Reduction Device in the Coronary Sinus for Refractory Angina

Reducer™ System

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ICD-10 Coordination and Maintenance Committee
September 8, 2020

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Clinical Need Background

Refractory Angina

- Disabling angina (RA) refractory to medical and interventional therapies defined as at least 3 months of angina due to demonstrated coronary insufficiency that persists despite:
  - Optimal medical therapy
  - Not amenable to percutaneous or surgical revascularization

Mannheimer C, Camici P, Chester MR et al. The problem of chronic refractory angina; report from the ESC Joint Study Group on the Treatment of Refractory Angina. Eur Heart J 2002;23:355-70.

Clinical Need Background (Continued)

Refractory Angina

- Estimate of 1.8 million patients in U.S. have refractory angina[1]
  - 50,000 to 100,00 new cases per year
- Following percutaneous coronary intervention and despite adequate anti-ischemic therapy, 20-30% of patients continue to experience angina [2]
- These patients have limited treatment options and are thus referred to as ‘no-option’ patients

1. Henry TD, Satran D, Jolicoeur EM. Treatment of refractory angina in patients not suitable for revascularization. Nat Rev Cardiol 2014;11:78-95
2. Gallone, et al. Refractory Angina from Pathophysiology to New Therapeutic Nonpharmacological Technologies JACC 2020;13:1-19

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Treatment Options Beyond Medical Therapy

- Enhanced External Counterpulsation (EECP)
- Neuromodulation Spinal Cord Stimulation
- Transcutaneous Electrical Neural Stimulation (TENS)
- Transmyocardial Laser Revascularization (TMLR)
- None of these available options are widely utilized today

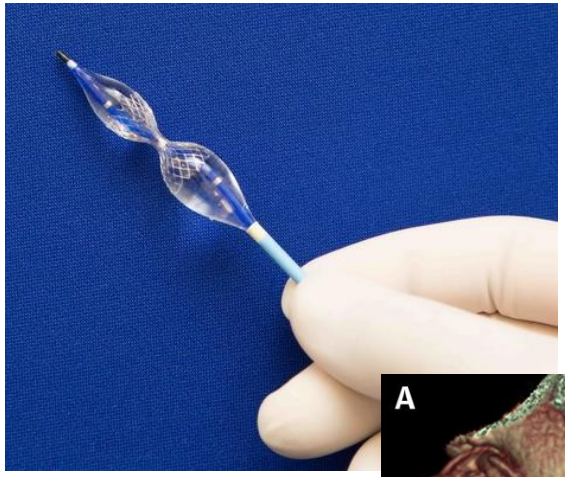
Neovasc Reducer ™ System

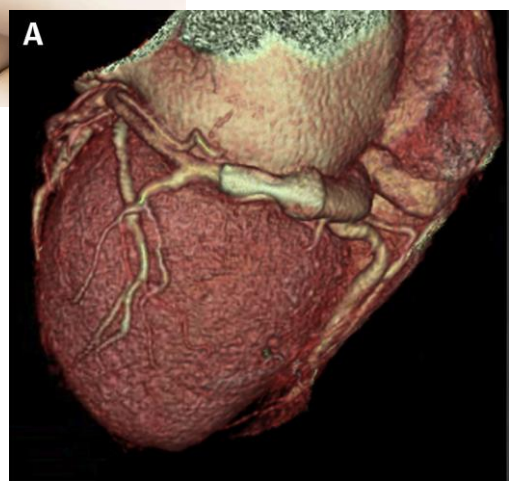
- The Reducer is intended for patients suffering from refractory angina pectoris despite guideline directed medical therapy, who are unsuitable for revascularization by coronary artery bypass grafting (CABG) or by percutaneous coronary intervention (PCI)
- Clinical evidence shows a very high safety profile with a 70-80% improvement in symptoms and quality of life

Data on file at Neovasc

Neovasc Reducer System

- Comprises the Reducer device pre-mounted on the Reducer Balloon Catheter
- Hour-glass shaped device placed in the coronary sinus (CS)
- Creates a permanent and controlled narrowing of the CS intended to improve perfusion to ischemic myocardium
  - Relieving symptoms of refractory angina

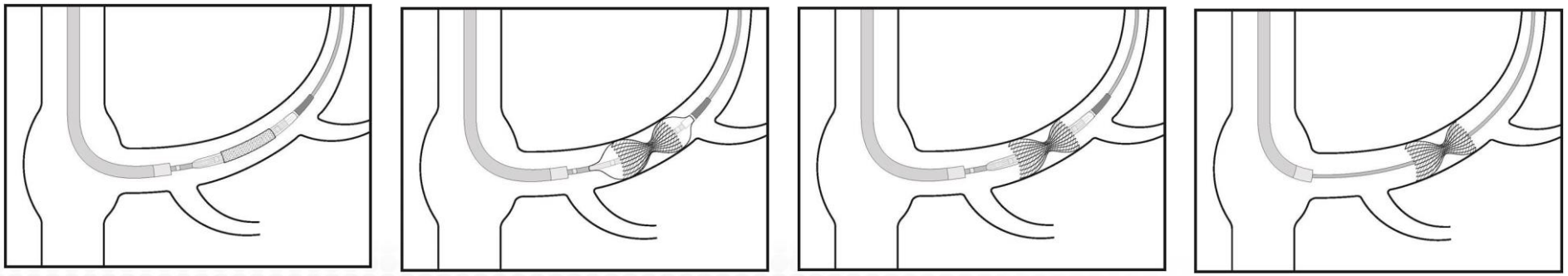




Parikh P: *J Am Coll Cardiol*. 2018 Dec 18;72(24):3227-3228

Procedure Description

- Right jugular venous access is obtained under ultrasound
- Catheter is advanced and inserted into the ostium of the coronary sinus
- Guidewire is advanced further into the coronary sinus
- Reducer catheter system is advanced over wire to landing zone in CS
- Balloon-expandable Reducer device is inflated
- Balloon catheter is deflated and removed from the CS leaving the Reducer permanently implanted



Medical Documentation

- Reduction device implanted into coronary sinus for treatment of refractory angina (RA)
- Reduction of the coronary sinus diameter with device implant
- Coronary sinus reduction implant
- Reducer
- Neovasc Reducer System

Data Concerns

Having a unique ICD-10-PCS code for implantation of a reduction device into the coronary sinus for refractory angina will allow:

- Identification of this procedure
- Tracking and quantifying of utilization
- Outcomes analysis