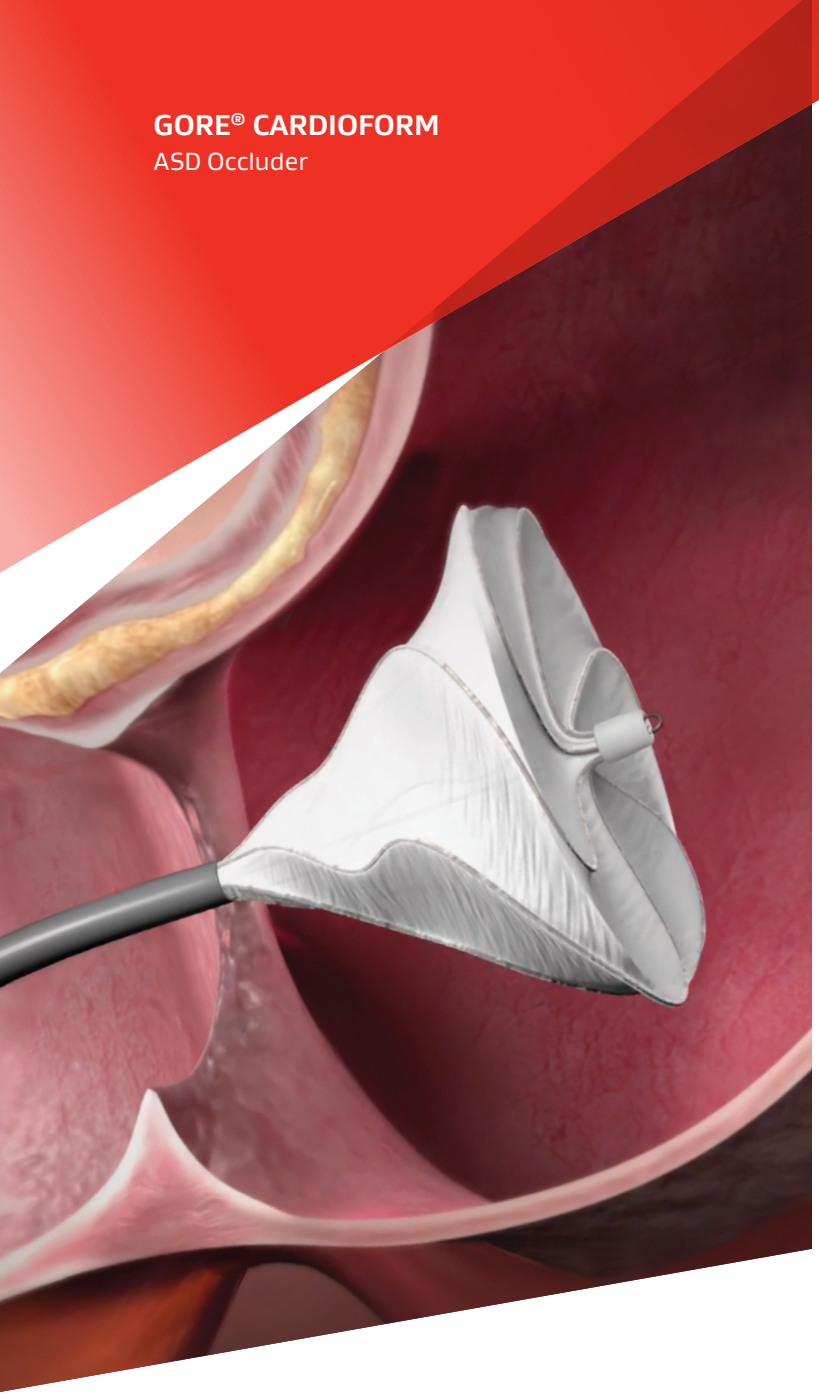
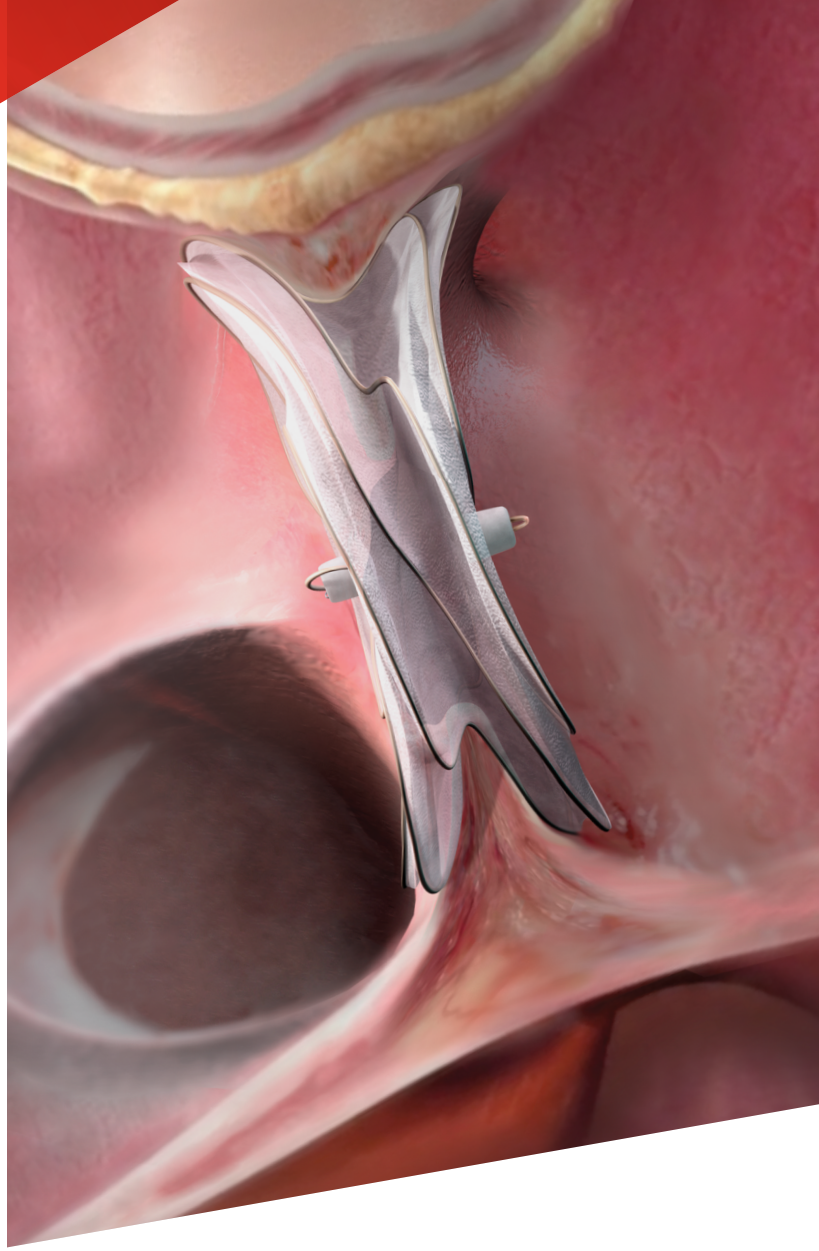
GORE® CARDIOFORM
ASD Occluder





ASDs WITH DEFICIENT RETRO-AORTIC RIMS* DEMAND 100% CLOSURE† AND NO EROSIONS‡,[1]

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

† 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]

‡ 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, 2023; W. L. Gore & Associates Inc.; Flagstaff, AZ.

Together, improving life

GORE

Table of contents

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* DEMAND 100% CLOSURE† AND NO EROSIONS‡,[1]

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	reported cardiac erosions‡,[1]
Trusted closure performance at six months†,§,[1,2]	100%	effective closure across a broad range of ASD anatomies at six months†,§,[1,2]
No retro-aortic rim required[2]	57%	of patients enrolled in the Gore ASSURED Clinical Study were reported to have deficient retro-aortic rims (< 5 mm)[1]
Trusted deployment[2]	1-2-3	straightforward delivery with the ability to reposition and retrieve[2]

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

† 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]

‡ 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, 2023; W. L. Gore & Associates Inc.; Flagstaff, AZ.

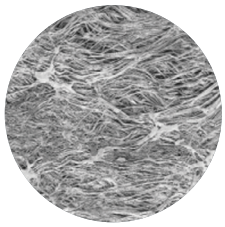
§ All ASD anatomies within indicated sizing parameters of the *Instructions for Use*.

ADVANCED MATERIALS DELIVERING EXCEPTIONAL CONFORMABILITY*,†,‡,[1]

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

ePTFE

Biocompatible, compliant material enables exceptional conformability and rapid endothelialization



ePTFE 250x magnification

30-days post-implant in canine model

* Closure success defined as a clinical residual defect status of occluded or clinically insignificant as determined by the Echo Core Lab at the six-month evaluation among subjects with technical success.[2]

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

‡ 100% closure success rate across ASD anatomies at six months.[*,†,1]

Anatomically adaptable waist

Designed to fill and conform to the defect

Minimal metal

- Six to eight platinum-filled nitinol* 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*,†, ‡,§

* Nickel titanium.

† 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.

‡ 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. $\text{R}_{\text{x Only}}$

§ Data on file. W. L. Gore & Associates, Inc.; Flagstaff, AZ.

A LEADER IN SAFETY

7+ years of clinical use

8,000+ devices sold globally

0 reported cardiac erosions*,[1]

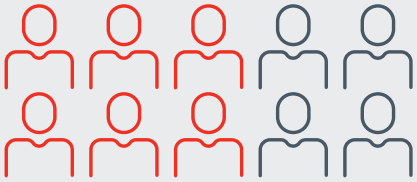
0 no reported clinical sequelae associated with wire frame fractures at six months†,[1]

* 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, 2023. W. L. Gore & Associates, Inc.; Flagstaff, AZ.

† 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 – May 31, 2023. W. L. Gore & Associates, Inc.; Flagstaff, AZ

CATSWeb is a trademark of AssurX, Inc.
SMARTSOLVE is a trademark of Ethos Technologies Inc.

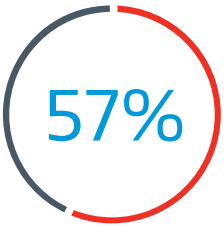
NO RETRO-AORTIC RIM REQUIREMENTS[2]



57% of patients

undergoing transcatheter ASD closure have been reported to have deficient retro-aortic rims.[*,1]

Gore ASSURED Clinical Study:



of patients enrolled in the Gore ASSURED Clinical Study were reported to have deficient retro-aortic rims (< 5 mm)[1]

effective closure at six months[†,1,2]

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.[*,1-4]

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

† 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]

NO REPORTED CASES OF CARDIAC EROSION FOR GORE® CARDIOFORM ASD OCCLUDER*,[1]

GORE® CARDIOFORM
ASD Occluder

0%

Reported cardiac erosion*,[1]

ABBOTT® AMPLATZER
Septal Occluder

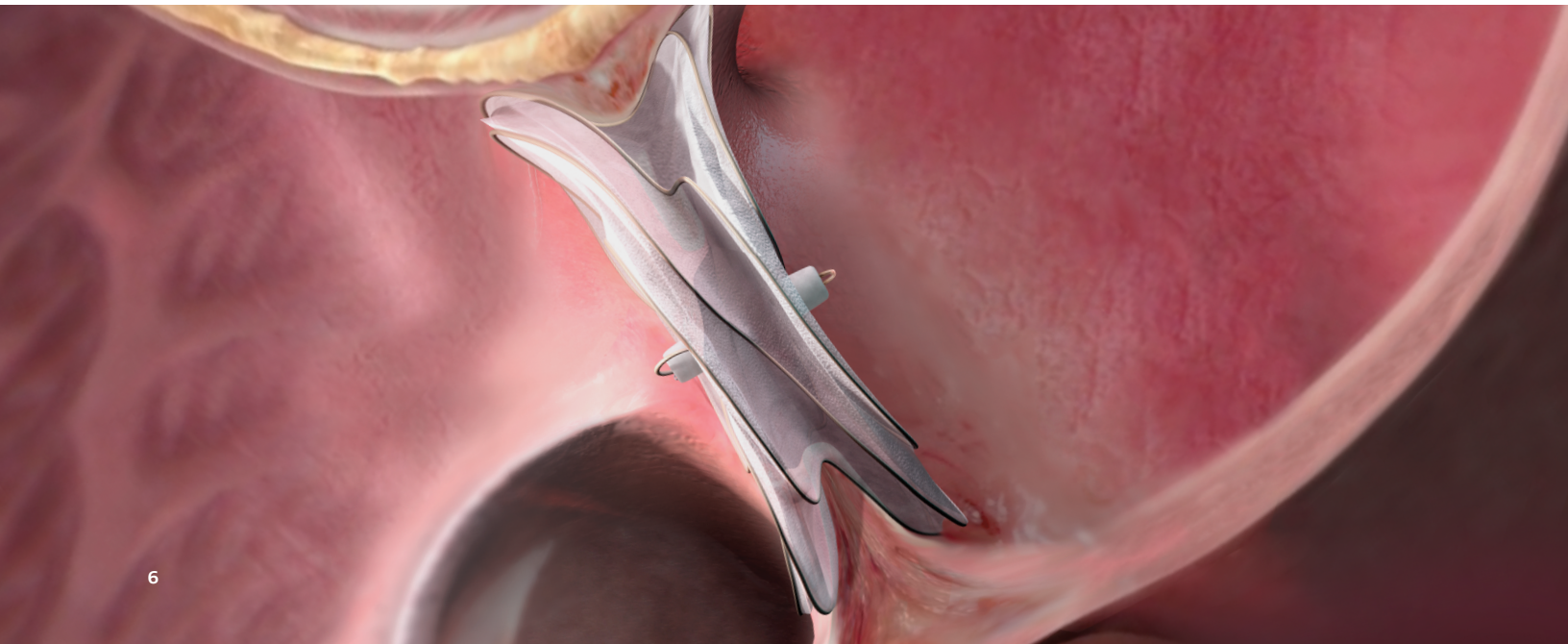
0.1–0.3%

Estimated rate of reported cardiac erosion[4-6]

Cardiac erosions reported for **ABBOTT® AMPLATZER** Occluders:[7,8]

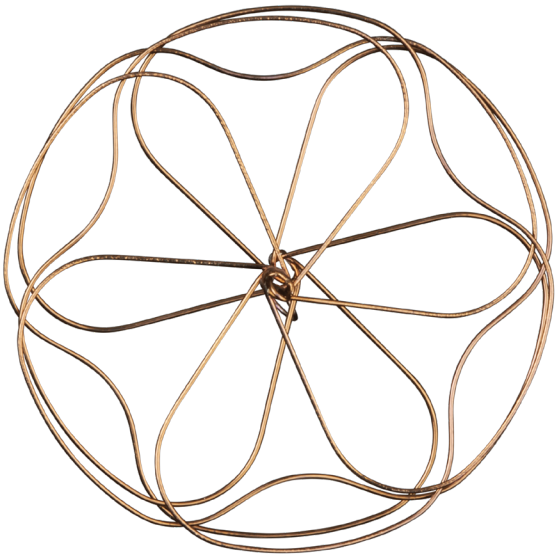
ABBOTT® AMPLATZER Septal Occluder *Reported between 2002 and 2014*[7]	125 Erosions[7]	9 Deaths[7]	7.2% Mortality rate for patients with reported erosions[7]
ABBOTT® AMPLATZER Septal Occluder (N = 83) **ABBOTT® AMPLATZER** PFO Occluder (N = 1) **ABBOTT® AMPLATZER** Multifenestrated Septal Occluder – "Cribriform" (N = 6) *Reported between 2012 and 2018*[8]	90 Erosions[8]	4 Deaths[8]	4.4% Mortality rate for patients with reported erosions[8]

* 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, 2023; W. L. Gore & Associates Inc.; Flagstaff, AZ.



WIRE FRAME FRACTURE ANALYSIS

No reported cases of clinical sequelae associated with device wire frame fracture*,[1]



Summary of reported incidence of clinical sequelae associated with device wire frame fractures for the GORE® CARDIOFORM ASD Occluder*,[1]

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 at six months
GORE® CARDIOFORM ASD Occluder	2015	2019	> 8,000	0

GORE® CARDIOFORM ASD Occluder Pivotal IDE Study for ASD closure: summary of wire frame fracture occurrence at six-month follow-up.[1,2]

All enrolled subjects (N = 125)	Overall	27 mm	32 mm	37 mm	44 mm	48 mm
Fluoroscopy completed at six months	104	19	38	23	19	5
Wire frame fracture at six months	37 (35.6%)	5 (26.3%)	9 (23.7%)	8 (34.8%)	12 (63.2%)	3 (60.0%)
Clinical sequelae at six months associated with device wire frame fracture	0	0	0	0	0	0

* 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 – May 31, 2023. W. L. Gore & Associates, Inc.; Flagstaff, AZ.

TRUSTED CLOSURE PERFORMANCE AT SIX MONTHS*,[1,2]

100%

Effective closures
across all ASD anatomies
at six months

Characteristics of complex ASDs

ASD Category	Anatomical Characteristics
Complex	▪ Deficient retro-aortic rim < 5 mm[9] ▪ Deficient posterior-inferior rim < 3 mm[9] ▪ Large defects—stretched diameter ≥ to 26 mm[9] ▪ Multiple or fenestrated defects ▪ Atrial septal aneurysm ▪ Combination of the above

* 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

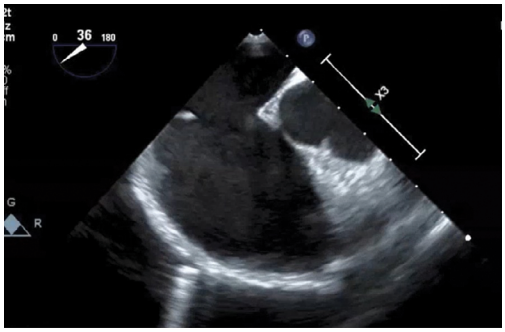


Image courtesy of Bryan Goldstein, M.D. Used with permission.

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

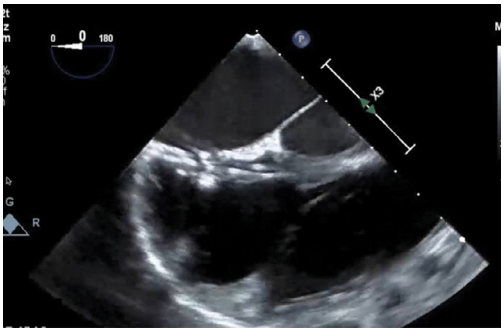


Image courtesy of Bryan Goldstein, M.D. Used with permission.

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

Large ASD with deficient posterior-inferior rim

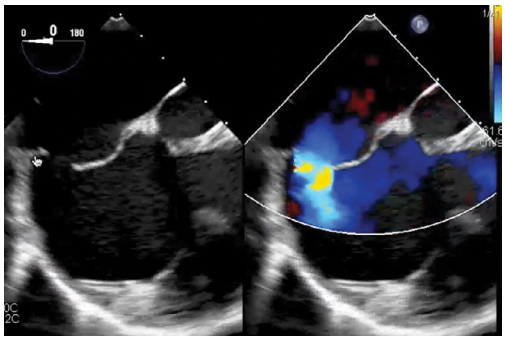


Image courtesy of Alvaro Galindo, M.D. Used with permission.

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

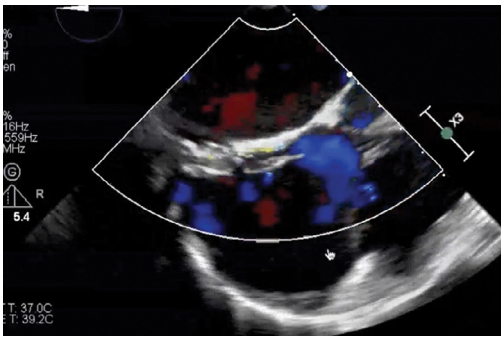


Image courtesy of Alvaro Galindo, M.D. Used with permission.

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

Multiple defects with ASA

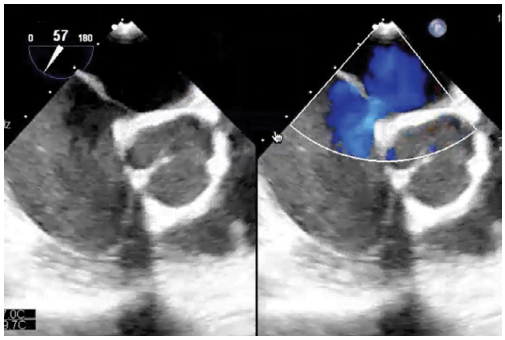


Image courtesy of Alvaro Galindo, M.D. Used with permission.

Image 3A TEE demonstrating multiple ASDs with ASA.

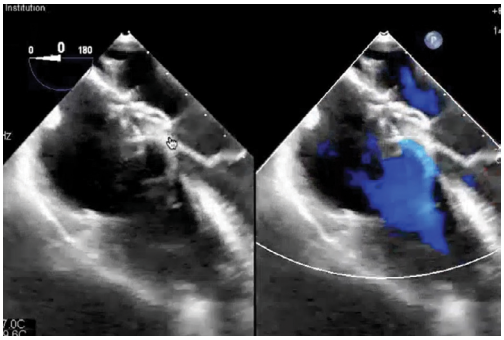
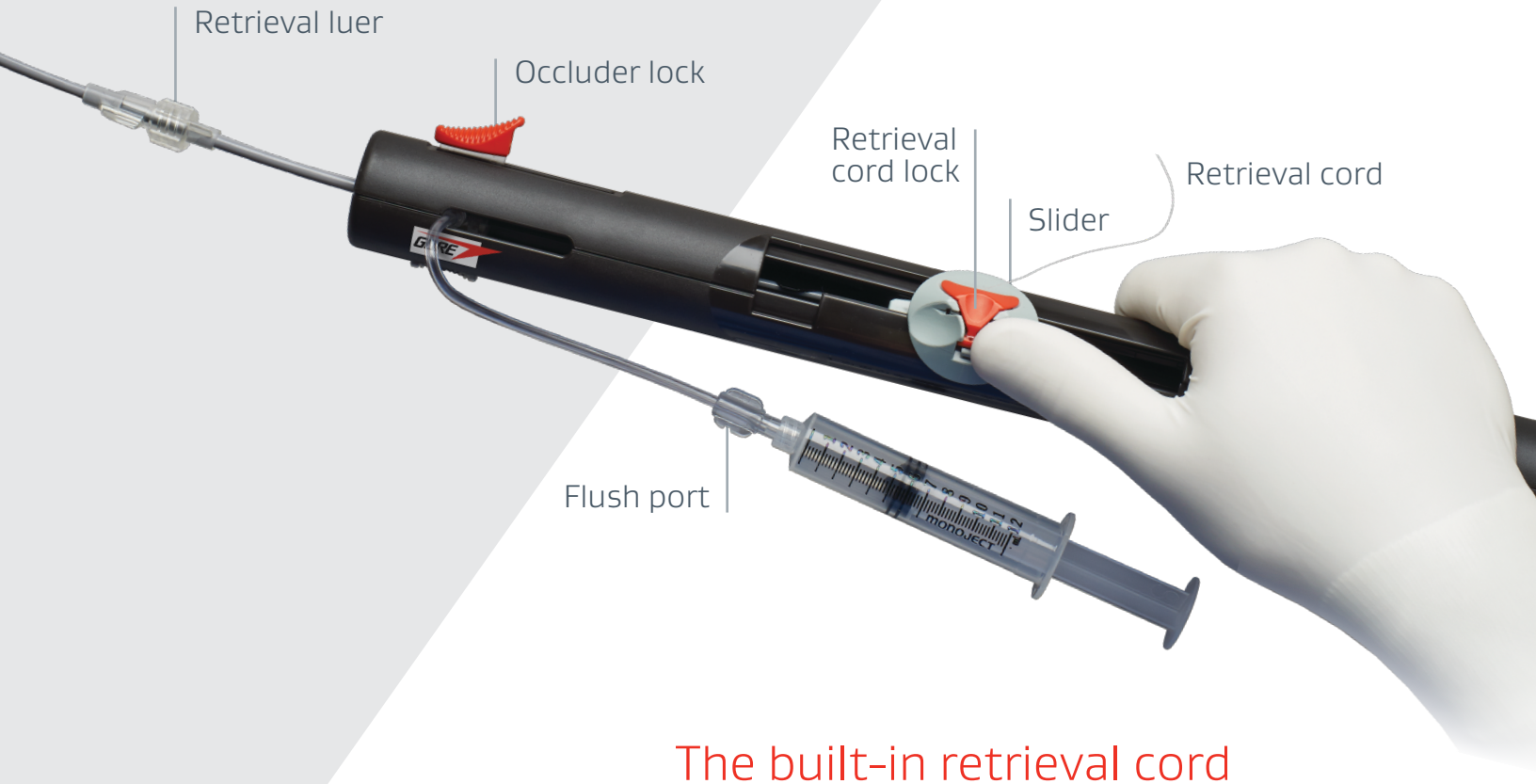


Image courtesy of Alvaro Galindo, M.D. Used with permission.

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

TRUSTED DEPLOYMENT*,2

- Straightforward delivery with the ability to retrieve and reposition*,2
- Pre-assembled occluder and delivery system[2] designed to reduce device preparation time



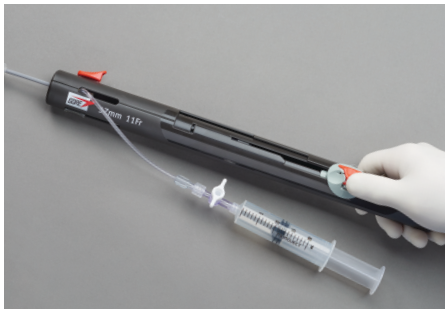
The built-in retrieval cord allows for tension-free assessment and post-lock retrieval, if needed.[2]

* 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. Rx_{Only}

1-2-3 DEPLOYMENT SEQUENCE*

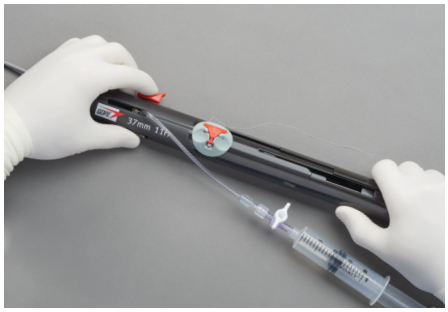
1. Deploy

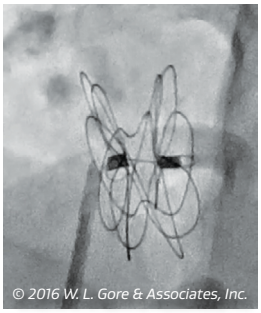
Handle design with slider enables accurate deployment with the ability to reposition.



2. Lock

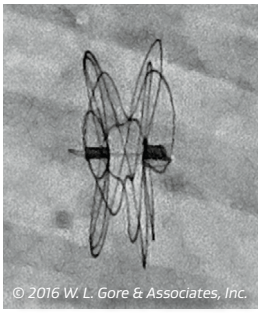
Simple-to-use locking mechanism. Tension-free assessment post-lock where the occluder remains tethered to the delivery system.





3. Release

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



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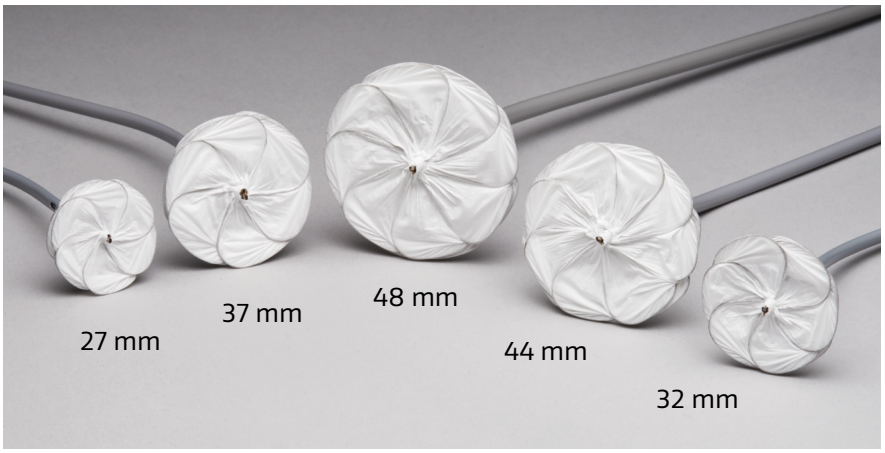
DEVICE SPECIFICATIONS

With the conformable design of the GORE® CARDIOFORM ASD Occluder, five catalogue numbers cover ASDs from 8 to 35 mm.*



Device size (Disc diameter)	Treatment range measured with stop flow balloon sizing	Sheath size†	Catalogue number
27 mm	8–15 mm	10 Fr	ASD27E
32 mm	13–20 mm	10 Fr	ASD32E
37 mm	18–25 mm	11 Fr	ASD37E
44 mm	23–30 mm	12 Fr	ASD44E
48 mm	28–35 mm	14 Fr	ASD48E

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† Recommendation for sheath size is 2 Fr larger when used with a wire.

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
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Products listed may not be available in all markets.

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