Generic implant safety procedure:

Review of Cardiac closure and occlusion devices to treat heart defects such as Patent Ductus Arteriosus (PDA), Atrial Septal Defect (ASD), Ventricular Septal Defect (VSD) and Patent Foramen Ovale (PFO)

Document Details	
Author	John McLean
MRSE	Ian Cavin
Radiographer	Heather Boylan
Other (add rows as required)	Callum Adams (Radiologist)
Authorisation date (MR safety committee / other committee sign off date)	Jan 2022
Review Date	June 2026

Version History		
Version	Date	Description
Version 1	Jan 2022	
v2	Aug2025/ June 2026	JM reviewing, this includes migrating document from old document to new template

About this document

1. This template follows the guidance document: Ashmore et al., **A framework for developing Generic Implant Safety Procedures for scanning medical implants and devices in MRI**. Further details on developing a GISP can be found there.
2. The procedure statement provides a simple overview of the practical implementation of the GISP (typically completed last).
3. The Evidence review contains all the evidence which backs up the risk assessment and procedure statement (typically completed first).
4. The risk assessment provides an overview of the risk associated with the GISP
5. Roll over each section title for information on how to complete the section

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1 Procedure Statement / Workflow

Disclaimer

Compiled here are Generic Implant Safety Procedures (GISP's) for MRI. While steps have been taken to minimise the risk of adoption of these procedures, it should be noted that these are not completely without risk. Health boards, integrated care systems, trusts or private medical institutions should consider carefully whether they wish to adopt these procedures. They should do so via their own governance process, and the procedures should be reviewed prior to use. Any institutions use of this policy shall be done so at their own risk. If you are a patient reading this, then we strongly advise you to contact your healthcare provider directly with any concerns prior to attending for your scan, as approaches may vary. It remains the responsibility of the individual registered radiographer to apply their MRI knowledge and professional judgment to the situation under consideration. If there is any doubt regarding the safety of the patient then additional advice should be sought from e.g. the MR Responsible person, MRSE or the lead Clinician for MR safety.

Brief description:

Some closure procedures are carried out using clips e.g. to repair PDA. More often closure or occlusion is performed with umbrella like devices/occlusion devices which have expandable, metal wire frame structures. These are often referred to as devices that repair a hole in the heart.

Clips can be used as part of surgical procedures, however, more commonly interventional procedures, using occlusion devices, are used. Once inserted, the umbrella like structure is expanded on either side of the pathology such as to repair the defect.

What the procedure covers:

Clips, closure and occlusion devices used for the repair of Patent Ductus Arteriosus (PDA), Atrial Septal Defect (ASD), Ventricular Septal Defect (VSD) and Patent Foramen Ovale (PFO). These are commonly referred to as repairs for a hole in the heart.

What the procedure does not cover, including notable exceptions:

This policy only covers closure or occlusion devices used in the heart. This policy does not cover coiling or embolization devices. Polices for these devices are covered elsewhere.

Advice summary:

Patients with clips, closure, or occlusion devices for the purposes of the repair of PDA, ASD, VSD, and PFO may be safely scanned using 1.5T and 3T MRI in normal operating mode. If first level is required to achieve the desired clinical imaging quality, we believe the risk of scanning is still low, and therefore first level can be used where necessary under this GISP.

2 Evidence Review

2.1 Clinical context

This review considers a range of cardiac closure or occlusion devices. We have adopted the same categorisation as detailed on Dr Shellock's MRIsafety.com for these devices. While some of the abnormalities in the heart are typically spotted prior to birth or soon after birth, some of the conditions can persist into adulthood unnoticed. Congenital heart disease more generally has a prevalence of around 8 births in every 1000 and as such are a frequent occurrence in healthcare (Norrish et al [4], Dolk et al [5]).

All these conditions can be closed by either surgical techniques or transcatheter techniques. There are several clinical factors which dictate the choice of intervention. Services have evolved over the years as device technologies have changed, but both approaches are still in use (Farooqi et al [7]).

Surgical techniques can enable closure by ligation, by clip or by suture.

The terms used will be briefly explained such as to provide context of the device and the underlying pathology the closure device or occluder is designed to repair.

Patent Foramen Ovale (PFO)

There are many types on congenital defect, some of the most common are: atrial septal defect (ASD) and a patent foramen ovale (PFO). Although both are holes in the wall of tissue (septum) between the left and right upper chambers of the heart (atria), their causes are quite different. An ASD is a failure of the septal tissue to form between the atria, and as such it is considered a congenital heart defect, something that you are born with. An ASD hole is typically larger than that of a PFO. The larger the hole, the more likely there are to be symptoms.

PFOs, on the other hand, can only occur after birth when the foramen ovale fails to close. The foramen ovale is a hole in the wall between the left and right atria of every human fetus. This hole allows blood to bypass the fetal lungs, which cannot work until they are exposed to air. When a newborn enters the world and takes its first breath, the foramen ovale closes, and within a few months it has sealed completely in about 75 percent of us. When it remains open, it is called a patent foramen ovale, patent meaning open. For most of the millions of people with a PFO, it is not a problem, even though blood is leaking from the right atrium to the left. Problems can arise when that blood contains a blood clot

Patent Ductus Arteriosus (PDA),

Information below was sourced from the Great Ormond Street Hospital website [2]. The ductus arteriosus is a blood vessel that connects the pulmonary artery (main vessel supplying the blood to the lungs) to the aorta (main vessel supplying the blood to the body). This connection is present in all babies in the womb but should close shortly after birth. In some babies, especially in those born prematurely, this vessel may remain open. This is called a patent or persistent ductus arteriosus.

Atrial Septal Defect (ASD),

Information below was sourced from the NHS website [3]. An atrial septal defect (ASD) is where there is a hole between the two collecting chambers of the heart (the left and right atria). When there is an ASD, extra blood flows through the defect into the right side of the heart, causing it to stretch and enlarge.

Ventricular Septal Defect (VSD)

Information below was sourced from the NHS website [3]. A ventricular septal defect (VSD) is a common form of congenital heart disease. It occurs when there's a hole between the 2 pumping chambers of the heart (the left and right ventricles). This means that extra blood flows through the hole from the left to the right ventricle, due to the pressure difference between them. The extra blood goes to the lungs, causing high pressure in the lungs and a stretch on the left- sided pumping chamber. Small holes often eventually close by themselves, but larger holes need to be closed using surgery.

2.2 Results

2.2.1 Online MRI implant safety databases (Date queried: 25/8/25)

Review of MRI implant safety databases [1] (MRIsafety.com**)**

What follows is a list from the MRI implant safety database with the name of the implant, the manufacturer, a link to information on the manufacturer website and the implant's MRI safety status.

PDA's

4 PDA devices with the following names and MRI status

Nit-Occlud PDA-R Occluder

PFM s.r.l.

https://www.pfmmedical.co.uk/products-category/cardio-vascular-technologies/

Status on MRIsafety.com: 3T, conditional 6

Notes: A company called PF medical also have a device called: Nit-Occuld ASD

Occlutech PDA Occluder

Occlutech, www.occlutech.com

https://www.occlutech.com/ (international i.e. non US site)

Status on MRIsafety.com: 3T, conditional 8

Rashkind PDA Occlusion Implant

12 mm, occluder (304V SS)

C.R. Bard, Inc.

Billerica, MA

Status on MRIsafety.com: 1.5T, conditional 5

Rashkind PDA Occlusion Implant

17 mm, occluder (304 V SS)

C.R. Bard, Inc.

Billerica, MA

Status on MRIsafety.com: 1.5T, conditional 5

Notes: Company ‘CR BARD’ became simply 'BARD'. C. R. Bard, Inc., now branded simply as Bard, headquartered in Murray Hill, New Jersey, USA, is a multinational developer, manufacturer, and marketer of medical technologies in the fields of vascular, urology, oncology, and surgical specialties. In April 2017, the company has announced that it will be acquired by Becton Dickinson.

The author’s impression of Rashkind product is that it is no longer available and was an early device developed in this area. Thus, we are not likely to get more information from commercial websites on this product, however the peer reviewed literature might contain some information.

PDA summary: All PDA devices on Dr Shellock’s site (as of Jan 2020) are MR conditional, though information for the Rashkind device is limited to 1.5T

Aug 2025 update: still only 4 PDA devices listed on the ‘the list’, all still MR conditional. Revision, there is a 5th device, which doesn’t appear if searching for PDA but is a PDA device, this is the Starflex.

The StarFlex septal repair implant

MP35N is MP35N alloy is a high-performance, nonmagnetic nickel-cobalt-chromium-molybdenum alloy known for its ultra-high tensile strength, good ductility, and excellent corrosion resistance

NMT medical

MR Safe (presumably MR conditional now under the revised terminology, given the device is made of Nitinol)

ASD’s

3 ASD devices with the following names and MRI status

Figulla Flex II ASD Occluder

All Sizes

Occlutech GmbH, www.occlutech.com

Status on MRIsafety.com: 1.5T, 3T, conditional 8

HELEX

ASD closure device

occluder

size 15 mm

nitinol

W. L. Gore and Associates, Inc.

Flagstaff, AZ

Status on MRIsafety.com: 1.5T, MR Safe (though this is unusual as usually Dr Shellock states all devices containing metal are (as a minimum), MR conditional.

HELEX

ASD closure device

Occluder

size 35 mm

nitinol

W. L. Gore and Associates, Inc.

Flagstaff, AZ

Status on MRIsafety.com: 1.5T, MR Safe (though this is unusual as usually Dr Shellock states all devices containing metal are (as a minimum), MR conditional.

ASD summary: All ASD devices on Dr Shellock's site (as of Jan 2020) are MR Safe or MR Conditional, though information for the Helex device is limited to 1.5T.

Aug 2025 update: No notable changes to ASD devices listed on the 'the list', all still MR conditional.

VSD's

6 VSD devices with the following names and MRI status

AMPLATZER Muscular VSD Occluder

AGA Medical Corporation

Plymouth, M

Status on MRIsafety.com: 3T, conditional 6

AMPLATZER Muscular VSD Occluder

St. Jude Medical, www.sjm.com

Status on MRIsafety.com: 1.5T,3T conditional 8

AMPLATZER Muscular VSD PI Occluder

AGA Medical Corporation

http://international.amplatzer.com

Status on MRIsafety.com: 3T, conditional 6

Occlutech Muscular VSD (mVSD) Occluder

Occlutech Ltd., www.occlutech.com

Status on MRIsafety.com: 1.5T, 3T conditional 5

Perimembranous Ventricular Septal Defect (PmVSD) Occluder

Occlutech, www.occlutech.com

Status on MRIsafety.com: 1.5T, 3T conditional 8

Post Myocardial Infarction Ventricular Septal Defect (PIVSD) Occluder

Occlutech, www.occlutech.com

Status on MRIsafety.com: 1.5T, 3T conditional 8

Notes: The Amplatzer device is now an SJM product.

VSD summary: All VSD devices on Dr Shellock's site (as of Jan 2020) are listed as MR conditional.

Aug 2025 update: No notable changes to VSD devices listed on the 'the list', all still MR conditional.

PFO's

5 PFO devices with the following names and MRI status

PFO's from Shellock's website

AMPLATZER PFO Occluder

Nitinol, SS, Platinum/iridium, Polyester

AGA Medical Corporation

Plymouth, M

Status on MRIsafety.com: 3T conditional 6

BioTREK

PFO closure device

NMT Medical,

Boston, MA

Status on MRIsafety.com: 3T conditional 6

Intrasept

patent foramen ovale (PFO) closure device

Nitinol, Titanium

Cardia Inc.

Burnsville, M

Status on MRIsafety.com: 3T conditional 6

Premere PFO Closure System

Patent foramen ovale (PFO) closure device

St. Jude Medical

www.sjmprofessional.com

Status on MRIsafety.com: 3T conditional 6

Note: An IFU or other *corporate information on this product could not be sourced. It could not be found on the SJM website. The company was emailed but no response was forthcoming.*

Ultrasept PFO Occluder

Cardia, Inc., www.cardiainc.com

Status on MRIsafety.com: 3T conditional 6

Note: *Emailed Cardia http://www.cardia.com/index.html for IFU for Intrasept and Ultrasept products and any other products. Note the FAQ site on Cardia states that MRI is ok for the Ultrasept device http://www.cardia.com/faq.html.*

Note: The Amplatzer PFO falls under several companies: AGA, SJM, Abbott. Some historical IFU's were obtained.

https://www.cardiovascular.abbott/us/en/hcp/resources/mri-ready-resources/structural-heart-mri-safety.html

PFO summary: All PFO devices on Dr Shellock's site (as of Jan 2020) are listed as MR conditional.

Aug 2025 update: No notable changes to VSD devices listed on the 'the list', all still MR conditional.

2.2.2 Implant manufacturers (Date queried: 25/8/25)

It is notable that there has been an evolution of devices. This can be seen on the Occultech website that here are now further ranges of 'derivative' devices https://www.occlutech.com See 'UNI', 'PLD', mVSD, PmVSD, and AFR. There is the potential for confusion between the acronym for the device and the acronym for the underlying pathology. However, it is expected that any derivative device, would not be 'worse' in terms of MR safety properties than its parent device

PDA's are sold by Occultech and Pfmmedical.

ASD

In addition to the devices list on Dr Shellock's website there is a further ASD device marketed by pfmmedical called Nit-Occult ASD (mirroring their PDA product).

PFO

NMT: also make CardioFlex and StarSeal, septal repair devices?

Ceraflex (see Abdelgani et al [33])

Note on WL Gore and associates became Gore Medical

https://www.goremedical.com/

https://www.goremedical.com/products

https://www.goremedical.com/products/helex

There are now many products on Gore's website now. The HELEX being only one such product. It is noted that the HELEX product is discontinued (noted at Jan 2020 but likely to have been discontinued earlier). No IFU for Helex product was readily available.

Note: The Nit-Occuld ASD-R device is not noted on Dr Shellock's website.

2.2.3 Review of the peer reviewed literature (Date queried: 22/4/25)

n/a

2.2.4 Internet search (non peer reviewed literature) (Date queried: 25/8/25)

The curious case of the Sideris Buttoned device. There was an ASD product known as the Sideris Buttoned device (Sideris et al [8]). This was manufactured by Custom Medical Devices, Athens, Greece; Amarillo, TX, USA. In a paper by Bock et al [13], who were reviewing the MR safety aspects of ASD's, this device is described as being ferromagnetic having failed a deflection text, the following was noted:

"During the deflection measurement, only one occluder, the Sideris Buttoned Device containing stainless steel (#7 in Tab. 1), moved from its position on the paper and was excluded from further tests. All other occluders showed no observable displacements."

#	Name	Hersteller	Indikation	Streben material	Segelmaterial	Charakteristische Dimension	Länge (cm)	Artefakte
1	PFO-Star Generation III	CARDIA	PFO	Nitinol	Polyvinylalkohol	Strebenlänge	3,02 ± 0,02	2
2	Angel Wing ASD Device	Micro Vena / EV3	ASD, PFO	Nitinol	Dacron®	Segeldurchmesser	2,60 ± 0,03	1
3	PFO-Star Generation I	CARDIA	PFO	Nitinol	Polyvinylalkohol	Strebenlänge	3,00 ± 0,02	2
4	Helex Septal Occluder	Gore	ASD, PFO	Nitinol	Polytetrafluoroethylen (ePTFE)	Gesamtdurchmesser	2,50 ± 0,02	1
5	Amplatzer ASD Occluder	AGA Medical Corp.	ASD, PFO	Nitinol	Dacron®	Gesamtdurchmesser	4,21 ± 0,03	2
6	Starflex	NMT	ASD	MP35 n	Dacron®	Segeldurchmesser	2,63 ± 0,02	2
7	Sideris Buttoned Device, Generation I	Custom Medical Devices	ASD	Edelstahl	Polyurethanschaum	Segeldurchmesser	3,30 ± 0,02	–

Table 1 from Bock et al [13]

The testing done by Bock et al [13] seems to have involved placing the devices on the couch on a sheet of paper. The couch was then driven in to isocentre, passing through a max |B|.dB/dxz product of 2.6 T^2/m and any movement across the paper was observed. Of the devices tested by Bock, the Sideris Button was the only one to have been considered to fail.

The test itself was not an ASTM deflection test. While the forces to forcefully remove an ASD have not been studied explicitly, the forces to remove a heart valve have. It is noted the forces needed to forcibly remove a heart valve are likely to be much smaller than any force exerted by the MRI or indeed the heart itself. While the mechanisms of attachment implantation are different between closure device and heart valves, we nevertheless feel the forces involved for closure devices are also likely to be much higher than the force exerted in the MRI B0 field. Therefore, while there was some deflection of the Sideris button, we do not believe the forces involved would be sufficient to cause dislodgement of an ASD occluder that is fixed in place either at 1.5T or 3T.

Of further consideration in relation to the Sideris button, from the commentary by Rao [12], as of 2008 the device was not likely to be getting implanted. It is not exactly clear the extent to which the Sideris button device would have been getting implanted across the world, though certainly given the product was registered for trials in the USA it is likely to have been implanted in the USA.

In summary, despite the report of deflection of the Sideris button device on account of its stainless steel. We do not believe these would pose a risk to a patient at 1.5T or 3T MRI.

Having reviewed the paper assessing the deflection of the Sideris Button device, there were a number of other historical devices that were tested, these were: the PFO star generation 3 (Cardia); the Angelwing ASD (Microvena EV3); the PFO star generation 2 (Cardia); the helex septal occluder (Gore); the Amplatzer ASD occluder (AGA Medical corp) and the Starflex (NMT). Of these, the PFO star generation models and Angelwing were not noted on mrisafety.com.

Also, there were several other historical devices listed on the website ‘ASD history’ [15]. A summary of these other devices and MRI safety opinion is detailed below.

Lock Clamshell device (USCI Angiographic systems)

The Lock Clamshell device was developed in the late 1980 and early 1990s with approximately 1000 successful patient implantations, though what followed was a considerable number of device fractures which ultimately let to the elective withdrawal of the device from the marketplace (King et al [17]; Hijazi et al [18]). The device had a stainless-steel frame covered with Dacron.

As this device predates the clinical implantation of MRI and also formal testing for MRI safety testing of devices, there is no testing data and little peer reviewed literature on this topic. That said, there are no known cases of adverse events of patients with this device as a result of exposure to the MRI environment.

The Angel Wing device

The Angel wings product which had a nitinol frame and polyester fabric was developed in the 1990's. The product later became known as the Guardian Angel Wings though it never made it to market. In any case, deflection tests done by Bock et al, showed no meaningful movement and therefore, we believe it is safe to assume this device, would be MRI conditional and suitable for MRI at 1.5T and 3T.

The Monodisk device

The Monodisk device, reported on by Pavčnik et al [31], consisted of a single disk of stainless steel covered by a double layer of nylon mesh and three pieces of braided hollow stainless-steel wire sutured to the back of the circular disk. This device was only implanted in two patients in 1993, and no further trials were conducted with the device being abandoned.

The CardioSeal and STARflex (NMT medical, Boston, MA)

The CardioSeal product has been described by Latson et al [30]. This device was developed in the early 1990's having evolved from the Lock Clamshell device. The CardioSeal was made from four MP35N ribs covered in polyester.

The Starflex device evolve from the Cardioseal, with the addition of fine nitinol spring coils. Both the Cardioseal and Starflex went through comprehensive clinical trials (King et al [17]). While there is not explicit MRI safety testing data for the Starflex, Boch et al did test this product for deflection and no significant deflection was noted. Therefore, we would assume there is no MRI safety concern for the Starflex or its predecessor, the Cardioseal.

The Biostar (NMT medical)

This Biostar replaced the Starflex device (from ~2006), with the covering of the MP35N frame covering changing from a dacron based cover to a heparin-coated acellular, porcine derived intestinal collagen mix that allows absorption and replacement with human tissue within 2 years (Mullen et al [23]). The nitonal frame remains unchanged.

Solysafe septal occluder (Swissimplant AG, Solothurn, Switzerland)

This was a device made of the cobalt-based alloy, phynox covered in polyester. The original device became CE marked in 2007 with two further models of a larger size in 2009. As time passed, an increasing number of device fractures were noted in device use for PFO. The device was then discontinued from manufacture. Note that other passive implants made from phynox are typically MRI Conditional as phynox is not ferrous.

Note that Nassif et al [6] lists devices that are now discontinued as well as ones that were currently on the market at the time of publication of their article in 2016.

The Amplatzer Septal occluder (AGA medical)

Developed by Kart Amplatz this device consisted of a nitinol frame and mesh. The first clinical trial of the device was conducted in 1997 and this device has been used extensively worldwide (Masura et al [20]). This device was one of the first ASD's to go on and have formal MRI safety testing, being noted as MR conditional on Dr Shellock's MRIsafety.com website.

The Gore Helex Septal Occluder (WL GORE and Associates, Flagstaff, AZ)

This device consisted of a single nitinol wire covered with a thin expanded PTFE membrane. The first implantation of this device was done in 1999 with the FDA feasibility trial being done in 2000 (Balzer et al [28]). Like the Amplatzer device, the Helex is another device that would go on to have widespread adoption worldwide and is also noted as being MR conditional on Dr Shellock's MRIsafety.com website.

The Sideris Transcatheter Patch (TP) (Custom Medical Devices, Inc) & Immediate Release Patch (IRP)

The TP device was further developed into the IRP device. The technique and devices are described in the peer-reviewed literature in 2000. Initially, this device required a double balloon and up to 48 hours for the patch to adhere to the septal wall, a clear disadvantage of this technique. The IRP uses a single Latex balloon, a safety bioabsorbable thread and a polyurethane path with surgical adhesive. The TP and IRP appear not to contain metal components and would therefore be considered MR Safe (Sideris et al [9,10] and Sideris and Coulson et al [11]).

The PFO-Star device and Ultrasept (Cardia Inc, Eagan MN)

There are several generations of this device used for both PFO and ASD repair. The device began with a nitinol frame with titanium caps and progressed to the Ultrasept. The initial clinical use of the Cardia device was reported by Braun et al [22].

The Ultrasept has been tested for MRI safety and the MRI safety information is also available on mrisafety.com.

The Occlutech flex (Occlutech, Helsingborg, Sweden)

The Occlutech flex was developed from earlier versions into a self-expanding double disc made of nitinol . These were first report as being in clinical use in 2008 by Halabi and Hijazi [19] and also by Krizanic et al [21] in adult case. Like other similar ASD devices from the late 1990's and into the 2000' and 2010's made from nitinol frames. The Occlutech flex is recorded as being MRI conditional at 1.5T and 3T.

The Premere PFO closure system (St Jude Medical, St Paul, MN)

This device, specifically designed for PFO closure consisted of a Nitinol frame covered in polyester. The device was noted as being in clinical trials by Donti et al [16]. This device is noted as being MR Conditional on mrisafety.com.

Nit-Occlud PFO ASD-R (pfm Medical, AG, Cologne, Germany)

These devices consisted of a Nitinol mesh with a polyester membrane. The device was first introduced in ~2007 for testing and trials becoming CE marked in 2012.

SeptRX intrapocket PFO occluder (SeptRX Inc, Freemont, CA)

This device was first developed in the early 1990's as the first device to only target the PFO tunnel. The device consisted of a nitinol frame and tantalum markers. Clinical trials began in 2006.

Coherex FlatStent EF PFO closure system (Coherex Medical Inc, Salt Lake City, UT)

This device has a nitinol frame covered in polyrethane foan and radiopaque markers. Clinical trials were started in 2007.

PFX-15 Radiofrequency technology (pfx-15 Closure system, Cierra, Ic, Redwood City, CA)

This device has been described by Sievert et al [29]. They note that the Paradigm 2 trial was conducted at 8 hospitals across Europe and one in New Zealand. The trial ran from 2005 to 2007 having recruited 144 patients across sites.

We note that application of RF energy via PFX is a procedure rather than a device implantation i.e. following the procedure, no implants are left in the patient. This was one of the arguments for this method, though it seems to not have become common practice. That being, the case, there are no MRI considerations in relation to an implant in this instance as no implant exists. See Anzola et al [26] and Sievert et al [27,29] regarding initial use of the pFX system.

The Biotrek (NMT medical)

This device evolved from the Biostar device and was designed to be completely reabsorbable (Baspinar et al [24]), with the MP35N frame of the Biostar being replaced by fully absorbable P4HB.

This device, along with the Biostar ceased to be manufacturer as a result of NMT medical being discontinued in March 2011.

The Carag Bioresorbable Septal Occluder (CBSO)

This device was developed by the same company that worked on the Solysafe Septal Occluder. The device doesn't have a metal framework, rather it has a flouroscopiclly visible polylacticcoglycolic acid that starts bioresorption after 6 months and is completed in 18-24months. The device also has a polyester mesh disc. First in human studies were presented in 2015 (Sievert et al [25]). Due to the lack of any metallic components the Carag device would be considered MRI Safe.

ASDOS (Atrial Septal Defect Occluder System)

Developed through the 1990's the device was developed culminating in CE approval in 1995. The device had nitinol arms and a polyurethane frame. The device also has a metal plug. The device was abandoned in 2001 due to a high incidence of frame fractures. The literature references two ASDOS devices, one first made with stainless steel and then another with Nitinol (a nickel-titanium allow) which is believed to be the first ASD made from Nitinol. The switch to Nitinol is seen as a step change in technology of ASD devices having both better centring characteristics and a lower risk of fracture.

Starclose, Abbott (MRI conditional on mrisafety.com, across clips and miscellaneous sections)

Amplatzer Talisman PFO

King Mills device. Developed in the 1970's, an early ASD device with a stainless-steel frame and Dacron covering. The type of stainless steel used is not known. This device was further developed in collaboration with Edwards labs. As this device predates the clinical implantation of MRI and formal testing for MRI safety testing of devices, there is no testing data and little peer reviewed literature

on this topic. That said, there are no known cases of adverse events of patients with this device because of MRI.

Another useful resource found online was the history of ASD by King et al [17]. Published in 2010, this has a nice list of historical ASD devices, as shown in figure 1 below.

TABLE 1. ATRIAL SEPTAL CLOSURE DEVICES AND SYSTEMS

Device	Frame	Covering	Company
King-Mills Umbrella	Stainless steel	Dacron	Custom made
King-Mills Umbrella	Stainless steel	Dacron	Edwards Laboratories
Rashkind Single Disk	Stainless steel	Foam	USCI
Lock Clamshell Device	Stainless steel	Dacron	USCI Angiographic Systems
Sideris "Buttoned" device	Teflon-coated stainless steel	Teflon-covered polyurethane foam	Custom made
Atrial Septal Defect Occluder System (ASDOS)	Stainless steel	Homologous pericardium (preserved)	Custom made
Angel Wing/Guardian Angel	Nitinol	Dacron	Formerly Microvena Corporation
Pavânik Monodisk	Stainless steel	Nylon mesh	Custom made
ASDOS	Nitinol	Thin polyurethane layer	Osypka Corporation GmbH
CardioSeal	MP35N	Dacron	NMT Medical
Amplatzer Septal Occluder	Nitinol	Dacron augmentation	AGA Medical
StarFlex	MP35N and nitinol	Polyester fabric	NMT Medical
Helex Septal Occluder	Nitinol	Polytetrafluoroethylene (ePTFE)	W. L. Gore & Associates
Sideris Detachable Balloon Device	Latex balloon	Polyurethane foam	Custom made
Sideris' Transcatheter Patch	None	Polyurethane foam	Custom Medical Devices
Cardia Devices	Nitinol with titanium end caps	PVA (Ivalon polyvinyl alcohol)	Cardia, Inc.
Occlutech Septal Occluder/	Nitinol	Mesh	Occlutech GmbH
Occlutech PFO Flex			Occlutech AB
Premere PFO Closure System	Nitinol	Knitted polyester	St. Jude Medical, Inc.
Solysafe Septal Occluder	Phynox	Polyester patches	Swissimplant AG
BioStar	Nitinol	Bioabsorbable porcine intestinal collagen layer	NMT Medical
SeptRx IPO	Nitinol with tantalum markers	Polyester	Secant Medical
Coherex Flat Stent EF	Nitinol with tantalum markers	Polyurethane foam	Coherex Medical, Inc.
PFO Closure System			
pfm Device	Nitinol	Mesh	pfm Medical AG
Pfx-15	N/A	N/A	Cierra, Inc.
Sideris Immediate Release Patch (IRP)	Latex balloon	Polyurethane foam with surgical adhesive	Custom Medical Devices
BioTrek	Poly-4-Hydroxibutyrate (P4HB)	Poly-4-Hydroxibutyrate (P4HB)	NMT Medical

Figure 1: From King et al [17], A history of ASD closure

There is also a timeline of ASD device development from Nassif et al [6], see figure 2 below.

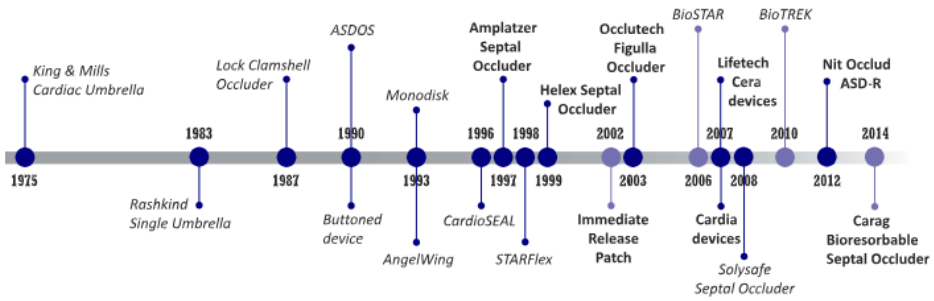


Figure 4. Timeline showing four decades of ASD devices in chronological order from year of introduction. Historical devices are shown in *italics* and currently available devices in **bold**.

Figure 2: Nassif et al [6]

Newer devices

The Amplatzer Cribriform by Abbott. An ASD product noted in the manufacturers IFU as being MRI Conditional, suitable for MRI up to and including 3T MRI (see manufacturers IFU for full MRI conditions).

The Cocoon septal occlusion device by Sahajanand Medical Technologies (SMT), Thailand. A septal occluder noted on MRIsafety.com as being MRI conditional up to and including 3T.

Cardi-O-Fix (Starway medical technology, Beijing, China). A ASD and PFO occluder device made in China. Some details about this device can be found in Jung et al, [34]. It is noted the device is made from nitinol. While explicit MRI conditions have not been obtained, the device appears similar in both materials and design to other similar products. Therefore, I believe it would be highly unlikely to pose a risk to MRI up to and including 3T MRI.

A note on the closure forces of ASD devices.

To try and understand what risk the force exerted by MRI on an ASD device or similar might pose to a patient, we wish to understand the force with which the ASD is held in place. This can be understood by considering the pull-out force for the device. Brudsche et al [32] studied the pull-out force of two separate ASD devices using bespoke testing equipment, note this testing was independent of MRI considerations though it does give us a sense of the pull-out force needed for an ASD. While only two devices were tested, both with nitinol frames and tested under two separate test conditions. Taking this all into consideration, the lower end of the pull-out forces observed was ~ 3N, with results ranging from ~3N to ~ 5.5N. While this is not an exhaustive of pull-out forces for all ASD's it does give us a sense of the order of magnitude of the force that one might expect to be needed to pull out an ASD. For context, the force of a beating heart is 7.2N [14].

2.2.5 Regulatory Medical Device Databases (Date queried: 16/5/25)

On the FDA's MAUDE database the product code for transcatheter septal occlusion device is 'MLV'. An all-years simple search was performed using product code MLV and MRI. This returned 40 entries, however, it is worth noting that any usage of MRI in the patient journey will flag up as an event i.e. in

most cases, the appearance of an adverse event involving MRI has little or nothing to do with MRI. Nevertheless, these 40 events were reviewed to confirm the role of MRI in each instance.

Of the 40 events reviewed up until August 2025, none of the events recorded were related to an adverse event as a result of an interaction between the implanted device and the MRI. The pull-out force of an ASD is notably similar to the force required for heart valve cardiac tissue yield (Edwards et al [14]).

2.2.6 Regulatory Professional and Standards bodies (Date queried: 28/5/25)

2.2.7 Locally implanting Teams (Date queried: N/A)

Given the breadth and size of NHS GGC and neighbouring health boards conducting cardiac surgery, and the lack of clear and detailed historical records it was determined that a local review would not be of benefit. That is, a review of the broader marketplace of devices was considered simpler to conduct and more generally applicable.

2.2.8 Anecdotal evidence (Date queried: N/A)

No anecdotal data in regard to these devices.

2.2.9 Local MR safety databases and empirical evidence (Date queried: 28/5/25)

Review of the SMRT MR Technologist mail base

The SMRT technologist google groups was searched for articles of relevance to this topic. This archive goes back to 2015. The following search terms were used: PFO, PDA, ASD, VSD, UNI, PLD, mVSD, pmVSD and Occluder.

For the most part these searches returned blank responses with the exception of 'PDA' which had a couple of responses.

One discussed the Rashkind device and stated it was MR Conditional (conditional 5 in Dr Shellock's terms). On another message thread discussing a PDA clip, Dr Shellock highlights that '…not all PDA implants have been tested'.

Overall, there is no suggestion of any occlusion device that has been tested is MRI unsafe though there is an acknowledgement that not all of these devices may have been tested. No specific examples of devices that have not been tested were noted.

No further updates were noted as this mailbase is no longer active.

Review of the UK MRI mail base

The MRIPhysics mailbase which dates back to June 2012 was searched using the same terms used above to search the SMRT google group.

There were very few questions raised about these devices. One query that did appear related to the Amplatzer device and satisfying maximum spatial gradient considerations. The two responses suggested to consider a risk/benefit approach for the patient with the implant.

Internet Search

No further internet search was conducted.

Facebook: MRI Safety group

Facebook review: MR safety of devices to correct PDA, PFO, VSD, ASD

ASD

A post from April 2019, regard an ASD repair done in 2004. Among a number of replies it was noted that Dr Shellock highlighted that at that time (of the Facebook post) there are no ASD on his website listed as MR unsafe.

VSD

From a post in Sept 2019 in regard to MR safety of PFO devices. Among a number of replies Dr Shellock noted that 'to the best of his knowledge, there are no MR unsafe PFO, VSD or ASD implants' and that 'All conditional PFO implants can be scanned immediately'. Other replies back up this statement indicating devices were either scanned safely or suggesting check make/model to determine the device MR safety status. That is, there was nothing to contradict Dr Shellock's view.

PFO

From a post in Sept 2019 in regard to MR safety of PFO devices. Among a number of replies Dr Shellock noted that 'to the best of his knowledge, there are no MR unsafe PFO, VSD or ASD implants' and that 'All conditional PFO implants can be scanned immediately'. Other replies back up this statement indicating devices were either scanned safely or suggesting check make/model to determine the device MR safety status. That is, there was nothing to contradict Dr Shellock's view.

PDA

It is notable that there are also coil devices as well as closure or occlusion devices that can be used to correct PDA.

Occluder

Summary from Facebook posts

From the Facebook posts reviewed there is no reliable information to suggest that any of the closure or occlusion device used for these assorted cardiac conditions are MR Unsafe.

Empirical evidence

Regarding the surgical methods for closure by ligation by clip or by suture. To the best of my knowledge, no such surgical intervention has ever led to a case where a patient has subsequently been injured as a result of an MRI scan. Though Dr Shellock has noted that not all clips have been tested and that therefore some might be MR Unsafe, clips are typically non-ferrous or weekly ferrous. Clips are also likely to be too small to be a concern in regard to heating in the MRI. Moreover, clips will typically become fibrosed, providing a degree of support.

It is the experience of the author that no device of this nature has been reported as leading to patient harm as a result of an MRI scan. Patients with these devices have been scanned in MRI, since the inception of MRI and no adverse event has been noted.

2.3 Discussion

All the evidence that was found indicate cardiac occlusion devices are either MR Safe or MR Conditional. There are few queries regarding these devices in the community. The inference of this being, that patients with these devices will typically be getting their MRI scan without any concern. Where queries have arisen. These typically reflect circumstances where MR conditions may have been exceeded, where a risk – benefit approach is advised.

There are no reported cases in the peer review literature highlighting injuries to patient that were a result of MRI scans being performed. Worldwide, it is expected that many patients have these devices and many will of these patients will have had MRI. It is therefore highly unlikely any such device poses a high risk of injury.

As these devices have evolved, the designs and material have become increasingly more subtle and specific. These 'derivative' devices typically have a lineage of device technology and therefore it is also highly unlikely any such derivative device would be designed that was MRI Unsafe.

Even in the event that such a device was developed that was MR Unsafe, the device would need to go through clinical trials and regulatory approval (e.g FDA or CE) before being released to the market. Therefore, it is highly unlikely any such device would catch the MRI community unaware i.e. if a new device was found to be an issue for MRI, this is likely to spread through the MRI safety community very rapidly.

This policy does not cover that of vascular closure devices i.e. occlusion or closure devices outside of the heart.

Based on the evidence above, it seems reasonable to state that the risk to patients with clips, occlusion and closure devices to treat a range of cardiac conditions coming to harm as a result of an MRI scan is very low.

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3 Risk Assessment

3.1 Hazards

There are a range of hazards the MRI scanner presents. The static magnetic field may affect ferrous metallic objects. RF fields can lead to heating in wires and metallic objects. The imaging gradients may interact with active implanted medical devices.

3.2 Description of Risk

Patients with PFO, ASD, VSD and PFO clips or closure devices will be exposed to high static magnetic fields, RF power and imaging magnetic field gradients. This topic has been subjected to a detailed review. Clips and closure devices are not typically ferrous in nature, thus the static magnetic field is not a concern. The size of these devices is also typically too small to be a concern in regard to RF heating. Moreover, the passive nature of these devices mean the imaging gradients will not have any impact on these clips or devices. Both from a review of the MR conditions for these devices and from

the large empirical base. There is no substantive physical evidence to suggest scanning patient with these devices is a risk to patients at 1.5T and 3T.

3.3 Existing precautions

- Patients are taken through an extensive MRI safety checklist to identify any implants that they may have.
- A detailed review of MR safety for devices in this category has been done
- MRI Clinical Scientists relevant mail forums and relevant social media channels for reports of adverse events in MRI with patient implants.
- MRI physics staff liaise with colleagues throughout the UK to cross check our knowledge on MRI safety for patient implants is up to date

3.4 Describe how they might fail to prevent an adverse outcome

- A historical device in this category which is MR unsafe has not been considered
- A patient presents with a new device in this category which is MR unsafe and has not yet been considered
- Some unforeseen and previously unreported device and scanner interaction occurs to cause patient injury

3.4 Level of Risk

	Likelihood	Consequence	Risk
Risk Description	Rare	Moderate	**Low**

Risk Matrix (example provided by NHS Greater Glasgow and Clyde)

Likelihood	*Impact/Consequences*				
	Negligible	**Minor**	**Moderate**	**Major**	**Extreme**
Almost Certain	Medium	High	High	V High	V High
Likely	Medium	Medium	High	High	V High
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Medium	Medium	Medium	High
Rare	Low	Low	**Low**	Medium	Medium

Medium (Yellow) High (Orange) or Very High (Red) risks are unacceptable. A GISP should not be created where the risk is High or V High.