ASD Closure using the Gore Cardioform Septal Occluder

Disclaimer: Non Financial but Emotionally involved

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Children’s Hospital Colorado
GSO Family
Composite delivery system & handle
Gore Septal Occluder Animal and Histopathology Studies

Rigorous testing

Finite element analysis

Biochemical leaching

Bench testing pulse duplicator

millions of cycles

Acute and chronic animal studies

Histological analysis
- **US Indication FDA Approval May 2015**
  The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs).

- **CE Mark (2011)**
  The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of atrial septal defects (ASDs), such as ostium secundum and patent foramen ovale.
Delivery Catheter (Blue)
10Fr diameter
Perforated to allow delivery over 0.035” wire
Pre-curved, 75cm working length
Radiopaque Distal Marker Band
Braided for excellent torque response
Device sizes 15-30mm in 5mm increments
Inert and Biocompatible

- ePTFE proven in over 23 million implants
- Reduced thrombogenicity
- Porosity engineered for optimal controlled tissue response
- Allows formation of functional intimal lining

After 30 days in canine model
Histological comparisons Dacron / Goretex

Goretex cellular paucity
Gore Cardioform Current Clinical Experience

>10,000 implants worldwide

- World First Clinical Implant June 2011
- Dr Lars Sondergardh Copenhagen Denmark
- CE Mark since June 2011
- Clinical approval in Canada
- FDA Approval USA 2015


Handle provides 'tactility'
ASD Closure with ICE
ASD Closure with ICE
Note reorientation on release and conformability with septum
TEE contrast echo in PFO

Thank You Dr Mario Carminati San Donato Milano
Gore Cardioform Clinical Experience

- >10,000 implants worldwide
- First 600 patients closure rates 93% at 1 month
- Complications rare
- No erosions
- No late embolisation
Implant success: UK Study n=229

- GSO implanted in all 229 cases
- 4 cases the initial device was removed and replaced (successfully) with a second device

Thank You Dr John Thomson Leeds UK
Complications

Atrial dysrhythmia 5/229 (2.2%)

3/5: no treatment
2/5: Beta blocker

4/5 resolved within 1/12
1/5 multiple episodes AF but in SR
Can be used alongside other devices

Fenestrated ASD with Cribriform residual shunt closed with cardioform
Gore Cardioform Septal Occluder

Reflections

• What could be better?
• Larger sizes needed
• 10Fr delivery system maximum