

## First comparative randomized ASD study published

A new multicentric, randomized study compares the Occlutech Figulla Flex-II Occluder (OFFII) versus the Amplatzer Septal Occluder (ASO) for percutaneous ASD closure.

The trial results prove non-inferiority of the OFFII with less complications and a better efficacy than the ASO.

- **176 randomized patients:** 107 OFFII / 51 ASO in 7 sites in Ireland, Germany, United Kingdom and Qatar.
- The OFFII is proven as non-inferior with **less complications and a better efficacy** than the ASO in children > 8 kg
- The primary endpoint: **Higher early efficacy success** for the OFFII (94.8% vs. 88.1%)
- Complication rates were 5.6% for the OFFII group compared to 9.8% for the ASO
- Despite all the objections on delivery sheath size, in this study the size of occluders was not associated with greater vascular complications in the OFFII cohort since it is the **OUTER DIAMETER that matters!**

Successful device placement on the first attempt was significantly higher in the OFFII group (99.1% vs. 90.2% (P < 0.05)). Discussed are the following reasons:

- **Softer left atrial disc**
- **Greater flexibility**
- **Greater operator confidence during deployment**

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# 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

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## Abstract

### Aims

The aim of this study was to compare the efficacy and safety of the Occlutech Figulla Flex II Occluder (OFFII) with the Amplatzer Septal Occluder (ASO) in patients >8kg undergoing transcatheter ASD closure.

### Methods and results

Randomized, controlled, multi-center prospective clinical trial with randomization 2:1 in favor of the OFFII. Primary efficacy endpoint was the rate of successful device placement and defect closure without major complications at hospital discharge. All data were assessed through a core laboratory. Interim analysis was performed when 70% of the patients were treated to evaluate for noninferiority.

From a total of 176 randomized subjects, interim analysis was performed on the first 158 patients (65.2% female) (107 OFFII/51 ASO) undergoing device closure at a median weight of 42 kg (range 13-125 kg). Seventy-six percent (120 patients) completed 6-month follow-up. Successful device placement (first attempt) was achieved in 99.1% of the OFF group vs 90.2% of the ASO group ( $P < 0.05$ ). Early efficacy success was achieved in 94.4% of the OFFII group vs 90.2% of the ASO group ( $P < 0.001$ ). The incidence of major complications was 5.6% for the OFFII group compared to 9.8% for the ASO.

### Conclusions

The OFFII device was not inferior to the ASO with less complications and greater efficacy than the ASO.

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