40.2 months a (mean 2.1 year	after PF ars, rang	a focal neurologic even O closure over 438 per ge 1 month to 7.1 years	rson-years of folles). There were 4	ow-up	N/A		
			recurrent stro	okes, 2 li	ikely directly device re	lated. Ten patient	ts had			



			emic attack (TIA) and 6 patients had clear evi inrelated to the device.	dence			
	Safety data - Event : recurrent strokes	rate for 0.91% per yea difference 3.4	r or 9.1 per 1,000 person-years (95% CI for		N/A		
	Safety data - Combi event-rate for stroke/transient isch attack (TIA)	ined 3.42% per yea	r or 34.2 per 1,000 person-years (95% CI for		N/A		
	Safety data - Compa with other studies	arison occlusion of P evaluated recu	stroke rate found in this study after CardioSE FO is comparable to rates from studies that irrence of stroke and TIA in patients with PF roke placed on various regimen of medical		N/A		
	Performance data - Successful implanta	100%			N/A	L	
	Benefits/claims data				N/A		
	Strengths		of subjects included (216)		N/A	L	
		FU of 2.1 year Study does no	rs (mean). t directly assess safety and performance of th	e sizing			
	Weaknesses/ Potential bias		as designed for assessment of the PFO occlud		N/A	L	
	Recurrence rate of cry from ongoing random	yptogenic FNE compares nized trials of transcatheter	inscatheter PFO occlusion can be accomplish Patients may have multiple possible causes o favorably with reports of medical management r PFO closure versus medical management m tts	nt. Analy	ysis of	results	
	Recurrence rate of cry from ongoing random to select the best treat Device used: Sizing I distinct indentation in was not inflated fully was measured angiog Safety & Performan Objective: This study mediated PFO closure Method: Retrospectiv Follow-up: 12 month	yptogenic FNE compares nized trials of transcatheter tment for individual patier balloon NuMED Inc.; adv n the balloon and eliminati to avoid the possibility of graphy and by echocardiog nce y sought to assess PFO and e to identify predictors of ve study	Patients may have multiple possible causes o favorably with reports of medical management r PFO closure versus medical management m ts anced over the guidewire and incompletely in on of any shunting by color Doppler was ide f inadvertently enlarging the defect. The diam	nt. Analy nay impro nflated (< ntified. T neter of th aneous su	ysis of ove ou: <1 atm The bal he inde uture-	results r ability) until a lloon	Populat 230 consecu patients
	Recurrence rate of cry from ongoing random to select the best treat Device used: Sizing I distinct indentation in was not inflated fully was measured angiog Safety & Performan Objective: This study mediated PFO closure Method: Retrospecti Follow-up: 12 month Appraisal	yptogenic FNE compares nized trials of transcatheter tment for individual patier balloon NuMED Inc.; adv n the balloon and eliminati to avoid the possibility of graphy and by echocardiog nce y sought to assess PFO and e to identify predictors of ve study	Patients may have multiple possible causes o favorably with reports of medical managemer r PFO closure versus medical management m ts anced over the guidewire and incompletely in ion of any shunting by color Doppler was ide f inadvertently enlarging the defect. The dian graphy. atomy by TEE in patients undergoing percuta post-procedural residual atrial right-to-left sh	nt. Analy nay impro- ntified. T neter of th aneous su nunt (RLS Oxford	ysis of ove ou: <1 atm The bal he inde ature- S).	results r ability) until a lloon	Populat 230 consecu patients underwo percutar
	Recurrence rate of cry from ongoing random to select the best treat Device used: Sizing I distinct indentation in was not inflated fully was measured angiog Safety & Performan Objective: This study mediated PFO closure Method: Retrospecti Follow-up: 12 month Appraisal	yptogenic FNE compares nized trials of transcatheter tment for individual patier balloon NuMED Inc.; adv the balloon and eliminati to avoid the possibility of graphy and by echocardiog nce y sought to assess PFO and to identify predictors of ve study ns or later if needed	Patients may have multiple possible causes o favorably with reports of medical managemer r PFO closure versus medical management m ts anced over the guidewire and incompletely in ion of any shunting by color Doppler was ide f inadvertently enlarging the defect. The dian graphy. atomy by TEE in patients undergoing percuta post-procedural residual atrial right-to-left sh	nt. Analy nay impro- nflated (« ntified. T neter of th aneous su nunt (RLS	ysis of ove ou: <1 atm The bal he inde ature- S).	results r ability) until a lloon entation	Populat 230 consecu patients underwo percutat suture- mediate
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et	Recurrence rate of cry from ongoing random to select the best treat Device used: Sizing I distinct indentation in was not inflated fully was measured angiog Safety & Performan Objective: This study mediated PFO closure Method: Retrospectir Follow-up: 12 month Appraisal Level of Evidence Suitability Device	yptogenic FNE compares nized trials of transcatheter tment for individual patier balloon NuMED Inc.; adv the balloon and eliminati to avoid the possibility of graphy and by echocardiog nee y sought to assess PFO an- e to identify predictors of ve study ns or later if needed Study Method/Design Retrospective study Relevant Data PTS-X NuMED Inc. to defect Placement in the superio- patients (in the remainin local anesthesia without 230 consecutive patient	Patients may have multiple possible causes o favorably with reports of medical management medical management medical management medical over the guidewire and incompletely in anced over the guidewire and incompletely in ion of any shunting by color Doppler was ide f inadvertently enlarging the defect. The diam graphy. atomy by TEE in patients undergoing percuta post-procedural residual atrial right-to-left sh Question Applied Treatment Benefit, Treatment Harms (Common) determine the size and the anatomy of the or pulmonary vein; TEE monitoring in 27	nt. Analy nay impro- ntified. T neter of th aneous su ount (RLS Oxford 2011 1 2 01 1 2	<pre>vsis of pve ou: <1 atm The bal he inde ature- S). I LOE 3 4 Gradin D2</pre>	results r ability) until a lloon entation 	Populat 230 consecu patients underwo percutat suture- mediate PFO clo Samplin n= N/A Mean A mean 40
	Recurrence rate of cry from ongoing random to select the best treat Device used: Sizing I distinct indentation in was not inflated fully was measured angiog Safety & Performan Objective: This study mediated PFO closure Method: Retrospectir Follow-up: 12 month Appraisal Level of Evidence Suitability Device Application	yptogenic FNE compares nized trials of transcatheter tment for individual patier balloon NuMED Inc.; adv the balloon and eliminati to avoid the possibility of graphy and by echocardiog nce y sought to assess PFO an- e to identify predictors of ve study ns or later if needed Study Method/Design Retrospective study Relevant Data PTS-X NuMED Inc. to defect Placement in the superio- patients (in the remainin local anesthesia without 230 consecutive patient PFO closure; mean 46	Patients may have multiple possible causes of favorably with reports of medical management models of the provided of the provid	nt. Analy nay impro- ntified. T neter of the aneous subunt (RLS) Oxford 2011 1 2 01 1 2 01 01 A1	<pre>vsis of ve ou: <1 atm The bal he inde ature- S). I LOE 3 4 Gradin D2 A2</pre>	results r ability) until a lloon entation <u>g</u> D3 A3	Populat 230 consecu patients underwo percutar suture- mediate PFO clo Samplin n= N/A Mean A mean 46 13, rang



Data Contr					<u> </u>			_		
Data Collu	ribution	Re	levant Data					Grad	ing	
Outcomes/	Endpoin		1		e measures (closure (RL		Yes		No 2	
) indirectly reflect the int	tended				
			rformance of			C: 1	.		N. 2	
Follow-up	llow-up The duration of follow-up (up to 12 months after th procedure) is acceptable to assess whether duration						Yes 1	L	No 2	
					the to assess whether during the second second terms and identify complicity complicity and the second s					
Statistical a	analysis				the data has been provid		Yes	1	No 2	
Clinical sig	-		•		treatment benefit observ				No 2	
	Sumeanc		nificant (clos					-	110 2	
					Data Contribution C	Grade (Range 4	-8)	4		
						-				
Overall S&I	P Appra		osition and V							
S&P Grade			- Suitability (Disposition and		and Pivot			
(Range 9-2	25)		ntribution (4)) =	Weighting (select)		but not Piv	otal,	13-21	
		12				Excluded,	22-25			
Relevant S&	&P Resu	ılts								
Criteria		Resul	ts					Р	value	
Safety data	ı	No pr	ocedural com	nplicat	ions.			N/	/A	
Performance	ce data	At ma	ximum follov	w-up,	TTE evaluation showed	a complete clo	sure (RLS	N	/A	
					tients and an effective cl					
			84%) patients	5.				_		
Benefits/cla	aims dat				(220)			N/		
Strengths	1		population st					N		11
Weaknesse	es/	Retros	spective analy			•, ,• •				
D-4- (11)	·			ysis w	ith obvious intrinsic limi	itation and pote	entially	N/	/A	
Potential bi	ias	leads	to biases.	-		-	-	N	/A	
Potential bi		leads The st	to biases. udy is focuse	ed on t	ith obvious intrinsic limi he assessment of the saf and not of the NuMED,]	ety and perform	nance of	N	/A	
State of the N/A – Articl Conclusions anatomies; h only. Device used	Art les does : s of the a nowever, l: PTS-X n 27 pati	leads The st the PH not contrib authors: Pr PFO >5 m C NuMED, ients (in the	to biases. udy is focuse <u>O occlude de</u> ute to SOA. ercutaneous s m in width ar Inc. for contra e remaining p	ed on t evice a suture- nd spo rast-en	he assessment of the saf	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as	nance of oon. e majority o e closed wi sessment;	of sep th 1 s	tal stitch	
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring in or intracardia	Art les does : s of the a nowever, l: PTS-X n 27 pati ac echo p	leads The st the PF not contrib authors: Pr PFO >5 m X NuMED, ients (in the monitoring	to biases. udy is focuse <u>O occlude de</u> ute to SOA. ercutaneous s m in width ar Inc. for contra e remaining p	ed on t evice a suture- nd spo rast-en	he assessment of the saf and not of the NuMED, 1 -mediated PFO closure is ontaneous large RLS are hanced sizing-balloon P	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as	nance of oon. e majority o e closed wi sessment;	of sep th 1 s	tal stitch	Рор
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring in or intracardia	Art les does : s of the a nowever, l: PTS-X n 27 pati ac echo : erformal	leads The st the PF not contrib authors: Pr PFO >5 m X NuMED, ients (in the monitoring	to biases. udy is focuse <u>FO occlude de</u> ute to SOA. ercutaneous s m in width an Inc. for contra- e remaining p).	ed on t evice a suture- ind spo rast-en patient	he assessment of the saf and not of the NuMED, 1 mediated PFO closure is ontaneous large RLS are hanced sizing-balloon P s the procedure was carr	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as ied out in local	nance of pon. e majority o e closed wi sessment; ' anesthesia	of sep th 1 s TEE	tal stitch out TE	Pop 282
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring is or intracardia Safety & Pe Objective: T	Art les does : s of the a nowever, l: PTS-X n 27 pati ac echo i erforman This stud	leads The st the PF not contrib authors: Pr PFO >5 m X NuMED, ients (in the monitoring nce ly aimed to	to biases. udy is focuse <u>CO occlude de</u> ute to SOA. ercutaneous s m in width ar Inc. for contra- e remaining p).	ed on t evice a suture- nd spo rast-en patient	he assessment of the saf and not of the NuMED, I omediated PFO closure is ontaneous large RLS are hanced sizing-balloon P s the procedure was carr	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as ied out in local	nance of pon. e majority o e closed wi sessment; ' anesthesia	of sep th 1 s TEE	tal stitch out TE	Pop 282 cons
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring is or intracardia Safety & Pe Objective: T (rCVEs) afte	Art les does : s of the a nowever, l: PTS-X n 27 pati ac echo i erforman This stud er closurd	leads The st the PF not contrib authors: Pr PFO >5 m X NuMED, ients (in the monitoring nce ly aimed to e of PFO d	to biases. udy is focuse <u>FO occlude de</u> ute to SOA. ercutaneous s m in width an Inc. for contra- e remaining p).	ed on t evice a suture- nd spo rast-en patient	he assessment of the saf and not of the NuMED, I omediated PFO closure is ontaneous large RLS are hanced sizing-balloon P s the procedure was carr	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as ied out in local	nance of pon. e majority o e closed wi sessment; ' anesthesia	of sep th 1 s TEE	tal stitch out TE	Pop 282
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring is or intracardia Safety & Pe Objective: T (rCVEs) afte Method: Re	Art les does : s of the a nowever, l: PTS-X n 27 pati ac echo i erforman This stud er closure etrospect	leads The st the PF not contrib authors: Pr PFO >5 m X NuMED, ients (in the monitoring hy aimed to e of PFO d ive study	to biases. udy is focuse <u>CO occlude de</u> ute to SOA. ercutaneous s m in width ar Inc. for contra- e remaining p). investigate th uring long-ter	ed on t evice a suture- nd spo rast-en patient the risk	he assessment of the saf and not of the NuMED, I omediated PFO closure is ontaneous large RLS are hanced sizing-balloon P s the procedure was carr	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as ied out in local	nance of pon. e majority o e closed wi sessment; ' anesthesia	of sep th 1 s TEE	tal stitch out TE	Pop 282 cons patie
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring is or intracardia Safety & Pe Objective: T (rCVEs) afte Method: Re	Art les does : s of the a nowever, l: PTS-X n 27 pati ac echo i erforman This stud er closure etrospect	leads The st the PF not contrib authors: Pr PFO >5 m X NuMED, ients (in the monitoring hy aimed to e of PFO d ive study	to biases. udy is focuse <u>CO occlude de</u> ute to SOA. ercutaneous s m in width ar Inc. for contra- e remaining p).	ed on t evice a suture- nd spo rast-en patient the risk	he assessment of the saf and not of the NuMED, I omediated PFO closure is ontaneous large RLS are hanced sizing-balloon P s the procedure was carr	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as ied out in local	nance of pon. e majority o e closed wi sessment; ' anesthesia	of sep th 1 s TEE	tal stitch out TE	Pop 282 cons patie und
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring in or intracardia Safety & Pe Objective: T (rCVEs) afte Method: Re Follow-up: 3 Appraisal Level of	Art les does : s of the a nowever, l: PTS-X n 27 pati ac echo i erforman This stud er closure etrospect: 8.4 (± 2)	leads The st the PF not contrib authors: Pr PFO >5 m X NuMED, ients (in the monitoring hy aimed to e of PFO d ive study	to biases. udy is focuse <u>FO occlude de</u> ute to SOA. ercutaneous s m in width ar Inc. for contra- e remaining p). investigate the uring long-ter n PFO closure	ed on t evice a suture- nd spo rast-en patient the risk erm fol	he assessment of the saf and not of the NuMED, I omediated PFO closure is ontaneous large RLS are hanced sizing-balloon P s the procedure was carr	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as ied out in local	mance of oon. e majority o e closed wi sessment; ' anesthesia	of sep th 1 s TEE with	tal stitch out TE	Pop 282 cons pati- und perc PFC
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring in or intracardia Safety & Pe Objective: T (rCVEs) afte Method: Re Follow-up: 3 Appraisal	Art les does : s of the a nowever, l: PTS-X n 27 pati ac echo i erforman This stud er closure throspect: 8.4 (± 2)	leads The st the PF not contrib authors: P PFO >5 m C NuMED, ients (in the monitoring ly aimed to e of PFO d ive study) years from Gtudy Meth	to biases. udy is focuse <u>FO occlude de</u> ute to SOA. ercutaneous s m in width and Inc. for contra- e remaining p). investigate the uring long-tention n PFO closured od/Design	ed on t evice a suture- nd spo rast-en patient: the risk erm fol	he assessment of the saf and not of the NuMED, 1 omediated PFO closure is ontaneous large RLS are hanced sizing-balloon P s the procedure was carr a factors for recurrent cry low-up.	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as ied out in local	mance of oon. e majority of e closed wi sessment; ' anesthesia	of sep th 1 s TEE with	tal stitch out TE tts	Pop 282 cons pati- und perc PFC San
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring in or intracardia Safety & Pe Objective: T (rCVEs) afte Method: Re Follow-up: 3 Appraisal Level of	Art les does : s of the a nowever, l: PTS-X n 27 pati ac echo i erforman This stud er closure throspect: 8.4 (± 2)	leads The st the PF not contrib authors: Pr PFO >5 m C NuMED, ients (in the monitoring ly aimed to e of PFO d ive study) years from	to biases. udy is focuse <u>FO occlude de</u> ute to SOA. ercutaneous s m in width and Inc. for contra- e remaining p). investigate the uring long-tention n PFO closured od/Design	ed on t evice a suture- nd spo rast-en patient: the risk erm fol re Qu	he assessment of the saf and not of the NuMED, 1 mediated PFO closure is ontaneous large RLS are hanced sizing-balloon P s the procedure was carr a factors for recurrent cry low-up.	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as ied out in local	mance of oon. e majority of e closed wi sessment; ' anesthesia	of sep th 1 s TEE with	tal stitch out TE tts	Pop 282 cons pati- und perc PFC
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring in or intracardia Safety & Pe Objective: T (rCVEs) afte Method: Re Follow-up: 3 Appraisal Level of	Art les does : s of the a nowever, l: PTS-X n 27 pati ac echo i erforman This stud er closure throspect: 8.4 (± 2)	leads The st the PF not contrib authors: P PFO >5 m C NuMED, ients (in the monitoring ly aimed to e of PFO d ive study) years from Gtudy Meth	to biases. udy is focuse <u>FO occlude de</u> ute to SOA. ercutaneous s m in width and Inc. for contra- e remaining p). investigate the uring long-tention n PFO closured od/Design	ed on t evice a suture- nd spo rast-en patient: the risk erm fol re Qu	he assessment of the saf and not of the NuMED, 1 omediated PFO closure is ontaneous large RLS are hanced sizing-balloon P s the procedure was carr a factors for recurrent cry low-up.	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as ied out in local	mance of oon. e majority of e closed wi sessment; ' anesthesia	of sep th 1 s TEE with	tal stitch out TE tts	Pop 282 cons pati- und perc PFC5San n=1
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring in or intracardia Safety & Pe Objective: T (rCVEs) afte Method: Re Follow-up: 3 Appraisal Level of Evidence	Art les does : s of the a nowever, l: PTS-X n 27 pati ac echo : erformar this stud er closure thospect: 8.4 (± 2) S R	leads The st the PF not contrib authors: Pr PFO >5 m C NuMED, ients (in the monitoring Numed to e of PFO d ive study) years from Study Meth Retrospective	to biases. udy is focuse <u>FO occlude de</u> ute to SOA. ercutaneous s m in width and Inc. for contra- e remaining p). investigate the uring long-tention n PFO closured od/Design //e study	ed on t evice a suture- nd spo rast-en patient: the risk erm fol re Qu	he assessment of the saf and not of the NuMED, 1 mediated PFO closure is ontaneous large RLS are hanced sizing-balloon P s the procedure was carr a factors for recurrent cry low-up.	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as ied out in local	mance of <u>oon</u> . e majority of e closed wi sessment; ' anesthesia	of sep th 1 s TEE with ord L(2 3	tal stitch out TE tts DE	Pop 282 cons pati- und perc PFC San
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring in or intracardia Safety & Pe Objective: T (rCVEs) afte Method: Re Follow-up: 3 Appraisal Level of Evidence Suitability	Art les does : s of the a nowever, l: PTS-X n 27 pati ac echo i erformai This stude er closure etrospect: 8.4 (± 2) S R R	leads The st the PF not contrib authors: P PFO >5 m C NuMED, ients (in the monitoring ly aimed to e of PFO d ive study) years from Study Meth Retrospectiv Relevant Da	to biases. udy is focuse <u>FO occlude de</u> ute to SOA. ercutaneous s m in width and Inc. for contra- e remaining p). investigate the uring long-term n PFO closured od/Design //e study	ed on t evice a suture- nd spo rast-en patient: the risk erm fol re Qu Tre (Co	he assessment of the saf and not of the NuMED, 1 mediated PFO closure is ontaneous large RLS are hanced sizing-balloon P s the procedure was carr c factors for recurrent cry low-up.	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as ied out in local yptogenic cereb	mance of bon.	of sep th 1 s TEE with e even	tal stitch out TE ts DE 4	Pop 282 cons pati- und perc PFC Sam n= 1 Mea 11.7
State of the N/A – Articl Conclusions anatomies; h only. Device used monitoring in or intracardia Safety & Pe Objective: T (rCVEs) afte Method: Re Follow-up: 3 Appraisal Level of Evidence	Art les does 1 s of the a nowever, l: PTS-X n 27 pati ac echo 1 erformar This stude er closure etrospect: 8.4 (± 2) S R R R	leads The st the PF not contrib authors: Pr PFO >5 m C NuMED, ients (in the monitoring ly aimed to e of PFO d ive study) years from Study Meth Retrospective Relevant Da The size and	to biases. udy is focuse <u>FO occlude de</u> ute to SOA. ercutaneous s m in width an Inc. for contra- e remaining p). investigate th uring long-ter n PFO closure od/Design //e study tta 1 anatomy of	ed on t evice a suture- nd spo rast-en patient: the risk erm fol re Qu Tre (Co	he assessment of the saf and not of the NuMED, 1 mediated PFO closure is ontaneous large RLS are hanced sizing-balloon P s the procedure was carr a factors for recurrent cry low-up.	ety and perform Inc. sizing balle s feasible in the less likely to b FO anatomy as ied out in local yptogenic cereb ent Harms	mance of <u>oon</u> . e majority of e closed with the sessment; 'anesthesia	of sep th 1 s TEE with ord L(2 3	tal stitch out TE ts DE 4	Pop 282 come patie unde perce PFC 5 n=1 mea 117

-	Summary		NuMED ty and Clinical SCP – Sizing	Performan	ce				
Application	PFO closure was panesthesia with flu		a catheterization laboratond TEE imaging.	ry under general	A1	A2	A:		
Patient	282 consecutive p \pm 11.7, range not		rwent percutaneous PFO c 176/F: 106.	losure; mean 48	P1	P2	P3		
Report	The article contain rational and object		information to be able to u	ındertake a	R1	R2	Râ		
			Suitability Gra	ide (Range 4-12)		5			
Data Contribution	n Relevant Data	L				Gradi	ing		
Outcomes/Endpo nts			asures (closure (RLS irectly reflect the intended	performance of	Yes 1		No 2		
Follow-up		her duration	low-up (up to 8.4 years fro of treatment benefits/harr		Yes 1		No 2		
Statistical analysi	s Statistical ana	lysis of the c	lata has been provided.		Yes 1		No 2		
Clinical significance	The magnitud significant (cl		tment benefit observed wa	s clinically	Yes 1		No 2		
6			Data Contribution G	rade (Range 4-8)		4			
Relevant S&P Re	sulte			(Range 9-25) + Data Contribution (4) = 12 Weighting (select) Accepted but not Excluded, 22-25					
	suits								
Criteria		Results					value		
		Intra-oper	ative complications: Temporary ST-elevation: Thrombus on catheter dur Device thrombus: 1 (0.7% Pericardial effusion: 1 (0.7 tions post-operative: Major bleeding: 0 Minor bleeding: 5 (1.8%) Stroke first 48 hours: 1 (0. Device dislocation: 5 (1.8%)	ing operation: 4 (1) 7%) 4%) %)		P N/			
Criteria Safety data – Cor	nplications (0 – 6	Intra-oper	Temporary ST-elevation: Thrombus on catheter duri Device thrombus: 1 (0.7% Pericardial effusion: 1 (0.7 ions post-operative: Major bleeding: 0 Minor bleeding: 5 (1.8%) Stroke first 48 hours: 1 (0. Device dislocation: 5 (1.8%) ut of the 282 consecutive pure suffered from rCVEs d	ing operation: 4 (1) 7%) 4%) %) patients who under uring a mean FU o	rwent	-	'A		
Criteria Safety data – Cor months) Performance data PFO closure Benefits/claims d	nplications (0 – 6 . – rCVEs after	Intra-oper - - - - - - - - - - - - - - - - - - -	Temporary ST-elevation: Thrombus on catheter duri Device thrombus: 1 (0.7% Pericardial effusion: 1 (0.7 ions post-operative: Major bleeding: 0 Minor bleeding: 5 (1.8%) Stroke first 48 hours: 1 (0. Device dislocation: 5 (1.8%) ut of the 282 consecutive pre suffered from rCVEs d rCVEs per 1000 patient-y	ing operation: 4 (1) 7%) 4%) 24%) 24%) 24%) 24%) 24%) 24%) 24%	rwent of 8.4	N/ N/	/A /A /A		
Criteria Safety data – Cor months) Performance data PFO closure	nplications (0 – 6 . – rCVEs after	Intra-oper - - - - - - - - - - - - - - - - - - -	Temporary ST-elevation: Thrombus on catheter duri Device thrombus: 1 (0.7% Pericardial effusion: 1 (0.7 ions post-operative: Major bleeding: 0 Minor bleeding: 5 (1.8%) Stroke first 48 hours: 1 (0. Device dislocation: 5 (1.8%) ut of the 282 consecutive pure suffered from rCVEs d	ing operation: 4 (1) 7%) 4%) 24%) 24%) 24%) 24%) 24%) 24%) 24%	rwent of 8.4 ars)	N/	/A //A //A		

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

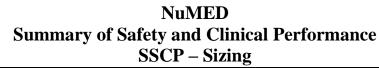
Device used: PTS NuMED, Inc. used to determine the size and anatomy of the PFO; general anesthesia; fluoroscopy and TEE imaging.

			S	SCP – Sizing					
	Safety & Perfo	ormance							
		he tricuspid va e in the pulmo	alve during advancent on ary position.	e DrySeal (GDS) sheaths (WL nent of the Commander deliver					
	Follow-up: pos	st-procedural							
	Appraisal								
	Level of Evide	ence Study	Method/Design	Aethod/Design Question Applied			rd LOE	Ξ	
		Retros	spective study	Treatment Benefit, Treatme (Common)	ent Harms	1 2	3	4 5	Population : 48 patients
	Suitability	Relevant Da	ita				Gradin	g	underwent
	Device	30 or 40mm right ventric	diameter PTS-X siz sular outflow tract (R	ing balloon NuMED, Inc. infla VOT) to determine the minimu ld be used as a landing zone.		D1	D2	D3	transcatheter placement of a SAPIEN valve in the
	Application	Internal jug	ular or femoral vein			A1	A2	A3	pulmonary
	Patient	-	-	3.2 and 25.9; 24 males		P1	P2	P3	position
	Report		contains sufficient int objective assessmen	formation to be able to undertaint.	ke a	R1	R2	R3	Sampling: Group I
				Suitability Grade (F	Range 4-12)		5		(without using a long
	Data Contribution	Relevant Da	ta				Grading		delivery sheath):
5. Stapleto	Outcomes/ Endpoints		outcome measures (procedural success) indirectly reflect the formance of the device. of follow-up (post-procedural) seems acceptable to assess tion of treatment benefits/harms and identify complications.			Yes 1	Yes 1 No		n=25 Group I (with):
n et al. (2020)	Follow-up					Yes 1	1	No 2	n=23
· · ·	Statistical analysis	Statistical a	nalysis of the data ha	alysis of the data has been provided. de of the treatment benefit observed was clinically significant success).			l l	No 2	Mean Age: Group I:
	Clinical significance	The magnitu (procedural					1	No 2	mean 25.9 ± 15.5, range
				Data Contribution Grade ((Range 4-8)	4			not reported Group II:
	Overall S&P A S&P Grade		position and Weigh) + Suitability (5) +	ting Disposition and	Accord	and D	votol 0	12	mean 23.2 \pm
	(Range 9-25)		(5) + 3011100 + 3011100 + 3011000 + 3011000 + 3011000 + 3011000 + 3011000 + 3011000 + 3011000 + 3011000 + 3011000 + 3011000 + 3011000 + 3011000 + 3011000 + 301000 + 301000 + 301000 + 301000 + 301000 + 301000 + 301000 + 301000 + 301000 + 3010000 + 301000000 + 3010000000 + 3010000000000	Weighting (select)	Accepted Accepted 21 Excluded,	but not			16.5, range not reported Sex:
	Delevert S P D	Dogultz							Group I:
	Relevant S&P Criteria	Results	Results				P va	alue	M: 15 (60%) Group II:
	Safety data –		Results 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 comple curves from the right atrium, through the tricuspid valve, right ventricle and into RVOT. Approach to valve delivery was modi to decrease risk after two patients developed tricuspid valve inju There were no vascular access or procedural complications.			e blex bdified	N/A		M: 9 (39%)
	Performance of tricuspid valve	e injury	•) vs. Group II: 0/23			N/A		
	Benefits/claim Strengths	ns data	None Comparative study	,			N/A N/A		
	Weaknesses/ Potential bias			ysis with obvious intrinsic limi	tation and		N/A		
	i otontiai olas			ed on the assessment of the safe	ety and				

		Sui	nmary of Sa	NuMED afety and Clinica SSCP – Sizing	ll Performa	nce			
				f the Gore sheath and not of	of the NuMED, Inc.	. sizing			
	of the Ar		balloon.						
Conclu	usions of	the autho		DS may protect the tricusp		y during	impla	antation	
Device	e used: 30) or 40mm	diameter PTS-X siz	is technically feasible in s ring balloon NuMED, Inc. we used as a landing zone.	-	DT to de	termiı	ne the	
Safety Object covere occlus Metho	• & Perfo tive: Rep ed stents a	rmance (o ort the first and the rero hepatic ve report	nly contributes to sa successful transcat uting of a partial an	afety due to quantity of pat heter closure of an inferior omalous pulmonary vein d	sinus venosus defe	ect with	bare a	ind	
Appra Leve		C to day	Matha J/Danian	Orrentian Annihis I		Orfe	rd LO	Б	
Evide		Study	Method/Design	Question Applied		2011		E	
		Case	report	Treatment Benefit, Trea (Common)	atment Harms	1 2	3	4 5	
	ability	Relevant					Gradin	-	
Devi	ce lication		S-X balloon (NuMI	ED) 1 atm pressure for sizing		D1 A1	D2 A2	D3 A3	Population
Patie				-	n van oue defeat)	P1	P2	P3	patient wit inferior sin
Repo	-	Case repo		(less common than superior ntain limited information t ctive assessment.		R1	R2	R3	venosus defect
			<u>J</u>		ade (Range 4-12)		5		resulting ir partial
Data	Contribu	tion Rel	evant Data			C	Gradin	g	anomalous pulmonary
	omes/ points	suc		measures (implantation indirectly reflect the inten	ded performance	Yes 1		No 2	vein drainage
	ow-up	The	e duration of follow- ess long-term of trea	up (one month) provides l atment benefits/harms and		Yes 1	I	No 2	Sampling: n=1
Statis	stical ana		plications. statistical analysis o	of the data has been provid	ed.	Yes 1	I	No 2	Mean Age
Clini		The	-	reatment benefit observed		Yes 1		No 2	29 years Sex:
				Data Contribution G	brade (Range 4-8)		6		M - 0 F - 1
S&P	Grade Grade ge 9-25)	LOE (4	Disposition and We + Suitability (5) + contribution (6) = 15	Disposition and	Accepted and Piv Accepted but no Excluded, 22-25			21	
	ant S&P	Results:						_	
Crite Safet resul	ty data - N	Aain	venosus defect wit	t successful transcatheter c th bare and covered stents pulmonary vein drainage i the hepatic veins.	and the rerouting o	f a	P v	alue	
	ty data – I -procedura		Intraprocedural co stents; suspected t	wered stent migration man hrombus on inferior vena of present at one month follo	cava treated with	g bare	N/A	x	

NuMED
Summary of Safety and Clinical Performance
SSCP – Sizing

		<u> </u>	SCP – Sizing					
	Benefits/claims					N/A		
	Strengths	venosus defect with p	ort. Transcatheter closure partial anomalous pulmona tts in the inferior vena cava	ry vein drainage	using	N/A		
	Weaknesses/ Potential bias	Single patient case stu	udy; study in a larger patie p is needed to assess effica			N/A		
		es not contribute to SOA. ae authors: Transcatheter closur	ra of an infarior sinus yang	osus defect with p	vartial	nomal	OUE	
	pulmonary vein du patient selection a	rainage using bare and covered s nd intensive assessment of puln ecessary to achieve a successful	stents in the inferior vena on the stents in the inferior vena of the stent stents of the stent stents of the stends of the sten	cava was shown to	o be fe	asible.		
		nm PTS-X balloon (NuMED)						
	Objective: To inv conductance syste examinations with Method: Prospect Follow-up: Not a arterial switch cor	nance (only contributes to safety restigate subtle functional param on (under baseline conditions and a cardiac MRI. tive, nonrandomized, monocentra pplicable; mean age at repair 1.1 rection is treatment of choice	eters by invasive measure id under dobutamine appli ric	ements with a pres cation) as well as	by nor	ninvasi	ve	Denulation
	Appraisal Level of	Study Method/Design	Question Applied		Ovf	ord LC)F	Population : patients with
	Evidence	Study Wethod/Design	Question Applied		201			D-
		Nonrandomized	Treatment Benefit, Treat (Common)	ment Harms		2 3	4 5	transposition of great arteries after
	Suitability	Relevant Data				Gradin	ø	atrial switch
	Device	PTS Sizing Balloon, Fa Num	ed Inc.: size: 20–25mm		Grading D1 D2 D3			surgery and
	Application	Preload reduction was achiev the inferior caval vein		on catheter in	A1	A2	A3	indication for invasive
7.	Patient	D-transposition of great arter for invasive hemodynamic ev catheterization			P1	P2	P3	hemodynami c evaluation by routine
Hornun g et al. (2021)	Report	The article contains sufficien rational and objective assessm		undertake a	R1	R2	R3	cardiac catheterizati on
(=====)			Suitability Grad	de (Range 4-12)		8		a r
	Data Contribution	Relevant Data				Gradin	-	Sampling: n=16
	Outcomes/ Endpoints	The reported outcome measu reflect the intended performa) indirectly	Yes 1	. 1	No 2	Mean Age: 28.2 ± 7.3
	Follow-up	Study seeking functional para applicable.	ameters of assessment; fol	low-up not	Yes 1]	No 2	years (range 22-50 years)
	Statistical analysis	Statistical analysis of the data	a has been provided.		Yes 1]	No 2	Sex: M – 13
	Clinical significance	The magnitude of the treatme significant (conductance anal		linically	Yes 1	.]	No 2	F-3
		•	Data Contribution Gra	ade (Range 4-8)		6		
		praisal, Disposition and Weigh						
	S&P Grade	LOE(3) + Suitability(8) +	Disposition and	Accepted and I			12 21	
	(Range 9-25)	Data Contribution $(6) = 17$	Weighting (select)	Accepted but a Excluded, 22-2		votal, 1	13-21	



	Relevant S&P Res	sults:					
	Criteria	Results				P va	lue
	Safety data - Mair		reported.			N/A	
	Benefits/claims da	ata None				N/A	
	Strengths	diastolic right	nalysis revealed intraventricular and pred ventricular dyssynchrony. To be determin rocess or precursor of contractility loss.		у	N/A	
	Weaknesses/ Potential bias	failure were ex cross-sectional follow-up stud correction is tr right ventricle	ied limitations include patients with sever ccluded, no interobserver variability, singl study with limited number of eligible paties ies no longer possible because arterial sw eatment of choice, conductance data for s are limited, and inflw tract may not be su conductance data due to arterial approach	e-center lents, tch vstemic ficiently		N/A	
	Conclusions of the	s not contribute to SOA. authors: Conductance in ues, but a significant relati	dices as well as the cardiac MRI-derived ionship was not present.	strain pa	ram	eters sh	owed
	Derice wood, DTC	Sizing Dolloon, Eo Numo	Inc. size 20. 25mm				
	Safety & Performa Objective: Describ		safety due to quantity of patients (n=1) and stration in the Fontan conduit using an NI				1)
		on a 10-mm balloon (Cool ort	bec, Canada) followed by implantation of Medical, Bloomington, Indiana).	a 20-mn	n 53	35 Form	ula
	Appraisal						
	Level of Evidence	Study Method/Design	Question Applied		201		
		Case report	Treatment Benefit, Treatment Harms (Common)		1	2 3	4 5
	Suitability	Relevant Data				Grading	n
			- (N-Mad Dava Datan Elarida)	Г	1	D2	-
	Device Application		on (NuMed, Boca Raton, Florida) o flare the distal and proximal ends (of th)1	A2	D3 A3
im	Patient	Recurrent plastic bronch		D	1	P2	P3
			itis on optimal medical therapy, history of ndrome and previous Fontan completion v		1		
	Report	a lateral tunnel	ndrome and previous Fontan completion v le contain limited information to be able t objective assessment.	rith D R	1	R2	R3
	Report	a lateral tunnel Case report thereby artic	ndrome and previous Fontan completion v le contain limited information to be able t	rith D R		R2 9	R3
		a lateral tunnel Case report thereby artic undertake a rational and	ndrome and previous Fontan completion v le contain limited information to be able t objective assessment.	rith D R		9	
	Data Contribution	a lateral tunnel Case report thereby artic undertake a rational and Relevant Data	ndrome and previous Fontan completion with le contain limited information to be able to objective assessment. Suitability Grade (Range 4	rith -12)	1	9 Grading	g
	Data	a lateral tunnel Case report thereby artic undertake a rational and Relevant Data The reported outcome r	ndrome and previous Fontan completion v le contain limited information to be able t objective assessment.	rith -12)		9 Grading	
	Data Contribution Outcomes/	a lateral tunnel Case report thereby artic undertake a rational and Relevant Data The reported outcome r indirectly reflect the int The duration of follow-	ndrome and previous Fontan completion with le contain limited information to be able to objective assessment. Suitability Grade (Range 4 neasures (technical success/recurrence)	rith -12)	1	9 Gradinş 1 N	g
al. 022)	Data Contribution Outcomes/ Endpoints	a lateral tunnel Case report thereby artic undertake a rational and Relevant Data The reported outcome r indirectly reflect the int The duration of follow- whether duration of treat complications.	ndrome and previous Fontan completion v le contain limited information to be able t objective assessment. Suitability Grade (Range 4 measures (technical success/recurrence) tended performance of the device. up (18 months) seems acceptable to asses	-12) R	7 es 1	9 Grading 1 N 1 N	g No 2
	Data Contribution Outcomes/ Endpoints Follow-up Statistical	a lateral tunnel Case report thereby artic undertake a rational and Relevant Data The reported outcome r indirectly reflect the int The duration of follow- whether duration of treat complications. No statistical analysis of	ndrome and previous Fontan completion v le contain limited information to be able to objective assessment. Suitability Grade (Range 4 measures (technical success/recurrence) tended performance of the device. -up (18 months) seems acceptable to assess atment benefits/harms and identify of the data has been provided. reatment benefit observed was clinically	ith o R -12)	(in the second s	9 Grading 1 P 1 P	g No 2 No 2

NuMED

F

NuMED	

					CP – Sizing					
	Overall S&P App S&P Grade (Range 9-25)	LOE (4)	$\frac{1}{1}$ + Suitability (9) ntribution (5) = 1	+	ng Disposition and Weighting (select)	Accepted and Accepted but Excluded, 22-2	not Piv		3-21	
	Relevant S&P Re	sults:								
	Criteria Safety data - Mai		Results No further recurrence of the plastic bronchitis at 18-month f up; patient was successfully weaned off oral and inhaled stered off or an and inhaled stered off or an				ollow- oids	P va		
	Benefits/claims d		over time. None		-			N/A		
	Strengths	atu	By using radiof		ency needles, can perfor force and greater contro			N/A		
	Weaknesses/ Potential bias		Single patient c	case si	tudy.			N/A		
	facilitated by a con Device used: 2.5 x Safety & Perform Objective: Report	nbination of <u>3-cm PTS-</u> ance (only the first hu venosus at ort	f RF needle punct X Balloon (NuM contributes to saf man implantation	ture f <u>led, B</u> fety d n of a	n conduit, creating a fen followed by placement of Boca Raton, Florida) lue to quantity of patient single custom-made lor partial anomalous pulmo	f a balloon expansion expansion of the second secon	ndable : ical app /S® to	stent.	vely patient. I	Population patient diagnosed
	Appraisal Level of Evidence	Study M	lethod/Design	Que	stion Applied		Oxf 201	ord LO 1	E r	with left-to right sinus venosus
		Case rep	oort		atment Benefit, Treatme mmon)	nt Harms	-	2 3	4 5 d	atrial septa defect, PF0 on
	Suitability	Relevan	t Data					Gradin	. U	ultrasound, and
	Device	30-mm/.	3-cm PTS sizing	ballo	on catheter (NuMED, Ir	ıc.)	D1	D2		anomalous
	Application	Balloon	interrogation of t	the ca	woatrial junction was pe	erformed	A1	A2		drainage of
ad	Patient	on ultras	sound, and anoma	alous	nus venosus atrial septa drainage of the right pu cross-sectional cardiac	lmonary veins	P1	P2		the right pulmonary veins into the superio
2)	Report	Case rep					R1	R2	R3 c	vena cava cross-secti al cardiac
					Suitability Grad	e (Range 4-12)		6		computed tomograph
	Data Contribution	Relevan	t Data					Gradin		angiogram
	Outcomes/ Endpoints				es (technical success/out performance of the devi		Yes 1			Sampling: n=1
	Follow-up		duration of treatr		nonth) seems acceptable benefits/harms and iden		Yes 1	1		Mean Age 70 years
	Statistical analysis	No statis	stical analysis of t		ata has been provided.		Yes 1		N	Sex: M - 1
	Clinical significance		gnitude of the trea int (sinus rhythm)		t benefit observed was	clinically	Yes 1			F - 0
	significance	8	ane (sinds my ann)	,	Data Contribution Gra					



	Overall S&P Ap		sposition and Weig						
	S&P Grade (Range 9-25)	+	4) + Suitability (6)	Disposition and Weighting (select)	Accepted and Accepted bu			13-	
		Data C	ontribution $(5) = 15$;	21 Excluded, 22	-25			
	Relevant S&P R	Results:	1						1
	Criteria		Results		1 (1 (1	1	P va	alue	
	Safety data - M	ain results	Discharge electrocardiogram showed sinus rhythm; one-month follow-up showed excellent outcomes as confirmed on control computed tomography angiogram.				N/A	X	
	Benefits/claims	data	None				N/A	1	
	Strengths		Used a single cus interlocking two	stent rather than necessary manipula	ations.	N/A	N/A		
	Weaknesses/ Potential bias		Single patient cas	e study.			N/A	Δ	
	superior sinus ve	he authors nosus atrial	Authors present ea	rly evidence of the feasibi artial anomalous pulmona atient.					
	Device used: 30-	-mm/3-cm P	TS sizing balloon c	atheter (NuMED, Inc.) ety due to clinical applicati					
				5 congenital heart patients		l RVO	Ts and	target	
	Method: From Ju transcatheter pulmonary valve prospectively ass Follow-up: 4.5 n	une 2020 to replacemen replacemen sessed.	November 2020, 1 t diameter ≥23 mm t using Edwards SA		with dysfunctionates before proceed	eding to	o transca	-	congenital heart patients wit
	Method: From Ju transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal Level of	une 2020 to replacemen replacemen bessed. nonths (med	November 2020, 1 t diameter ≥23 mm t using Edwards SA	5 congenital heart patients received Optimus-XXL st	with dysfunctionates before proceed	eding to nes wer	o transca re	atheter	congenital heart patients wit dysfunctior
	Method: From Ju transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal	une 2020 to replacemen replacemen bessed. nonths (med	November 2020, 1: t diameter ≥23 mm t using Edwards SA lian) thod/Design omized,	5 congenital heart patients received Optimus-XXL st PIENTM valve. Standard	with dysfunctiona ents before procee safety and outcon	eding to nes wer Oxf 201	o transca re	atheter	congenital heart patients wit dysfunctior l RVOTs at target transcathete pulmonary
	Method: From Ju transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal Level of Evidence	une 2020 to replacemen ressed. nonths (med Study Me Non-rand prospecti	November 2020, 1: t diameter ≥23 mm t using Edwards SA lian) thod/Design omized, ve	5 congenital heart patients received Optimus-XXL st PIENTM valve. Standard Question Applied Treatment Benefit, Treatm	with dysfunctiona ents before procee safety and outcon	Oxf 201 1	o transca re ford LO 1 2 3	E 4 5	congenital heart patients wit dysfunctior l RVOTs at target transcathete pulmonary valve
	Method: From Ju transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal Level of Evidence	une 2020 to replacemen ressed. nonths (med Study Me Non-rand prospecti Relevant	November 2020, 1: t diameter ≥23 mm t using Edwards SA lian) thod/Design omized, ve Data	5 congenital heart patients received Optimus-XXL st PIENTM valve. Standard Question Applied Treatment Benefit, Treatt (Common)	with dysfunctiona ents before procees safety and outcom ment Harms	Oxf 201 1	o transca e ford LO 1 2 3 Gradina	E 4 5 g	congenital heart patients wir dysfunction l RVOTs at target transcathete pulmonary valve replacemen
laddad	Method: From Ja transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal Level of Evidence Suitability Device	une 2020 to replacemen ressed. nonths (med Study Me Non-rand prospecti Relevant 40 mm la	November 2020, 1: t diameter ≥23 mm t using Edwards SA lian) ethod/Design omized, ve Data rge PTS sizing ballo	5 congenital heart patients received Optimus-XXL st PIENTM valve. Standard Question Applied Treatment Benefit, Treat (Common)	with dysfunctiona ents before procees safety and outcom ment Harms	Oxf 201 1 D1	o transca e ford LO 1 2 3 Gradina D2	E 4 5 g D3	congenital heart patients wir dysfunction l RVOTs at target transcathete pulmonary valve replacemen
Iaddad t al.	Method: From Ju transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal Level of Evidence	une 2020 to replacemen ressed. nonths (med Study Me Non-rand prospecti Relevant 40 mm la Balloon i	November 2020, 1: t diameter ≥23 mm t using Edwards SA lian) ethod/Design omized, ve Data rge PTS sizing ballenterrogation of large	5 congenital heart patients received Optimus-XXL st PIENTM valve. Standard Question Applied Treatment Benefit, Treath (Common) Doon catheter (NuMED, Inc e conduit-free RVOTs	with dysfunctiona ents before procees safety and outcon ment Harms	Oxf 201 1	o transca e ford LO 1 2 3 Gradina	E 4 5 g	congenital heart patients wir dysfunction l RVOTs an target transcathete pulmonary valve replacemen diameter ≥.
Haddad t al.	Method: From Ja transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal Level of Evidence Suitability Device	 une 2020 to replacement replacement ressed. nonths (median Study Median Non-rand prospection Relevant 40 mm la Balloon i Congenitie transcathed 	November 2020, 1: t diameter ≥23 mm t using Edwards SA lian) ethod/Design omized, ve Data rge PTS sizing balle nterrogation of large al heart patients wit eter	5 congenital heart patients received Optimus-XXL st PIENTM valve. Standard Question Applied Treatment Benefit, Treatr (Common) Doon catheter (NuMED, Inc e conduit-free RVOTs h dysfunctional RVOTs ar	with dysfunctional ents before proceed safety and outcome ment Harms	Oxf 201 1 D1	o transca e ford LO 1 2 3 Gradina D2	E 4 5 g D3	congenital heart patients with dysfunction l RVOTs an target transcathete pulmonary valve replacemen diameter ≥ 2 mm Sampling: n=15
Iaddad t al.	Method: From Ja transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal Level of Evidence Suitability Device Application Patient	 une 2020 to replacemen replacemen ressed. nonths (med Study Med Non-rand prospecti Relevant 40 mm la Balloon i Congenit transcathe pulmonar 	November 2020, 1: t diameter ≥23 mm t using Edwards SA lian) ethod/Design omized, ve Data rge PTS sizing balle nterrogation of large al heart patients wit eter y valve replacemen	5 congenital heart patients received Optimus-XXL st PIENTM valve. Standard Question Applied Treatment Benefit, Treatr (Common) Doon catheter (NuMED, Inc e conduit-free RVOTs h dysfunctional RVOTs ar t diameter ≥23 mm; media	with dysfunctiona ents before procees safety and outcom ment Harms) nd target an age 25.8 years	Oxf 201 1 D1 A1 P1	o transca e ford LO 1 2 3 Gradina D2 A2 P2	E 4 5 D3 A3 P3	congenital heart patients with dysfunctior l RVOTs an target transcathete pulmonary valve replacemen diameter ≥2 mm Sampling:
Iaddad t al.	Method: From Ja transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal Level of Evidence Suitability Device Application	 une 2020 to replacemen replacemen ressed. nonths (med Non-rand prospecti Relevant 40 mm la Balloon i Congeniti transcathe pulmonar The articl 	November 2020, 1: t diameter ≥23 mm t using Edwards SA lian) ethod/Design omized, ve Data rge PTS sizing ballenterrogation of large al heart patients wite eter y valve replacementer e contains sufficienter y valve replacementer e contains sufficienter ballenter ballenter ballenter ballenter y valve replacementer ballenter	5 congenital heart patients received Optimus-XXL st PIENTM valve. Standard Question Applied Treatment Benefit, Treatr (Common) pon catheter (NuMED, Inc e conduit-free RVOTs h dysfunctional RVOTs ar t diameter ≥23 mm; media t information to be able to	with dysfunctiona ents before procees safety and outcom ment Harms) nd target an age 25.8 years	Oxf 201 1 D1 A1	o transca e ord LO 1 2 3 Gradina D2 A2	E 4 5 D3 A3	congenital heart patients with dysfunction l RVOTs and target transcathete pulmonary valve replacement diameter ≥2 mm Sampling: n=15 patients Mean Age:
Haddad t al.	Method: From Ja transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal Level of Evidence Suitability Device Application Patient	 une 2020 to replacemen replacemen ressed. nonths (med Non-rand prospecti Relevant 40 mm la Balloon i Congeniti transcathe pulmonar The articl 	November 2020, 1: t diameter ≥23 mm t using Edwards SA lian) ethod/Design omized, ve Data rge PTS sizing balle nterrogation of large al heart patients wit eter y valve replacemen	5 congenital heart patients received Optimus-XXL st PIENTM valve. Standard Question Applied Treatment Benefit, Treat (Common) pon catheter (NuMED, Inc e conduit-free RVOTs h dysfunctional RVOTs ar t diameter ≥23 mm; media t information to be able to nent.	with dysfunctiona ents before procees safety and outcom ment Harms) nd target an age 25.8 years	Oxf 201 1 D1 A1 P1	o transca e ford LO 1 2 3 Gradina D2 A2 P2	E 4 5 D3 A3 P3	heart patients wit dysfunction l RVOTs ar target transcathete pulmonary valve replacemen diameter ≥ 2 mm Sampling: n=15
Haddad et al.	Method: From Ja transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal Level of Evidence Suitability Device Application Patient	une 2020 to replacemen ressed. nonths (med Study Me Non-rand prospecti Relevant 40 mm la Balloon i Congenit transcathe pulmonar The articl rational a	November 2020, 1: t diameter ≥23 mm t using Edwards SA lian) ethod/Design omized, ve Data rge PTS sizing ballenterrogation of large al heart patients wite eter y valve replacementer e contains sufficienter y valve replacementer e contains sufficienter ballenter ballenter ballenter ballenter y valve replacementer ballenter	5 congenital heart patients received Optimus-XXL st PIENTM valve. Standard Question Applied Treatment Benefit, Treat (Common) pon catheter (NuMED, Inc e conduit-free RVOTs h dysfunctional RVOTs ar t diameter ≥23 mm; media t information to be able to nent.	with dysfunctional ents before proceed safety and outcome ment Harms) and target un age 25.8 years undertake a	Oxf 201 1 D1 A1 P1 R1	o transca e ford LO 1 2 3 Grading D2 A2 P2 R2	E 4 5 D3 A3 P3 R3	congenital heart patients with dysfunctior l RVOTs an target transcathete pulmonary valve replacemen diameter ≥2 mm Sampling: n=15 patients Mean Age: 25.8 years
0. Haddad et al. 2022)	Method: From Ju transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal Level of Evidence Suitability Device Application Patient Report	une 2020 to replacemen replacemen ressed. nonths (med Non-rand prospecti Relevant 40 mm la Balloon i Congenit transcathe pulmonar The articl rational a	November 2020, 1: t diameter ≥23 mm t using Edwards SA lian) ethod/Design omized, ve Data rge PTS sizing balle nterrogation of large al heart patients wit eter y valve replacemen e contains sufficien nd objective assessi ant Data eported outcome me ents, complications)	5 congenital heart patients received Optimus-XXL st PIENTM valve. Standard Question Applied Treatment Benefit, Treatr (Common) Doon catheter (NuMED, Inc e conduit-free RVOTs h dysfunctional RVOTs ar t diameter ≥23 mm; media t information to be able to nent. Suitability Gra easures (technical success/ indirectly reflect the inten	with dysfunctional ents before proceed safety and outcome ment Harms) and target undertake a ade (Range 4-12) procedure	Oxf 201 1 D1 A1 P1 R1	o transca e ord LO 1 2 3 Grading D2 A2 P2 R2 R2 Grading	E 4 5 D3 A3 P3 R3	congenital heart patients with dysfunction l RVOTs and target transcathete pulmonary valve replacement diameter ≥ 2 mm Sampling: n=15 patients Mean Age: 25.8 years (median)
Haddad et al.	Method: From Ju transcatheter pulmonary valve prospectively ass Follow-up: 4.5 m Appraisal Level of Evidence Suitability Device Application Patient Report Data Contributi Outcomes/	une 2020 to replacemen replacemen ressed. nonths (med Non-rand prospecti Relevant 40 mm la Balloon i Congenit: transcathe pulmonar The articl rational a ion Relev The r incide perfor The d to ass	November 2020, 1: t diameter ≥23 mm t using Edwards SA lian) ethod/Design omized, ve Data rge PTS sizing ballenterrogation of large al heart patients wite eter y valve replacement e contains sufficient nd objective assessing ant Data eported outcome me ents, complications) mance of the device uration of follow-up	5 congenital heart patients received Optimus-XXL st PIENTM valve. Standard Question Applied Treatment Benefit, Treatr (Common) Doon catheter (NuMED, Inc e conduit-free RVOTs h dysfunctional RVOTs ar t diameter ≥23 mm; media t information to be able to nent. Suitability Gra easures (technical success/ indirectly reflect the inten	with dysfunctiona ents before proceed safety and outcome ment Harms) ad target undertake a ade (Range 4-12) procedure ded ems acceptable	Oxf 201 1 D1 A1 P1 R1	o transca e ord LO 1 2 3 Grading D2 A2 P2 R2 R2 Grading	E 4 5 g D3 A3 P3 R3 g	congenital heart patients with dysfunctior l RVOTs an target transcathete pulmonary valve replacemen diameter ≥2 mm Sampling: n=15 patients Mean Age: 25.8 years (median) Sex: M - 8

Clinical significance		magnitude of the ificant (valve fund	treatment benefit observed w	as clinically	Yes 1	N	o 2
significance	Data Contribution Grade (Range 4-8)						
						5	
		Disposition and W					
S&P Grade (Range 9-25)) +) + Suitability (5) ontribution $(5) = 1$	Disposition and Weighting (select) 3	Accepted and I Accepted but Excluded, 22-2	not Pivo		-21
Relevant S&P	P Results:						
Criteria	Results.	Results				P valu	ie
Safety data - Intraprocedur	ral	expansion, sten sheath during d	incidents/complications cons t slipping from Altosa-XL Ge elivery, stent slipping off BII l conduit rupture; none were	emini balloon insid 3 into RVOT during	e g	N/A	
Safety data –	Follow/up	During a media	n follow-up of 4.5 months (ra ction or rapid increase of val- ak was noted.		no	N/A	
Benefits/claim	ms data	None				N/A	
Strengths		sizes and anatom Optimus-XXL	acy were proven across a wid mical variations; first 15 succ stents to secure large dysfunc ulmonary valve replacement (essful implantation tional RVOTs prio	is of r to	N/A	
Weaknesses/ Potential bias		Thin struts of th	ne Optimus stent can be a disa landing zone is required.			N/A	
Conclusions o RVOTs with e armamentariur	of the author xcellent preli n for routine	iminary results. O and complex tran	the first implantations of Opt ptimus-XXL should be consi scatheter pulmonary valve re	dered as a valuable placement procedu	adjunct res.	ctional in the	
Device used: 4	40 mm large	PTS sizing balloo	n catheter (NuMED, Inc., Ho	pkinton, NY, USA)		
Objective: Pre Method: Case	esent the first report		safety due to quantity of pati e with the Venus P-valve (Ve				tients. wit tetr Fal
Follow-up: 2 v	~ .		o			rd LOE	unu cor
Appraisal	Appraisa Level of Study Question Applied						
Appraisal Level of		d/Design			2011		4 5 ana
Appraisal		d/Design eport	Treatment Benefit, Treatmen (Common)	nt Harms	1 2	3	unc sur
Appraisal Level of Evidence	Metho Case re	eport		nt Harms			unc sur rep
Appraisal Level of	Metho Case re Releva		(Common)	nt Harms		Grading D2	g mo
Appraisal Level of Evidence Suitability	Metho Case re Releva 40 mm Check	eport ant Data a PTS-X sizing ba the size and diste	(Common) lloon (NuMed) nsibility of the outflow tract;		(Grading	g unc sur g D3 pul A3 hor
Appraisal Level of Evidence Suitability Device	Metho Case re Releva 40 mm Check distal f Born v prior h	eport Int Data In PTS-X sizing ba the size and diste flare of the percuta vith tetralogy of F istory of surgical	(Common)	adaptation of the rtery anatomy,	D1	Grading D2	g D3 pul A3 hor P3 pre wit
Appraisal Level of Evidence Suitability Device Application	Metho Case re 40 mm Check distal f Born v prior h mean a Case re	eport ant Data h PTS-X sizing ba the size and diste flare of the percuta with tetralogy of F history of surgical age 17.5 years eport thereby artic	(Common) lloon (NuMed) nsibility of the outflow tract; aneous pulmonary valve allot with unusual coronary a	adaptation of the rtery anatomy, y regurgitation;	D1 A1	Grading D2 A2	g Understand



		r c	SSCP – Sizing				
	Data Contribution	Relevant Data			Gra	ding	Mean Age:
	Outcomes/ Endpoints		ures (technical success/echoor) indirectly reflect the intend		Yes 1	No 2	13.5 years Sex:
	Follow-up	The duration of follow-up (pre-discharge, six months) se r duration of treatment benef		Yes 1	No 2	M - 1 F - 1
	Statistical analysis	No statistical analysis of the	data has been provided.		Yes 1	No 2	
	Clinical significance	The magnitude of the treatm significant (valve function, a	ent benefit observed was cli arrhythmia).	nically	Yes 1	No 2	
		<u> </u>	Data Contribution Grac	le (Range 4-8)	5	5	
	Overall S&P An	praisal, Disposition and Weig	hting				
	S&P Grade (Range 9-25)	LOE (4) + Suitability (6) + Data Contribution (5) = 15	Disposition and Weighting (select)	Accepted and Accepted but 21 Excluded, 22-	t not Pivot		
	Relevant S&P Ro	agulte.					
	Criteria	Results			Р	value	
	Safety data – Intra-procedural	function of valve and exclu 17 year-old male: P-valve outflow tract during uncov narrowed the distal flare of expansion of the valve with a trace of regurgitation.	angiogram confirmed prop aded coronary artery compre- shifted below the bifurcation ering, but was recovered and the valve. Final angiogram h unobstructed flow to the pu	ssion. to the middle of redeployed whi confirmed full ilmonary arterie	ich N	/A	
	Safety data – Follow-up	echocardiograms showed g regurgitation; ECG-Holter 17 year-old male: Pre-discl	scharge and six-month follow good function of the valve wi monitoring showed no arrhy harge and follow-up echocar Holter monitoring showed a	th trivial central thmia. diograms confir	N	/A	
	Benefits/claims data	None			N	/A	
	Strengths	First Polish experience wit pediatric patients.	h the Venus P-valve (Venus	MedTech) in tw	'0 N	/A	
	Weaknesses/ Potential bias	None reported			Ν	/A	
	Conclusions of th	es not contribute to SOA. he authors: None nm PTS-X sizing balloon (Nul	Med)				
organ al.	Safety & Perform Objective: Preser	nance (only contributes to safe at the first clinical experience w isease applications. port ks	ety due to quantity of patient	s (n=2) and clini re covered stent	ical applica , designed	for	Population : patients diagnosed with a superior sinus venous defect
)22)	Evidence	Method/Design Case report Trea	ttment Benefit, Treatment Ha	arms	2011	3 4 5	Sampling: n=2 patients



errogation over an in to right internal 30mm diameter PT 500 (Numed Inc.) th a superior sinus t thereby article co a rational and object tata	venous defect; mean age 38 y ntain limited information to be	ears e able to	D1 A1 P1 R1	D2 A2 P2 R2 5	D3 A3 P3 R3	
in to right internal 30mm diameter PT 5000 (Numed Inc.) th a superior sinus t thereby article co a rational and object rata	jugular was first performed wi S venous defect; mean age 38 ye ntain limited information to be ctive assessment.	ears e able to	P1	P2 R2	P3	
th a superior sinus t thereby article co a rational and object	ntain limited information to be ctive assessment.	e able to		R2	-	
t thereby article co a rational and object	ntain limited information to be ctive assessment.	e able to	R1		R3	
	Suitability Grade (Range 4-12)		5		
d outcome measur	evant Data			Grading		
e reported outcome measures (technical success) indirectly reflect Yes 1 intended performance of the device.					No 2	
e duration of follow-up (post-procedure, two weeks) seems Yes 1 No 2 ceptable to assess whether duration of treatment benefits/harms and intify complications.					No 2	
statistical analysis of the data has been provided. Yes 1				No 2		
te magnitude of the treatment benefit observed was clinically gnificant (no evidence of pulmonary vein or superior vena cava enosis, complete stent stability).					No 2	
I		(Range 4-8)		5		
		21 Excluded, 22	2-25			
ilts				Pv	value	
Safety data – Post- proceduralHemodynamic, angiographic, and echocardiographic parameters at end of the procedures suggested a minimal left-right shunt with no evidence of pulmonary vein stenosis, or superior vena cava stenosi		the NI/A				
Safety data – Follow/upFollow-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				N/2	A	
enefits/claims data None				N/2	A	
First-in-human description of G-ARMOR stent.				N/2		
Dr. Morgan is a consultant for NuMED Inc.						
	to assess whether of mplications. al analysis of the of tude of the treatme (no evidence of pur omplete stent stabil) position and Weig Suitability $(5) +$ ibution $(5) = 14$ dts odynamic, angiographic of the procedures serve of pulmonary plete stability of the ow-up at two week factory. The clinic uction to pulmona ight shunt on the t w-up for the patient	to assess whether duration of treatment benefits/ mplications. al analysis of the data has been provided. Tude of the treatment benefit observed was clinic (no evidence of pulmonary vein or superior vena mplete stent stability). Data Contribution Grade Dosition and Weighting Suitability $(5) +$ ibution $(5) = 14$ Disposition and Weighting (select) Disposition and	to assess whether duration of treatment benefits/harms and mplications. al analysis of the data has been provided. Tude of the treatment benefit observed was clinically (no evidence of pulmonary vein or superior vena cava mplete stent stability). Data Contribution Grade (Range 4-8) Dosition and Weighting Suitability $(5) +$ ibution $(5) = 14$ Disposition and Weighting (select) Accepted by 21 Excluded, 22 Its odynamic, angiographic, and echocardiographic parameters at of the procedures suggested a minimal left-right shunt with no ence of pulmonary vein stenosis, or superior vena cava stenosis olete stability of the stents. w-up at two weeks including a negative bubble study was equa factory. The clinical result in all cases was excellent with no uction to pulmonary venous return and no visible ight shunt on the transthoracic echo on 24 hours and two weeks w-up for the patient with sinus venosus defects.	to assess whether duration of treatment benefits/harms and mplications. al analysis of the data has been provided. Yes 1 Tude of the treatment benefit observed was clinically (no evidence of pulmonary vein or superior vena cava mplete stent stability). Data Contribution Grade (Range 4-8) osition and Weighting Suitability (5) + ibution (5) = 14 Disposition and Weighting (select) Accepted and Pivot Accepted but not 1 21 Excluded, 22-25 Accepted suggested a minimal left-right shunt with no ence of pulmonary vein stenosis, or superior vena cava stenosis and olete stability of the stents. w-up at two weeks including a negative bubble study was equally factory. The clinical result in all cases was excellent with no uction to pulmonary venous return and no visible ight shunt on the transthoracic echo on 24 hours and two week w-up for the patient with sinus venosus defects.	to assess whether duration of treatment benefits/harms and mplications. al analysis of the data has been provided. Yes 1 tude of the treatment benefit observed was clinically (no evidence of pulmonary vein or superior vena cava omplete stent stability). Data Contribution Grade (Range 4-8) 5 position and Weighting Suitability (5) + ibution (5) = 14 Disposition and Weighting (select) Accepted and Pivotal 9-1 Accepted but not Pivota 21 Excluded, 22-25 Mts Product and echocardiographic parameters at the of the procedures suggested a minimal left-right shunt with no ence of pulmonary vein stenosis, or superior vena cava stenosis and belet stability of the stents. w-up at two weeks including a negative bubble study was equally factory. The clinical result in all cases was excellent with no uction to pulmonary venous return and no visible ight shunt on the transthoracic echo on 24 hours and two weeks w-up for the patient with sinus venosus defects.	



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

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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 - <u>Ongoing planned post-market clinical follow-up</u> – 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				