**MRI Generic Implant Safety Policy (GISP): Detailed review**

*‘Guidance in italics’*

**Title: *‘Non-Coronary Vascular Stents’***

**Executive summary: *‘Non-Coronary Vascular Stents’***

The purpose of this work is to develop a GISP document to cover MRI safety of all types of vascular stents that can be used as implants in patients. Vascular stent implants can be considered to fall within two different broad categories as follows:

* Coronary stents - those stents associated with the heart and the vascular supply around the heart (e.g., the coronary arteries).
* Non-coronary stents - those stents associated with the cardiovascular system in any area away from the heart. Examples of these include the abdominal aorta, vena cava, iliac, celiac, vertebral, aorta, subclavian, mesocaval, mesenteric, and femoral arteries.

From an MRI safety perspective, it is important to consider two key potential risks to the patient – namely the projectile effect (translation or rotational forces as a result of the static magnetic field or spatial gradient), and RF induced heating effects at the site of the implant and tissues close proximity to the implant. As part of this review process, it is also necessary to consider the many different makes/models of available stents, both in the UK and worldwide, and whether there are any ‘MRI conditions’ associated with their implantation.

Considering the projectile effect, most stents are made of non-ferromagnetic materials although some historical devices may benefit from the identification of make and model details. The safety advice may occasionally alter over time, and recent safety updates have served to confirm this (certain devices that were originally deemed ‘MR safe’ are now considered to be ‘MR conditional’). These examples will be highlighted and reviewed later within the document.

From the perspective of RF heating, it is helpful to consider which body region is being examined in relation to the location of the stent. In some cases, the stent may be in or near the field of view (e.g., prostate scan with iliac stents) whilst in others the stent may be distant from the field of view (e.g., head scan with renal stent). SAR limits do vary quite considerably, and manufacturer guidance reflects this. Variations include, for example, 2W/kg for landmarks above the umbilicus, down to 1W/kg for landmarks below the umbilicus and above the mid-thigh, and as low as 0.5W/kg for landmarks below the mid-thigh. There is evidence in the literature (see later review) that blood flow does have a significant cooling effect which may not be accounted for when devices are tested for MR conditionality using the ASTM F2182 procedure. This is an important consideration towards the development of a risk assessment to support the policy.

Additionally, there may be situations where the use of local ‘transmit’ coils at 1.5T, 3T or even 7T may present a safer configuration for minimisation of RF heating effects, relative to more standardised imaging approaches using an integrated body coil. Conversely, there may be examples of stent configurations where the use of standard ‘body coil transmit’ and ‘local coil receive’ is recommended. These situations will be considered as part of the ongoing review process.

Finally, at higher field strength such as 7T (or even just 3T) it is possible that scanning may be ‘off-label’ in some cases (from the point of view of the manufacturer). In these instances, it is quite possible that the stents may simply have not been tested at these higher field strengths - as opposed to posing a significant risk.

With the above considerations in mind, the rest of the GISP will review all available evidence in order to draw up a policy recommendation for all non-coronary vascular stent implants.

**Results**

**MRISafety.Com:**

The main body of evidence related to the MR safety of vascular stents can be found at MRISafety.com (Frank Shellock). A review of the safety information can be found at the following link: <http://mrisafety.com/SafetyInformation_view.php?editid1=171>. In brief, it is summarised that after six weeks (to allow for tissue in-growth) ‘it is unlikely that coils, stents, filters and vascular grafts would become moved or dislodged as a result of exposure to MR systems operating at 1.5-Tesla or less’. Many, but not all, have also been evaluated at 3-Tesla.

There are many cases where patients with passive non-ferrous implants may be scanned immediately after implantation. Historically, organisations tended to adopt a cautious approach after stent implantation, where a delay period of 6-8 weeks was recommended in order to enable the process of endothelialisation to take place. However, there are no specific scientific data to support this action, and since there are no known stents with ferromagnetic components on the market there is no known evidence to suggest that this approach would be of any clinical benefit.

On the subject of tissue heating, it is stated by Shellock that ‘there has been no reported case of excessive heating in association with MRI and these types of implants’. However there are a few cases that are not covered by the safety advice provided by MRIsafety.com. For example, it is not explicitly stated whether multiple overlapping stents are covered by the above safety statements. Further subtleties associated with the type of RF coil to be used (e.g., transmit-receive or receive-only) are not considered, and the area of anatomy under investigation relative to the stent is not discussed.

**Review of Manufacturer Implant Information**

It is widely accepted that it is not possible to document the specific MR safety conditions of vascular stents on an individual basis – primarily due to the sheer number of different devices that are available for clinical use. A quick search of MRISafety.com (Aug 2022) has identified 641 hits when the word ‘stent’ was inputted into the search facility. For this reason, the approach within this document has been to review the literature of those devices that are known to have relatively stringent MR safety conditions.

The majority of non-coronary vascular stents are labelled as ‘MR conditional’ at 1.5T or 3.0T. The term ‘MR conditional’ varies widely in relation to the threshold levels for static field, spatial gradient field, maximum gradient strength, and SAR over duration of scanning. The following limits are considered to represent a reasonable threshold for a wide range of stents: field strength - 1.5T or 3.0T; maximum spatial gradient field - 720-2500 gauss/cm; and maximum whole body averaged SAR - 2.0 W/Kg for scanning over a 15-minute continuous period.

These conditions can be largely satisfied by operating the scanner in the normal mode of operation. However there are several exceptions where the recommended SAR limits fall below the normal mode threshold. These devices are listed below - together with comments associated with SAR limits. Note that in many cases, the SAR limits are lower than the normal mode threshold of 2.0 W/kg. For example, a number of the peripheral vascular devices recommend SAR limits of 1.0 W/kg if the anatomical landmark is below the umbilicus, and this may drop as low as 0.5 W/kg in some cases (for landmark areas below mid-thigh). The opposite is true for one carotid stent example (Boston Scientific Carotid Wallstent) where the reverse recommendation is the case (landmarked areas above the umbilicus require SAR limits of 1.0 W/kg and areas below the umbilicus are SAR limited to the higher 2.0 W/kg value). Other complications include the fact that some stents (e.g., Bard Covera) are only designed specifically for use in areas such as the arms, and these are associated with the lower 1W/kg SAR limit. Finally, there are warnings against the use of local transmit coils in certain cases (e.g., Boston Scientific Epic) which complicates the guidance associated with RF coil usage.

Abbot

* Supera Peripheral Stent – 2W/kg for landmarks above the umbilicus, 1W/kg for landmarks below the umbilicus and above the mid-thigh, 0.5W/kg for landmarks below the mid-thigh.
* Vascular Omnilink Elite. 1W/Kg for landmark below the umbilicus, 2W/kg for landmark above the umbilicus.

Bard

* Covera. Implant in the arm. 1W/kg SAR limit.
* Eluminexx. 1W/Kg for landmark below the umbilicus, 2W/kg for landmark above the umbilicus.
* LifeStent 5F – Implant in the arm. 1W/kg SAR limit.
* LifeStent Vascular Stent - 1W/Kg for landmark below the umbilicus, 2W/kg for landmark above the umbilicus.
* LifeStent XL - 1W/Kg for landmark below the umbilicus, 2W/kg for landmark above the umbilicus.
* Venovo venous stent system. 1W/Kg for landmark below the umbilicus, 2W/kg for landmark above the umbilicus.
* Fluency plus – endovascular stent graft. 1W/Kg for stent graft placement in the arms. 2W/Kg for stent graft placement in the torso.

Boston Scientific

* Carotid Wallstent - 1W/Kg for landmark above the umbilicus, 2W/kg for landmark below the umbilicus but above mid-thigh.
* Eluvia - over the wire drug-eluting vascular stent system. 2W/kg for landmarks above the umbilicus. 1W/kg for landmarks below the umbilicus and above the mid-thigh. 0.5 W/kg for landmarks below the mid-thigh.
* Epic vascular self-expanding stent system – 2W/kg for landmarks above the umbilicus. 1W/kg for landmarks below the umbilicus and above the mid-thigh. Use whole body transmit/receive coils only. No local transmit coils. Local receive coils can be used.
* Express LD pre-mounted stent system – 1W/kg for landmarks below the umbilicus, 2W/kg for landmarks above the umbilicus.
* Innova over-the-wire vascular self-expanding stent system. 2W/kg for landmarks above the umbilicus. 1W/kg for landmarks below the umbilicus and above the mid-thigh. 0.5 W/kg for landmarks below the umbilicus below the mid-thigh.

Cordis

* Cordis SMART stent – 1W/kg for landmarks below the umbilicus, 2W/kg for landmarks above the umbilicus.
* Cordis PRECISE stent – 0.8 W/kg for 20 minutes of MRI. The SAR limits are reported differently in different publications though (some reports quote 1.6 W/kg for 16 minutes of scanning).
* Palmaz-Shcatz ballon-expandable stent systems – recommended not to perform MRI after stent implantation until the stent has completely endothelialised (8 weeks) to minimise the potential for migration. The stent may also cause artefacts in MRI due to distortion of the magnetic field.

The above examples are intended to be for guidance, and do not represent every stent on the market at the time of writing. These examples do convey the considerable variations associated with SAR limits in this genre of implants.

**Review of the peer reviewed literature**

The MRI safety of stents has been widely reported in the scientific literature. Some early initial work by Taal et al in 1997 [1] supported the fact that not all oesophageal stents are safe for patients undergoing MR procedures. This investigation was performed to evaluate four different types of stents in the MR environment: the Ultraflex (titanium alloy), the covered Wallstent (Nitinol), the Gianturco stent (Cook), and the modified Gianturco stent (Song). The authors reported an appreciable attraction force and torque for both types of Gianturco stents, and the Gianturco (Cook) stent pulled toward the head with a force of 7g. It is uncertain whether this is a potential risk for dislodgment, but the investigators advised that specific information on the type of stent is necessary before a magnetic resonance imaging examination is planned. Although this work did not include non-coronary vascular stents, the basic approach related to MRI safety is still important and merits consideration.

In 1999, Shellock et al [2] conducted experiments on 10 different metallic stents in order to assess static magnetic field interactions (movement or dislodgement), heating and artefact formation at 1.5T. The stents tested included those for coronary, iliac, bronchial and oesophageal applications, and had a variety of diameters (3.5-28.0 mm) and lengths (25.0-130.0 mm). Deflection testing was used to measure static field interactions, and an infrared thermometer was used to measure temperature changes of the stents in a physiological saline solution with the use of a T1W spin echo sequence run for 30 minutes. The authors found that none of the stents (elgiloy, platinum-nickel alloy, tantalum) tested exhibited any magnetic field interaction, and the highest temperature changes measured were up to 0.3oC. They concluded that field interactions, heating and artefacts for the stents tested were insufficient to affect scans being conducted safely in patients on systems at 1.5T or less.

The question as to whether stents are required to be left for 6-8 weeks post-implantation prior to MRI has posed considerable debate. The anecdotal theory is that the time delay of 6-8 weeks enables in-stent endothelialisation to occur, and thus the stent is then held more securely at its intended position (as an example, these guidelines are prescribed by Cordis in the instructions for use for the Palmaz-Schatz balloon expandable stent). Gerber et al 2003 [3] tested the validity of this hypothesis on 111 patients who underwent MRI (of various body areas) at 1.5T within 8 weeks (median of 18 days) after coronary stent placement. They recorded n=4 non-cardiac deaths and n=3 cases where repeat revascularisation was required, but no evidence of in-stent thrombosis. These figures were not beyond those events ‘normally expected’ for such a cohort, and the authors concluded that MRI examinations at 1.5T can be performed safely within 8 weeks after coronary artery stent placement, and delays until 6-8 weeks post-implantation do not seem necessary. Although this work was undertaken on coronary stents, it appears possible to extend these findings to stents elsewhere in the body, since coronary stents (associated with flow to the heart and the forces attributable to cardiac motion) are likely to represent a ‘severe example’. These findings have also been supported by Porto et al 2005 [4], who reported similar clinical data in 50 patients who underwent drug-eluting stent implantation and MRI 1-3 days after stent placement. Very similar results were reported by Syed et al 2006 [5] in a CMR study, where they concluded that ‘CMR on a 1.5T scanner can be safely performed within one to seven days after coronary bare-metal stent implantation and is not associated with an increased risk of adverse clinical cardiac outcomes’.

In an extensive review of MRI safety in patients with cardiovascular devices, Levine et al 2007 [6] considered coronary artery and peripheral vascular stents and reported that most are constructed from 316L stainless steel or nitinol. Less commonly, some are constructed with components of platinum, cobalt alloy, gold, tantalum, MP35N or other materials. The magnetic properties of these stents are such that they are either non-ferromagnetic or very weakly ferromagnetic – experiencing localised forces due to blood flow that are stronger than the base interaction with the MRI static field. The only exception noted was a Zenith/Cook iliac stent that had reported ferromagnetic properties. However, since this manuscript was published, the vendors have updated their own MR safety records to state that these stents are now considered MR conditional up to 3.0T. The authors summarise that for patients with nonferrous peripheral stents, MRI may be performed immediately after implantation. For those stents that are weakly ferromagnetic, MRI should be determined on a case-by-case basis, and where there is a clear potential benefit to scanning early after implantation MRI should be performed since the benefits of the examination will outweigh the risks.

The issue of RF-induced heating at or within the stent is one of the causes for careful consideration. In experimental simulation work on cardiac stents, Elder 2013 [7] performed simulations of in-stent heating using a 1.5T system in the presence of blood flow rates controlled by a flow meter. It was established that in the case of ‘no flow’, the temperature rise scaled to the local background SAR was 0.89 oC/(W/kg), and this decreased markedly to 0.39 oC/(W/kg) in the case of the maximum flow simulated. Local computer simulations verified this finding. The author concluded that in-vivo temperature rises for a coronary stent during MRI will be less than half the value predicted from in-vitro tests that do not account for the cooling effects of the blood.

Scandling 2016 [8] extended this work to consider 3.0T simulations applied to a Zilver 635® Vascular Self-Expanding Stent. Constant flow was found to significantly reduce the maximum temperature when the device was subjected to MRI-powered RF induced heating. The maximum temperature rise measured approximately 10°C without flow, while physiologic flow rates decreased temperature rises by up to 70%. The conclusion was that blood flow has a significant cooling effect, and patients with these implants should have access to clinically indicated MR scans where possible.

The possible heating effect in carotid stents was further examined by Gross et al 2016 [9] who studied RF-mediated heating effects of carotid stents implanted in 7 anaesthetised pigs at 3T. Using fibre optic probes, an average temperature rise of 0.8oC was measured near the distal end of the stent during RF heating in-vivo (with blood flow and perfusion), which rose to 2.4oC without flow and 2.7oC post-mortem. Control experiments (animals without stents fitted) elicited equivalent temperature rises of 0.7oC with flow present and 0.9oC post-mortem at the right carotid artery. The conclusion was that blood flow has a significant cooling effect that reduces the overall temperature rise of a vascular stent during MR-powered RF heating. These data fall outside the scope of the standard test method and should be considered when evaluating RF heating.

In a recent paper from 2018, Fujimoto et al [10] performed computer modelling simulations to examine RF safety assessment of stents in blood vessels during MRI. The authors analysed the tangential electric field (Etan) and SAR in anatomical model vessels (Austin Man) to characterise heating associated with passive implants (e.g., stents). Their rationale for the work was to address challenges with experimental ASTM phantom simulations, where simplifications in stent/phantom design, orientations and positions within the RF field may not be representative of reality.

Their computer modelling simulations examined SAR and Etan for different stent trajectories and different locations (ascending aorta, brachial, femoral, iliac, popliteal arteries), along with different ‘landmark’ simulations (brain, heart, hip bones, knee), and the key objective was to compare the simulations in Austin Man versus those using the experimental ASTM set-up.

The results established that SAR values measured on the Austin Man model were consistently higher (up to 10x) than the ASTM values at all landmarks. The recorded Etan values were highly related to the landmark site, and ASTM Etan values were exceeded by simulations in 3 of 20 examples (brachial simulation at the heart; iliac simulation at the hip; and popliteal simulation at the knee).

One key aspect of this work was that thermal simulations were not calculated. Although the data do not translate directly into temperature effects, it is recommended that similar literature is reviewed on a regular basis - particularly those that cross-link simulation work to real temperature rises.

One question that remains is whether the length of the stent (or multiple overlapping stents) affects the temperature rise within the stent configuration? Song et al 2018 [11] conducted a retrospective study of RF heating measurements (ASTM testing reports) of n=56 stents to look at heating trends and length dependence. They established a positive trend between local body SAR and device length, with maximum heating occurring at lengths of approximately 100mm (3.0T) and >150mm (1.5T). Stents were assessed in three length groups, namely 0-50 mm, 50-120 mm, and 120-185 mm. The biggest heating effect was observed for the longest stent configurations at 1.5T, where a temperature rise of around 0.8oC/(W/kg) was measured. At 3.0T, the maximum heating was less, and occurred at stent lengths of around 100mm.

The physical construction of the stent, e.g., the shape, length and helical composition was studied by Ji et al 2019 [12]. They performed ASTM testing to measure simulated and measured temperature rises in n=4 different stent configurations. Their results (normalised to a WB averaged SAR of 2.0 W/kg) highlighted temperature rises that varied from 2.1 to 8.6 oC, with around 20% error associated with the measurements. This work did not take into account flow related cooling effects, which have proved to be significant.

Finally, a recent 2020 review by Maralani et al [13] has addressed MRI safety and devices - with an update and expert consensus. Coronary and carotid stents were considered in detail, and it is reported that most currently available carotid stents are made of nitinol, 316L stainless steel, or cobalt alloy. Less commonly, they include platinum, carbon, gold, MP35N, or tantalum. Most coronary and carotid stents exhibit non-ferromagnetic or weakly ferromagnetic behaviour at both 1.5T and 3T, and there is no compelling data to support delay for MRI of 6-8 weeks after stent deployment. Their key statement is that “the primary concern is displacement, since no studies have found concern with heating”. Despite this, their recommendation is that the date of stent placement and the device manufacturer should be ascertained, and patients with unknown stents can be scanned at 1.5T or 3.0T with whole-body averaged SAR <= 2W/kg, and maximum of 15 minutes per sequence. Scanning may be performed six weeks after implantation, and a reduction to this six-week delay can be considered on a case-by-case basis.

As far as non-vascular stents are concerned, the chief focus has been centred on the safe use of MRI in patients with oesophageal stents. In addition to the early work by Taal et al [1], a recent review by Xia et al [14] has reviewed the use of MRI in patients with airway stents. The authors reviewed the available literature, experimental data and manufacturer information on non-metallic, stainless steel and nickel-titanium alloy stents. They concluded that stainless steel stents may shift in a magnetic field and generate significant artefacts. Nickel-titanium alloy stents are not at risk of dislodgement or heating, but they may create some artefacts affecting image quality. Their final recommendation was that both non-metallic and nickel-titanium alloy stents are safe for patients who must undergo MRI, but the safety of SS stents depends on the type of steel used.

In summary, there are no known MR unsafe vascular stents. It is apparent that ‘real world’ in-vivo temperature rises associated with non-coronary vascular stents cannot easily be predicted. The calculation is complex, involving variables such as: (i) the stent length, material composition/construction and orientation within the vessel; (ii) RF coil architecture and overlap with the stent in question, and whether single or multiple overlapping stents are present; (iii) presence of local eddy currents (including those outside the RF coil), and other MR hardware variables such as field strength, and RF exposure characteristics (i.e. the pulse sequence); (iv) tissue properties (electrical conductivity, permittivity, mass density), in-vivo perfusion and flow effects, and whether the tissue is superficial or deep. Recommendations from the available literature suggest that patients with non-coronary vascular stents may be scanned at 1.5T or 3.0T in ‘normal mode’ after 6-8 weeks post-implantation. Cases where scanning may be required at an earlier stage may need to be reviewed on a case-by-case basis. It is recommended that extensive archives of empirical evidence should be considered carefully in support of these recommendations. For non-vascular stents, one of the key concerns is the oesophageal stent – where the material construction consists of stainless steel in some cases. It is recommended that this particular genre of stent remains outside the scope of this GISP, and cases of these implants should be reviewed on an individual basis.

References:

[1] Taal BG, Muller SH, Boot H, Koops W. Potential Risks and Artifacts of Magnetic Resonance Imaging of Self-Expandable Oesophageal Stents. Gastrointestinal Endoscopy 1997; 46; 424-429.

[2] Shellock FG, Shellock VJ. Metallic Stents: Evaluation of MR Imaging Safety. AJR 1999; 173: 543-547.

[3] Gerber TC, Fasseas P, Lennon RJ, Valeti VU, Wood CP, Breen JF, Berger PB. Clinical Safety of Magnetic Resonance Imaging Early After Coronary Stent Placement. JACC 2003; 42(7): 1295-1298.

[4] Porto I, Selvanayagam J, Ashar V, Neubauer S, Banning AP. Safety of Magnetic Resonance Imaging One to Three Days After Bare Metal and Drug-Eluting Stent Implantation. Am J Cardiol 2005; 96: 366–368.

[5] Syed MA, Carlson K, Murphy M, Ingkanisorn WP, Rhoads KL, Arai AE. Long-Term Safety of Cardiac Magnetic Resonance Imaging Performed in the First Few Days After Bare-Metal Stent Implantation. J Magn Reson Imaging 2006; 24: 1056-1061.

[6] Levigne GN, Gomes AS, Arai AE, Bluemke DA, Flamm SD, Kanal E, Manning WJ, Martin ET, Smith JM, Wilke N, Shellock FS. Safety of Magnetic Resonance Imaging in Patients with Cardiovascular Devices - An American Heart Association Scientific Statement from the Committee on Diagnostic and Interventional Cardiac Catheterization, Council on Clinical Cardiology, and the Council on Cardiovascular Radiology and Intervention. Circulation 2007; 116: 2878-2891.

[7] Elder NI. Effects of Blood Flow on the Heating of Cardiac Stents Due to Radiofrequency Fields. Purdue University PhD Thesis. <https://docs.lib.purdue.edu/open_access_theses>.

[8] Scandling BW. Radio Frequency Induced Heating of a Medical Device with Vascular Flow Conditions. Ohio State University PhD Thesis. <https://kb.osu.edu/handle/1811/76471>.

[9] Gross DC, Simonetti OP. In vivo and post-mortem measurements of radio frequency induced heating during MRI of pigs implanted with vascular stents. Journal of Cardiovascular Magnetic Resonance 2016; 18 (Suppl 1): P53.

[10] Fujimoto K, Angelone LM, Lucano E, Rajan SS, Iacono MI. Radio-Frequency Safety Assessment of Stents in Blood Vessels During Magnetic Resonance Imaging. Frontiers in Physiology 2018; vol 9: article 1429.

[11] Song T, Xu Z, Iacono MI, Angelone LM, Rajan S. Retrospective analysis of RF heating measurements of passive medical implants. Magn Reson Med 2018; 2726–2730.

[12] Ji X, Zheng J, Yang R, Kainz W, Chen Ji. Evaluations of the MRI RF-Induced Heating for Helical Stents Under a 1.5T MRI System. IEEE Transactions on Electromagnetic Compatibility. 2019; 61(1): 57-64.

[13] Maralani PJ, Schieda N, Hecht EM, Litt H, Hindman N, Heyn C, Davenport MS, Zaharchuk G, Hess CP, Weinreb J. MRI Safety and Devices: An Update and Expert Consensus. J Magn Reson Imaging 2020; 51: 657-664.

[14] Xia Y, Jin R, Li W, Shen H. Magnetic Resonance Imaging of Patients with Airway Stents. J Thorac Dis 2018; 10 (10): 5939-5945.

**Review of the SMRT MR Technologist mail base**

The authors do not currently have access to the above mail base. It is therefore recommended that any comments or statements required under this topic are highlighted by Lead MRI Radiographer colleagues during the GISP document review process.

**Review of the UK MRI Mail Base and Social Media Groups**

A review of the UK MRI mail base has proved useful for establishing the many types of vascular stent that are currently used across the UK, and also those that have recently been re-classified with more stringent MR conditions. The mail base has also highlighted that some vascular stents have no MR safety statement associated with them at all.

In the ‘Literature Review’ and the ‘Review of Manufacturer Implant Information’ sections reported above, we have identified cases of non-coronary vascular stents with conditions below the Normal Mode, for example, the Suprastent which requires a 0.5W/kg SAR limit in some instances. Discussion from the UK MRI mail base has also included the Cordis SMART stent (<https://www.gov.uk/drug-device-alerts/field-safety-notice-11-to-15-november>), and this was reported to the MHRA at the time since there were noted discrepancies between the published instructions for use (IFU) and the MR safety guidance. Cordis has now reverted back to their original MR safety conditions from 2013 (SAR limit of 1 W/kg for scanning below the umbilicus). It is important that the current conditions are considered ahead of other IFU’s that may still be in circulation.

For non-vascular stents, one strand of discussion has centred on the Cook Zimmon biliary stent (Ref Number ZSO-7-5). In the instructions for use, the following is stated: WARNING: For stents with radiopaque bands, MRI compatibility has not been established. Information provided by Frank Shellock on his MRIsafety.com website lists these stents as ‘conditional 8’, although further information is awaited from the vendor to confirm this.

Information gleaned from social media postings on the International MRI safety Facebook group has highlighted two cases of non-vascular stents that are known to be MR unsafe. The first of these is the Spanner prostatic stent, which is a temporary prostatic stent for men with bladder outlet obstructions. The stent is inserted within the urethra and into the neck of the bladder, and this permits patients to urinate voluntarily. The material composition of the metal component is not clear, but the manufacturer guidance is clear that the stent has not been evaluated for use with MRI and should be removed prior to a scan. The second unsafe stent is the Magnetic Black-Star ureteral stent (Urotech) and this has a small magnetic connected at its tip within the bladder. This allows a magnetic retriever device to be inserted to capture the stent and remove it without the need for cystoscopy, but requires complete removal prior to an MRI scan.

The outcome of these reviews has vindicated the strategy of separating ‘vascular’ from ‘non-vascular’ stents for the purposes of preparing this GISP document. There remains clear MR safety concern associated with certain oesophageal stents, and also with the Spanner prostatic stent and the Magnetic Black-Star ureteral stent. Conversely, for vascular stents there is building evidence to suggest that MR scanning may proceed safely provided that the implant is inserted correctly and functioning as intended, and RF induced heating effects are considered carefully.

**Internet Search**

**“Peripheral stents and MRI safety”** searched using Google on 08/04/20

<https://www.rad.pitt.edu/sites/rad_docs/mrrc-docs/ContraindicationsMRI.pdf>

“Most ...peripheral vascular stents are made of stainless steel or nitinol. Some stents may be composed of, or contain, variable amounts of platinum, cobalt alloy, gold, tantalum, MP35N, or other materials. That means most ...peripheral vascular stents are non-ferromagnetic or weakly ferromagnetic. Extensive studies have led to the conclusion that MR scanning of patients after stent implantation can be performed without risk at any time at 3 T or less. There is no risk of dislodgement as implantation against the vessel wall provides sufficient stability and no increased risk for acute stent thrombosis (for bare metal stents as well as drug eluting stents (DES). The effect of heating induced by the radiofrequency field on the polymer of DES is unknown. However, stents generally cause artefacts that impair evaluation of the stent itself.”

**“Non-coronary stents and MRI safety”** – searched using Google on 03/01/22

Levine GN et al. Safety of Magnetic Resonance Imaging in Patients with Cardiovascular Devices. Circulation 2007; 116: 2878-2891.

“Most coronary artery and peripheral vascular stents are composed of either 316L stainless steel or nitinol. Less commonly, stents may be composed of or contain variable amounts of platinum, cobalt alloy, gold, tantalum, MP35N, or other materials. Most coronary and peripheral vascular stents exhibit nonferromagnetic or weakly ferromagnetic characteristics. Most of the stents currently used for carotid procedures are made of nitinol and are nonferromagnetic or only weakly ferromagnetic. Implantation of the stent against the vessel wall provides for immediate anchoring of the stent. It is generally believed that additional anchoring of the stent into the vessel wall occurs over ≈6 to 8 weeks primarily due to tissue in-growth. Although this latter phenomenon may have led to recommendations that MR scanning be deferred for 6 to 8 weeks in patients treated with nonferromagnetic coronary stents, there are no good clinical data or rationale to support this recommended delay.”

“…ex vivo studies of various coronary stents also led to the conclusions that MR examination with those stents tested would be safe. Studies of peripherally implanted stents yielded generally similar results…”

“…for drug-eluting stents, it is believed that MR examination may be performed immediately after implantation. In those studies that evaluated stent heating, only minimal to modest heating (<1°C for a single stent and <2°C for 2 long, overlapping stents) was evident. The effect of the MR examination on heating of the drug or polymer coating used in drug-eluting stents is unknown, although heating of the stent (and possible resultant effects on the drug/polymer coating) might be somewhat mitigated by flowing blood.”

“Most coronary and peripheral vascular stents that have been tested have been labelled as “MR safe”; the remainder have been labelled as “MR conditional. MR examination at ≤3 T in patients with peripheral stents that are non-ferromagnetic can be performed immediately after implantation. The timing of MR examination at ≤3 T in patients with peripheral stents that are weakly ferromagnetic should be determined on a case-by-case basis. For cases in which there is a clear potential clinical benefit of scanning in the days to weeks after implantation, the benefits of the MR examination will likely outweigh the risks of the examination, and MR examination should generally be performed. In patients with chronic conditions in which it makes little difference whether the scan is performed at a given time or weeks later, it may be prudent to defer MR examination until ≈6 weeks after device implantation.”

**“Vascular stents and MRI safety”** – searched using Google on 03/01/22

<https://mriquestions.com/vascular-stentsgrafts.html> - Are all stents and stent grafts safe to scan? Isn't there a waiting period after implantation?

“To my knowledge, there are no currently implanted stents that are considered MR Unsafe. In the past the Zenith AAA stainless steel stent-graft was placed in this category by its manufacturer (Cook), but this restriction has now been lifted. Like other metallic stents it is considered MR Conditional at 1.5T and 3.0T. Although safe to scan as long as conditions are followed, some stents like the Zenith produce a substantial susceptibility artefacts making assessment of stent patency by MRI difficult.

Another outdated concept is that one must wait 4-8 weeks before scanning a patient with a newly implanted metal stent. The idea was that the stent needed time to "settle in" and become incorporated in the vessel wall before risking displacement by magnetic forces. As recently as 10 years ago, the package inserts of many stents, especially uncovered coronary stents, carried a warning not to scan patients in the first 6 weeks unless absolutely necessary. Since that time, several papers have been published demonstrating the safety of scanning patients immediately after stent placement; so that is the protocol I follow and recommend.

Metallic stents may indeed undergo heating during RF-excitation, but this also does not seem to be a major problem even with overlapping stents or with big aortic stent-grafts, in part because flowing blood serves to diffuse away whatever heat is locally generated. The "conditions" associated with some stents recommend that whole-body-averaged SAR levels not exceed 2 W/kg and a maximum of 15 minutes per sequences, while other stents permit up to 4 W/kg. If you don't know the exact model of the stent you are scanning it is therefore safer to use the lower limit.”

**Empirical Evidence and Anecdotal Data**

A retrospective review of MRI safety implant database records at NHS Tayside was undertaken - using the search term ‘stent’. All cases over a five-year period (2017-2021 inclusive) were examined, and those associated with ‘non-coronary’ arteries were selected for further review.

The database itself contains the majority of MR safety evaluations that have been sent to MRI physics for safety evaluation. Note that there may be certain omissions, such as those associated with ‘at the scanner’ cases where on-the-spot MRI safety advice was sought at the time of the MRI appointment. There may also be omissions in some cases where experienced radiographers chose to make an MRI safety decision themselves - rather than pass it on to the MRI physics team. Nevertheless, the data presented are considered to be a reasonable representation of those non-coronary vascular stents that have been seen at NHST over the time period.

Note that the following analysis has required the consideration of some local empirical evidence. In 2012, a patient with a Cook Medical EVAR stent with additional accessories (i.e., a FEVAR) was referred to Ninewells Hospital for an emergency MRI scan of a spinal abscess. MR physics safety guidance was provided, stating that it would be advisable to wait 6-8 weeks after implantation before scanning (normal mode of operation at 1.5T). However a clinical decision was made to proceed with the scan, with the implant having been placed just a few days beforehand. The patient subsequently reported heating and felt unwell following the scan, which was terminated early. Following discussion with vascular interventional radiologist colleagues, it was felt appropriate to consider EVAR’s and FEVAR’s separately, with the latter to be earmarked as MR unsafe.

The scanning details of the above incident were studied after the event, and there was nothing of concern identified with the protocol itself (all scanning was performed in the normal mode). It is assumed that the reasons for the safety incident were multi-factorial – i.e., potentially relating to the anatomical area under investigation (close to the stent location), together with the patient position within the coil and the scanner, and possibly also the very short implant duration time. Further, the pain reported by the patient could well have been related to the clinical condition (a spinal abscess) following the need to lie motionless in a supine position within the scanner for half an hour.

Published knowledge at the time of writing indicates that there are no EVAR or FEVAR stents that present a contraindication to ‘normal mode’ MRI at 1.5T or 3.0T, at any stage after implantation. The GISP recommendation is to follow these widely published guidelines, although centres within NHS Scotland may wish to follow their own localised policies (the GISP is an advisory document, and individual centres should remain free to apply site-specific MR safety advice if they wish to do so).

Key details of the MRI safety spreadsheet findings are summarised below:

* On average, n=10 MRI physics safety evaluations of non-coronary vascular stents were recorded per annum. A total of n=50 patient cases were recorded, with a range of n=9-14 cases per annum, over the five-year period.
* All of the n=50 patient MRI scans were performed safely and without any incident.
* Specific locations examined included the iliac, celiac, vertebral, aorta, subclavian, mesocaval, mesenteric, superior vena cava, and femoral arteries.
* Some referral requests were provided with very non-specific information, containing details such as ‘stent in lower leg’, ‘stent in groin’, or simply just ‘stent’.
* Approximately n=19 safety requests were requested for patients with abdominal aortic stents or grafts – often referred to as abdominal aortic aneurysm (AAA), endovascular aneurysm repairs (EVAR) or fenestrated EVAR (FEVAR) repairs.
* There were at least n=3 cases where overlapping stents were positively identified, although in reality this figure may have been higher.
* If the proposed guidance from the GISP is simplified to enable scanning in normal mode at 1.5T or 3.0T, then this would have provided sufficient safety guidance for n= 43 of the 50 cases (by calculating this number, it is assumed that the manufacturers’ advice for EVAR and FEVAR stents applies).
* Of the n=7 cases where the GISP advice could have proved questionable, there were n=4 cases where a localised restriction of 1W/Kg SAR was advised by the implant manufacturers. This was taken into consideration within the issued MR physics safety advice by recommending a 1 minute gap between successive sequences, combined with the use of low SAR sequences where possible. There were also n=2 cases where multiple overlapping stents were declared. In these instances a 1 minute gap between successive sequences was recommended as a way of minimising heat build-up. Finally, there was one case where a patient with a thoracic aortic stent was referred, but without any implant information declared or available. In this case, a clinical risk/benefit assessment was undertaken and the scan went ahead as intended without incident.
* If the GISP advice were to incorporate a recommendation to avoid ‘sequence stacking’ – i.e. to enable a brief pause between successive sequences, then this would help to compartmentalise the RF power delivery as a way of further minimising heating effects. When this is combined with the scientific advice reported in [6] and [7] (describing the effectiveness of blood flow as a way of reducing heating effects), then this risk reduction should be considered enough to allow the GISP to cover cases of ‘low-SAR’ stents and multiple overlapping stents.

In summary, with GISP advice extended to recommend “scanning in normal mode at 1.5T or 3.0T, but with no consecutive sequence stacking”, then it is likely that the advice would be applicable to n=49 of the 50 cases studied over the five year period in this review. The one incompatible case was presented with very poor referral details, and it is likely that this type of referral would always require a deeper MR physics check outside the framework of the GISP.

**Summary of risks from implant associated with static field, RF and imaging gradients**

A list of the key risks/questions is as follows:

* Will an MRI scan performed less than 6 weeks after implantation result in any translational or rotational motion due to the lack of tissue endothelialisation?
* Will an MRI scan in the normal mode of operation (at 1.5T or 3.0T) be sufficient to mitigate risk associated with RF heating of the implant?
* Do fenestrated EVAR stents present any ongoing risk of heating or motion?
* Is there any risk that the patient physiological processes may reduce the effects of cooling from flowing blood?
* Are stents that are implanted across the globe likely to be as ‘reliable’ in terms of MRI safety as those implanted in the UK?
* Are ‘older stents’ (e.g., those implanted before the year 2000) likely to present a more serious MR safety condition than more modern models?
* Is there any significant difference between the risks associated with MRI at 1.5T versus the risks associated with MRI at 3.0T?

**Summary Statement - Consideration of Risks**

**Field Strength:** There is no convincing evidence to suggest that MR safety concerns exist for MRI at 1.5T and 3.0T with respect to the projectile effect. The main point of contention related to attractive forces associated with the static field, is whether a delay period of 6-8 weeks is warranted to enable endothelialisation to occur around the implant. A recent publication that discusses this issue is presented by Maralani et al [13], and they state that most coronary and carotid stents exhibit non-ferromagnetic or weakly ferromagnetic behaviour at both 1.5T and 3T, although there is no compelling data to support a delay for MRI of 6-8 weeks after stent deployment. Coupled with this, local MR safety assessment audit review has identified no examples of cases where non coronary vascular stent migration has occurred due to the presence of the static field. **The evidence from the perspective of the static field thus points towards it being safe to scan patients with non-coronary vascular stents at either 1.5T or 3.0T - immediately after stent deployment, if the clinical situation requires it. However, a prudent approach would be to implement a 6-8 week delay rule until further local data are collected. The GISP therefore applies to correctly deployed non-coronary vascular stents that have been inserted for 6-8 weeks or more, and are functioning as intended. Any stents that are <6 weeks post-implantation should be referred for a standard MRI safety review.**

**RF Power Deposition:** A key point of contention related to SAR limits for non-coronary vascular stents relates to certain implants (e.g., the Boston Scientific Eluvia) that have exposure limits as low as 0.5 W/Kg for 15 minutes of continuous scanning. This tends to be location-dependent, and typically relates to imaging performed at the thigh area when the stent is located nearby. Operating the scanner in the normal mode of operation may not always satisfy these SAR limits, but there are certain key factors that provide reassurance that this may not be such a concern. Firstly, work by Elder [7] and Scandling [8] have evaluated the cooling effects of flowing blood in detail, and the former has predicted that in-vivo temperature rises during MRI may be less than half the value predicted from in-vitro tests (e.g., the ASTM F2182 procedure) that do not account for the cooling effects of the blood. The latter author recommends that patients with these implants should have access to clinically indicated MR scans wherever possible. It is most likely that the advice provided by the stent manufacturers is very conservative and has not taken into account the potential cooling effects of the blood. Secondly, the RF ‘critical length’ at 1.5T and 3.0T (based on the half-wavelengths of the electromagnetic field inside a patient) for 1.5T systems is around 25 cm, and for 3.0T systems is around 12 cm. For the vast majority of stent configurations this will not be an issue, and even for multiple overlapping stents the fact that the combined length does not form a true continuum is likely to further encourage cooling effects. Thirdly, by invoking a small delay between successive pulse sequences to avoid ‘sequence stacking’, the MRI user may be able to minimise risk associated with continuous scanning (i.e., the possibility that the 15-minute recommended limit could be exceeded). Empirical evidence derived from local MR safety assessment audit review has identified no examples of cases where RF power deposition has resulted in any safety events when the scanner is operated within the normal mode of operation. The only exception to this was one example of a FEVAR stent of a patient being scanned for a spinal abscess very soon after stent deployment. It has not been possible to associate this incident with the technical details of the MRI sequences used, and the event was quite possibly related to the clinical condition of the patient. It is concluded that from evidence available **there is no known contraindication to MRI scanning of non-coronary vascular stents in the normal mode of operation at 1.5T or 3.0T, provided that the stent is deployed correctly and is functioning as intended. It is recommended that a short delay of approximately 20 seconds is implemented between successive MRI pulse sequences to avoid ‘sequence stacking,’ as an additional way of minimising risk of RF heating effects**. Not only will this approach simplify the process of safe scanning, but it will also ensure that the image quality can be optimised for patients, and not be restricted by the processes of SAR reduction.

**Other Considerations:** For the GISP to function safely there has been some discussion as to whether a back-dated time ‘cut-off’ would be appropriate. For example, should the GISP apply to only those cases where the referrer is able to declare that the stent was deployed after the year 2000, or some similar date? Similarly, the GISP should only apply to those patients where it is known that the stent has been deployed correctly by a responsible healthcare professional. This has led to discussion as to whether the country of stent deployment should be declared as part of the referral process.

Taking both factors into consideration, there does not appear to be any evidence in support of using a ‘date cut-off’ for stent deployment. From the literature work it is clear that patients with vascular stents have been scanned safely using MRI from at least the late 1990’s, and probably for considerably longer. **To the best of our knowledge, extensive review of the scientific literature and MR safety databases does not provide data in support of using a date cut-off for vascular stent deployment.**

As far as the country of stent deployment is concerned, there is no clear evidence to suggest that the country of stent deployment is associated with increasing concern related to vascular stent implant safety. There is a very small possibility that lesser-known stents may be used that have not been identified as part of this review process. **However, to the best of our knowledge there are no convincing data to limit the extent of GISP validity. The GISP is therefore considered valid for all non coronary vascular stents inserted worldwide.**

Limited empirical evidence from one Scottish Centre (NHS Tayside) has established a single case of a patient who experienced feelings of discomfort during an MRI scan shortly after having a fenestrated EVAR (FEVAR) stent implanted. The scientific evidence available suggests that the case concerned may have been a ‘one off’, but it is recommended that centres are free to implement this advisory GISP alongside their own local procedures. Future sharing of MR safety experiences is encouraged.

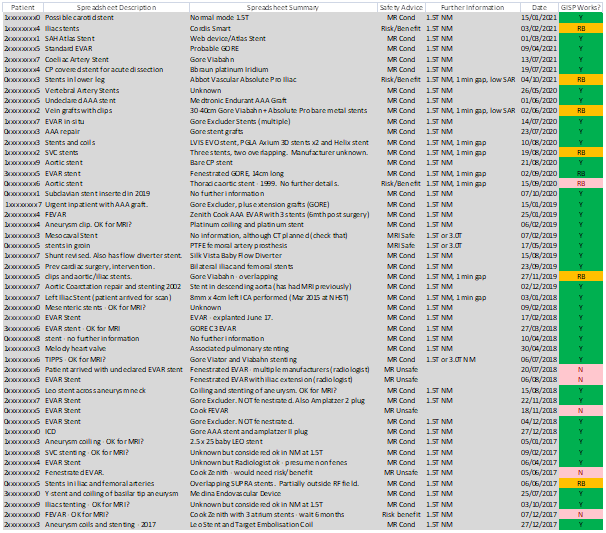
**Conclusion:**

As a result of this review, a simplified approach to the MR safety of non-coronary vascular stents based on minimal risk is proposed. There is evidence in the literature that blood flow has a significant cooling effect which is not accounted for when devices are tested for MR conditionality using the ASTM F2182 procedure. This GISP supports the use of MRI at 1.5T or 3.0T for scanning patients who have non-coronary vascular stents in-situ that have been deployed correctly and are functioning as intended. The following conditions apply:

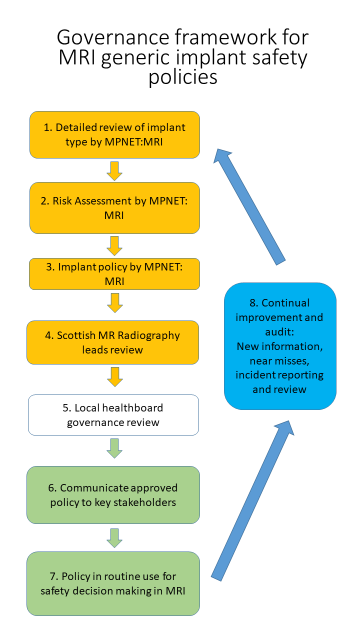
* Scanning should be performed in the normal mode of operation to minimise RF power deposition. A short delay of 20 seconds should be routinely implemented between successive pulse sequences to avoid ‘sequence stacking.’
* Scanning may occur at any time after vascular stent deployment, but if the scan is required within 6 weeks of stent implantation then it should be referred for a standard MR safety assessment (where make/model details can be ascertained).

Note that this GISP is only valid for non-coronary vascular stents and does not cover other non-vascular stent types such as biliary, pancreatic, oesophageal, bronchial, and ureteric stents. The GISP is not yet valid for MR safety assessments intended for 7.0T work, but this will be kept under continuous review and updated as/when possible.

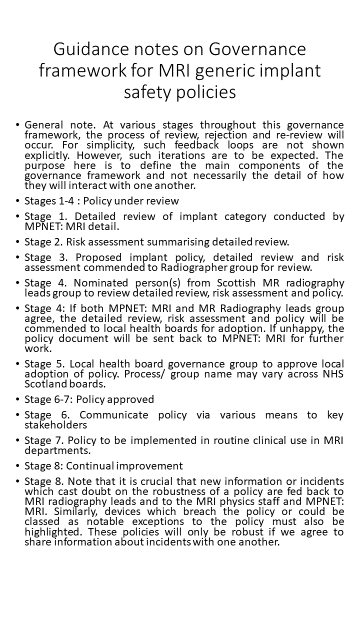
**Appendix 1**



**Appendix 2**

****

**Figure AX: Governance Framework for Generic Implant Safety Policies, creation to deployment**

****

**Figure AY: Notes on Governance Framework for Generic Implant Safety Policies**

**References**

*‘Include any relevant references used throughout this detailed review here’*