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: ☐ Within 24 Hours ☐ Other (Specify):	

2. DEVICE INFORMATION:

Catalog Number:	Lot Number:

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:

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

5. PROCEDURAL COMPLICATIONS REPORTED:

☐ Femoral Artery Injury, Thrombosis or Pseudoaneurysm
☐ Stent Migration
☐ Stent Fracture
☐ Aortic Rupture / Tear
☐ Hematoma
☐ Thrombosis / Thromboembolism
☐ Death
☐ Endocarditis
☐ Cell Necrosis
☐ Balloon Rupture _____ ATMS

☐ Stent Stenosis
☐ Aortic Aneurysm / Pseudoaneurysm
☐ Stent Malposition
☐ Sepsis / Infection
☐ AV Fistula Formation
☐ Transitory Arrhythmia
☐ Bleeding
☐ Cerebrovascular Incident
☐ Uncontained Disruption (RVOT)
☐ None

Inflation device with pressure gauge used?
☐ Yes ☐ No

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6. DEVICE COMPLICATIONS REPORTED:

☐	Guidewire Issue	☐	Inflation / Deflation Issues
☐	Device / Stent Damage During Procedure	☐	Difficulty Withdrawing Device
☐	Stent Deployment	☐	Sheath Retracting Issues
☐	Balloon Rupture _____ ATMS	☐	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.