

MEDIA RELEASE

Carag first-ever septal occluder with bioresorbable, metal-free framework available to patients through new European registry

First 3-year-old patient successfully implanted and discharged from hospital in Berlin

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CARAG AG, a Swiss privately held medical device development company, announced today the successful implantation of the first-ever transcatheter septal occluder with bioresorbable, metal-free framework, as part of a new international post-market registry. The study will grow the scientific body of evidence on the use of the CE-marked Carag Bioresorbable Septal Occluder (CBSO), which is designed to reduce complications and to improve patient options for further cardiological interventions, in children and adults.

The CBSO was implanted in a 3-year-old patient with atrium septum defect (ASD) at the German Heart Center Berlin by Professor Stephan Schubert, Senior Cardiologist and Head of the Heart Catheterization Laboratory from the Department of Congenital Heart Disease – Pediatric Cardiology. „The procedure went very well, with excellent closure result and flat device profile. We are excited to be able to offer this novel technology to our pediatric and adult patients,” stated Professor Schubert.

„Having a device without a metal framework has been a desire among physicians since the beginning of transcatheter septal closure. Thanks to its resorbable framework, the CBSO allows us to preserve all options for our patient in case we need to perform a left-sided procedure in the future,” confirmed Professor Felix Berger, Director of the Department of Congenital Heart Disease – Pediatric Cardiology at the German Heart Center Berlin.

Several other leading centers in Germany, Switzerland and in other European countries will participate in the CBSO registry, which is aiming to enroll up to 100 patients. Carag is planning to initiate a clinical study for its CBSO in trials centers in the United States under U.S. FDA Investigational Device Exemption (IDE).

Transcatheter closure is the current standard of care for the treatment of atrial septal defects and patent foramen ovale worldwide. Current implants utilize a metal framework to support the occlusive material and to permanently clamp the septum. The long-term presence of a significant amount of metal in the heart leads to rare but serious complications such as erosion, arrhythmia and thrombus formation. In addition, it forbids crossing of the septum to access the left-side of the heart in following interventions, which significantly reduces future treatment options for those patients.

„CBSO employs a device framework that disappears after fulfilling its primary function following implantation,” explained Jérôme Bernhard, Carag CEO. „This may potentially reduce major device complications and enable future transseptal access for these patients. The number of procedures requiring a transcatheter approach to the left-side of the heart, such as mitral valve repairs and replacements, left atrial appendage closure, or ablation is growing exponentially. Therefore, CBSO addresses an important unmet clinical need by preserving this access route and represents the first major advance in septal occlusion technology in over a decade,” he added.

Note: In the USA, CBSO has not currently received regulatory approval and it is not available for commercial distribution.

About Carag

CARAG AG is a Swiss privately held medical device development company and an innovation think-tank for the medtech industry. As a leading Swiss engineering company, Carag is a 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 of engineers, physicians, medical technicians, electronic technicians and software developers. The company offers a broad range of services, from technical feasibility assessments to product development and market approvals, regardless of the regulatory complexity, in addition to developing own technologies and products.

For further information

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