

# PATIENTS WITH REFRACTORY ANGINA ARE OFTEN CALLED NO OPTION PATIENTS



The Neovasc Reducer™ System  
Puts a Solution in Your Hands

innovative cardiovascular devices

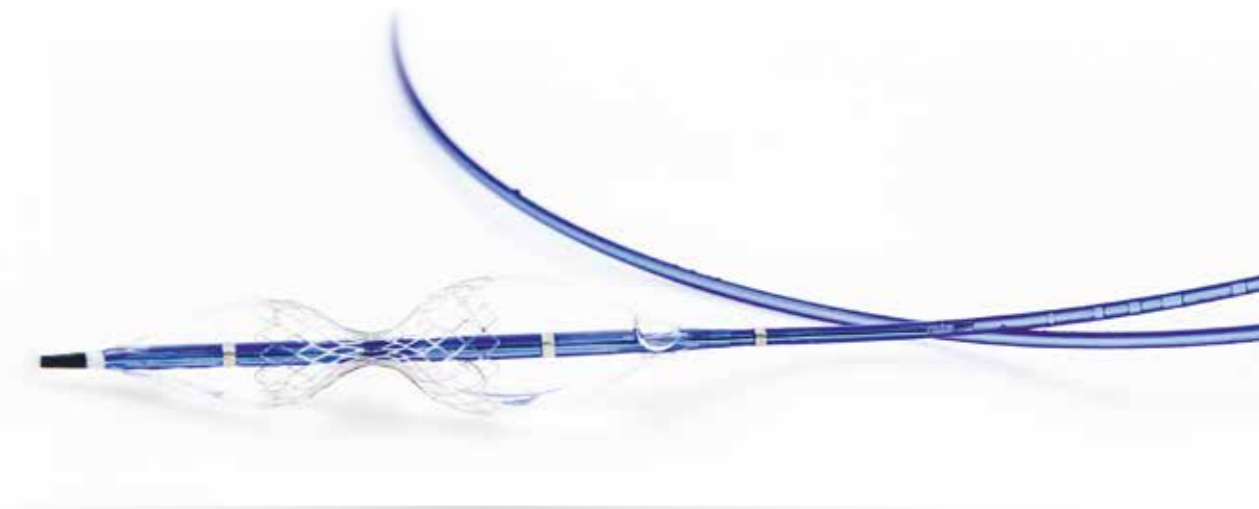


# THE PROBLEM OF REFRACTORY ANGINA

Refractory angina is caused by coronary insufficiency due to obstructive coronary artery disease. It is a type of reversible myocardial ischemia that cannot be controlled by a combination of medical therapy, angioplasty or coronary bypass surgery<sup>1</sup>. Consequently patients are typically labelled "no option" patients<sup>2</sup>.

Refractory angina leads to

- Significant disability
- Limited quality of life
- Multiple medications
- Frequent hospital admissions<sup>1, 3, 4, 5, 6, 7</sup>

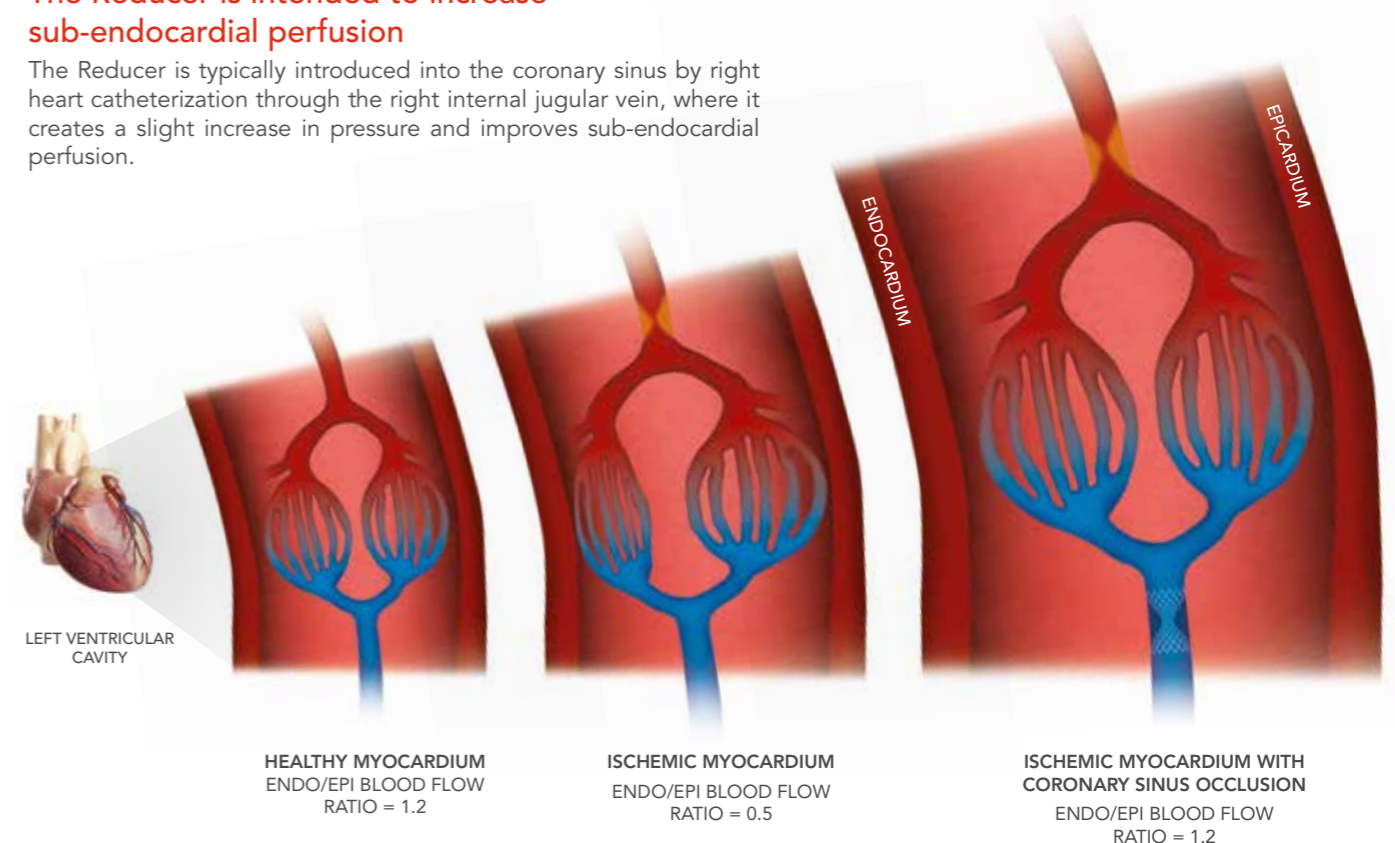


## The Neovasc Reducer™ System: A novel solution

The Reducer is a balloon expandable hourglass-shaped metal mesh. When implanted in the coronary sinus (CS) it creates a focal narrowing to modulate flow and elevate CS pressure. CS narrowing has been demonstrated to improve perfusion to ischemic territories of the myocardium<sup>10</sup> and can lead to relief of symptoms in patients with refractory angina.

## The Reducer is intended to increase sub-endocardial perfusion

The Reducer is typically introduced into the coronary sinus by right heart catheterization through the right internal jugular vein, where it creates a slight increase in pressure and improves sub-endocardial perfusion.



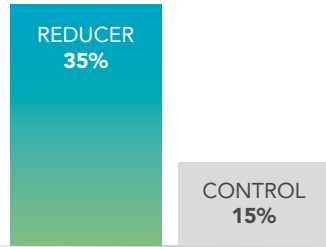
It has been estimated that between **2 and 4%** of the population have angina<sup>8</sup>.

Up to **10%** of these patients have refractory angina<sup>9</sup>, the prevalence of which continues to increase<sup>1</sup>.

<sup>1</sup> European Heart Journal 2002;23:355-370  
<sup>2</sup> Nature Review Cardiology 2014;11:78-95  
<sup>3</sup> European Heart Journal 2013 34, 2949-3003  
<sup>4</sup> European Heart Journal 2006;27:1007-1009  
<sup>5</sup> Heart 2004;90:225-230

<sup>6</sup> Am J Cardiol 1999;84:598-600  
<sup>7</sup> Can J Cardiol 2009;25(7):399-401  
<sup>8</sup> ESC 2006  
<sup>9</sup> ESC Joint Study Group 2002

<sup>10</sup> Am J Physiol Heart Circ Physiol 280:H13610-H1367, 2001



### COSIRA successful randomized trial

The aim of the COSIRA trial (Neovasc Reducer™ System for Treatment of Refractory Angina) was to examine whether implantation of the Reducer could effectively and safely improve angina symptoms in patients with obstructive coronary artery disease, CCS class 3 or 4, having concomitant evidence of reversible myocardial ischemia and unsuitable for revascularization. The study involved 104 patients at 11 clinical centers in Belgium, UK, Sweden, the Netherlands, Denmark and Canada.

“Reducer implantation was significantly better than a sham intervention to improve angina symptoms in patients with advanced coronary artery disease unsuitable for revascularization and treated with optimal therapy”<sup>11</sup>

### Percentage of patients with $\geq 2$ CCS Class improvement at 6 months

35% (18/52) of the patients in the Reducer group vs. 15% (8/52) of patients in the control group improved by  $\geq 2$  CCS classes (p =0.024).

### Outstanding safety profile at 6 months

	Reducer	Control
Cardiac death	0	1
MI	2*	3

\* Two events occurred in the same patient. One peri-procedural NSTEMI adjudicated as possibly related to the timing of the procedure. The second NSTEMI was adjudicated as not related to the procedure or device, but a progression of disease in the LCx artery.

### FIM Long-term safety after 3 years<sup>12</sup>

	Baseline	6 months	3 years	P value
CCS class	3.07 ± 0.11	1.73 ± 0.22	1.57 ± 0.23	0.006
Dobutamine Echo ischemia severity	1.33 ± 0.28	0.55 ± 0.25	0.45 ± 0.16	0.02
Thallium SPECT ischemia severity	1.93 ± 0.06	1.47 ± 0.13	0.82 ± 0.26	0.03
Maximal ST segment depression	1.67 ± 0.33	0.78 ± 0.22	0.67 ± 0.33	0.03

The safety and performance of the Neovasc Reducer™ System is maintained 3 years after implantation. The improvement in angina and ischemia severity observed 6 months after implantation of the Reducer was maintained for 3 years<sup>12</sup>.

As with any medical procedure there are risks associated with use of the Neovasc Reducer™ System including, but not limited to, myocardial infarction, continued angina, and implant migration/dislodgement requiring medical intervention. For a complete list of potential complications consult the device Instructions for Use.

<sup>11</sup> New England Journal of Medicine, 2015;372:517-25

<sup>12</sup> JACC March 9 2010 Volume 55 Issue 10A A98.E927



Neovasc Inc., headquartered in Vancouver, B.C. Canada, is a specialty medical device company that develops, manufactures and markets products for the rapidly growing cardiovascular marketplace. Its products include the Neovasc Reducer™ System for the treatment of refractory angina, Tiara™ Mitral Valve with the Tiara™ Delivery System (in development) for the transcatheter treatment of mitral valve disease, and a line of advanced biological tissue products that are used as key components in a variety of third-party medical products, such as transcatheter heart valves.

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