

NuMED
Post Market Clinical Follow-up Form
NuDEL System

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:

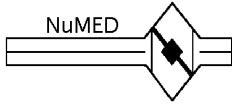
Coarctation of the Aorta (CoA) Other: _____
 Right Ventricular Outflow Tract (RVOT)

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

<input type="checkbox"/>	Patients too small to allow safe delivery of the stent without compromise to the systemic artery used for delivery
<input type="checkbox"/>	Unfavorable aortic anatomy that does not dilate with high pressure balloon angioplasty (CoA only)
<input type="checkbox"/>	Occlusion or obstruction of systemic artery precluding delivery of the stent (CoA only)
<input type="checkbox"/>	Clinical or biological signs of infection
<input type="checkbox"/>	Active endocarditis
<input type="checkbox"/>	Known allergy to aspirin, other antiplatelet agents or heparin (CoA only)
<input type="checkbox"/>	Pregnancy

5. PROCEDURAL COMPLICATIONS REPORTED:

<input type="checkbox"/> Femoral Artery Injury, Thrombosis or Pseudoaneurysm <input type="checkbox"/> Stent Migration <input type="checkbox"/> Stent Fracture <input type="checkbox"/> Aortic Rupture / Tear <input type="checkbox"/> Hematoma <input type="checkbox"/> Thrombosis / Thromboembolism <input type="checkbox"/> Death <input type="checkbox"/> Endocarditis <input type="checkbox"/> Cell Necrosis <input type="checkbox"/> Balloon Rupture _____ ATMS Inflation device with pressure gauge used? <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Stent Stenosis <input type="checkbox"/> Aortic Aneurysm / Pseudoaneurysm <input type="checkbox"/> Stent Malposition <input type="checkbox"/> Sepsis / Infection <input type="checkbox"/> AV Fistula Formation <input type="checkbox"/> Transitory Arrhythmia <input type="checkbox"/> Bleeding <input type="checkbox"/> Cerebrovascular Incident <input type="checkbox"/> Uncontained Disruption (RVOT) <input type="checkbox"/> None
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6. DEVICE COMPLICATIONS REPORTED:

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

Guidewire Issue
Device / Stent Damage During Procedure
Stent Deployment
Balloon Rupture _____ ATMS

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

Inflation / Deflation Issues
Difficulty Withdrawing Device
Sheath Retracting Issues
None

Inflation device with pressure gauge used?
 Yes No

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.