

Miracor Medical granted FDA Breakthrough Device Designation for the PiCSO Impulse System

Awans, Belgium, August 22nd, 2019 - Miracor Medical SA (Miracor Medical) has been granted Breakthrough Device Designation by the U.S. Food and Drug Administration (FDA) for its PiCSO[®] Impulse System for treatment of STEMI patients.

The FDA Breakthrough Device designation is intended to speed time to market for treatments of life-threatening or irreversibly debilitating diseases or conditions and recognizes the novelty of the PiCSO Impulse System and its potential to benefit patients with anterior STEMI heart attacks. The Centers for Medicare & Medicaid Services (CMS) also recently acknowledged the importance of this designation by establishing an alternative reimbursement pathway for products that receive FDA marketing authorization and held the Breakthrough Designation.

PiCSO therapy is provided by interventional cardiologists during PCI (Percutaneous Coronary Intervention) in patients experiencing ST-elevated myocardial infarction (STEMI). The PiCSO Impulse System clears the coronary microcirculation by intermittently occluding the coronary sinus outflow resulting in improved perfusion of the infarcted area of the heart. This mechanism of action is unique and very differentiated.

The PiCSO Impulse System is intended to reduce infarct size after STEMI, which is strongly associated with reductions in heart failure hospitalizations and reduced mortality¹. Heart failure occurs in 18-28% of patients within the first 90 days after STEMI² and the one-year mortality rate for STEMI is 14% despite all improvements and widespread use of reperfusion strategies and adjuvant pharmacological therapies³.

“The Breakthrough Designation demonstrates FDA’s continued commitment to encouraging medical device innovation to address clinical needs and improve patient care. This designation highlights the need for improving care of STEMI patients and will help Miracor accelerate the pathway in the USA.” said Olivier Delporte, CEO.

“Despite effective treatment, patients with STEMI often have large heart attacks, resulting in heart failure. Early studies have shown the potential for PiCSO to reduce infarct size in STEMI. The FDA Breakthrough designation acknowledges the need for therapies like PiCSO that may be able to reduce infarct size in patients with STEMI.” said Prof. Dr. Gregg Stone, NY, USA.

In July of this year, Miracor announced the start of its European randomized study, PiCSO-AMI-I, to further evaluate the benefits of PiCSO therapy as compared with conventional PCI for the treatment of anterior STEMI patients.

About Miracor Medical

Miracor Medical (www.miracormedical.com), located in Awans, Belgium, provides innovative solutions for the treatment of severe cardiac diseases, aiming to improve short and long-term clinical outcomes and reduce associated cost.

Miracor Medical has developed the PiCSO Impulse System, the first and only coronary sinus intervention designed to reduce infarct size, improve cardiac function by clearing microcirculation and potentially reduce the onset of heart failure following acute myocardial infarction.

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NOTE: The PiCSO® Impulse System is not commercially available.

¹ Stone et al. Relationship Between Infarct Size and Outcomes Following Primary PCI: Patient-Level Analysis From 10 Randomized Trials. *J Am Coll Cardiol*. 2016 Apr 12, 67(14), 1674-1683.

² Cahill et al. Heart failure after myocardial infarction in the era of primary percutaneous coronary intervention: Mechanisms, incidence and identification of patients at risk. *World J Cardiol*. 2017 May 26;9(5), 407-415.

³ Szummer, K., et al., Improved outcomes in patients with ST-elevation myocardial infarction during the last 20 years are related to implementation of evidence-based treatments: experiences from the SWEDEHEART registry 1995–2014. *European Heart Journal*, 2017. 38(41): p. 3056-3065.

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