

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:
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3. TYPE OF PROCEDURE BEING PERFORMED:

Balloon Atrioseptostomy Other: _____

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

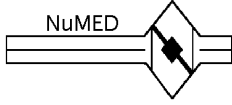
Not Applicable

5. PROCEDURAL COMPLICATIONS REPORTED:

<input type="checkbox"/> Perforation of Left Atrial Appendage	<input type="checkbox"/> Embolization
<input type="checkbox"/> Balloon Detachment	<input type="checkbox"/> Infection / Inflammation
<input type="checkbox"/> Rhythm / Conduction Disturbances	<input type="checkbox"/> Bleeding
<input type="checkbox"/> Balloon Rupture _____ CCs	<input type="checkbox"/> Death

6. 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	



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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