

Media release

Innovative implant for occlusion of heart defects CARAG Completes CE Marking for its Breakthrough Carag Bioresorbable Septal Occluder (CBSO)

Innovative bioresorbable implant of Carag removes risks associated with conventional metal frameworks and expands treatment options for patients with heart defects.

Baar, SWITZERLAND – September 18, 2017

CARAG AG, a privately held medical device development company, today announced that it has completed CE (Conformité Européenne) marking for its Carag Bioresorbable Septal Occluder (CBSO). CE marking allows to fully market the CBSO in the European Union, Switzerland, and other countries.

The CBSO is a first in class structural heart device for treatment of common heart defects. It was developed and clinically tested by Carag and is the world's first transcatheter septal occluder employing a framework which is fully resorbed by the human body. The innovative device is the first major advance in septal occlusion technology in nearly thirty years.

Clinical testing of the CBSO was performed by Prof. Dr. Horst Sievert at the Cardiovascular Center, Frankfurt, Germany, where it was implanted in a series of patients with atrial septal defect (ASD) or patent foramen ovale (PFO). The new implant demonstrated results equal to currently marketed metal framework (legacy) devices. "The CBSO is really a breakthrough!", commented Prof. Sievert. "Since decades we have been waiting for a resorbable device for transcatheter closures. Patients have already heard about this resorbable device and are asking about its availability. I am looking forward to finally providing this alternative to my patients."

An ASD is a hole in the wall between the right and the left atrium of the heart and is one of the most common congenital heart defects. A PFO is a tunnel-like defect between the two atria. It can be responsible for a stroke when a blood clot passes through and travels to the brain.

Currently, ASD and PFO are typically treated using catheter delivered implants composed of a metallic framework. Metal implants remain in the heart for the life of the patient, and are associated with major complications such as erosion, arrhythmia and thrombus formation. "Clinicians believe that a framework which is resorbed by the patient's body after new tissue has grown over the implant will lead to better results and fewer complications." explains Jérôme Bernhard, Chief Executive Officer of Carag. "This is a major benefit for patients requiring a septal closure device."

Carag intends to perform a clinical trial in the United States under an Investigational Device Exemption (IDE), and is in negotiations with multiple international medical device companies for marketing rights.

Further Information/contact

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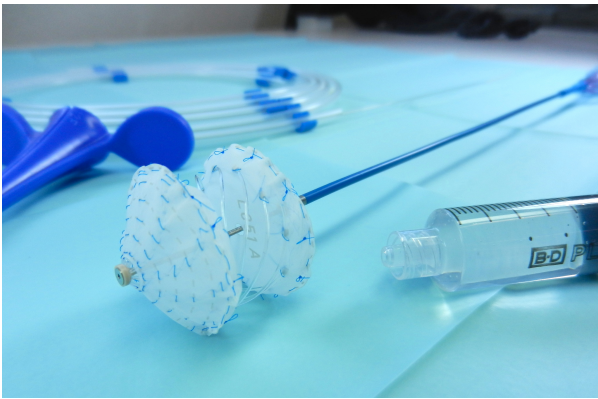
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Picture download: www.carag.com/CBSO

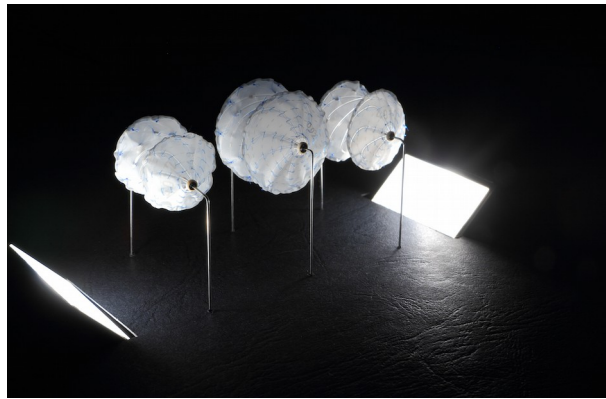
Note: CBSO is not available for commercial distribution in the U.S. and CBSO has not currently received regulatory approval for sale in the U.S.

About CARAG AG

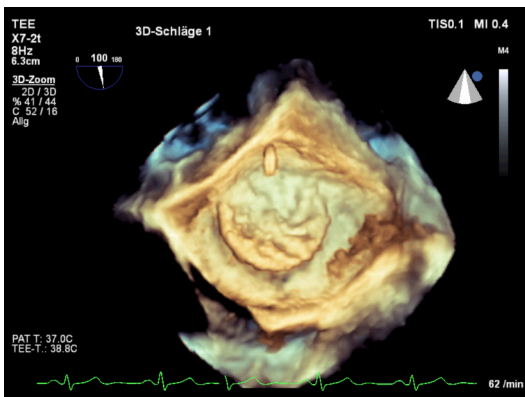
CARAG AG is an innovation–think tank for the medtech industry. As is a leading Swiss engineering company, Carag is point of contact for physicians and medtech companies developing high-quality products for cutting-edge medical applications. Carag has an experienced, performance-driven, interdisciplinary team consisting of engineers, physicians, medical technicians, electronic technicians and software developers. The broad range of services starts with technical feasibility checks and continues with product development through marketing approvals, regardless of the regulatory complexity.



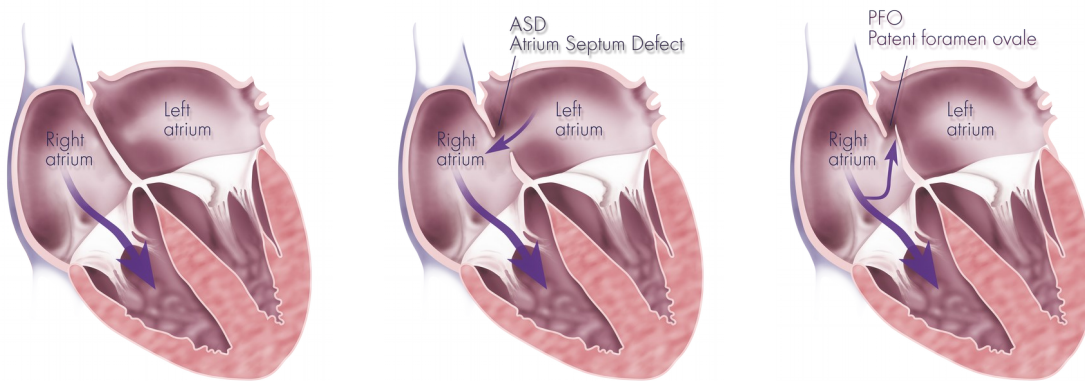
Carag Bioresorbable Septal Occluder (CBSO)



3 sizes of CBSO



Visibility in 3D-Echocardiography



Healthy heart, heart with ASD, and heart with PFO



Picture download: www.carag.com/CBSO