

PRESS RELEASE

CARAG AG announces successful First-In-Man implantation of the Carag Bioresorbable Septal Occluder – breakthrough in septal occlusion technology!

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CARAG AG announced today the first ever human use of a septal implant with bioresorbable framework.

The Carag Bioresorbable Septal Occluder (CBSO) was implanted in a First-In-Man clinical investigation being performed at the Cardiovascular Center Frankfurt (Frankfurt am Main, Germany). The investigation is being led by Prof. Dr. Horst Sievert and Dr. Björn Söderberg.

Two patients with patent foramen ovale underwent the CBSO procedure. „The procedures went very well, with good closure results. The implant was straightforward to place on the septum, and easy to visualize on X-ray and echo despite not having a metal frame“, stated Prof. Sievert. Physicians have long desired a septal occluder that is resorbable after facilitating defect closure, but previous efforts to create such a device failed due to the challenges associated with resorbable frameworks. The main challenge has been with the implant staying in place on the septum and providing defect closure during the resorption process. „This is an easy device to use, and a very important breakthrough for septal occlusion technology, one we’ve desired as physicians since the beginning of transcatheter septal closure“, stated Dr. Söderberg, who also performed the animal trials supporting the investigation.

Transcatheter device closure of atrial level shunts is the standard of care worldwide. Though complications are typically low, those that do occur are thought to be a result of the metal framework of these devices. „Current septal implants utilize a metal framework to support the occlusive material and to 'clamp' the septum, holding the device in place. CBSO employs a device framework that 'goes away' after fulfilling its primary function following implantation“, explains Jérôme Bernhard, chief executive officer of Carag. „We believe this will lead to fewer major device complications such as erosion, arrhythmia and thrombus formation. CBSO represents the first major advance in septal occlusion technology in over a decade, and takes a major step forward towards the truly 'ideal' septal implant. We expect confirmation of the clinical success of CBSO by fall 2014.“

Further Information:

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About Carag

Carag is part of the Olle Larsson Holding as is the Medela Group. Carag is an innovation-think tank for the medtech industry. As a leading Swiss engineering company and point of contact for physicians, developers, 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.