

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: <input type="checkbox"/> Within 24 Hours <input type="checkbox"/> Other (Specify): | |

2. DEVICE INFORMATION:

| | |
|-----------------|-------------|
| Catalog Number: | Lot Number: |
|-----------------|-------------|

3. INDICATION FOR BAS PROCEDURE BEING PERFORMED:

| | |
|---|---|
| <input type="checkbox"/> Transposition of Great Arteries (TGA) <input type="checkbox"/> Tricuspid Atresia <input type="checkbox"/> Hypoplastic Left Heart Syndrome <input type="checkbox"/> Other: _____ | <input type="checkbox"/> Total Anomalous Pulmonary Venous Drainage without Pulmonary Obstruction <input type="checkbox"/> Mitral Stenosis <input type="checkbox"/> Pulmonary Atresia with Intact Ventricular Septum |
|---|---|

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

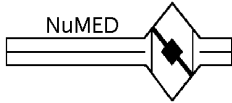
Balloon atrioseptostomy should not be performed for infants older than six weeks. These infants will have thick atrial septums. Reference AHA/ACC guidelines.

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:

| | |
|--|--|
| <input type="checkbox"/> Perforation of Left Atrial Appendage <input type="checkbox"/> Balloon Detachment <input type="checkbox"/> Rhythm / Conduction Disturbances <input type="checkbox"/> Air embolism <input type="checkbox"/> Damage to Vascular Intima <input type="checkbox"/> Vascular Perforation <input type="checkbox"/> Other: _____ | <input type="checkbox"/> Thromboembolic Events <input type="checkbox"/> Infection / Inflammation <input type="checkbox"/> Bleeding <input type="checkbox"/> Death <input type="checkbox"/> Hematoma Formation <input type="checkbox"/> Conduction System Injury |
|--|--|



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7. DEVICE COMPLICATIONS REPORTED:

| | | | |
|--------------------------|----------------------------|--------------------------|---------------------------------|
| <input type="checkbox"/> | Guidewire Issue | <input type="checkbox"/> | Inflation/Deflation Issues |
| <input type="checkbox"/> | Kinking | <input type="checkbox"/> | Difficulty Withdrawing Catheter |
| <input type="checkbox"/> | Difficulty with Introducer | <input type="checkbox"/> | Balloon Detachment |
| <input type="checkbox"/> | Balloon Rupture: _____ CCs | <input type="checkbox"/> | Other: _____ |

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

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9. OTHER COMMENTS:

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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.