INDICATIONS FOR USE:

The NuDEL™ CP Stent® delivery system is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta where there is adequate size and patency of at least one femoral artery associated with one or more of the following: acute or chronic wall injury; nearly atretic descending aorta of 3mm or less in diameter; a non-compliant stenotic aortic segment found on pre-stent balloon dilation; a genetic or congenital syndrome associated with aortic wall weakening or ascending aortic aneurysm.

The NuDEL is indicated for use in the treatment of right ventricle to pulmonary artery (right ventricular outflow tract) conduit disruptions that are identified during conduit pre-dilatation procedures performed in preparation for transcatheter pulmonary valve replacement.

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician. **Contraindications:** Clinical or biological signs of infection. Active endocarditis. Pregnancy. **Contraindications (CoA only):** 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. Curved vasculature. Occlusion or obstruction of systemic artery precluding delivery of the stent. Known allergy to aspirin, other antiplatelet agents, or heparin. **Contraindications (RVOT only):** Patients too small to allow safe delivery of the stent without injury to a systemic vein or to the right side of the heart. **Warnings / Precautions:** Administer appropriate anticoagulation therapy to reduce potential thrombosis. If the patient is not appropriately anticoagulated, thrombus formation may occur. The sheath must be flushed with heparinized saline via the proximal side port prior to introducing the delivery system into the body. The inflated diameter of the stent should at least equal the diameter of the intended implant site. Excessive handling and manipulation of the covering while crimping the stent may cause the covering to tear off of the stent. Retracting the covered stent back into the sheath may cause the covering to catch and tear off of the stent. Do not exceed the RBP. An inflation device with pressure gauge is recommended to monitor pressure. Pressure in excess of the RBP can cause balloon rupture and potential inability to withdraw the catheter into the sheath. Confirm that the distal end of the introducer sheath is at least 2.5cm back from the most proximal image band before inflating the outer balloon. Failure to do so may stretch the outer tubing and severely hinder balloon deflation. Exercise caution when handling the stent to prevent breakage. The NuDEL system, especially at the stent, is rigid and may make negotiation through vessels difficult. The inflation diameter of the balloon used during stent delivery should approximate the diameter of the obstructive vessel and the intended implant site. If resistance is encountered upon removal, the whole system (balloon, guidewire and sheath) should be removed as a single unit, particularly if balloon rupture or leakage is known or suspected. **Warnings / Precautions (CoA only):** Coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta should be confirmed by diagnostic imaging. The NuMED CP Stent has not been evaluated in patients weighing less than 20kg. The platinum/iridium stent may migrate from the site of the implant. As with any type of implant, infection secondary to contamination of the stent may lead to aortitis, or abscess. Over-stretching of the artery may result in rupture or aneurysm formation. **Warnings / Precautions (RVOT only):** During the Premarket Approval study the Medtronic Melody valve was used for valve restoration. The safety and effectiveness of the Covered CP Stent for pre-stenting of the right ventricular outflow tract (RVOT) landing zone (i.e. prophylaxis or prevention of either RVOT conduit rupture or TPVR fracture; use as a primary RVOT conduit) in preparation of a transcatheter pulmonary valve replacement (TPVR) has not been evaluated. As with any type of implant, infection secondary to contamination of the stent might lead to endocarditis, or abscess formation. The Covered Stent can migrate from the site of implant potentially causing obstruction to pulmonary artery flow. Over-stretching of the RVOT may result in rupture or aneurysm of the RV-PA conduit or the native pulmonary artery. **Refer to the IFU for a complete listing of indications, contraindications, warnings and precautions. www.bisusa.org**

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NuMED

Enhanced Delivery

NuDEL™
CP Stent® Delivery System

For Treatment of Coarctation of the Aorta and RVOT Conduit Disruption

ALL-IN-ONE FOR ENHANCED DELIVERY

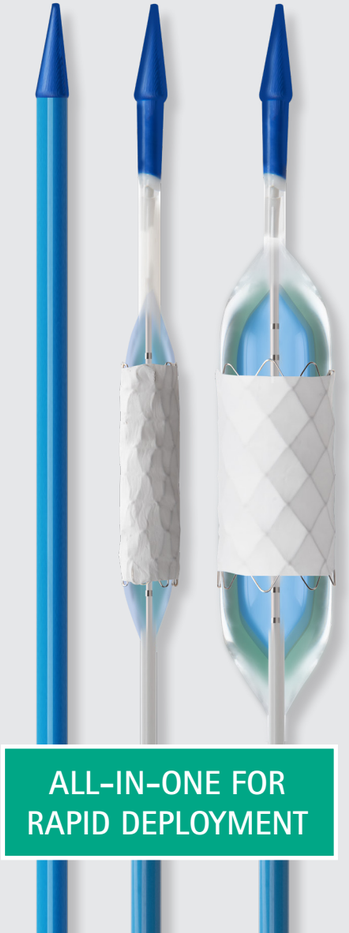
The NuDEL™ CP Stent® Delivery System is an all-in-one device comprised of a pre-mounted Covered CP Stent™ on a balloon in balloon (BIB®) catheter that is pre-loaded inside of a kink-resistant sheath for enhanced delivery and ease of use.

- Integrated sheath eliminates the need for a separate introducer and protects the stent during delivery
- Pre-loaded system eliminates the need to hand crimp or load the mounted stent into an introducer
- Soft, atraumatic, tapered catheter tip allows for safe tracking through the vasculature
- BIB catheter allows for controlled and incremental expansion of the Covered CP Stent

NuDEL™ SIZE MATRIX

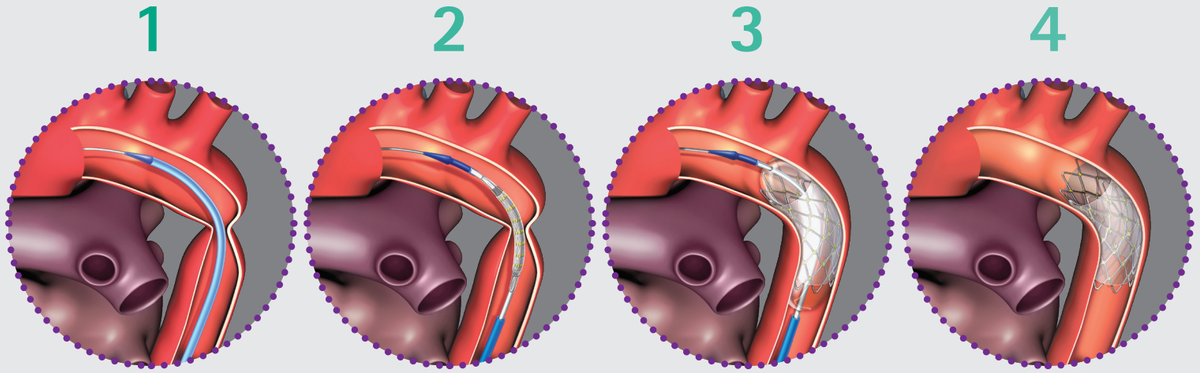
Stent Length (cm)	Balloon Diameter (mm)						
	12	14	16	18	20	22	24
1.6	MTO	MTO	MTO				
2.2	MTO	MTO	MTO	MTO			
2.8		MTO	✔	✔	✔		
3.4		✔	✔	✔	✔	MTO	
3.9		✔	✔	✔	✔	✔	✔
4.5		MTO	MTO	MTO	✔	✔	✔

All NuDEL configurations have a usable length of 100cm and 0.035" guidewire compatibility.
MTO indicates a size that is made to order with an approximate lead time of 6-8 weeks.
✔ Indicates a size that is stocked and available to order.



ALL-IN-ONE FOR RAPID DEPLOYMENT

FOUR-STEP DEPLOYMENT PROCESS



1. The guidewire is advanced to the target area, followed by the NuDEL System
2. The sheath is retracted, exposing the Covered CP Stent prior to expansion
3. Controlled stent expansion by inflation of the inner and outer balloon
4. Covered CP Stent is implanted