

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	<ul style="list-style-type: none">▪ Deficient retro-aortic rim < 5 mm³▪ Deficient posterior-inferior rim < 3 mm³▪ Large defects—stretched diameter ≥ to 26 mm³▪ Multiple or fenestrated defects▪ Atrial septal aneurysm▪ Combination of the above

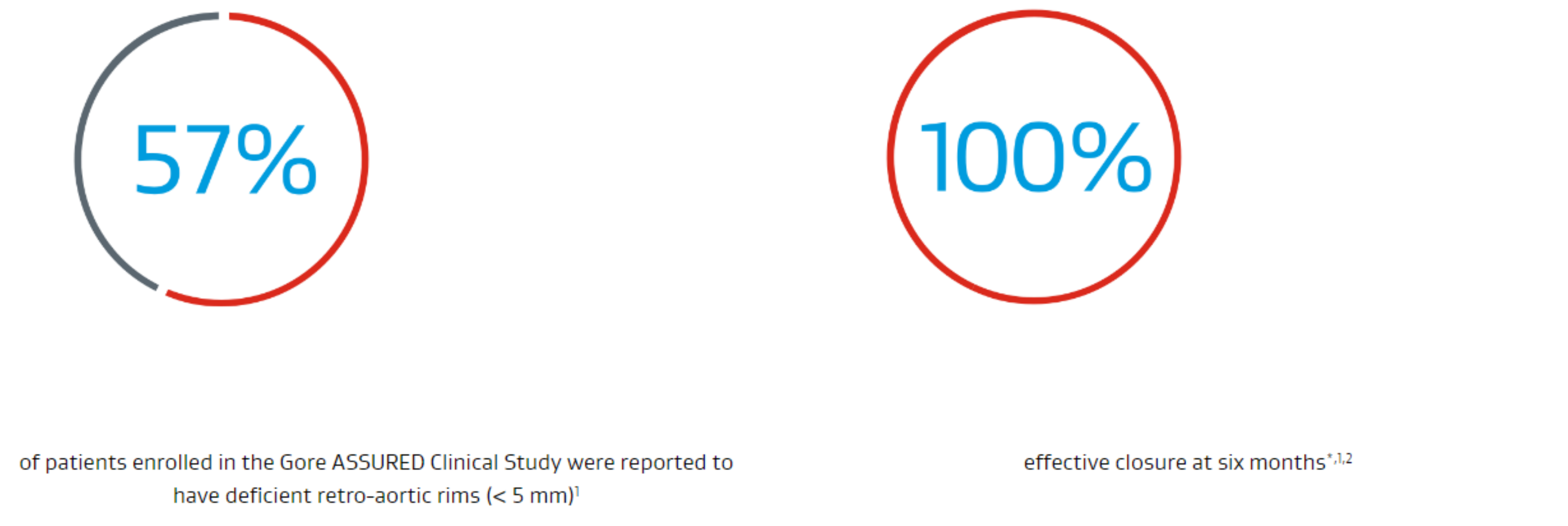
No retro-aortic rim requirements²



57% of patients

undergoing transcatheter ASD closure have been reported to have deficient retro-aortic rims.^{†,1}

Gore ASSURED Clinical Study:



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.^{*,1,2,4,5}



[Download brochure for more information](#)

Case examples

Deficient retro-aortic rim < 5 mm

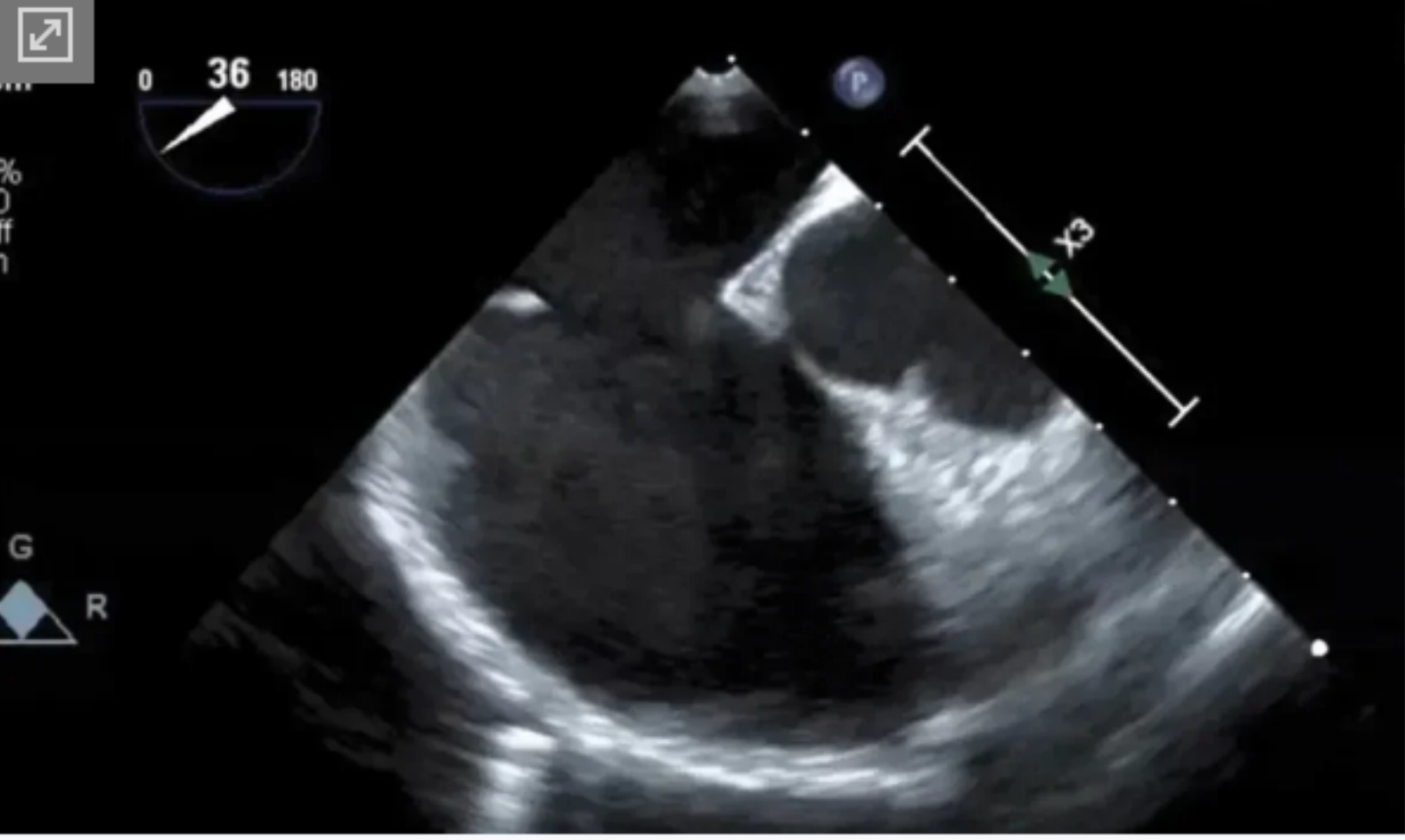


Image courtesy of Bryan Goldstein, M.D. Used with permission.

Image 1A. Transesophageal echocardiogram (TEE) showing interrogation of ASD with deficient retro-aortic rim.

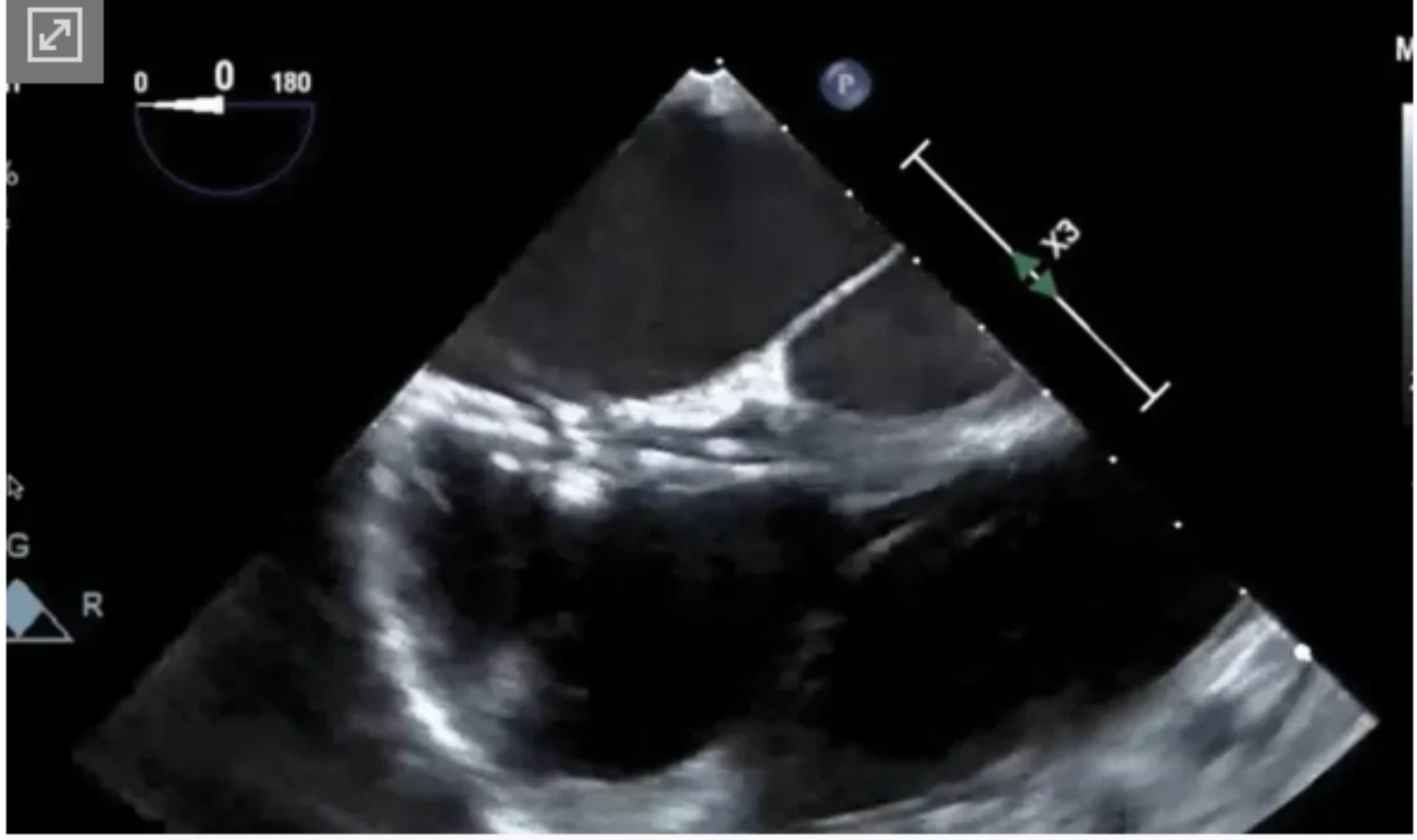


Image courtesy of Bryan Goldstein, M.D. Used with permission.

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

Large ASD with deficient posterior-inferior rim

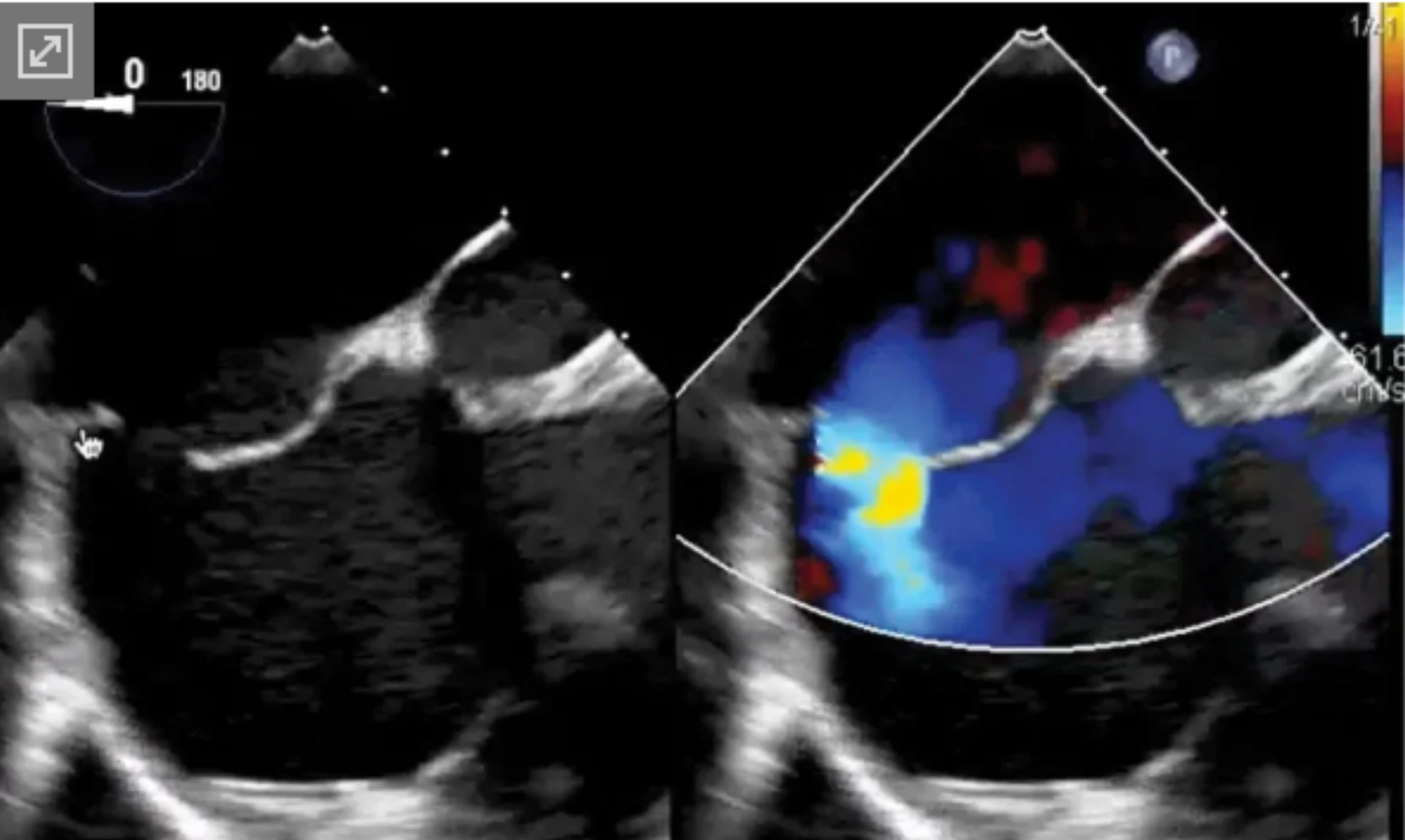


Image courtesy of Alvaro Galindo, M.D. Used with permission.

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

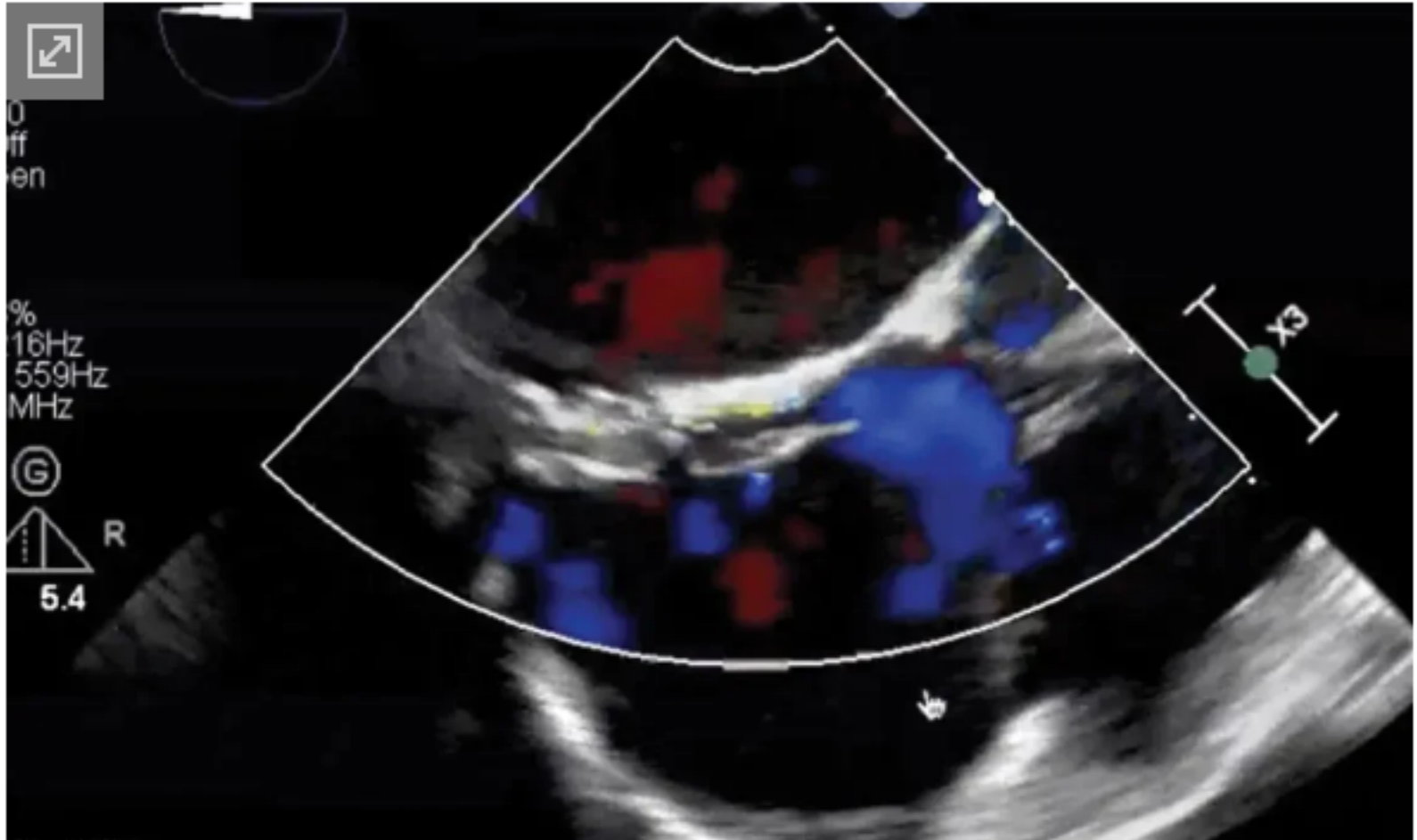


Image courtesy of Alvaro Galindo, M.D. Used with permission.

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

Multiple defects with atrial septal aneurysm (ASA)

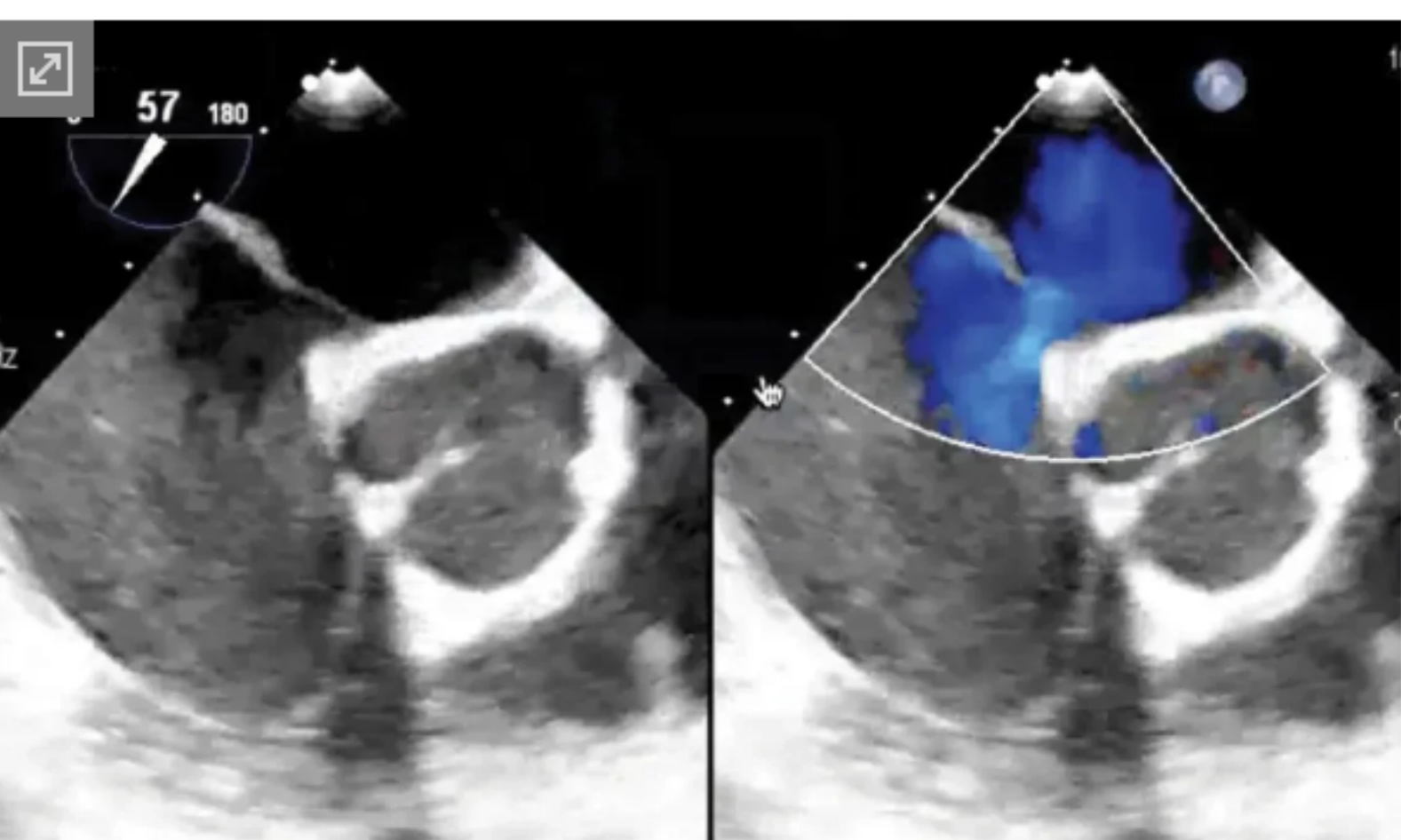


Image courtesy of Alvaro Galindo, M.D. Used with permission.

Image 3A. TEE demonstrating multiple ASDs with ASA.

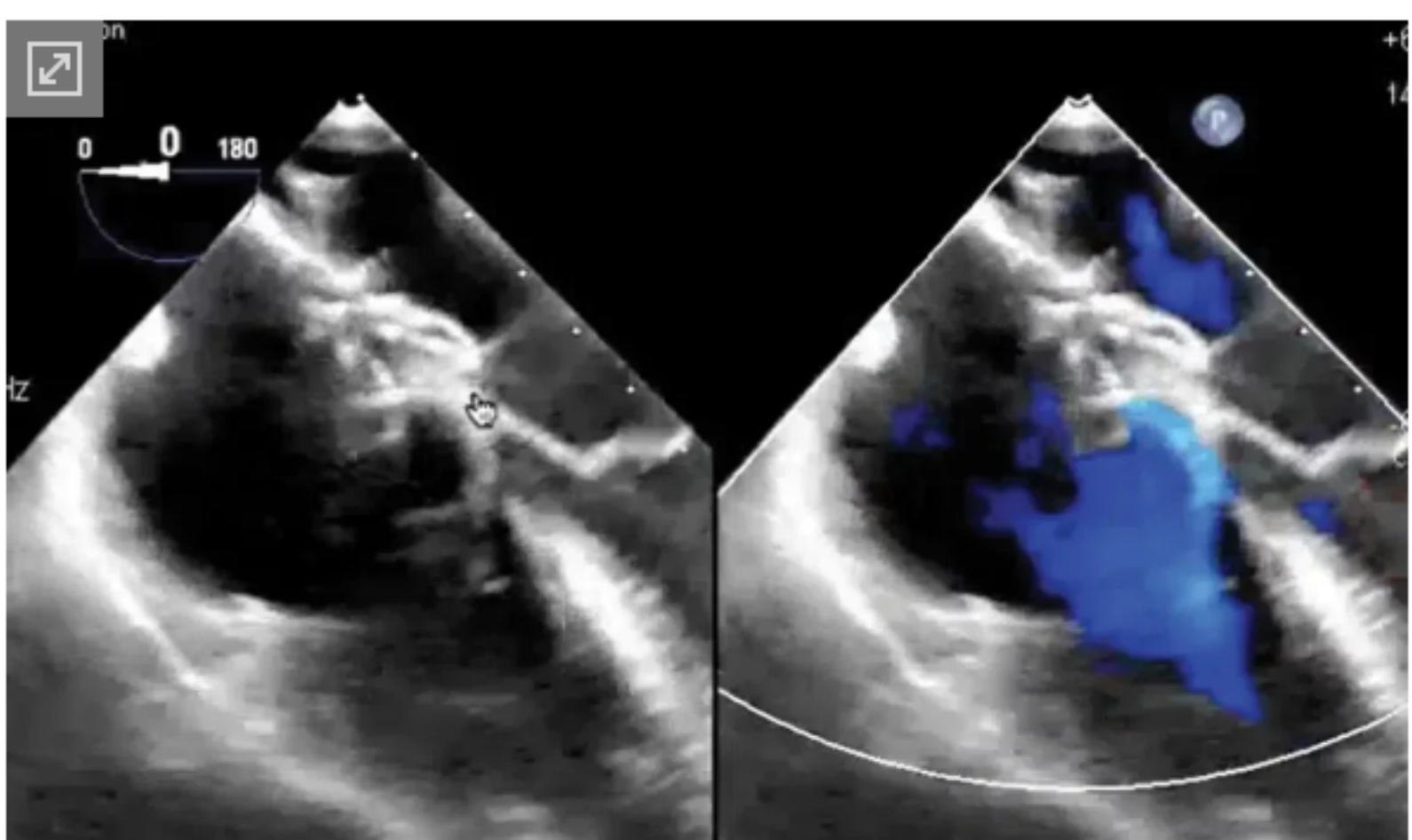


Image courtesy of Alvaro Galindo, M.D. Used with permission.

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

[See why we are a leader in safety](#)



Magnetic Resonance Imaging (MRI) Safety Information

[VIEW INFO >](#)



A Leader In Safety

[SEE WHY >](#)



GORE® CARDIOFORM ASD Occluder Product Brochure

[DOWNLOAD>](#)

^{*} 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

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


¹ Sommer RJ, Love BA, Paolillo JA, et al.; ASSURED Investigators. ASSURED clinical study: new GORE® CARDIOFORM ASD Occluder for transcatheter closure of atrial septal defect. *Catheterization & Cardiovascular Interventions* 2020;95(7):1285-1295.

² GORE® CARDIOFORM ASD Occluder [Instructions for Use]. Flagstaff, AZ.: W. L. Gore & Associates, Inc; 2023. MD190349.

³ Hijazi ZM, Feldman T, Mustafa H, et al. Transcatheter Closure of ASDs and PFOs: A Comprehensive Assessment. 1st Edition. Cardiotext Publishing. 2010.

⁴ AMPLATZER™ Multifenestrated Septal Occluder – “Cribiform” [Instructions for Use]. Plymouth, MN: Abbott Medical; 2022. ARTEN600196098 B.

⁵ AMPLATZER™ Septal Occluder [Instructions for Use]. Plymouth, MN: Abbott Medical; 2022. ARTEN600196097 B.



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. R₀₁, en