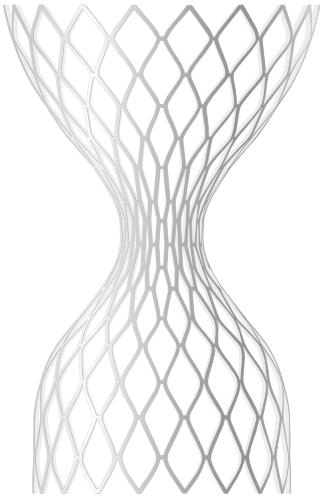
SHOCKWAVE

REDUCER

PROVIDING MUCH-NEEDED RELIEF TO PATIENTS WITH REFRACTORY ANGINA



Millions of patients suffer from angina pain, which is often a symptom of CAD, when plaque buildup occurs in the arteries supplying oxygen-rich blood to the heart, forcing the heart to work harder. Many of these patients can get relief from their angina through revascularization from a coronary intervention or surgery. However, 25-40% continue to suffer from refractory angina even after successful revascularization.[1,2]

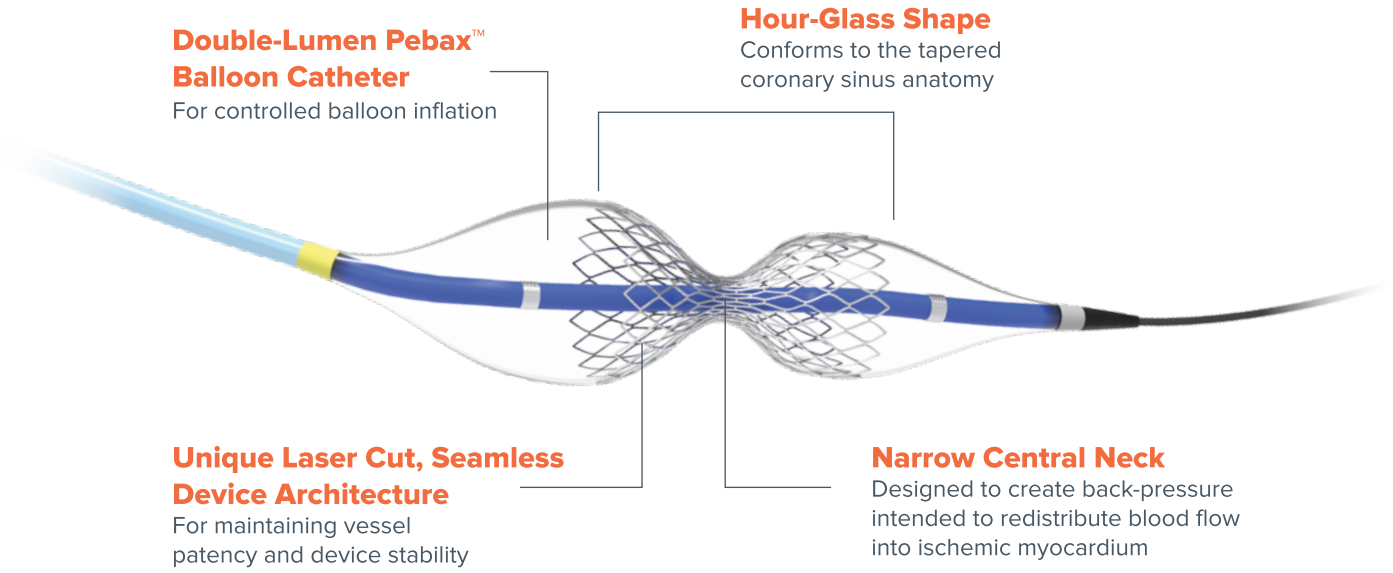
Additionally, angina with no obstructive coronary arteries (ANOCA) is increasingly recognized and may affect nearly one-third of patients undergoing invasive coronary angiography for suspected CAD.[3,4] These patients do not have plaque buildup as a cause for their angina, and currently have limited options.

However, a game-changer is at hand: **Shockwave Reducer is an innovative technology designed to treat symptoms of refractory angina by creating a permanent, controlled narrowing of the coronary sinus**.

INGENIOUSLY DESIGNED FOR ANGINA TREATMENT

Reducer is a small, balloon-expandable, hourglass-shaped device that establishes a narrowing in the coronary sinus. The resulting increase in back pressure redistributes blood into the ischemic myocardium to help reduce angina symptoms.[5]

Before Reducer, there were limited options for treating refractory angina. Now, an effective, innovative solution is on hand for patients and physicians alike to improve perfusion to ischemic myocardium.



PROVEN SAFETY, AND EFFICACY, TO TREAT REFRACTORY ANGINA

COSIRA PROSPECTIVE RANDOMIZED SHAM CONTROLLED TRIAL

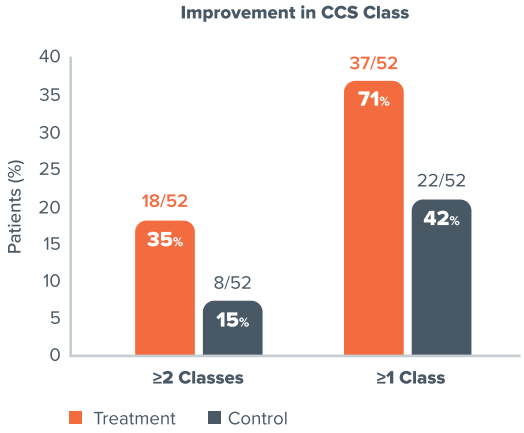
COSIRA trial enrolled 104 patients with Canadian Cardiovascular Society (CCS) class III or IV angina and myocardial ischemia who were not candidates for revascularization. The trial demonstrated patients receiving the Reducer device achieved a statistically significant improvement in angina symptoms and quality of life compared to patients in a sham control group.[6]

71% of patients

improved 1 or more CCS angina classes at 6 months.

35% of patients

improved 2 or more CCS angina classes at 6 months.



Quality of life improved 17.6 points for patients who received the implant, vs. 7.6 points for patients in the control group.

REDUCER I PROSPECTIVE, MULTI-CENTER, POST-MARKET STUDY

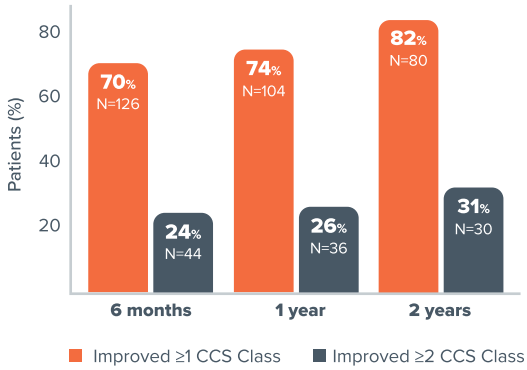
In September 2021, interim results from the REDUCER I trial augmented the findings from the initial COSIRA trial.[7] Patients were enrolled at 20 centers and followed up to 2 years.

82% of patients

improved 1 or more CCS angina classes at 2 years.

31% of patients

improved 2 or more CCS angina classes at 2 years.



For Important Safety Information visit: shockwavemedical.com/reducer-important-safety-information

REDUCER MAY BE A TREATMENT OPTION FOR PATIENTS:

- With refractory angina pectoris and objective evidence of reversible myocardial ischemia.
- Either not amenable to, or are high risk for, revascularization by coronary artery bypass grafting (CABG) or by initial or additional percutaneous coronary intervention (PCI).
- Who are not amenable to available medical treatment.

The coronary microvasculature (rather than epicardial vessels) is now being recognized as significantly contributing to maximal flow to myocardium.[8,9,10] Patients diagnosed with microvascular dysfunction should be considered as potential candidates for Reducer.[11]

References:

1. Abdallah, M. J Am Coll Cardiol 2017;69:2039-50.
2. Stone, G. 2-year results from the ABSORB IV randomized trial. TCT 2019.
3. Patel, M. N Engl J Med 2010; 362:886-895.
4. Samuels, B. J Am Coll Cardiol 2023; 82:1245-1263.
5. Verheye S., *et al.* N Engl J Med 2015;372:519-27.
6. Verheye, S., Jolicœur, E. M., Behan, M. W., Pettersson, T., Sainsbury, P., Hill, J., Vrolix, M., Agostoni, P., Engstrom, T., Labinaz, M., de Silva, R., Schwartz, M., Meyten, N., Uren, N. G., Doucet, S., Tanguay, J.-F., Lindsay, S., Henry, T. D., White, C. J., & Edelman, E. R. (2015). Efficacy of a Device to Narrow the Coronary Sinus in Refractory Angina. New England Journal of Medicine, 372(6), 519-527. https://doi.org/10.1056/nejmoa1402556.
7. Verheye S, Jolicoeur EM, Behan MW, *et al.* Efficacy of a device to narrow the coronary sinus in refractory angina. N Engl J Med 2015; 372: 519–527.
8. Verheye *et al.* Coronary sinus narrowing for the treatment of refractory angina: a multicentre prospective open-label clinical study (the REDUCER-I study) EuroInterv 2021;17:561-68 (report of the first 228 patients).
9. Gallone *et al.* Refractory angina. From pathophysiology to new therapeutic nonpharmacological technologies. JACC CV Interv 2020;13:1-19
10. Padro *et al.* ESC working group on 'coronary pathophysiology and microvascular position paper on coronary microvascular dysfunction in cardiovascular disease' Cardvasc Research 2020; 116:741-755.
11. Data on file at Shockwave Medical.

CAUTION In the United States, Shockwave Reducer is an investigational device, limited by United States law to investigational use.
The Reducer is subject of Investigational testing and is being studied in the COSIRA-II trial in Canada. The Reducer is commercially available in certain countries outside the U.S. and Canada. Please contact your local representative for specific country availability.
Prior to use please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events: ifu.neovasc.com.

Contact Us to Learn More

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