PRESS RELEASE
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Occlutech® Announces Commercial Cases of Occlutech ASD Occluder Device Implantation in the U.S.

- *Procedures carried out at a number of leading cardiac centers across the country.*
- *The Occlutech ASD Occluder is associated with "positive procedural outcomes, low rate of complications and low rate of supraventricular arrythmias."[i]*

Occlutech, a world leading specialist provider of minimally invasive structural heart devices and their exclusive United States (U.S.) distributor, B. Braun Interventional Systems Inc. (BIS) today announced a significant milestone. Following approval by the Food and Drug Administration (FDA) in December 2023, commercial procedures using the Occlutech ASD Occluder to treat Atrial Septal Defect (ASD) have commenced in the U.S.

ASDs are one of the most common Congenital Heart Defects (CHD) seen in pediatric cardiology.[ii] An ASD is a hole in the septum between the atria, the wall between the two upper chambers of the heart. This opening causes abnormal blood flow between the atrium chambers and usually results in too much blood flow to the lungs. If left untreated, an ASD can lead to fatigue, shortness of breath, pulmonary hypertension, and/or enlargement of the heart.

"*We are excited to witness the successful completion of the first Occlutech ASD Occluder implantation cases in the U.S. following our FDA approval."* said Sabine Bois, CEO of Occlutech. "*This marks yet another significant milestone for Occlutech and underscores our commitment to advancing patient care in the largest congenital and structural heart disease market in the world. We remain dedicated to expanding access to our innovative technologies and improving outcomes for patients worldwide.*"

Several cases have been performed so far at selected catheterization labs prior to roll out across the U.S.

"*The treatment of choice for ASDs is minimally invasive transcatheter closure, a procedure that provides patients with a safe and effective alternative to traditional surgical interventions."* said Dr. Gareth Morgan, Interventional Cardiologist – Children's Hospital Colorado, Aurora, CO. "*The Occlutech ASD Occluder device has demonstrated excellent closure rates and implantation success in over 5,000 studied patients and has been used to treat nearly 100,000 patients in the world so far.[iii] We welcome this device as it gives us an additional option for treating ASDs and enhances our ability to offer patients individualized treatment strategies."*

"In a rare, randomized trial comparing two similarly designed yet different ASD occluder devices, the Occlutech ASD Occluder achieved a higher rate of successful defect closure with less major complications.[iv]" said Dr. Darren Berman, Congenital Interventional Cardiologist – Children's Hospital Los Angeles, Los Angeles, CA. *"It is a soft, conformable, self-centering Occluder, that adapts well to varying patients' anatomies. Moreover, I appreciate the ease of use and relatively small delivery system. I am excited to have this available in the U.S. and available to our patients."*

The Occlutech ASD Occluder is distributed in the U.S. under an exclusive partnership with BIS which also assumes commercialization activities for the Occlutech ASD Occluder with the support of the global Occlutech team.

"The BIS/Occlutech team is very encouraged by the initial successful procedures and physician user experiences with the U.S. commercial launch of the Occlutech ASD Occluder," said Dave Mittl, VP Sales and Marketing, BIS. "*The U.S. introduction of this clinically proven, differentiated ASD device provides interventional cardiologists additional armament to achieve the best possible outcomes for their patients."*

The BIS/Occlutech team will conduct a full launch of their latest product at the PICS (Pediatric and Congenital Interventional Cardiovascular Society) Annual Symposium this September in San Diego, CA. The symposium is a key event in the field, bringing together leading experts and practitioners. The launch will showcase the Occlutech ASD Occluder, demonstrating our commitment to advancing medical technology and improving patient outcomes.

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About Occlutech
Occlutech is a leading specialist provider of minimally invasive structural heart devices, with a mission to improve the quality of life for people with heart conditions. The vision is to become a leading global specialist in cardiac devices, addressing congenital heart defects, stroke prevention and heart failure. Since 2003, the company has developed, manufactured, and commercialized occluders and interatrial shunt products. Occlutech has a broad and proven portfolio, based on proprietary technology, and over 200 patents with over 190,000 products sold. The company markets and sells its products in approximately 85 countries. The company has around 350 employees and is a public limited liability company registered in Switzerland. For more information, connect with Occlutech on LinkedIn. For U.S. important safety information on the Occlutech ASD Occluder, visit: www.us.occlutech.com

About B. Braun Interventional Systems Inc.
B. Braun Interventional Systems offers interventional solutions designed with the patient in mind. Many of the products offered have been developed in response to the needs of physicians, technicians, and nurses. The company is committed to delivering safety, precision, and convenience to interventional procedures. B. Braun Interventional Systems Inc. is part of the B. Braun Group of Companies in the U.S., which is headquartered in Bethlehem, PA., and includes B. Braun Medical Inc., Aesculap® and CAPS®. Globally, the B. Braun Group of Companies employs more than 64,000 employees in 64 countries. Guided by its Sharing Expertise® philosophy, B. Braun continuously exchanges knowledge with customers, partners, and clinicians to address the critical issues of improving care and lowering costs. To learn more about B. Braun Interventional Systems Inc., visit www.bisusa.org/about-us and connect with B. Braun Interventional Systems on LinkedIn.

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[i] Aparisi et al., Comparison of Figulla Flex® and Amplatzer™ devices for atrial septal defect closure: A meta-analysis, Cardiol J . 2020;27(5):524-532. doi: 10.5603/CJ.a2020.0058. Epub 2020 Apr 24.
[ii] Moake, L., & Ramaciotti, C., Atrial Septal Defect Treatment Options (2005). AACN Clinical Issues, 16(2), 252-266.
[iii] Occlutech Data on file.
[iv] Kenny D et al., Catheter Cardiovasc Interv. 2019 Feb 1;93(2):316-321.

Attachments

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