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

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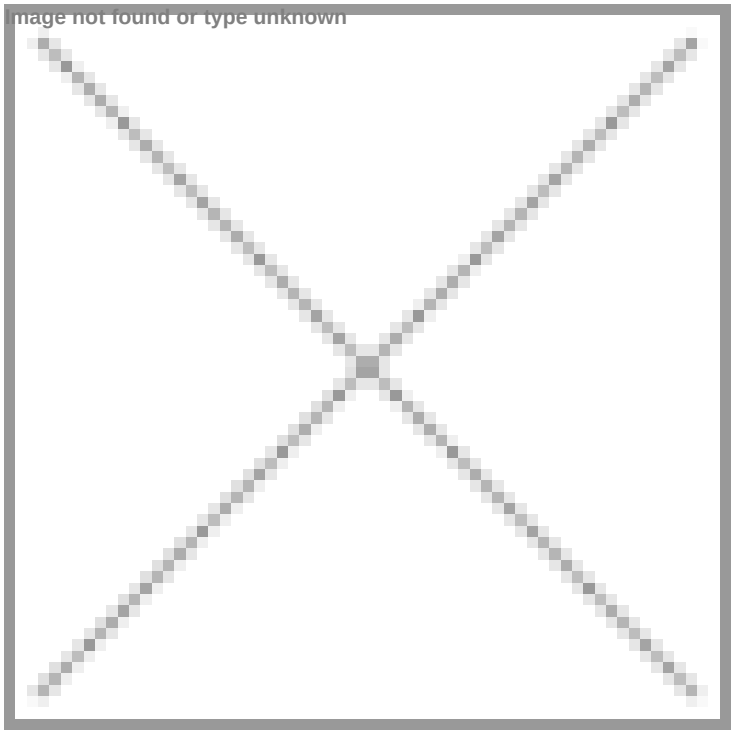

Belgium based Miracor Medical SA (Miracor Medical) has been granted Breakthrough Device Designation by the U.S. Food and Drug Administration (FDA) for its PiCSO® Impulse System for treatment of STEMI patients.

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 mortality[1]. Heart failure occurs in 18-28% of patients within the first 90 days after STEMI[2] and the one-year mortality rate for STEMI is 14% despite all improvements and widespread use of reperfusion strategies and adjuvant pharmacological therapies[3].

“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.