This is the only randomized controlled trial comparing two ASD closure devices. Its results supported the FDA PMA Approval for the Occlutech ASD Occluder.

A Randomized, Controlled Trial on Safety and Efficacy of the Occlutech® ASD Occluder Compared to the Amplatzer™ Septal Occluder

Deliver Confidently.

Study Design and Endpoints

Randomized, controlled, multi-center (7 sites) trial.

All echocardiograms were read by a core laboratory.

The primary endpoint was early efficacy success rate, defined as the rate of a successful placement of the device, and successful closure of the defect without major complication, surgical reintervention, device embolization or moderate or large residual shunt the day after the procedure (moderate: 2-4 mm and large ≥4 mm).

Secondary endpoints included the rate of closure success (residual shunt ≤ 2 mm) without the need for surgical repair within 6 months postprocedure.

Safety endpoints included major and minor complication rates at 6 and 12 months post procedure and all other device or procedure related adverse events at 6 and 12 months post procedure.

Patient Population

176 patients were randomized (2:1 in favor of OFFII):
- 116 implanted with Occlutech ASD Occluder (OFFII)
- 60 implanted with Amplatzer Septal Occluder (ASO).

There were no statistically significant differences in patient demographics between the two groups.

Kenny D et al. A randomized, controlled, multi-center trial of the efficacy and safety of the Occlutech Figulla Flex-II Occluder compared to the Amplatzer Septal Occluder for transcatheter closure of secundum atrial septal defects. Catheter Cardiovasc Interv. 2019 Feb 1;93(2):316-321

For more information or to place an order, please contact your local B. Braun Interventional Systems Inc. representative or call 1-877-836-2228.

Interventional Systems B|BRAUN SHARING EXPERTISE | Occlutech

Successful Device Placement and Closure Without Complications

"The primary endpoint of early efficacy success was significantly higher for the OFFII cohort."

Successful Device Placement on the First Attempt

"Successful device placement at first attempt was significantly higher in the OFFII group. A number of design features of the OFFII device may have contributed to this outcome."

Closure Success at 6 Months

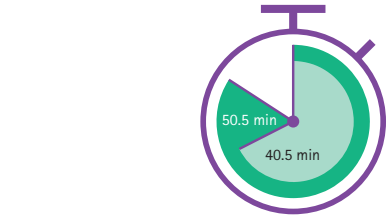
At 6 months, Occlutech® ASD Occluder showed a 10.55% higher closure success rate than Abbott Septal Occluder (81.74% vs. 71.19%).

+10.53%

Higher closure success rate for Occlutech vs. Abbott

Mean Procedure Duration

The mean procedure duration was 10 minutes less for Occlutech ASD Occluder than for Abbott Septal Occluder.



+19.80%

Shorter procedure duration Occlutech vs. Abbott

Conclusion

"In this clinical trial setting, the OFFII was not inferior to the ASO, with less complications and greater early efficacy success than the ASO."

Occlutech® ASD Occluder is a registered mark of Occlutech Holding AG.

Rx Only. Please refer to product instructions for use for complete listing of indications, contraindication, warnings, precautions, and potential adverse events and directions for use.

Distributed by:

B. Braun Interventional Systems Inc. - a member of the B. Braun Group of Companies

Bethlehem, PA | 1-877-836-2228 | bisusa.com

Scan for more information