PRESS RELEASE
08 January 2024 08:00:00 CET

Occlutech® Announces FDA Approval of its Occlutech® ASD Occluder and Occlutech® Pistol Pusher, a Minimally Invasive Cardiac Device and Delivery System to Treat Atrial Septal Defects

Occlutech ASD Occluder delivers positive procedural outcomes with strong efficacy and a low rate of complications[i]

Occlutech®, a world leading specialist provider of minimally invasive structural heart implants, today announced that the United States Food and Drug Administration (FDA) has approved the Occlutech® ASD Occluder and Occlutech® Pistol Pusher for the treatment of Atrial Septal Defects (ASD). With this approval, Occlutech will immediately begin commercialization in an exclusive partnership with distributor B. Braun Interventional Systems Inc. (B. Braun Interventional Systems).

ASDs are one of the most common congenital heart defects (CHD) seen in pediatric cardiology[ii]. An ASD is a hole in the septum, or wall, between the two upper chambers of the heart (atria)[iii]. This opening causes abnormal blood flow between the atria and may result in too much blood flow to the lungs. If left untreated, an ASD can lead to fatigue, shortness of breath, pulmonary hypertension, heart failure, arrhythmia and/or an enlarged heart.

Sabine Bois, Occlutech CEO commented, *"Today marks a momentous occasion for Occlutech and a significant leap forward in our commitment to advancing healthcare around the globe. I am thrilled the FDA has granted approval for the Occlutech ASD Occluder and Occlutech Pistol Pusher. Our mission has always been to improve the quality of life for patients; indeed, we have sold over 90,000 of our ASD devices outside of the U.S. Now, with the FDA's approval, we are poised to leverage our experience in the largest congenital and structural heart disease market in the world, with ASD closure representing a $40 million market in the US with solid growth predicted.*

Bois continued, *"We extend our deepest gratitude to the patients, partners and all stakeholders who have been instrumental in this journey."*

An ASD can be closed by a minimally invasive procedure. A catheter is inserted via a blood vessel in the groin and guided to the heart. The Occlutech ASD Occluder is a self-expanding Nitinol double disc occlusion device comprised of two umbrella-shaped flexible discs with a 'waist' in the middle that connects the two discs. Designed to be a lifelong solution, the discs attach to both sides of the atrial septum, bridging the defect and closing the hole.

Prof. Ziyad M. Hijazi, Chairman, Department of Cardiovascular Diseases and Professor of Pediatrics & Medicine, Sidra Medicine and Weill Cornell Medicine- Doha commented, "*This landmark approval is a huge milestone. The Occlutech ASD Occluder has demonstrated excellent procedural outcomes and a low complication rate, per rigorous scientific study and clinical trials of >5000 studied patients in retrospective, prospective and randomized clinical trials as well as comparative meta-analysis. Therefore, to have the device available to our patients in the U.S. will only serve to help thousands more people in need.*"

In an agreement signed May 2022, B. Braun Interventional Systems will immediately initiate the U.S. commercialization activities for the Occlutech ASD Occluder with the support of the global Occlutech team. Through the collaboration, Occlutech positions itself for success in the strategically important U.S. market, which is characterized as a premier and commercially attractive healthcare system, while B. Braun Interventional Systems increases its portfolio's relevancy around its strong congenital and structural heart focus.

"We are honored to bring the trusted Occlutech ASD Occluder, with its strong body of clinical evidence into our portfolio of devices developed to treat congenital heart defects,[i,iv] " said Dave Mittl, VP Sales and Marketing, B. Braun Interventional Systems. "*Our legacy at B. Braun Interventional Systems has been to deliver solutions to interventionalists treating these often-overlooked patients. This portfolio addition builds on that commitment,*" Mittl concluded.

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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 177,000 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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[ii] Moake, L., & Ramaciotti, C., Atrial Septal Defect Treatment Options (2005). AACN Clinical Issues, 16(2), 252-266.
[iii] Kuijpers et al., Secundum atrial septal defect in adults: a practical review and recent developments, Neth Heart J. 2015 Apr; 23(4): 205–211
[iv] Haas N et al. Closure of Secundum Atrial Septal Defects by Using the Occlutech Occluder Devices in More Than 1300 Patients: The IRFACODE Project: A Retrospective Case Series Catheter Cardiovasc Interv. 2016. DOI: 10.1002/ccd

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Attachments

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