



NEWS RELEASE

Occlutech AFR Heart Failure Device obtains CE mark approval.

Occlutech AG announced today that its atrial flow regulator, the Occlutech AFR device, has obtained CE mark approval clearing it for sales on the European CE regulated market. Occlutech AFR is a next generation intra-atrial shunt device, intended to treat heart failure symptoms by decompressing abnormal intra-atrial pressure. It is placed in the septum between the left atrium and right atrium in a minimally invasive procedure. It is manufactured in different sizes thereby allowing unique patient-oriented and individualized treatment.

In Europe and around the world, millions of patients suffer from heart failure and several hundred thousand die from this condition every year. Many of these patients suffer from decreasing cardiac output that originates from a malfunction of the left heart. As a consequence, the left atrium will dilate and become volume and pressure overloaded. This leads to the most important clinical symptom of heart failure, i.e. pulmonary congestion and shortness of breath. By placing the Occlutech AFR device into the septum and creating a restrictive atrial septal opening by maintaining the correct sizing of a created shunt, the intra cardiac pressure is substantially reduced, thereby improving the heart's function.

"With CE mark approval of the Occlutech AFR we are taking another big step towards becoming a multi-franchise congenital and structural heart disease therapy provider." says Sabine Bois, Co-CEO of Occlutech AG. Additionally, she states that "the Occlutech AFR with its efficacy, versatility, convenience and safety has true potential to revolutionize the way heart failure patients are treated."

Occlutech is one of the leading companies in its field, with several major products including state-of-the-art PFO occluders, ASD occluders among others. Occlutech has sales of congenital and structural heart products in over 80 countries and maintains manufacturing and R&D facilities in Jena, Germany and Istanbul, Turkey. Occlutech has developed many novel products and technologies to improve treatment of patients in these and related areas. (www.occlutech.com).

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