NuMED
Post Market Clinical Follow-up Form
Z-6 Atrioseptostomy Catheter

1. PATIENT INFORMATION:

Date of Procedure:	Patient Date of Birth:
Physician:	Hospital:
Physician Phone No.:	Email Address:
Type of Follow-up: ☐ Within 24 Hours ☐ Other (Specify):	

2. DEVICE INFORMATION:

Catalog Number:	Lot Number:

3. INDICATION FOR BAS PROCEDURE BEING PERFORMED:

☐	Transposition of Great Arteries (TGA)	☐	Total Anomalous Pulmonary Venous Drainage without Pulmonary Obstruction
☐	Tricuspid Atresia	☐	Mitral Stenosis
☐	Hypoplastic Left Heart Syndrome	☐	Pulmonary Atresia with Intact Ventricular Septum
☐	Other: _____		

4. CONTRAINDICATIONS: Did the following apply to the patient: _____ Yes _____ No

Balloon atrioseptostomy should not be performed for infants older than six weeks. These infants will have thick atrial septums. Reference AHA/ACC guidelines.

5. PROCEDURAL INFORMATION (please provide at least one dataset below):

	PRE-PROCEDURE:	POST PROCEDURE:
Aorta Saturation	_____	_____
SVC Saturation	_____	_____
Pulse-Ox Saturation	_____	_____
LA to RA Gradient (mean)	_____	_____

6. PROCEDURAL COMPLICATIONS REPORTED:

☐	Perforation of Left Atrial Appendage	☐	Thromboembolic Events
☐	Balloon Detachment	☐	Infection / Inflammation
☐	Rhythm / Conduction Disturbances	☐	Bleeding
☐	Air embolism	☐	Death
☐	Damage to Vascular Intima	☐	Hematoma Formation
☐	Vascular Perforation	☐	Conduction System Injury
☐	Other: _____		

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7. DEVICE COMPLICATIONS REPORTED:

☐	Guidewire Issue	☐	Inflation/Deflation Issues
☐	Kinking	☐	Difficulty Withdrawing Catheter
☐	Difficulty with Introducer	☐	Balloon Detachment
☐	Balloon Rupture: _____ CCs	☐	Other: _____

8. EXPLAIN ANY COMPLICATION NOTED AND ITS RELATIONSHIP TO THE DEVICE:

9. OTHER COMMENTS:

10. DO YOU CONSIDER THE PROCEDURE A SUCCESS: ☐ **Yes** ☐ **No**

Please email or fax the completed form and any associated follow up to: mthomas@numedusa.com or 1-315-328-4941.