CLINICAL SUMMARY

Cardiac erosions associated with septal defect closure devices

Together, improving life

Cardiac erosion: A potentially fatal complication associated with septal defect closure devices[1–13]

Transcatheter closure of **Patent Foramen Ovale (PFO)** and **Atrial Septal Defects (ASDs)** is generally recognized as a safe and effective procedure.[1,14]

Cardiac erosions may require emergent open surgical intervention and pose a potential risk of death.[1–13,15]

Cardiac erosion of a septal device through the atrial wall or pericardial space[2] may result in pericardial effusion, cardiac tamponade or death.[1–13,15]

Cardiac erosions

have been reported for both ASD and PFO devices.[1–13,15]

Specific mechanisms and risk factors for cardiac erosion are likely to be multifactorial[2,4,6,7,15]

Mechanical risk factors

- Occluder type – potential stiffness of device
- Device movement within the heart – motion of relatively stiff occluder device against adjacent cardiac structures

Patient risk factors

- Patient age
- Absent/Deficient rims (Anterior and/or superior)
- Incorrect device sizing (Over sizing or under sizing)

Cardiac erosions have been reported up to 12 years after implantation[10]

EARLY AFTER IMPLANTATION[1-8,11,12,13,15]

6 YEARS[9,13]

12 YEARS[10]

Cardiac erosions reported for septal defect closure devices

Commercially available devices with reported **cardiac erosions**[1–13,15]**:**

Device	Manufacturer
ABBOTT® AMPLATZER Septal Occluder[1–8,10,12,13,15]	Abbott Medical
ABBOTT® AMPLATZER PFO Occluder[9,11,12]	Abbott Medical
ABBOTT® AMPLATZER Multifenestrated Occluder – "Cribriform"[12]	Abbott Medical

GORE® CARDIOFORM Occluders have **no reported history of cardiac erosion**[*,†]

GORE® CARDIOFORM Septal Occluder[‡]

0
reported cardiac erosions[*]

11+ years
of clinical use beginning in June 2011

68,000+
devices sold globally

GORE® CARDIOFORM ASD Occluder[§]

0
reported cardiac erosions[†]

7+ years
of clinical use beginning in February 2015

8,000+
devices sold globally

* Data on file. July 2011–January 2023; W. L. Gore & Associates, Inc.; Flagstaff, AZ.
† Data on file. March 2015–January 2023; W. L. Gore & Associates, Inc.; Flagstaff, AZ.
‡ Clinical experience has reported three cases of clinical sequelae associated with wire frame fracture for GORE® CARDIOFORM Septal Occluder[*,16] from a total of > 68,000 devices sold globally (correlating to a reported incidence rate of 0.004%). In two of these cases, it was reported that both patients suffered from pericardial tamponade due to perforation of the atrial wall induced by device wire frame fracture.[16] In the third case it was reported that device wire frame fracture was a likely cause for the formation of a fistula between the left atrium and aorta.[*] It was also reported that urgent medical care surgical reintervention was required with all three patients making a full recovery.[*,16]
§ Since first clinical use in February 2015, there have been no reported incidents of clinical sequelae associated with wire frame fracture for GORE® CARDIOFORM ASD Occluder from a total of > 8,000 devices sold globally.[†]

Cardiac erosions reported in literature for ABBOTT® AMPLATZER Occluders:

ABBOTT® AMPLATZER Septal Occluder

Reported between 2002 and 2014[2]

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

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

Reported between 2012 and 2018[17]

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

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ABBOTT® AMPLATZER Septal Occluder

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

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

ABBOTT® AMPLATZER PFO Occluder

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

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

Estimates for cardiac erosion following ABBOTT® AMPLATZER Septal Occluder implantation reported to range from 0.1–0.3%.[13]

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

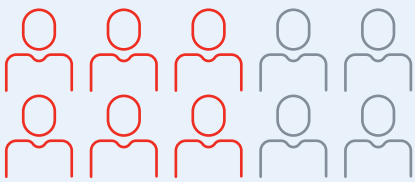
Cardiac erosion: A potential risk for ASD patients with deficient retro-aortic rims

ABBOTT® AMPLATZER Septal Occluder – *Instructions for Use* (IFU)

2012 modification to IFU included a warning statement that patients with a retro-aortic rim of less than 5 mm in any echocardiographic plane may be at risk of erosion.[2,17,18]

IFU warnings, potential adverse events and precautions related to cardiac erosion:

Device	Related IFU Content
ABBOTT® AMPLATZER Septal Occluder	Warning: Patients with a retro-aortic rim of less than 5 mm in any echocardiographic plane, or patients in whom the device physically impinges on (i.e., indents or distorts) the aortic root, may be at increased risk of erosion.[18] Potential adverse event: tissue erosion.[18]
ABBOTT® AMPLATZER PFO Occluder	Potential adverse event: device erosion.[19]
ABBOTT® AMPLATZER Multifenestrated Septal Occluder – "Cribriform"	Patient selection: Certain patients may be at higher risk for complications such as tissue erosion and device embolization. If higher risk patients have devices implanted, closer follow-up is warranted. Higher risk patients include the following: ▪ Patients with deformation of the device at the aortic root ▪ Patients with high defects (Minimal aortic and superior rims) ▪ Patients with less than a 9 mm distance from the central defect to the aortic root or superior vena cava orifice[20] Potential adverse event: erosion[20]
GORE® CARDIOFORM Septal Occluder	**No warnings, potential adverse events or precautions related to cardiac erosions or use in patients with deficient retro-aortic rims.[21]**
GORE® CARDIOFORM ASD Occluder	**No warnings, potential adverse events or precautions related to cardiac erosions or use in patients with deficient retro-aortic rims.[22]**



60% of patients

undergoing transcatheter ASD closure have been reported to have deficient retro-aortic rims*,[23]

In the Gore ASSURED Clinical Study, 57% of patients had a deficient retro-aortic rim and were treated with the GORE® CARDIOFORM ASD Occuder.*,[24]

For more information on GORE® CARDIOFORM Occluders, contact your Field Sales Associate.

* Deficient retro-aortic rim was defined as a retro-aortic rim measuring less than or equal to 5 mm on any view on echocardiogram.[23]

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INDICATIONS FOR USE IN THE U.S.: The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of the following defects of the atrial septum: ostium secundum atrial septal defects (ASDs); patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke. **CONTRAINDICATIONS:** The GORE® CARDIOFORM Septal Occluder is contraindicated for use in patients: unable to take antiplatelet or anticoagulant medications such as aspirin, heparin or warfarin; with anatomy where the GORE® CARDIOFORM Septal 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.

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.

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