

ASD Closure using the Gore Cardioform Septal Occluder

Disclaimer: Non Financial but Emotionally involved

Neil Wilson MB BS DCH FRCP FRCP(CH)
FSCAI

Director Paediatric Cardiac Catheter
Laboratory

Professor of Pediatrics Childrens
Hospital Colorado

University of Colorado Denver USA

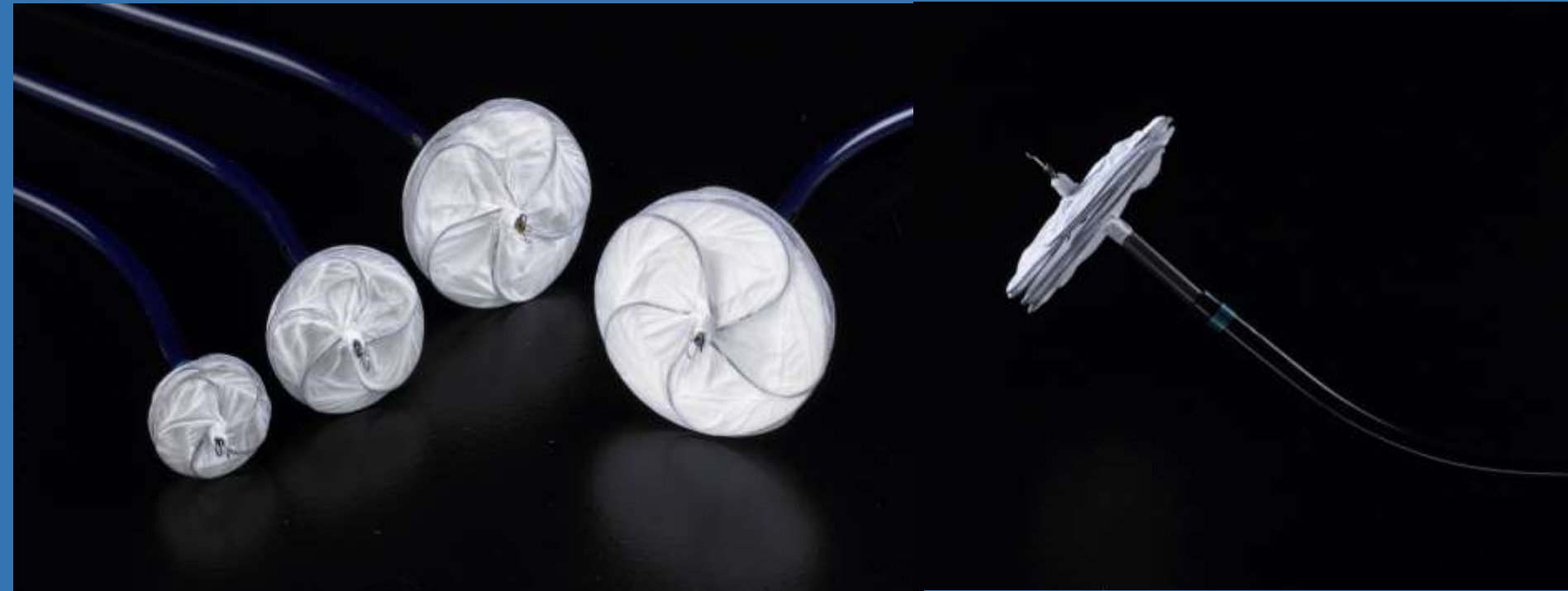


Children's Hospital Colorado



Children's Hospital
Colorado

GSO Family





Children's Hospital
Colorado

Composite delivery system & handle

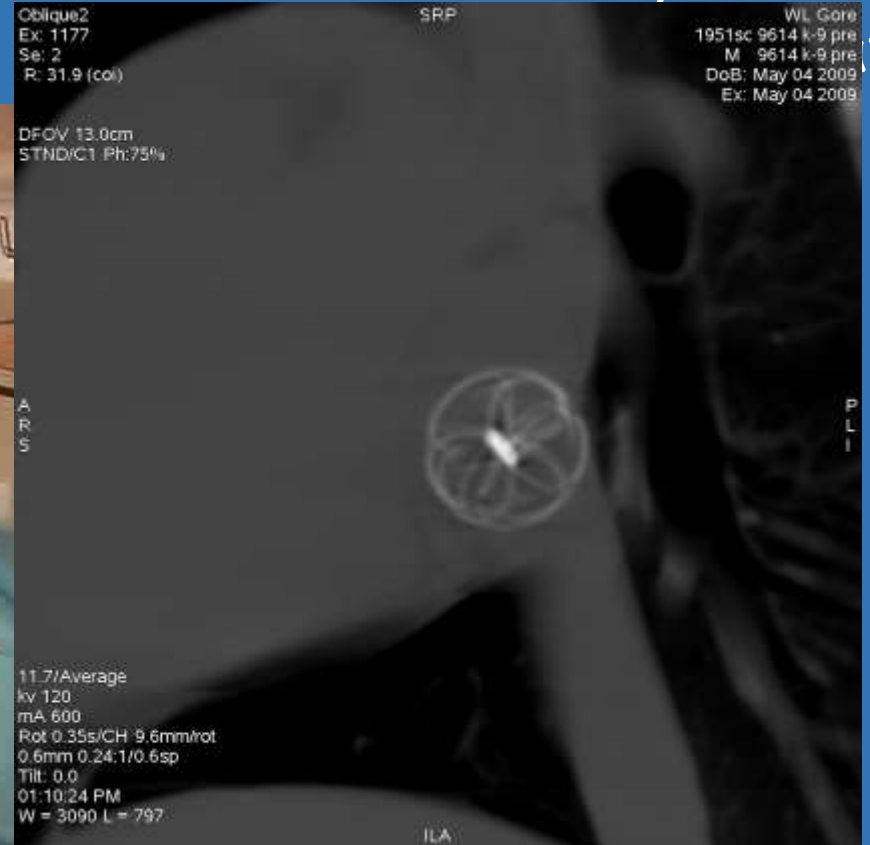


Core Septal Occluder Animal and Histopathology Studies

Children's Hospital
Colorado

Pre-clinical testing

Finite element analysis
Biochemical leaching





Children's Hospital
Colorado

Gore Cardioform Septal Occluder

- 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

Children's Hospital
Colorado

Delivery Catheter (Blue)

10Fr diameter

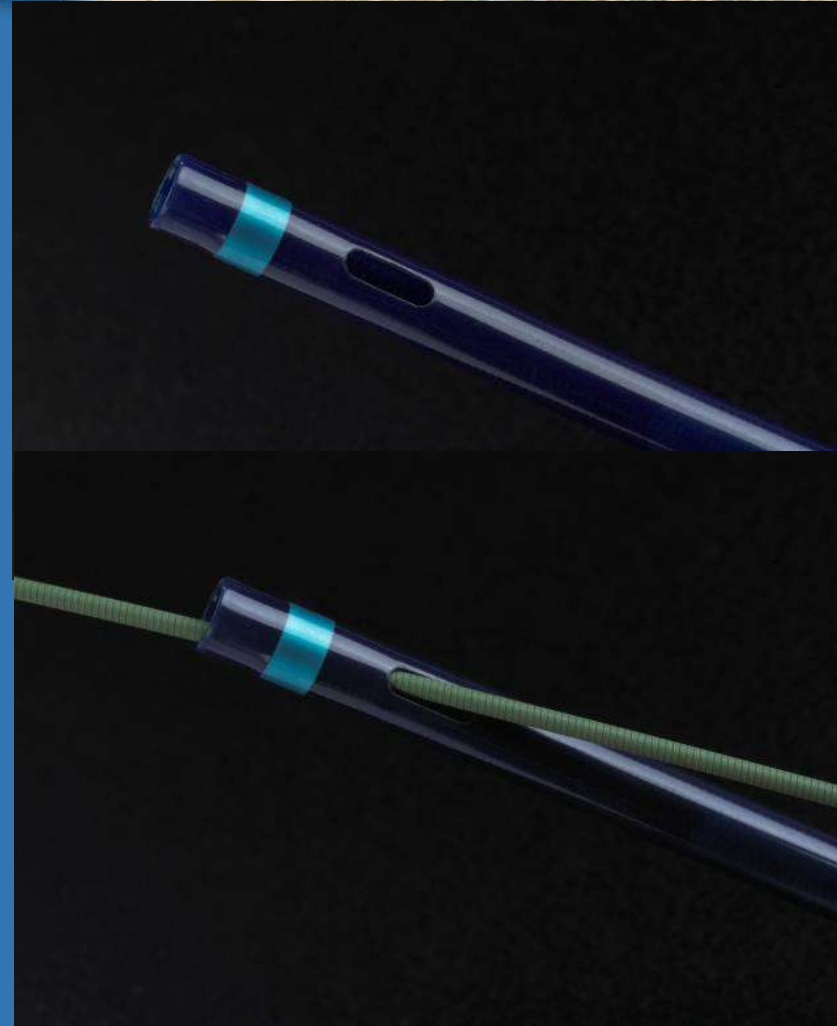
Perforated to allow delivery
over 0.035" wire

Pre-curved, 75cm working
length

Radiopaque Distal Marker Band

Braided for excellent torque
response

Device sizes 15-30mm in 5mm
increments

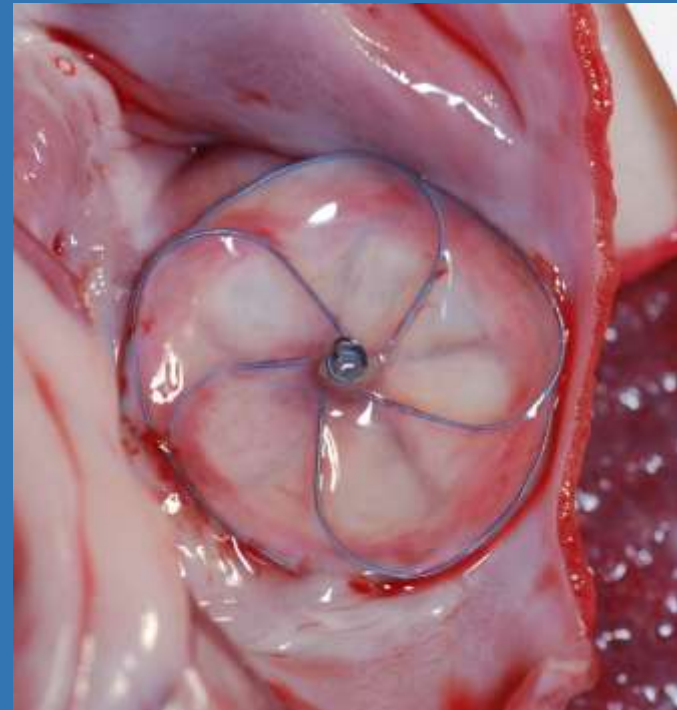




Inert and Biocompatible

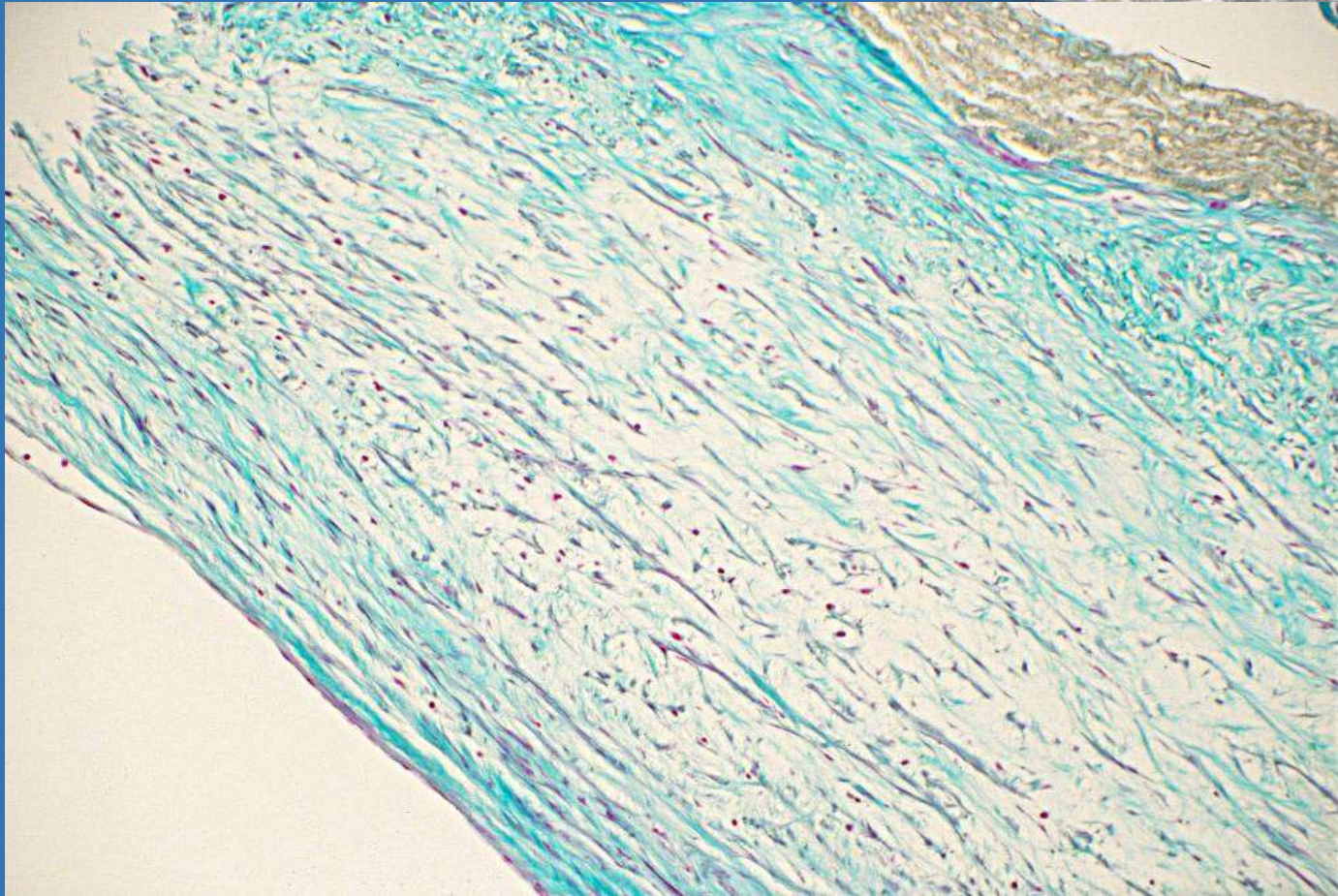
Children's Hospital
Colorado

- 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



Children's Hospital
Colorado

GSO Current Clinical Experience

- Butera G, Danna P, Musto C, Sacra C, Violini R, Viecca M, Farahani V, Chessa M, Carminati M. GORE® Septal Occluder: early clinical results. *Congenital Cardiology Today* 2012;10(6):1, 3-7.
- MacDonald ST, Daniels MJ, Ormerod OJ. Initial use of the new Gore® Septal Occluder in patent foramen ovale closure: implantation and preliminary results. *Catheterization & Cardiovascular Interventions* 2013;81(4):660-665.
- Nyboe C, Hjortdal VE, Nielsen-Kudsk JE. First experiences with the GORE® Septal Occluder in children and adults with atrial septal defects. *Catheterization & Cardiovascular Interventions* 2013. DOI: 10.1002/ccd.24851.
- Søndergaard L, Loh PH, Franzen O, Ihlemann N, Vejlstrup. The first clinical experience with the new GORE® Septal Occluder (GSO). *EuroIntervention* 2013.

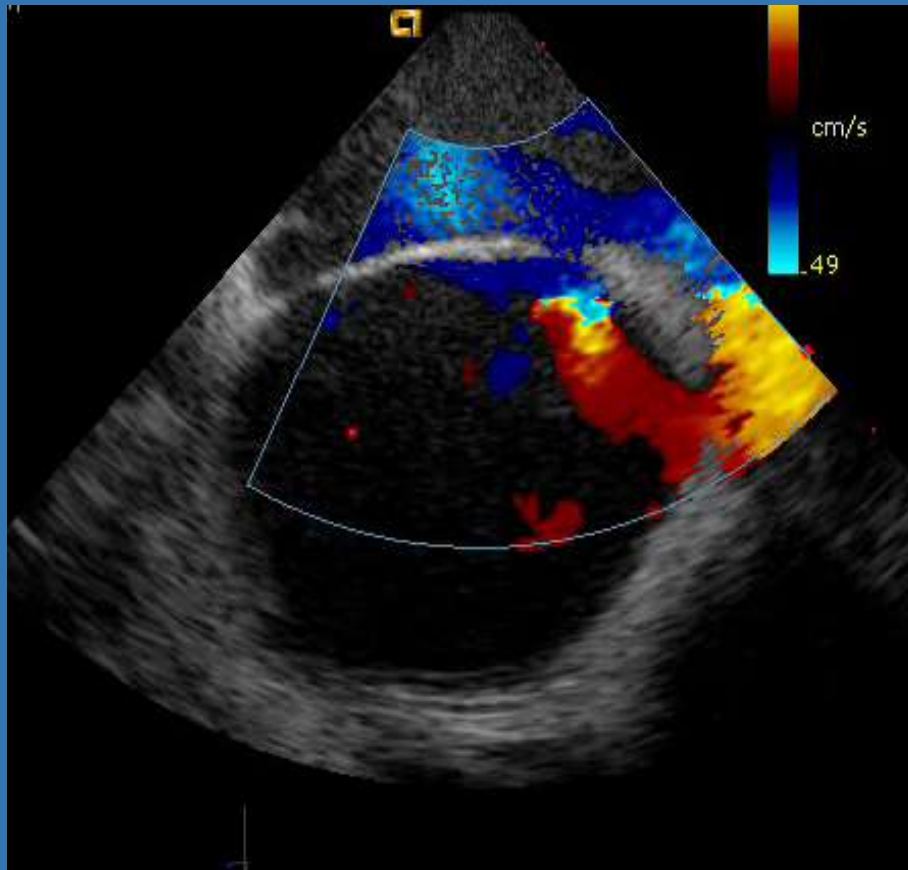


Children's Hospital
Colorado

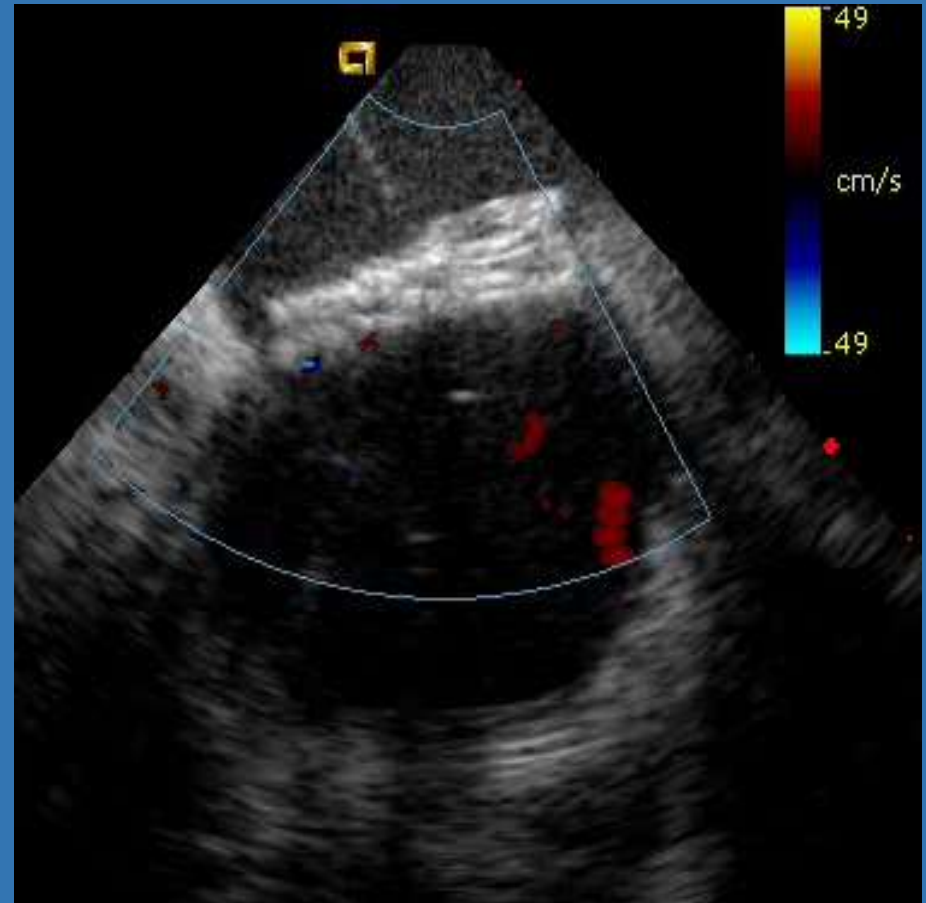
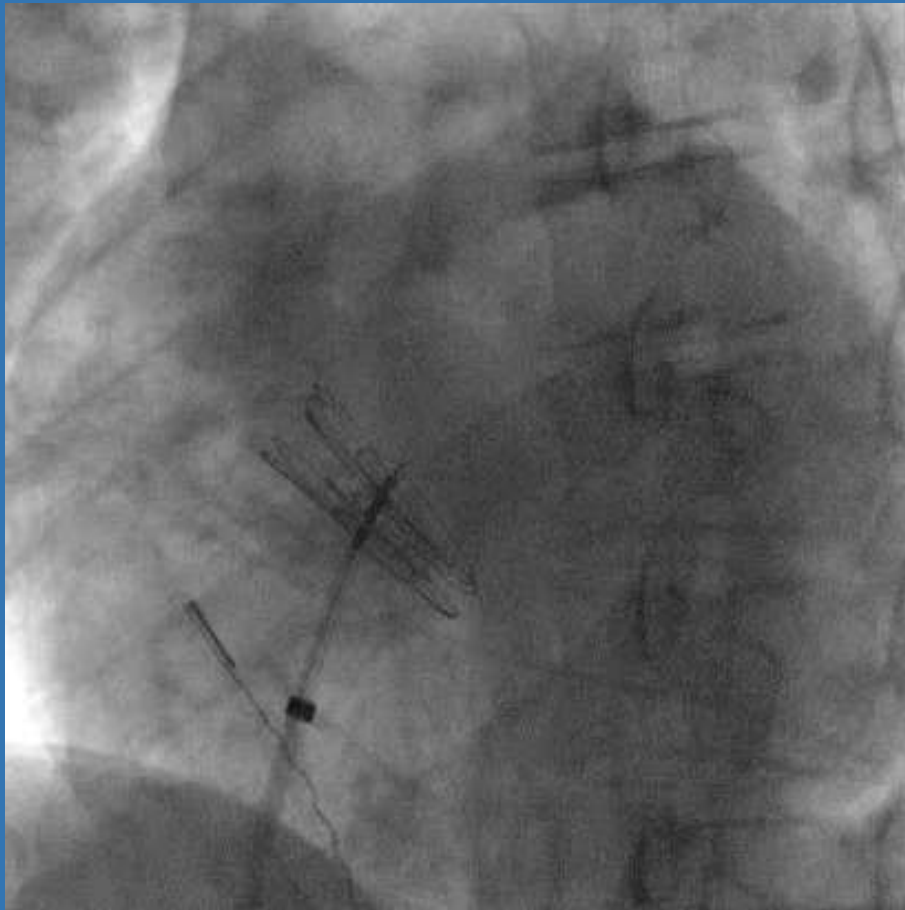
Handle provides 'tactility'



ASD Closure with ICE



ASD Closure with ICE

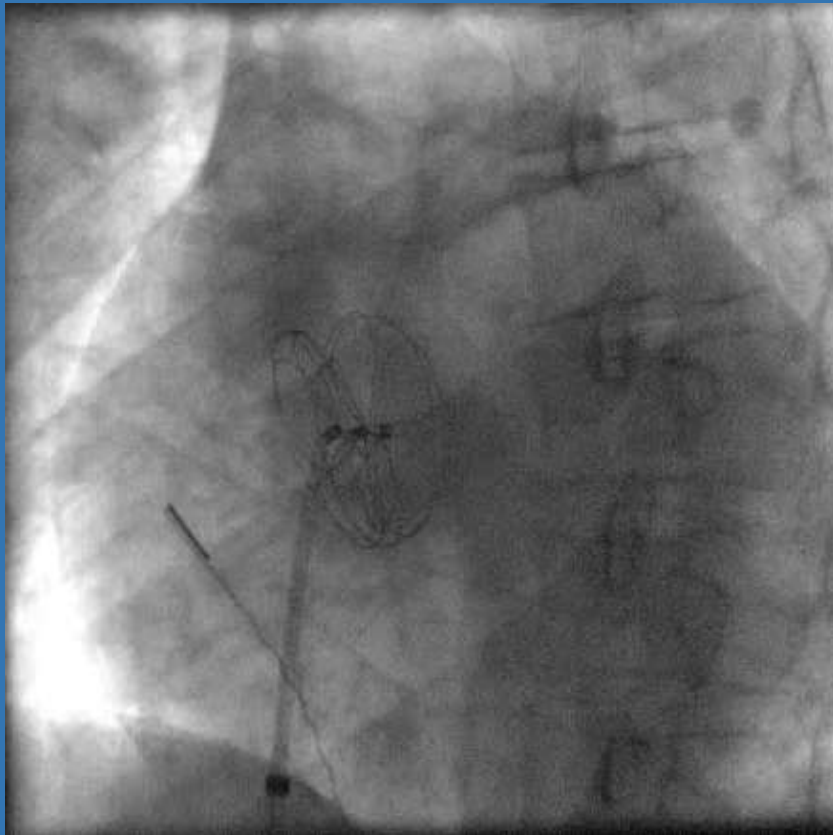




Children's Hospital
Colorado

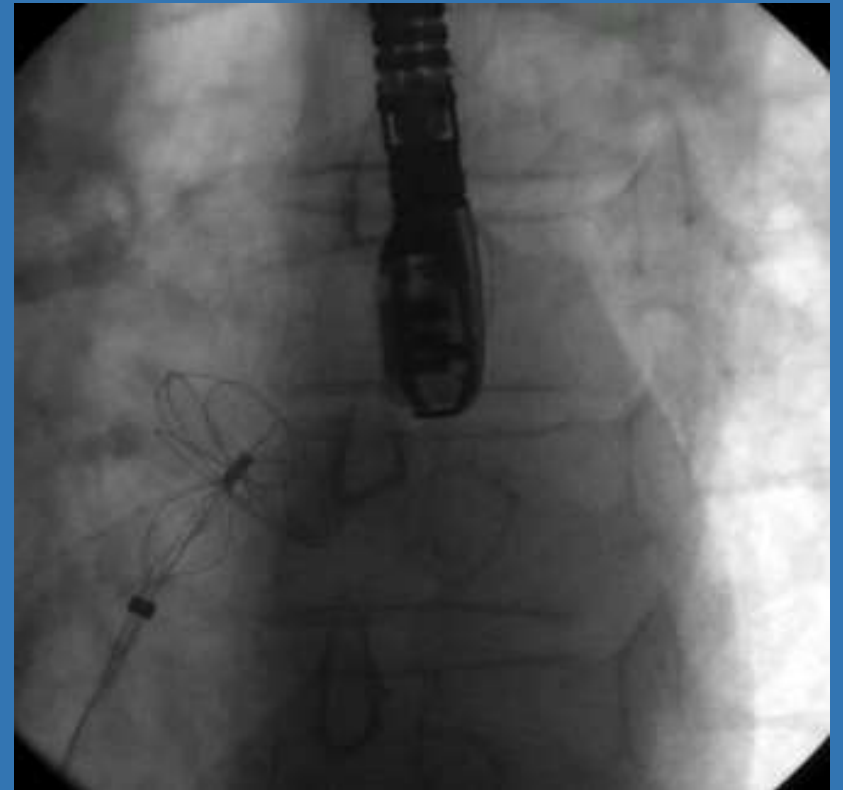
Gore Cardioform Clinical Experience

Note reorientation on release and conformability with septum



TEE contrast echo in PFO

Thank You Dr Mario Carminati San Donato Milano



Device Released





Children's Hospital
Colorado

Gore Cardioform Clinical Experience

- >10,000 implants worldwide
- First 600 patients closure rates 93% at 1 month
- Complications rare
- No erosions
- No late embolisation

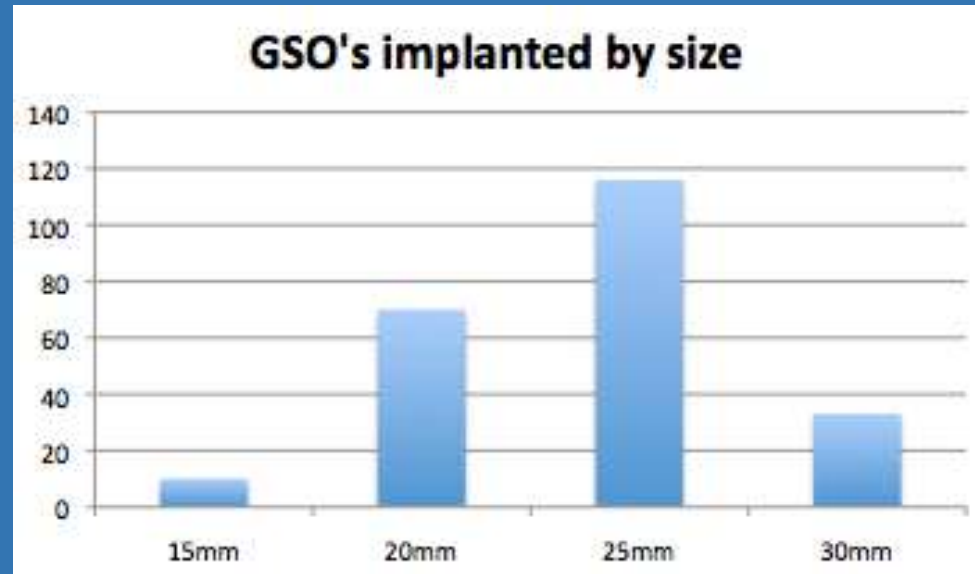


Children's Hospital
Colorado

Implant success: UK Study n=229

Thank You Dr John Thomson Leeds UK

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

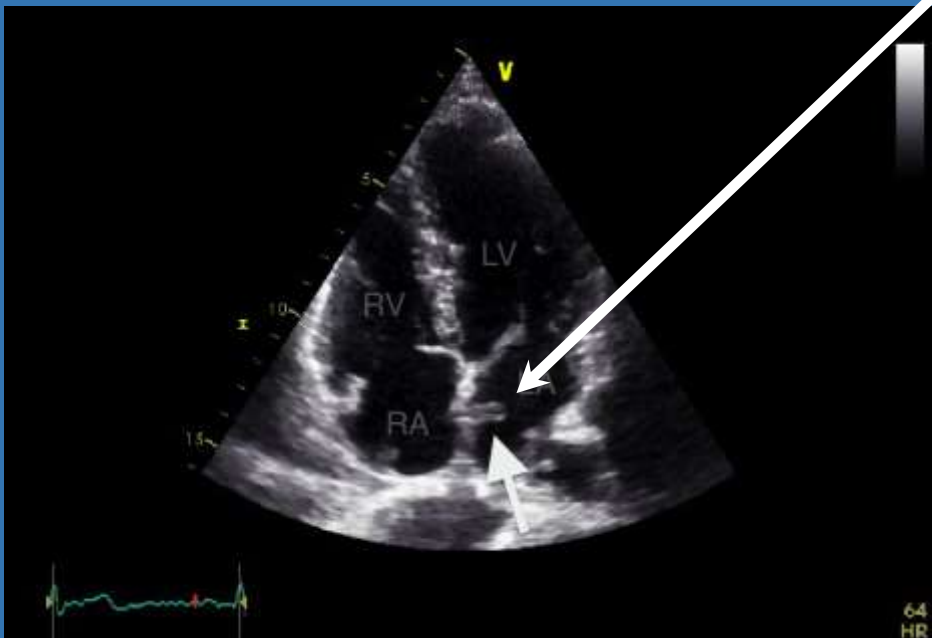




Complications

Complications-early		
Access site haematoma		2
Arterio-venous fistula		1
Perforated femoral vein requiring covered stent		1
Failed locking of device (removal)		2
Vaso-vagal event following closure		1
Total		7

Complications-late	
Atrial fibrillation/flutter	5
Atrial ectopics	3
Palpitations (sinus rhythm)	3
Nodal escape	1
Thrombus on left atrial disc	1
Total	13



Atrial dysrhythmia 5/229 (2.2%)

3/5: no treatment

2/5: Beta blocker

4/5 resolved within 1/12

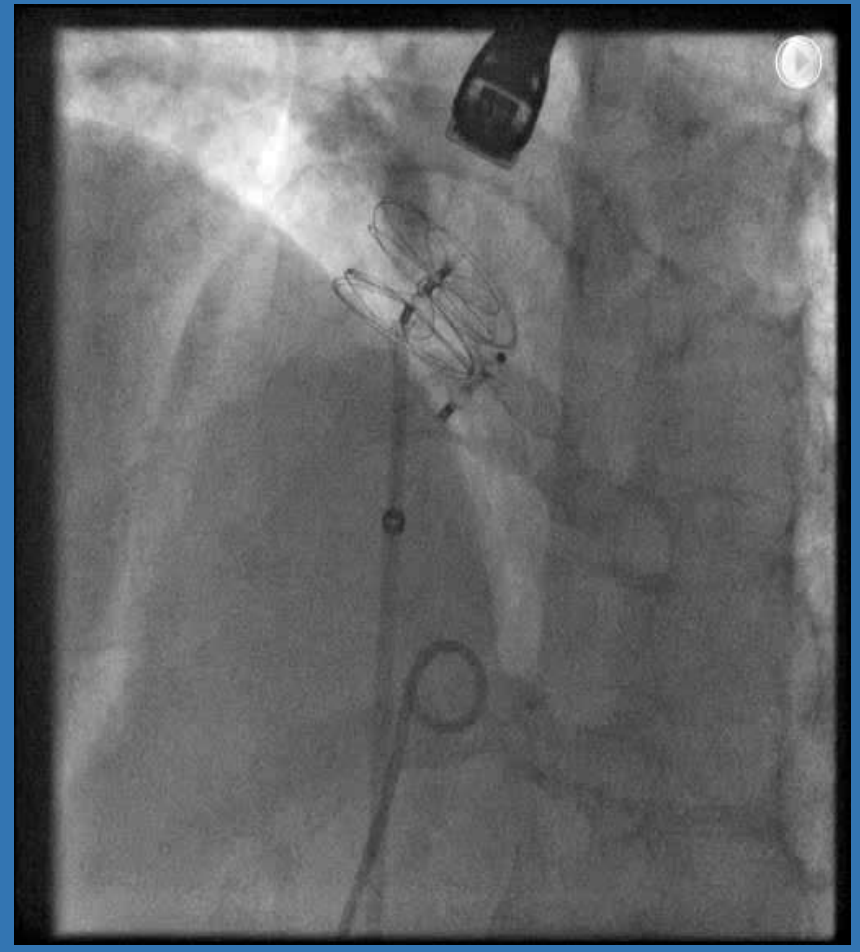
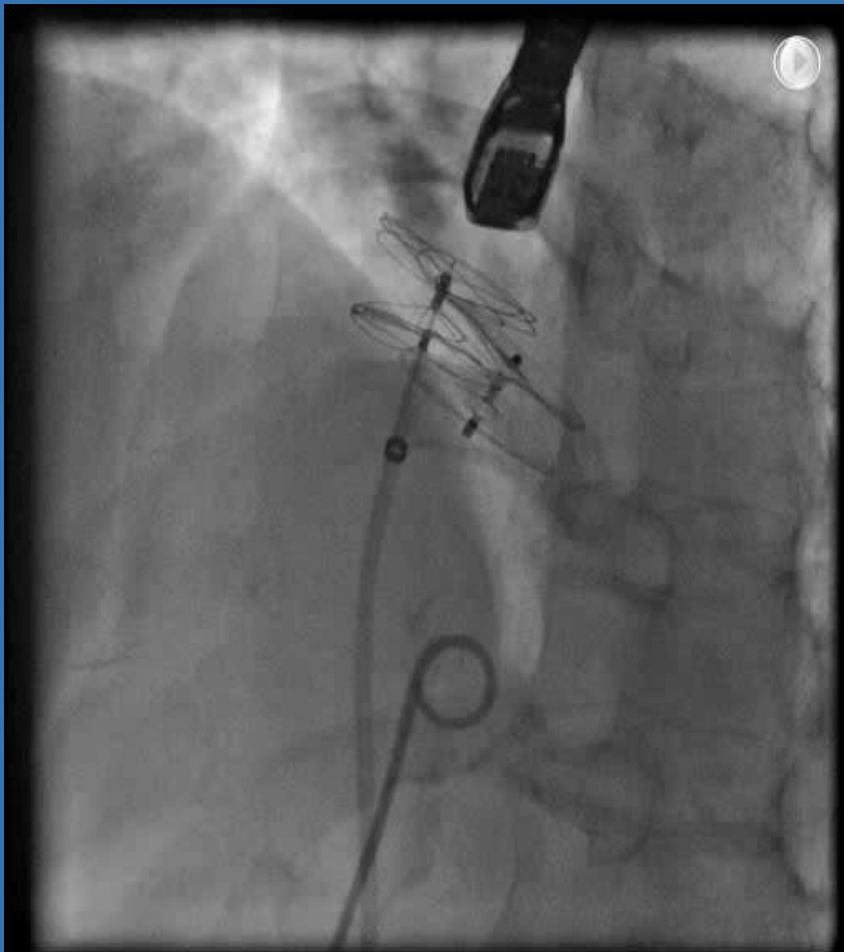
1/5 multiple episodes AF but in SR



Children's Hospital
Colorado

Can be used alongside other devices

Fenestrated ASD with Cribriform residual shunt closed with cardioform



Gore Cardioform Septal Occluder

Children's Hospital
Colorado



Reflections

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