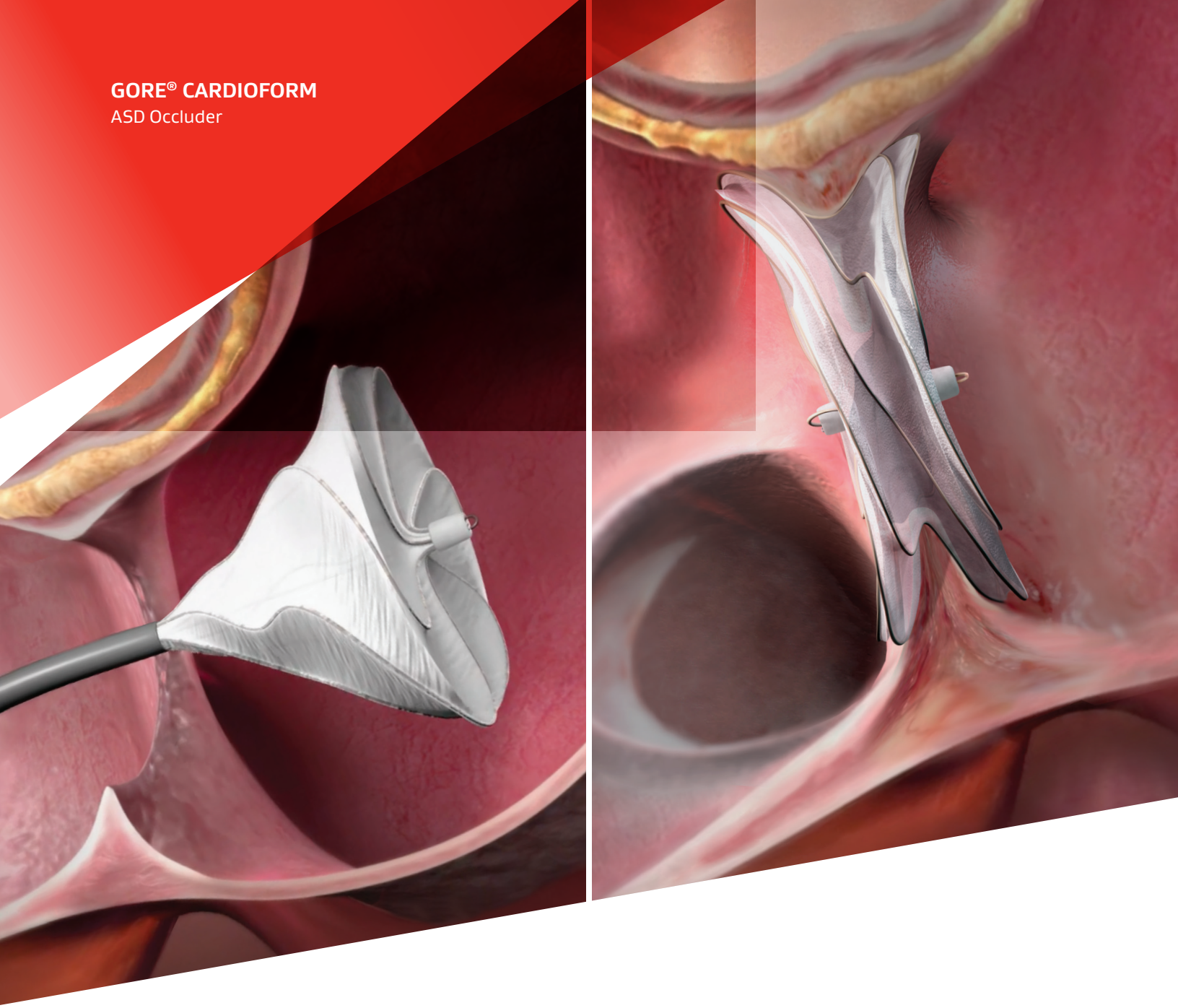
GORE® CARDIOFORM
ASD Occluder



ASDs WITH DEFICIENT RETRO-AORTIC RIMS[a] DEMAND SAFE AND EFFECTIVE CLOSURE[1,2]

[a] Deficient retro-aortic rim was defined as a retro-aortic rim measuring less than or equal to 5 mm on any view on echocardiogram.

Together, improving life

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Acronym glossary

Atrial septal aneurysm (ASA)

Atrial septal defect (ASD)

expanded polytetrafluoroethylene (ePTFE)

Product surveillance tracking system (PSTS)

Transesophageal echocardiogram (TEE)

ASDs WITH DEFICIENT RETRO-AORTIC RIMS[b] DEMAND SAFE AND EFFECTIVE CLOSURE[1,2]

The GORE® CARDIOFORM ASD Occluder advances ASD closure with a solution designed to naturally conform to each unique defect, delivering on a legacy of safety and performance.

A leader in safety	0	confirmed reports of cardiac erosion[c,1,2]
Trusted closure performance at 36 months[c,d,2]	100%	effective closure across a broad range of ASD anatomies at 36 months[c,d,e,2]
No retro-aortic rim required[3]	56.4%	of patients enrolled in the Gore ASSURED Clinical Study were reported to have deficient retro-aortic rims (< 5 mm)[2]
Trusted deployment[3]	1-2-3	straightforward delivery with the ability to reposition and retrieve[3]

[b] Deficient retro-aortic rim was defined as a retro-aortic rim measuring less than 5 mm on any view on echocardiogram.

[c] Reported incidence rate of device-related cardiac erosions for GORE® CARDIOFORM ASD Occluder calculated using data from CATSWeb® Product Surveillance Tracking System [PSTS] and SMARTSOLVE®. Data on file. March 1, 2015 – May 31, 2025; W. L. Gore & Associates Inc.; Flagstaff, AZ.

[d] Closure success defined as completely occluded or clinically insignificant shunt as determined by the Echo Core Lab at the 6-month evaluation among subjects with technical success.[3]

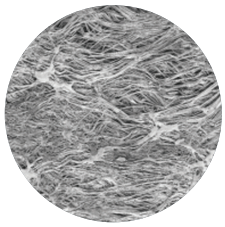
[e] All ASD anatomies within indicated sizing parameters of the *Instructions for Use*.

ADVANCED MATERIALS DELIVERING EXCEPTIONAL CONFORMABILITY[f,g,h,1,2]

- Developed by a company with over 60 years of materials science experience
- Engineered to conform to a broad range of ASD anatomies[g,1,2]
- No minimum retro-aortic rim requirements[3]

ePTFE

Biocompatible, compliant material enables exceptional conformability and rapid endothelialization



ePTFE 250x magnification

30-days post-implant in canine model

[f] Closure success defined as a clinical residual defect status of occluded or clinically insignificant as determined by the Echo Core Lab at the 6-month evaluation among subjects with technical success.[3]

[g] All ASD anatomies were eligible for inclusion into the ASSURED Clinical Study within indicated sizing parameters of the *Instructions for Use*.

[h] 100% closure success rate across ASD anatomies at 36 months.[f,g,1,2]

Anatomically adaptable waist

Designed to fill and conform to the defect

Minimal metal

- 6 or 8 platinum-filled nitinol[i] wires
- Low metal mass solution for defect closure
- Designed to reduce the risk of tissue damage
- Minimal nickel elution and exposure relative to other competitive nitinol-framed devices[i,j,k,l]

[i] Nickel titanium.

[j] Patients allergic to nickel may suffer an allergic reaction to the GORE® CARDIOFORM ASD Occluder. Certain allergic reactions can be serious; patients should be instructed to notify their physicians immediately if they suspect they are experiencing an allergic reaction such as difficulty in breathing or inflammation of the face or throat. Some patients may also develop an allergy to nickel if this device is implanted.

[k] Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. $\text{R}_{\text{X Only}}$

[l] Data on file. W. L. Gore & Associates, Inc.; Flagstaff, AZ.

A LEADER IN SAFETY

10+ years of clinical use

17,000+ devices sold globally

0 confirmed reports of cardiac erosion[m,1,2]

1 reported case of clinical sequelae associated with wire frame fractures[n,o]

[m] Reported incidence rate of device-related cardiac erosions for GORE® CARDIOFORM ASD Occluder calculated using data from CATSWeb® Product Surveillance Tracking System [PSTS] and SmartSolve.® Data on file. March 1, 2015 – October 31, 2025. W. L. Gore & Associates, Inc.; Flagstaff, AZ.

[n] Reported incidence rate of clinical sequelae associated with wire frame fracture for GORE® CARDIOFORM ASD Occluder. Calculated using data from CATSWeb® Product Surveillance Tracking System [PSTS] and SMARTSOLVE®. Data on file. March 1, 2015 – October 31, 2025. W. L. Gore & Associates, Inc.; Flagstaff, AZ.

[o] Clinical experience with GORE® CARDIOFORM ASD Occluder has reported 1 case of clinical sequelae associated with wire frame fracture from a total of >17,000 devices sold globally. It was reported that the patient presented with onset mitral regurgitation due to perforation of the mitral leaflet induced by device wire frame fracture. It was reported that surgical intervention was required, with the patient making a full recovery.

CARDIAC EROSION HAS OCCURRED WITH ALTERNATIVE OCCLUDER DEVICES[4–11]

ABBOTT® AMPLATZER® Septal Occluder

Reported between 2002 and 2014[9]

125 erosions | **9** deaths | **7.2%** mortality rate for patients with reported erosions

ABBOTT® AMPLATZER® Septal Occluder, ABBOTT® AMPLATZER® PFO Occluder and ABBOTT® AMPLATZER® Multifenestrated Septal Occluder – "Cribriform"

Reported between 2012 and 2018[10]

90 erosions | **4** deaths | **4.4%** mortality rate for patients with reported erosions

ABBOTT® AMPLATZER® Septal Occluder

Reported in a prospective, multicenter, post-approval study[8]

3 erosions | **0.3%** reported incidence rate

Estimates for cardiac erosion following ABBOTT® AMPLATZER® Septal Occluder implantation reported to range from 0.1–0.3%.[7]

ABBOTT® AMPLATZER® PFO Occluder

Reported in the AGA Registry between October 2000 and December 2006[11]

2 erosions | **0.018%** reported incidence rate

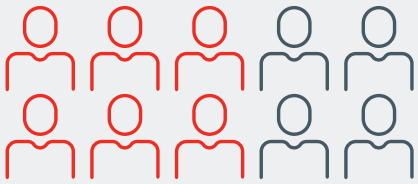
Cardiac erosion incidence rate of 0.018% reported for ABBOTT® AMPLATZER® PFO Occluder.[11]

OCCLUTECH® ASD Occluder

7 erosions reported through 2018[6]

The data presented are compiled from individual published studies and reports, each of which is cited accordingly. Rates of erosions and deaths reflect findings from separate data sources with varying methodologies, patient populations, and reporting criteria. No direct, head-to-head comparison between devices is intended or should be inferred. The information is provided for general reference only and should not be interpreted as establishing comparative performance or safety.

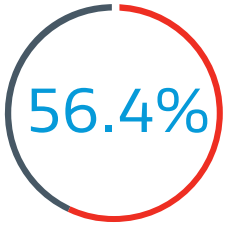
NO RETRO-AORTIC RIM REQUIREMENTS[3]



60% of patients

undergoing transcatheter ASD closure have been reported to have deficient retro-aortic rims.[p,12]

Gore ASSURED Clinical Study:



of patients enrolled in the Gore ASSURED Clinical Study were reported to have deficient retro-aortic rims (< 5 mm)[2]

effective closure at 36 months[q,2]

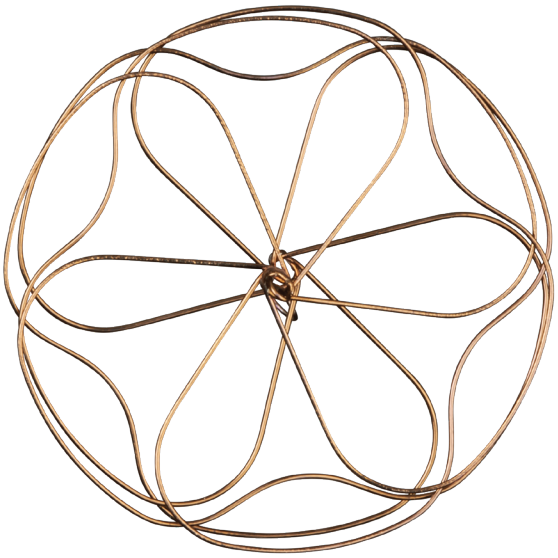
GORE® CARDIOFORM
ASD Occluder

The only ASD occluder with no warnings, potential adverse events or precautions related to cardiac erosions or use in patients with deficient retro-aortic rims.[p,1,3–5]

[p] Deficient retro-aortic rim was defined as a retro-aortic rim measuring less than 5 mm on any view on echocardiogram.

[q] Closure success defined as completely occluded or clinically insignificant shunt as determined by the Echo Core Lab at the 6-month evaluation among subjects with technical success.[3]

WIRE FRAME FRACTURE ANALYSIS



Clinical sequelae associated with device wire frame fracture is rare[r]

Summary of reported incidence of clinical sequelae associated with device wire frame fractures for the GORE® CARDIOFORM ASD Occluder.[r]

Occluder	First use in humans	Approval year (EU and U.S.)	Devices sold globally	Reported incidence of clinical sequelae associated with device wire frame fracture[s]
GORE® CARDIOFORM ASD Occluder	2015	2019	> 17,000	1

GORE® CARDIOFORM ASD Occluder Pivotal IDE Study for ASD closure: summary of wire frame fracture occurrence at 36-month follow-up.[2,13]

All pivotal and CA subjects (N = 569)[t,u]	Overall	27 mm	32 mm	37 mm	44 mm	48 mm
Technical success	526 (92.4%)	122 (21.4%)	168 (29.5%)	118 (20.7%)	74 (13.0%)	44 (7.7%)
36-month fluoroscopy completed	185 (35.2%)	42 (34.4%)	50 (29.8%)	49 (41.5%)	25 (33.8%)	19 (43.2%)
Wire frame fracture	105 (56.8%)	16 (38.1%)	24 (48.0%)	26 (53.1%)	22 (88.0%)	17 (89.5%)
Clinical sequelae	0	0	0	0	0	0

[r] Reported incidence rate of clinical sequelae associated with wire frame fracture for GORE® CARDIOFORM ASD Occluder. Calculated using data from CATSWeb® Product Surveillance Tracking System [PSTS] and SMARTSOLVE®. Data on file. March 1, 2015 – October 31, 2025. W. L. Gore & Associates, Inc.; Flagstaff, AZ.

[s] Clinical experience with GORE® CARDIOFORM ASD Occluder has reported 1 case of clinical sequelae associated with wire frame fracture from a total of >17,000 devices sold globally. It was reported that the patient presented with onset mitral regurgitation due to perforation of the mitral leaflet induced by device wire frame fracture. It was reported that surgical intervention was required, with the patient making a full recovery.

[t] All WFF measurements are calculated on a per-subject basis; by protocol, all subjects who retained the study device received 1, and only 1, study device. Denominator for wire frame fracture and clinical sequelae percentages is number of subjects completing fluoroscopy.

[u] 36-month fluoroscopy was added in a post-enrollment protocol amendment to identify and assess WFF.

TRUSTED CLOSURE PERFORMANCE THROUGH 36 MONTHS[v,2]

100%

Effective closures
across all ASD anatomies
at 36 months

Characteristics of complex ASDs

ASD category	Anatomical characteristics
Complex	▪ Deficient retro-aortic rim < 5 mm[14] ▪ Deficient posterior-inferior rim < 3 mm[14] ▪ Large defects — stretched diameter ≥ to 26 mm[14] ▪ Multiple or fenestrated defects ▪ Atrial septal aneurysm ▪ Combination of the above

[v] Closure success defined as completely occluded or clinically insignificant shunt as determined by the Echo Core Lab at the six-month evaluation among subjects with technical success.[2]

CASE EXAMPLES

Deficient retro-aortic rim < 5 mm

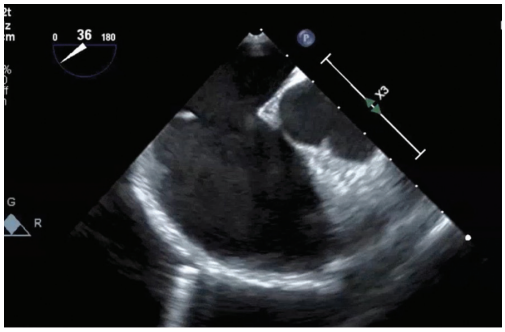


Image courtesy of Bryan Goldstein, MD. Used with permission.

Image 1A TEE showing interrogation of ASD with deficient retro-aortic rim.

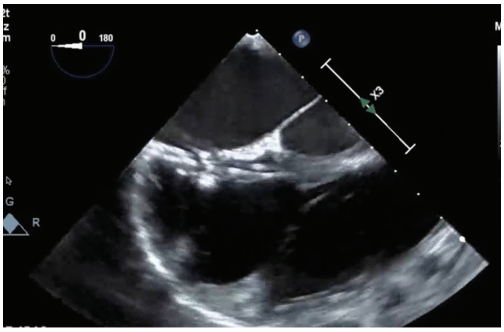


Image courtesy of Bryan Goldstein, MD. Used with permission.

Image 1B Closure of ASD with a deficient retro-aortic rim with the GORE® CARDIOFORM ASD Occluder.

Large ASD with deficient posterior-inferior rim

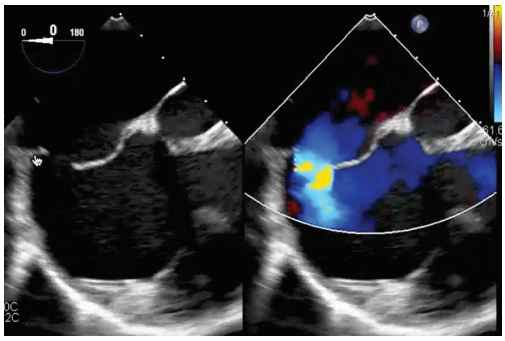


Image courtesy of Alvaro Galindo, MD. Used with permission.

Image 2A TEE demonstrating large ASD with a deficient posterior-inferior rim.

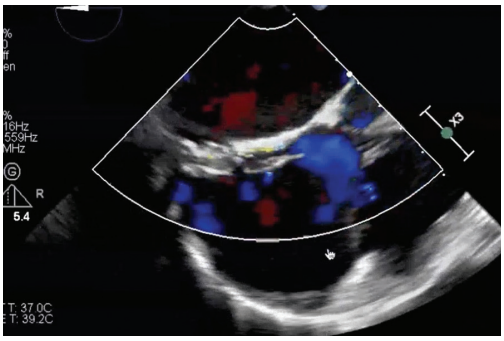


Image courtesy of Alvaro Galindo, MD. Used with permission.

Image 2B Closure of ASD with a deficient posterior-inferior rim with a GORE® CARDIOFORM ASD Occluder.

Multiple defects with ASA

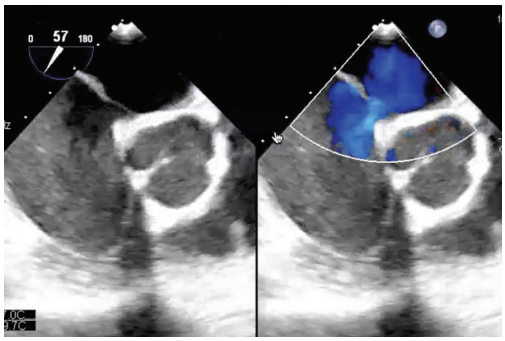


Image courtesy of Alvaro Galindo, MD. Used with permission.

Image 3A TEE demonstrating multiple ASDs with ASA.

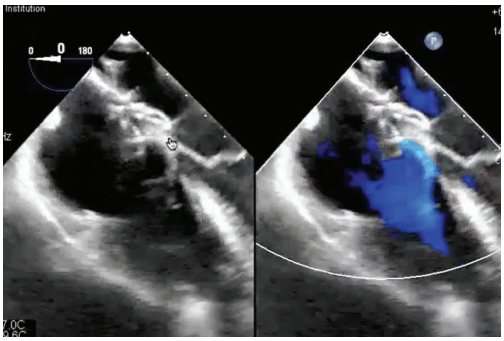
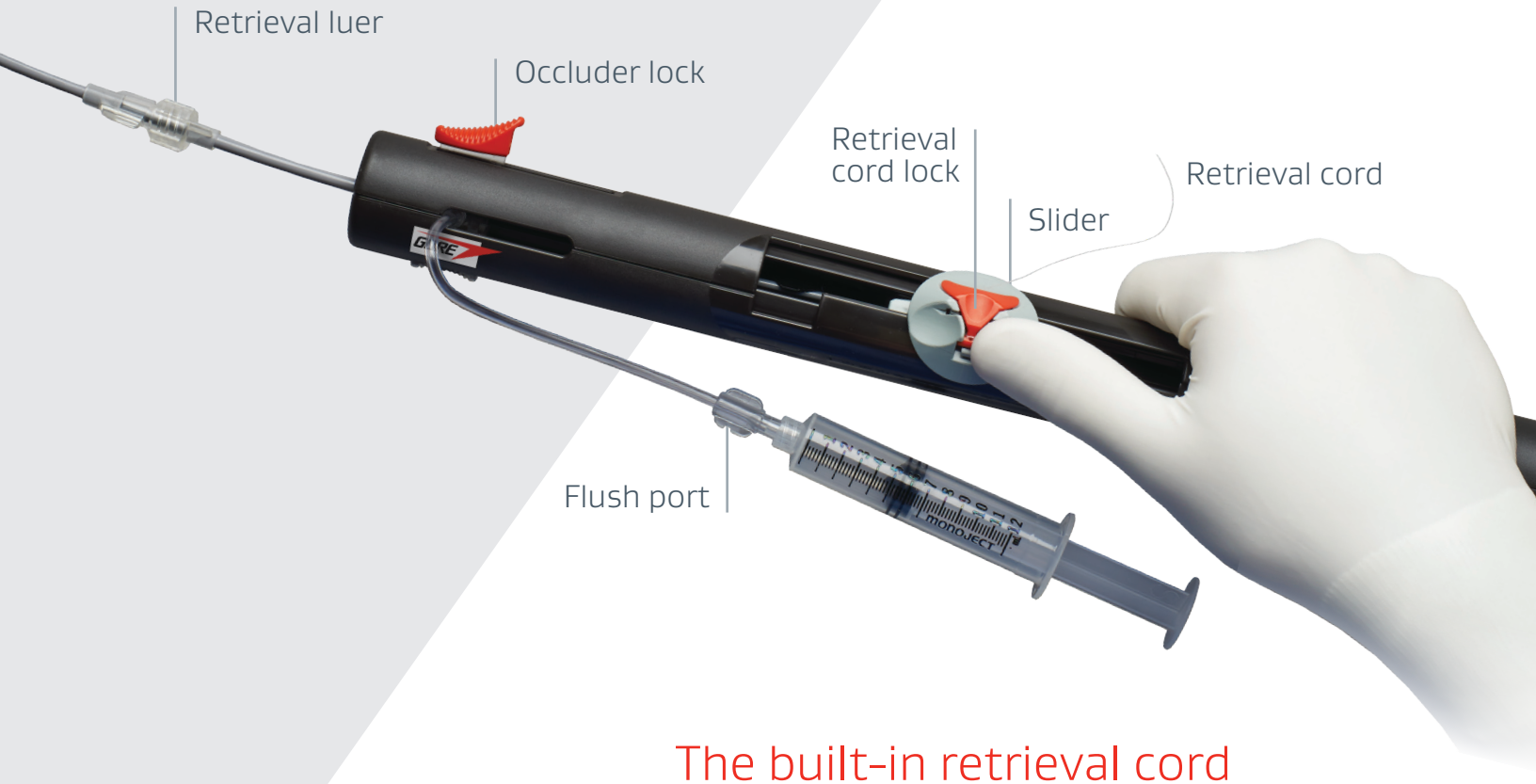


Image courtesy of Alvaro Galindo, MD. Used with permission.

Image 3B Closure of multiple ASDs with ASA with a GORE® CARDIOFORM ASD Occluder.

TRUSTED DEPLOYMENT[w,3]

- Straightforward delivery with the ability to retrieve and reposition[w,3]
- Pre-assembled occluder and delivery system[3] designed to reduce device preparation time



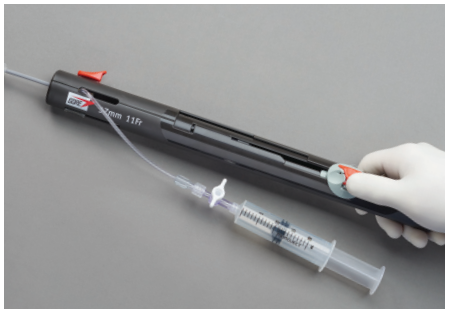
The built-in retrieval cord allows for tension-free assessment and post-lock retrieval, if needed.[3]

[w] Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. $\mathrm{R}_{\mathrm{x\ Only}}$

1-2-3 DEPLOYMENT SEQUENCE[x]

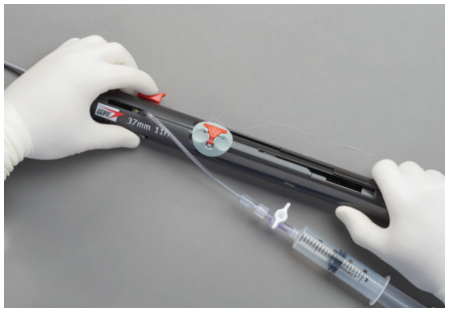
1. Deploy

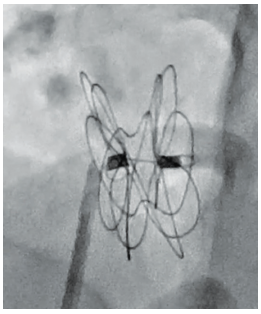
Handle design with slider enables accurate deployment with the ability to reposition.



2. Lock

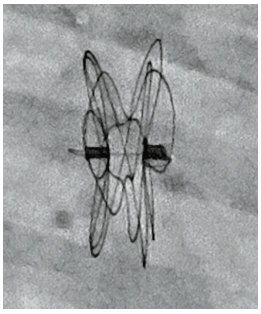
Simple-to-use locking mechanism. Tension-free assessment post-lock where the occluder remains tethered to the delivery system.





3. Release

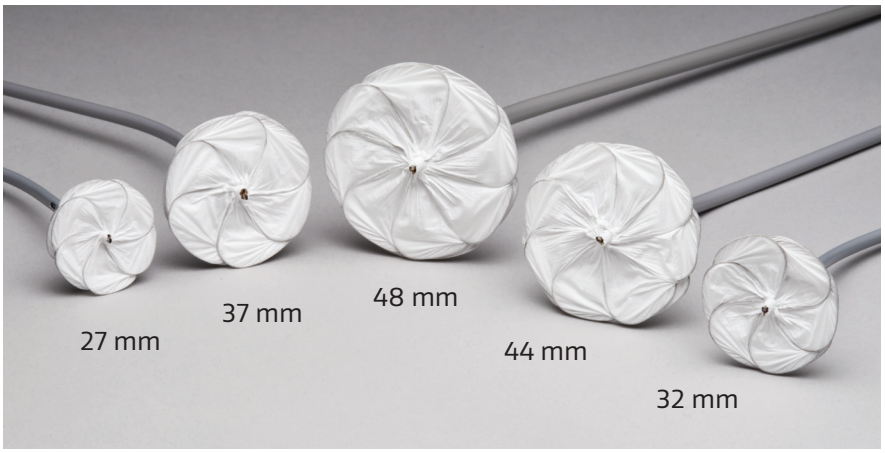
Pull the retrieval cord until completely removed to release the device from the delivery system.



[x] Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. $\text{R}_{\text{X Only}}$

DEVICE SPECIFICATIONS

With the conformable design of the GORE® CARDIOFORM ASD Occluder, 5 catalogue numbers cover ASDs from 8 to 35 mm.[y]



Device size (Disc diameter)	Treatment range measured with stop flow balloon sizing	Sheath size[z]	U.S. catalogue number[aa]
27 mm	8–15 mm	10 Fr	ASD27A
32 mm	13–20 mm	10 Fr	ASD32A
37 mm	18–25 mm	11 Fr	ASD37A
44 mm	23–30 mm	12 Fr	ASD44A
48 mm	28–35 mm	14 Fr	ASD48A

[y] Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

[x] Recommendation for sheath size is 2 Fr larger when used with a wire.

[aa] Catalogue numbers may vary by country or region.

Scan to access valuable GORE® CARDIOFORM ASD Occluder case studies, patient materials and deployment videos.

To learn more about the **GORE® CARDIOFORM** ASD Occluder, contact your Gore Representative.

References

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Consult Instructions for Use
eifu.goremedical.com

INDICATIONS FOR USE IN THE U.S.: The GORE® CARDIOFORM ASD Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs). **CONTRAINDICATIONS:** The GORE® CARDIOFORM ASD Occluder is contraindicated for use in patients: Unable to take anti-platelet or anticoagulant medications such as aspirin, heparin or warfarin; with anatomy where the GORE® CARDIOFORM ASD Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins; with active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement; with known intracardiac thrombi.

Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

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