Clinical Summary

Closure of patent foramen ovale defects using GORE® CARDIOFORM Septal Occluder: Results from a prospective European multicenter study

Design

Study size: 150 subjects were included from 10 sites within Germany, Denmark, Italy, United Kingdom, and Sweden. Follow-up time was six months.

Study population: Subjects of at least 18 years of age with a PFO confirmed by TTE or TEE and an estimated defect size < 17 mm. The majority of the subjects had a history of stroke or TIA (86%). The remaining indications included patients with peripheral embolism, diver with a risk of decompression disease, patients with planned neurosurgery in supine position and risk of paradoxical air embolism during surgery or significant shunting of an ASD in the presence of an additional PFO.

Results

Age (years, median ± std dev): 46.4 ± 12.4

Weight (kg, mean ± std dev): 77.9 ± 16.4

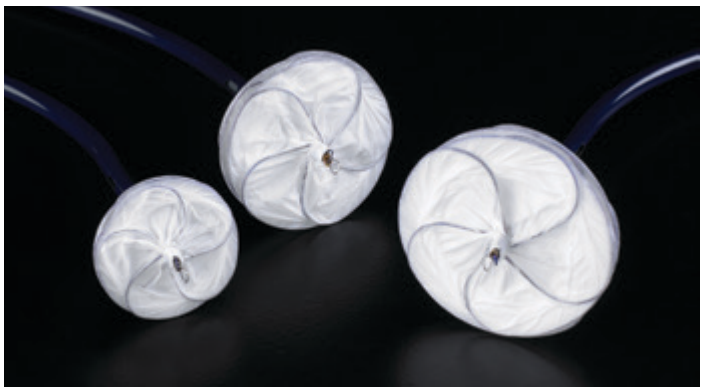
Defect characteristics:

- Stop flow balloon size (mm, mean ± std dev): 9.3 ± 3.7
- PFO length by balloon sizing (mm, mean ± std dev): 10.7 ± 5.1
- PFO tunnel > 10 mm by balloon sizing: 41 / 67 (61.2%)
- Atrial septal aneurysm: 34 / 150 (22.7%)

Conclusions

- No post-procedure embolization or re-intervention
- Composite clinical success was high in this cohort of 150 PFO subject implants. This included:
  - Ability to successfully implant the device
  - Completely occluded or trivial residual shunt at six-month follow-up
  - Freedom from serious adverse events or device-related events

"The GORE® CARDIOFORM Septal Occluder is an easy-to-use and efficient device for patent foramen ovale closure. In particular, it has an excellent midterm safety profile with very high procedural and closure success in various anatomies."[1]



GORE® CARDIOFORM Septal Occluder

Procedure outcomes	
Mean (std dev) total procedure time (minutes)	41.3 (24.8)
Mean (std dev) fluoroscopy time (minutes)	5.7 (4.6)
Technical success[1]	99.3%
Procedural success[2]	99.6%
Closure results	
Clinical closure success[3]	
Discharge	94.2%
6 months measured	96.9%
Composite clinical success	
6 months	96.0%
Safety	
Adverse events	4.0%
Paroxysmal atrial fibrillation	2.7%
Thrombus	0.6%
TIA	0.6%
Six-month device events[4]	0.0%

1. Successful deployment and retention of a GORE® CARDIOFORM Septal Occluder.
2. Successful implantation of a GORE® Septal Occluder and demonstration of successful PFO-closure during the intervention.
3. Clinical closure success discharge and at six-month follow-up (completely occluded or a trivial residual shunt).
4. Post-procedural device embolization, post-procedural device removal, or any reintervention to the septal defect.

1. Hardt SE, Eicken A, Berger F, *et al.* Closure of patent foramen defects using GORE® CARDIOFORM septal occluder. *Catheterization & Cardiovascular Interventions* 2017;90(5):824-829.

W. L. Gore & Associates, Inc. | Flagstaff, AZ 86004 | goremedical.com

Products listed may not be available in all markets.

GORE CARDIOFORM SEPTAL OCCLUDER