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. TYPE OF PROCEDURE BEING PERFORMED:

☐ Balloon Atrioseptostomy ☐ Other: _____

4. CONTRAINDICATIONS: Did the patient have any of the following:

Not Applicable

5. PROCEDURAL COMPLICATIONS REPORTED:

☐ Perforation of Left Atrial Appendage
☐ Balloon Detachment
☐ Rhythm / Conduction Disturbances
☐ Balloon Rupture _____ CCs
☐ Embolization
☐ Infection / Inflammation
☐ Bleeding
☐ Death

6. DEVICE COMPLICATIONS REPORTED:

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

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

8. OTHER COMMENTS:

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

Please email or fax the completed form to: mthomas@numedusa.com or 1-315-328-4941