Title: MRI safety of penile prosthesis implants

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About this document

1. This template follows the guidance document "A framework for developing Generic Implant Safety Procedures (GISPs) for scanning medical implants and devices in MRI". Further details on developing a GISP can be found here.
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**
6. Each section title links through to relevant online material – mostly this is the joint society published guidance for developing GISPS (still to be published – so currently the links send you nowhere).

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2 Procedure Statement

Disclaimer

Compiled here are Generic Implant Safety Policies (GISPs) for MRI. While steps have been taken to minimise the risk of adoption of these policies, it should be noted that these are not completely without risk. Health boards, integrated care systems, trusts or private medical organisations 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 and MR Clinician.

Brief description:

- Used to treat erectile dysfunction.
- Designs broadly split into two categories:
    - Malleable, which are often composed of silicone with a metal core
    - Inflatable, which may contain metallic components within the pump section
- Two historical models of malleable/mechanical penile prostheses contain ferrous materials and have demonstrated significant forces when exposed to magnetic fields associated with MRI – the Dacomed Omniphase and Duraphase devices.

What the procedure covers:

- Commercial penile prosthesis implants, with the exception of the Dacomed Omniphase and Duraphase devices
- Valid for scanning at 1.5 and 3T in the Normal Mode of operation.
- Valid for implanted devices where the implant is inserted correctly.
- Valid for MR scanning activity immediately post-implantation.

What the procedure does not cover, including notable exceptions:

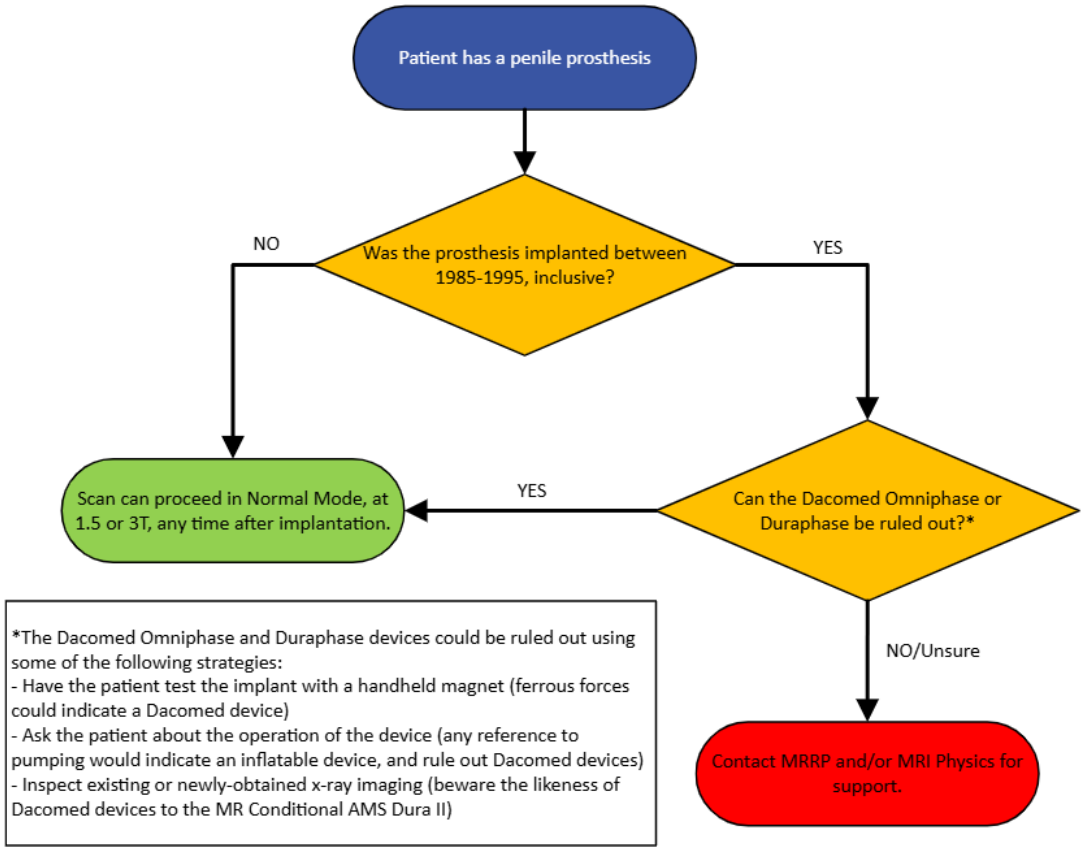
- Not valid for scanning outside the Normal Mode of operation.
- Not valid for implants that are not inserted correctly.
- Not valid for implants other than penile prostheses.
- Not valid for the Dacomed OmniPhase and DuraPhase devices

MRI Generic Implant Safety Procedure (GISP) V12

Advice summary:

Almost all penile prostheses can safely undergo an MRI scan under the following conditions:

- Field strength of 1.5 or 3 Tesla, regardless of the value of the spatial gradient magnetic field.
- Maximum whole-body averaged specific absorption rate (SAR) of 2 W/kg, operating the scanner in the Normal Operating Mode for RF.
- Maximum imaging time, 15 minutes per pulse sequence (multiple sequences per patient are allowed).
- EXCEPTIONS – The mechanical Dacomed OmniPhase and DuraPhase, implanted between 1986 and around 1995 are not included in this GISP, since they have been shown to experience ferrous interactions with MRI static magnet fields.
- For devices implanted between 1986 and 1995, further investigation is required. The make and model of penile prostheses implanted in this date range should ideally be obtained, or else the Dacomed Omniphase and Duraphase should be ruled out using patient discussion (e.g., mechanism of operation), x-ray imaging or handheld magnet testing.
- It is noted that the Dacomed implants are not considered an absolute contraindication to MRI, since risk mitigation strategies can be employed to counter the risk of ferrous interactions (forces and torques). These cases should risk assessed on a patient-specific basis.



3 Evidence Review

3.1 Introduction

Implementing a GISP within an MRI department has a number of advantages for the department and the patient. These are outlined below:

- Facilitates scanning when implant information is not available and avoids the need for multidisciplinary team review of the specific patient case
- Facilitates immediate scanning when implant information takes some time to obtain, removing delays to patient care.
- Immediate scanning avoids wasted scan slots leading to an improved and more cost-effective MR utilization.
- Reduces the need for staff resources to obtain and evaluate specific implant information.
- Provides an evidence-based methodology for managing patients with implants where there appears to be overly conservative MR conditions.
- Allows greater emphasis to consider implants not covered by the GISP and ensures the safety focus is on these implants which are typically higher risk.
- Evidence based and therefore a more proportionate attitude towards risk

There are also a number of risks of implementing GISPS as outlined below:

- Newly developed or previously unrecognized unsafe implant (or MR Conditional where the GISP does not follow the conditions)
- Updated MR safety information that changes the safety status of an implant such that it is no longer safely scanned under a GISP
- When following a GISP, implants not disclosed by the patient at screening might not be discovered, whereas identifying implant specifics in patient notes can highlight inaccuracies in the patients account of their own medical history.
- Confusion regarding exactly what implants or patient groups a GISP covers. When make and model are identified this ambiguity is removed (e.g. an active orthopaedic implant mistakenly categorised as a passive orthopaedic implant).

3.2 Clinical Context

Penile prostheses are indicated for treatment of erectile dysfunction (ED) due to variety of causes including pelvic organ transplant, neurological impairment, spinal injury, radiotherapy or prostatectomy cancer treatments, or Peyronie's disease (scar tissue formation). Additionally, penile prostheses can be encountered following phalloplasty resulting from genital reconstruction or transgender surgery.

For treatment of ED, less invasive treatments such as oral drugs or intracavernosal injection are typically pursued first, although penile prostheses may be considered if patients become refractory to medical therapy.

MRI is actually considered to be the most valuable diagnostic tool in understanding penile prosthesis complications, due to its excellent soft tissue contrast and detail of penile anatomy [Moncada2004,Ramanathan2018,Uski2022]. MRI offers the ability to investigate the mechanical integrity of the device, its positioning and the presence of infection.

In general, implanted penile prostheses comprise elongated structures inserted into the two bilateral corpora cavernosa compartments along the shaft of the penis, in order to simulate an erection and hence restore sexual function. Penile prostheses can be grouped into two categories, as follows:

(i) Malleable, or semi-rigid prostheses

Here, two prosthetic rods are implanted which are malleable to a degree that the patient can alter the degree of inflection in order to either simulate an erection, or conceal the device in a relaxed state. Conversely, the devices must provide sufficient rigidity to mimic a natural erection to the extent that sexual function can be achieved.

Typically, these devices comprise a silicone rubber body, with a core which tends to be a metal wire or coil. In order to achieve the optimal fit, modern malleable implants are available with a range of sizes and rear tip extenders (RTEs) to alter the length of the implant and ensure a secure fit in the crus of each corpus cavernosum.

(ii) Inflatable penile prostheses (IPPs)

These devices comprise two cylinders inserted into the two corpora cavernosa, as for the malleable category introduced above, but additionally utilise fluid reservoirs and pumps to achieve inflation of the cylinders to simulate a natural erection. It is noted that 'hydraulic' might be a more accurate term than 'inflatable', but the current terminology has been in accepted use for decades. Depending on the design of the cylinders, inflation results in an increased girth, either with or without a concomitant increase in length.

IPPs tend to be further divided into subcategories according to their physical design. Three-piece IPPs are most common today, where the cylinders are accompanied by a reservoir to store the fluid and a pump to move the fluid between reservoir and cylinders (Figure 1). Reservoirs typically reside under the abdominal wall, while pumps are typically placed in the scrotum to be accessible for manual manipulation. Two-piece designs integrate the reservoir into the base of the cylinder. Historically, there have been examples of single-piece or unitary IPPs too, where reservoirs and inflate/deflate components are all embedded within the cylinders.

As for malleable prostheses, IPPs are available in a range of sizes, and RTEs are available to customise the fit to a patient's specific anatomy. Manufacturers have developed sophisticated pump and valve mechanisms for ease of use and to avoid inadvertent inflation.

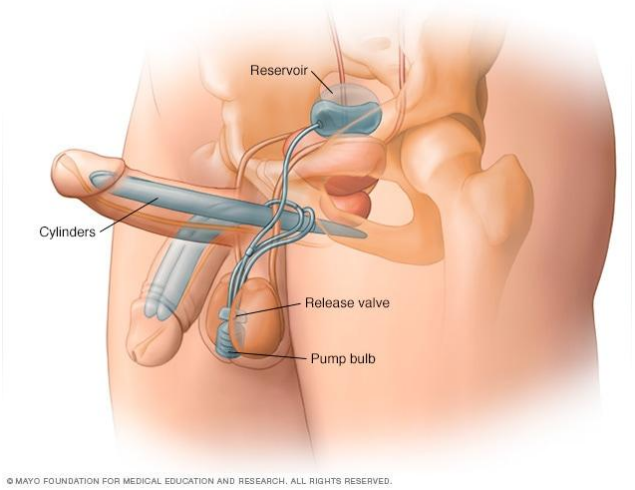


Figure 1: Generic structure of a three-piece IPP. Image credit: Mayo Clinic.

Both malleable prostheses and IPPs contain metal components which are of potential concern for MRI safety.

The interaction of metal penile prosthesis components and an MRI scanner could create the following hazards:

1. The strong static magnetic field and its spatial gradient could induce displacement and/or torque forces in ferrous components that may cause an implanted device to be moved, rotated or otherwise dislodged. There is a risk of damage to neighbouring tissues, or impact on device function.
2. RF energy deposition may be increased in the vicinity of electrically conducting metallic components, which could risk thermal injury to neighbouring tissues.

3.3 Results

Online MRI implant safety databases (Date queried: 08/07/25)

Source: www.mrisafety.com

Date of query: 03/04/2025

Comments: Search on www.mrisafety.com using search term 'penile'.

Results: The search on 'The LIST' returned 42 results: 19 MR Safe, 21 MR Conditional 6, and 2 MR Unsafe, plus a specific Safety Topic/Article (ID# 193) on the Safety Topic/Subject 'Penile Implants'.

The 2 MR Unsafe results are the Dacomed OmniPhase and DuraPhase devices, with the article stating that these two devices "demonstrated substantial ferromagnetic qualities when exposed to a 1.5-Tesla MR system". The entries for these devices on the list state that: "To mitigate possible issues related to force and torque, you can scan the pt in the prone position and/or use a rib belt or 6 inch elastic bandage to stabilize the penile implant. MRI-related heating is not an issue for this penile implant."

The article goes on to state that the likelihood of severe injury incurred by MR scanning of these devices is 'unlikely' since the forces induced by the static field are not too severe, particularly compared to forces encountered by these implants during their intended use. However, Dr Shellock (the author) then recommends that MR scanning of patients with these two devices would be considered inadvisable unless proper stabilisation can be used, to secure the anatomy to prevent inadvertent movement of the rods.

The article does not raise safety concerns for MRI scanning of any other penile prosthesis implants, and references the Lowe *et al.* article [lowe2012] which reviews MR safety of penile implants, together with Shellock's own paper from 1987 [shellock1987].

The MR Safe devices include various devices that are known to contain metal components and could therefore not be labelled as MR Safe under the ASTM F2503 standard. However, the definition of MR Safe used on list hosted on mrisafety.com includes the following caveat:

> NOTE: Implants and devices tested prior to 2005 when the terminology changed indicate labeling using the outdated terms "MRI Safe" or "MRI Compatible". Those items are listed on www.MRIsafety.com as "MR Safe".

Hence, it seems reasonable to interpret these entries on the list as not meaning those devices are strictly MR Safe, but rather having historically demonstrated safety in the MR Environment/Scanner.

21 entries on the list are categorised as MR Conditional 6, defined as safe to scan at 3 T or less in Normal Mode of operation for SAR (maximum whole-body average SAR of 2 W/kg) for 15 minutes of scanning per pulse sequence, and maximum spatial gradient of 7.2 T/m (720 G/cm). This statement is based on non-clinical testing demonstrating temperature rises of 6 degrees Celsius or less after 15 minutes of scanning at 2 W/kg on a 3 T scanner.

mriquestions.com (Date queried: 08/07/25)

Allen Elster's website mriquestion.com has a page regarding the MR safety of penile implants. Here, he asserts that over 90% of currently-implanted prostheses are IPPs, acknowledges that these tend to contain small metal components, but that they can be safely scanned according to their specific MR Conditions.

The page further notes that malleable penile implants contain metal cores and are generally MR Conditional without presenting a concern for MRI.

However, the page notes that the Dacomed OmniPhase and DuraPhase malleable penile prostheses, manufactured in the 1980s and 90s contain an appreciable amount of metal which have demonstrated significant magnetic deflection in in-vitro testing at 1.5 T. However, it further notes that there have been no reported adverse events arising from MRI, and that the field-induced forces might not be clinically significant, given the forces experienced by these devices in their intended use. It concludes by stating "The common wisdom has thus been to avoid MRI in patients with these two rare legacy implants unless medically necessary".

The webpage references publications by Lowe *et al.* [lowe2012], and Ramanathan et al. [ramanathan2018].

Locally implanting Teams

A review of penile prostheses implanted in NHS Lothian was performed in 2023, with the intention of creating a local policy for MRI scanning of devices implanted in Lothian. The two implanting consultant urologists based in NHS Lothian provided the following responses, when queried about the penile prosthesis devices implanted in Lothian:

> "I can confirm that we have only used either Coloplast or AMS penile implants in NHS Lothian since I started as andrologist in 2004. My colleague, who also does penile implants uses the same devices / manufacturers."

> "I cannot comment on before 2012 when I became a consultant here but in my experience of patients pre that era, none have come across other than ams or coloplast ones.
> I cannot make a blanket statement on all patients prior to my coming here but would be surprised if there was another competitor implant prior to that."

AMS and Coloplast penile prostheses are reviewed in the following section.

Implant Manufacturers

- **Coloplast**

Coloplast acquired the urology division of Mentor in 2006, including its penile prosthesis range.

With respect to MRI safety, the Coloplast website hosts a letter with a section titled 'Magnetic Resonance Imaging (MRI) COMPATIBILITY', signed by the VP of Global R & D. The online version was dated August 2026. The contents of this document are summarised in Table 1, below.

The Coloplast Titan IPP (including Classic, Touch, Press and Prime varieties) has the following MR Conditions:

- 1.5 or 3T
- Spatial gradient field of 30 T/m or less
- Normal operating Mode (max whole body average SAR 2 W/kg)
- CP mode for RF
- Maximum 60mins of continuous RF scanning

Under these SAR conditions, measured temperature rises at 3 T were < 1.9°C.

The NHS Scotland MR Physics Group concluded that adherence to CP mode at 3T is not necessary, since the use of Normal Mode provides sufficient protection to lead minimal residual risk of RF-induced thermal heating injury.

All of the remaining malleable or legacy IPP devices (including the Titan OTR) listed have the same MR Conditions:

- 3 T or less
- Spatial gradient field of 720 G/cm (7.2 T/m) or less
- Maximum whole-body averaged SAR of 3 W/kg for 15 minutes of scanning

Under these SAR conditions, measured temperature rises at 3 T were < 1.9°C.

All devices may produce image artefacts in the vicinity of the implant, but no dimensions are provided.

- **AMS (Boston Scientific)**

Boston Scientific acquired the urology portfolio of American Medical Systems (AMS) in 2015.

With respect to MRI safety, Boston Scientific have issued a letter titled 'MRI Information' which lists their MR Conditional penile prosthesis devices, dated Sept 2020. Additional MR safety statements are available in the Instructions for Use of certain devices. The devices covered by this letter are presented in Table 1.

MR Conditions for the AMS IPPs are as follows, at 1.5 T:

- Spatial gradient field of 450 G/cm (4.5 T/m) or less
- Maximum whole-body averaged SAR of 1.5 W/kg for 15 minutes of scanning

Under these SAR conditions, measured temperature rises at 1.5 T were ≤ 0.4°C.

and, at 3 T:

- Spatial gradient field of 720 G/cm (7.2 T/m) or less
- Maximum whole-body averaged SAR of 2.9 W/kg for 15 minutes of scanning

Under these SAR conditions, measured temperature rises at 3 T were ≤ 1.9°C.

Comparing the spatial field gradient Conditions for 1.5 T and 3 T, it is apparent that these quoted values represent the limit of testing rather than the limit of safety for these devices. The Condition value at 1.5 T of 450 G/cm (4.5 T/m) appears to be rather low and could easily be exceeded by modern 1.5 T MR scanners. However, the higher quoted Condition of 720 G/cm (7.2 T/m) at 3 T provides reassurance that this higher value does not pose a hazard to a patient with these devices implanted, since any forces experienced at this higher field strength and steeper field gradient would be higher than any forces found at 4.5 T/m generated by a 1.5 T scanner.

It is also noted that the whole-body average SAR Condition of 1.5 W/kg at 1.5 T is more restrictive than Normal Mode of Operation (2 W/kg). However, the measured temperature rise of ≤ 0.4°C after 15 minutes of scanning at 1.5 W/kg indicates that scanning at 2 W/kg would not produce unsafe levels of heating. This is corroborated by the SAR Condition at 3 T being nearly double that for 1.5 T (2.9 W/kg), with a measured temperature rise of ≤ 1.9°C which does not pose a risk to a patient.

MR Conditions for the AMS Spectra malleable implant are as follows:

- 3 T or less
- Spatial gradient field of 720 G/cm (7.2 T/m) or less
- Maximum whole-body averaged SAR of 2.9 W/kg for 15 minutes of scanning

Under these SAR conditions, measured temperature rises at 3 T were ≤ 1.6°C.

MR Conditions for the AMS Tactra malleable implant are as follows:

- 1.5 T or 3 T
- Spatial gradient field of 13,000 G/cm (130 T/m) or less
- Normal Operating Mode; Maximum whole-body averaged SAR of 2 W/kg for a maximum of 15 minutes per pulse sequence.

Under these SAR conditions, theoretical temperature rises at 1.5 T (3 T) are expected to be 1.1°C (0.6°C) after 15 minutes of continuous scanning.

The letter also includes statements regarding ‘acceptable’ results of torque and deflection angle tests for a range of legacy products at 1.5 T and 3 T, plus ‘acceptable’ heating/temperature change results for these products at 1.5 T only. It is noted that all of these legacy products are listed as ‘MR Safe’ at 3 T on ‘The LIST’ on mrisafety.com, suggesting there is no cause to believe that RF-induced heating is a risk at 3 T. No specific MR Conditions are available for these legacy products, however no reported MR-related incidents could be found to indicate the need to adhere to particularly restrictive scanning conditions.

Further to the ‘MRI Information’ letter detailed above, MR Conditions can be found in the IFU for specific AMS devices.

The IFU for the AMS Ambicor IPP and the Tactra duplicate the MR Conditions detailed for IPPs in the 'MRI Information' letter, presented above.

IFU for the AMS 700 with MS and TENACIO pump specify the following MR Conditions:

- 1.5 or 3 T
- Spatial gradient field of 40 T/m or less
- Maximum whole-body averaged SAR of 2 W/kg for 60 minutes of continuous scanning
- Circularly Polarized (CP)

It is therefore noted that these IFU show that scanning at 1.5 T in Normal Mode for whole-body averaged SAR (2 W/kg or less) would only breach the MR Conditions for the AMS Ambicor IPP, not for the AMS 700 range of devices.

With respect to image artefacts, the following information is provided:

- AMS 700 with TENACIO pump: image artefacts may extend approx. 33 mm from the device
- AMS 700 with MS pump: image artefacts may extend approx. 36 mm from the device
- AMS Tactra: image artefacts may extend approx. 29.5 mm from the device
- AMS Ambicor signal voids with dimensions as follows:

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	6,244 mm^2	1,589 mm^2	10,295 mm^2	2,779 mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

- **Zephyr**

The Swiss company Zephyr markets the ZSI 475 IPP (also available in Female To Male, FTM, variant) and the malleable ZSI 100 prosthesis (also available in FTM variant, plus D4 variant for metoidioplasty, and CF soft variant).

Specific statements regarding MRI safety are available for the ZSI 100 and ZSI 475 devices, which state that the theoretical safety concern would be temperature increase of the device due to the presence of 316 L (austenitic steel) components. This statement appears to contradict the commercial flyers promoting the ZSI 100 devices, in which it is stated that the core is constructed from 'pure silver'. The MRI Safety leaflets describe experiments conducted at 1.5 T which demonstrate no perceptible heating from application of an MR Prostate protocol to the devices placed in-vitro within ultrasound gel together with thermometers, and placed alongside a gel-filled phantom. It also reports that no movement of the devices within the gel, or of the container housing the gel, was observed.

The MRI safety leaflets conclude with "The test is conclusive. Patient with Malleable Penile Implant ZSI 100 can take MRI" and an equivalent statement for the ZSI 475 IPP.

Analogous MRI Safety leaflets are provided on the website for the FTM versions of the ZSI 100 and ZSI 475 devices, however the second pages of each are not provided, and hence the results are not available. The promotional flyers for all Zephyr penile prostheses state the devices are "safe in

medical scanner and MRI". The FTM variants include a steel plate which is affixed to the periosteum to provide anchorage for the prosthesis for gender affirmation patients.

Overall, the MRI safety information provided by Zephyr falls short of confirming the devices' MRI Conditional status, in the strict sense, particularly since there are no explicit Conditions provided. For example, it appears no testing has been performed at 3 T for any of the Zephyr products. However, the quoted MR safety testing results and the product design and materials do not indicate any reason to be concerned about RF induced heating or displacive or torque forces. It therefore seems appropriate to consider these devices safe to scan at field strengths up to 3 T in Normal Mode of operation.

No information is provided regarding the presence or extent of MRI image artefacts in the presence of these devices.

- **Rigicon**

The Rigicon Rigi10 malleable penile prosthesis device is MR Conditional, as follows:

- 1.5 T or 3 T
- Spatial gradient field of 4,000 G/cm (40 T/m) or less
- Maximum whole-body averaged SAR of 2 W/kg for 15 minutes of scanning

Under these SAR conditions, expected temperature rises are ≤ 1.6°C. The Rigi10 device can lead to image artefacts extending approximately 55 mm from the device when imaged with a gradient-echo pulse sequence at 3 T.

The Rigicon Infla10 three-piece IPP device is MR Conditional, as follows:

- 1.5 T or 3 T
- Spatial gradient field of 720 G/cm (7.2 T/m) or less
- Maximum whole-body averaged SAR of 2.9 W/kg for 15 minutes of scanning

Under these SAR conditions, expected temperature rises are ≤ 1.9°C. Image artefacts may be produced, but specific dimensions are not provided.

The Rigicon Infla2P two-piece IPP does not have MR Safety status provided. Email contact with Rigicon received a reply (16/09/2016) that that the product is not currently available in the UK, and they were unable to provide any device details due to the sensitivity of a new product launch.

- **Surgitek**

According to Mulcahy *et al.*, Surgitek released the Uniflate 1000 two-piece IPP in 1983 [mulcahy2022]. I believe this device is erroneously termed the 'Uniflex 1000' in Lowe et al.'s article from 2012 [lowe2012], and on the LIST on Shellock's mrisafety website.

Accounting for this inaccuracy, Lowe's review article mrisafety's the LIST regard the following four Surgitek devices as safe for MRI:

  - Uniflate 1000
  - Flexi-Flate IPP (released in 1986, according to Simmons *et al.* [simmons2008])

- Flexi-Rod malleable prosthesis
- Flexi-Rod II malleable prosthesis

It is noted that the LIST on mrisafety website lists these four devices as ‘MR Safe’ at 1.5 T, with the caveat that devices labelled as MR Compatible based on testing performed prior to 2005 are currently listed as MR Safe on the website. The entries make no reference to the safety or otherwise of scanning these devices at 3T.

According to Mulcahy *et al.*, Surgitek (a division of Bristol Myers) closed for business in the mid 1990s [mulcahy2022].

Table 1: A summary of MR Safety references from penile prosthesis manufacturers.

Manufacturer	Document	Comments	Date Accessed
Coloplast	"Magnetic Resonance Imaging (MRI) COMPATIBILITY" Coloplast_MRI_Compability	Titan IPP tested July 2025. All malleable implants, including Genesis, Malleable and Acu-Form are MR Conditional, tested 2007. (Materials: silicone, 99.97% pure silver, polypropylene, polyurethane) Titan OTR, Alpha I, Excel and Mark II IPPs are MR Conditional, tested in 2005 and 2011. (Materials: silicone, polyurethane, polysulfone, nylon, glass fiber and MP35N, a nickel-cobalt alloy).	15/09/2026
AMS (Boston Scientific)	"MRI Information" BostonScientific_AMS_MRI_Info IFU for AMS Tactra, AMS 700 with Tenacio pump, AMS 700 with MS pump, and AMS Ambicor	AMS 700 (CX, CXM, CXR, Ultrex, Ultrex Plus, LGX) and AMS Ambicor IPPs are MR Conditional Spectra and Tactra malleable IPPs are MR Conditional Legacy implants: AMS 600, 600M, 650, Dura II malleable implants, plus single-piece IPPs Dynaflex and Hydroflex have all demonstrated 'acceptable' results with respect to torque, deflection angle, and heating/temperature changes	15/09/2026
Zephyr	ZSI implants website – MRI safety leaflets	Reported results of MR safety testing of ZSI 100 range of malleable penile prostheses and the ZSI 475 range of IPPs. No statement of MR Conditionality consistent with ASTM standards.	15/09/26
Rigicon	"MRI Compatibility Statement" Rigi10_MRI_Statement IFU	Rigi10 malleable device and Infla10 IPP are MR Conditional. No MR Safety status info was available for the Infla2P IPP.	15/09/26

Review of the peer reviewed literature

Several published articles specifically address the use of MRI for patients with penile prostheses.

- **Lowe et al., 2012 [Lowe2012]**

This paper from 2012 reviews the literature for documented results of MRI on penile prosthesis devices, both in vivo and in vitro. Manufacturers were also contacted for device IFUs and statements regarding MRI safety of legacy devices.

For in vivo MR scanning of patients with penile prostheses in-situ, no adverse events were found within the literature. Once case study is described where a malleable prosthesis (specific device model unknown) is believed to have rotated/twisted during MRI, without any pain or changes to device function, from ref [kirkham2008].

Based on the 2006 edition of Frank Shellock's Reference Manual for MR Safety, Implants and Devices, the authors report that the Omniphase and Duraphase malleable penile prostheses have ferromagnetic properties which could lead to movement and/or dislodgement of these devices when exposed to MRI. These ferrous interactions have potential for patient discomfort during scanning, but are not believed to risk severe injury, based on results of in vitro testing.

Correspondence with, and documentation from, the manufacturers Coloplast and AMS is summarised. This information is either consistent with, or superseded by, the content of the Implant Manufacturers section, above.

The paper concludes by noting that their review encompassed 88 individuals with penile prostheses who underwent MRI, although they believe many more patients will have been scanned, with no reported adverse events. Therefore the authors believe that 'for the majority of prosthetic devices, it is safe for a man with a penile prosthesis to undergo an MRI', as summarised in the following table:

Table 2: Summary of MR Safety of common penile prostheses, from [Lowe2012].

In vitro or in vivo penile prosthesis data documented in the literature—safe products:
AMS 600 series including malleable 600, 600 M, 650
AMS 700 series including CX, CXR, LGX, Ultrex, Ultrex Plus
AMS Ambicor
AMS Dura II
AMS Dynaflex
AMS Hydroflex
Coloplast Acu-Form
Coloplast (formerly Mentor Corp.) Alpha I
Coloplast Excel
Coloplast Genesis
Coloplast (formerly Mentor Corp.) Mark II
Coloplast Titan and Titan OTR
Dacomed Jonas
Osmond
Surgitek Flexi-Flate
Surgitek Flexi-Rod
Surgitek Flex-Rod II
Uniflex 1000
In vitro penile prosthesis data to suggest possible risk:
Dacomed Duraphase
Dacomed Omniphase

- **Shellock et al., 1991 [Shellock1991]**

This paper presents the results of MRI safety testing of a range of implantable devices, including nine penile prostheses, for which results are from an earlier Shellock publication [Shellock1987] are summarised. The summary states that of the tested penile implants, only the Dacomed Omniphase device demonstrated significant deflection forces (it is noted that this publication pre-dates the release of the Dacomed Duraphase device). Consistent with other sources, it is noted that the MRI-induced forces on an Omniphase device are unlikely to pose a risk of severe injury, but that scanning of this implant is nevertheless 'inadvisable' due to the risk of patient discomfort.

- **Uski et al., 2022 [Uski2022]**

Since Lowe *et al.*, 2012 [Lowe2012], another review of MRI of penile prostheses has been published by Uski *et al.*, which was inspected for any evidence to suggest changes to the MR Safety of known devices, or introduction of new devices which present a concern for MRI.

The only reference to the MR Safety status of penile prostheses is as follows:

> "Both 1.5-T and 3.0-T MRI can be safely performed for evaluation of penile prostheses of all types. There are two types of MPPs that are incompatible with MRI—OmniPhase and DuraPhase (Dacomed). However, both types are no longer available owing to safety problems."

Other review articles covering MRI of the penis [vossough2002,kirkham2008,ramanathan2018] draw the same conclusion regarding MR safety of penile prostheses, and cite Shellock resources (papers,

book and mrisafety website) as evidence to support the claim that penile prostheses are generally safe for MRI scanning, besides the specific exception of the Dacomed Omniphase and Duraphase devices.

There are multiple other published articles that review penile prostheses more generally, with information regarding specific implants which are either a concern for MRI, or lacking MRI Safety information. These articles also detail the state of the art and describe advances in penile prosthesis design which could carry implications for MR Safety in the future.

- **Patel et al., 2024 [Patel2024]**

In Patel *et al.*'s review of recent technological developments of penile prostheses, we learn that the Duraphase II penile prosthesis was created in 1992, including a "polyethylene disc exterior encircling a metal cable core". The Dacomed Omniphase/Duraphase model is listed as being first introduced in 1986.

The Coloplast Genesis (from 2004) and AMS Spectra (from 2009) are claimed to continue to be the most popular malleable implants in the USA.

Reference is made to a novel memory shape penile prosthesis which utilises a nickel-titanium alloy (nitinol) exoskeleton design. The nitinol is expanded and hardened in response to heating generated by magnetic induction via an external magnetic wand. Whilst initial research results seem promising, the urological community has doubts that the technology be widely adopted.

The Mentor GFS (Girth, Flaccidity and Simplicity) two-piece IPP was introduced in 1987 (Figure 2), and subsequently revised to the GFS Mark II in 1988 [polchert2021]. I note that MRI Safety information is not readily available for the original Mentor GFS, while the GFS Mark II appears to be the 'Mark II' referenced in the Coloplast MRI Compatibility letter detailed above.

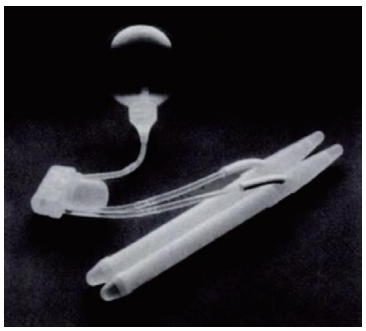


Figure 2: Mentor GFS three-piece IPP. Figure from Ref [patel2024]

The paper also references a novel patent filed by Boston Scientific for a piezoelectric pump which would be operated by an external magnetic field. To date, no products have incorporated this technology, but it would clearly have implications for safe access to the MR Environment.

- **May et al., 2023 [may2023]**

In their review of technical advances in penile implants, May *et al.* provide further detail regarding the Dacomed devices. In the mid 1980s, Dacomed was founded and released the mechanical penile

prosthesis Omniphase. The design is described as “This cylinder consisted of a series of polysulfone segments that articulated in a ball and socket fashion and were held together by a central cable”. The Omniphase was “soon succeeded” by the Duraphase device, with adjustments to how the central cable functioned (Figure 3). The Duraphase was subsequently succeeded by the Dura II device (later acquired by AMS in 2003, according to AMS 40th anniversary timeline from 2013) and further by the AMS Spectra device in 2009. However, the expensive production costs of the mechanical Spectra design led AMS to ultimately replace it with the malleable Tactra device. May et al. assert that the Omniphase/Spectra lineage was removed from the marketplace by the early 2000s due to low demand and sales.

The current market is dominated by the three-piece IPPs produced by AMS and Coloplast. Only a single two-piece IPP is available on the market, the AMS Ambicor, and is generally only chosen when an abdominal reservoir is contraindicated. Malleable implants are now less popular, and are typically selected for patients with limited manual dexterity or mental capacity or in other specific circumstances.

The paper concludes by summarising potential future developments, which could carry implications for MRI safety. Specifically, prototype products have been designed with reservoirs activated by active electronic components, or thermally activated devices which rely on external magnetic induction mechanisms to heat a nickel-titanium core.

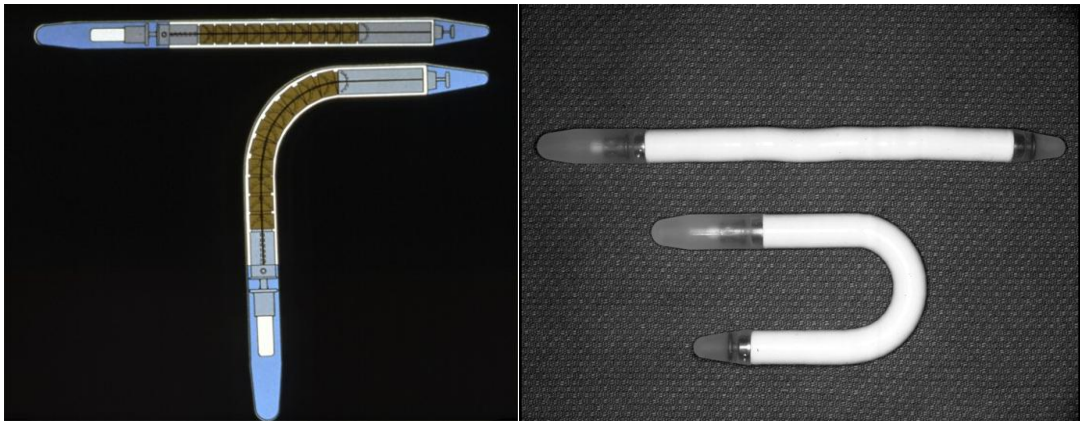


Figure 3: Omniphase (left) and Duraphase (right) penile prostheses. Figure from Ref [May2023].

- **Trost et al., 2020 [trost2020]**

Trost reviews future considerations in urology prosthetics. Patent submissions by Boston Scientific in recent years could indicate development directions for penile prostheses, including a sub-amplifier to augment manual pressure applied to the pump of an IPP. Patents also include those for an automated pump, which would be controlled wirelessly via an external control.

An innovative prosthetic device design incorporates a nitinol alloy which would straighten in response to temperature increases caused by an external magnetic induction device. Technical and safety considerations for achieving the elevated temperature to achieve the erect state remain a concern. All of these novel technologies would have implications for MRI safety.

- **Simmons et al., 2008 [simmons2008]**

Simmons et al. present further discussion regarding the future designs of penile prostheses, including the possibility of mechanised methods for cylinder inflation, utilising a motorised pump. Such a pump would constitute an active medical implant, with a power supply and electronic components, with clear ramifications for MRI Safety. Additionally, any designs involving an external component for remote control of the implant, via radiofrequency, would also carry implications for safe exposure to MRI.

Several papers have described clinical outcomes from trials and routine use of the Dacomed Omniphase and Duraphase implants, together with their successor, the Dura II. These papers shed light on the designs of these implants, which in turn provide insight into the reasons for their respective MR safety statuses. Additionally, the papers provide information regarding the dates of implantation of these three models, which can help inform a choice of implant date threshold, which is one possible approach to ruling out the problematic Dacomed devices without needing to positively identify the implant present in a given patient.

- **Kearse et al., 1996 [kearse1996]**

In 1996 Kearse et al. report on a clinical evaluation of the Dacomed Dura II implant, which was the successor to the Duraphase device. The data reported were acquired during the first 2 years of the prospective evaluation of the Dura II device, with first patients undergoing implantation surgery in April 1992. The article states that approximately 4,000 Dura II devices were implanted at the time of writing, since 1992. This report therefore provides information to help determine when the dura II's predecessor, the Duraphase, was succeeded and would therefore cease to be implanted.

- **Ferguson et al., 2003 [ferguson2003]**

A subsequent long-term review of the Dura II device was published in 2002, with participating patients having their devices implanted between 1992 and 1996. The paper states that the Dura II device was introduced in 1992 as the successor to the Duraphase device. The paper details two device differences between the Dura II and the Duraphase:

  - Replacement of polysulfone segments to updated polyethylene material
  - Additional strands of MP35N (cobalt-chrome alloy) added to add strength

AMS and mrisafety website both provide assurance that the Dura II device does not present a hazard within the MR Environment, although further detail is required to why this difference arises from the updated Dura II design compared to the Duraphase.



Figure 4: Dura II implant, Figure from Ref [ferguson2003].

- **Mulcahy et al., 2016 [mulcahy2016]**

Greater detail regarding the design of the Omniphase, Duraphase and Dura II devices is provided in Mulcahy's review article from 2016.

The paper states that Dacomed released the Omniphase device in the early 1980s, and that the design contained a stainless steel cable set within ball and socket polysulfone segments. Furthermore, proximal and distal tips were attached to the cylinder body using hex screws and Allen wrenches, of unknown materials. A schematic diagram of the Omniphase shows this construction.

The Dacomed Duraphase 'soon followed', where the cable was now attached to fixed posts at the two ends. The Omniphase and Duraphase were on the market simultaneously, until the former was phased out and ultimately discontinued due to the increased popularity of the latter.

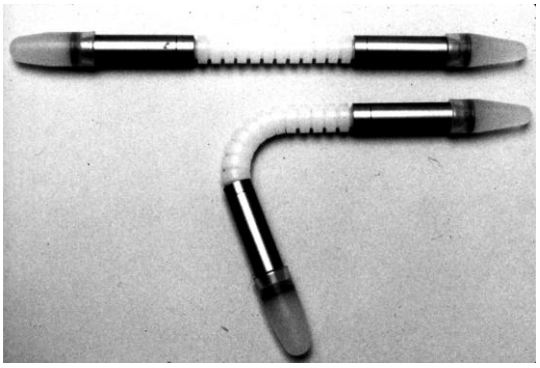


Figure 5: Dacomed Duraphase with outer sleeve removed to expose the articulating components, from Ref [mulcahy2016]

The Duraphase was then re-engineered into the updated Dura II device, by replacement of the polysulfone components with polyethylene (as described by [ferguson2003]) plus a revision of the cable design: smaller but more numerous cables were used. Together with the details from [ferguson2003], which states the new cables are composed of MP35N, this could explain why the Dura II is not found to suffer the same ferrous forces as the Duraphase, when exposed to the static field of an MRI scanner.

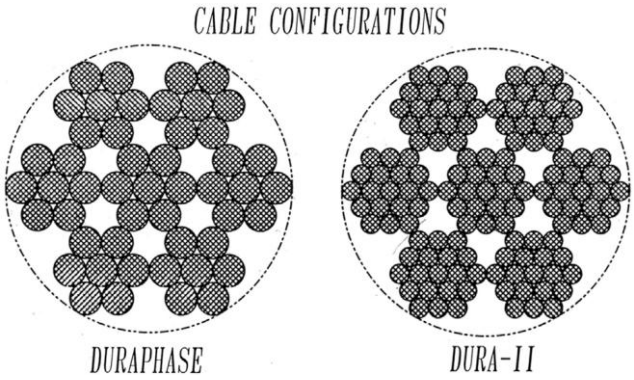


Figure 6: cable configurations of the Duraphase and Dura II, Figure from Ref [mulcahy2016]

- **Hovsepian et al., 1989 [hovsepian1989]**

Hovsepian et al. Provide a radiographic atlas comprising x-ray imaging of penile prosthesis devices commercially available in 1989. The Dacomed Omniphase and Duraphase devices are discussed, including similarities and differences in their design. An x-ray of an in-situ Omniphase device is included (Figure 7), which could be useful for centres investigating penile prostheses implanted around this time, and wishing to either exclude or confirm the possibility of a Dacomed implant being present.

This paper pre-dates the development of the Dura II prosthesis (around 1992) which succeeds the Duraphase, and hence no x-ray images of the Dura II device have been found for this GISP. However, similarities in design and construction (see [mulcahy2016] above) between these two devices could make them hard to distinguish from x-ray images alone.

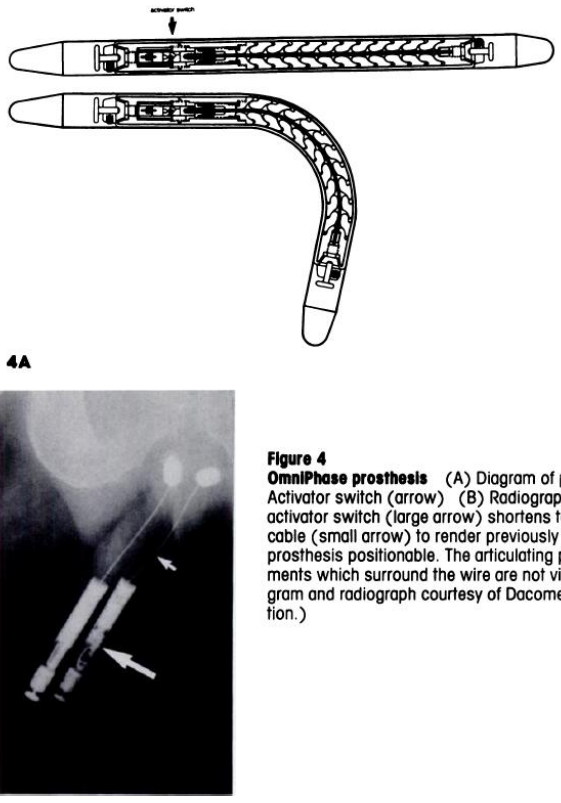


Figure 7: Dacomed Omniphase device schematic and x-ray. Figure from Ref [hovsepian1989]

Internet search (non peer reviewed literature)

Source: Google

Date of Query: 25/04/2025

Comments: A search of "penile prosthesis MRI incidents" and "penile implant MRI incidents" was conducted.

Results: The search did not reveal any incidents related to penile prostheses and MRI.

Source: Facebook MRI Safety Group

Date of Query: 27/06/2025

Comments: A search of "penile" was conducted.

Results: The search revealed numerous posts asking questions relating to penile prostheses and MRI safety. A selection of these is summarised in the following Table. The remainder of the questions were along similar lines to the ones listed. There were no reports of any incidents.

It is worth noting that many responses state that 'no info means no scan' with respect to implanted medical devices.

Date of Question	Question	Comments
02/04/22	SAR discrepancy between 1.5 and 3 T for AMS 800 artificial urinary sphincter – lower SAR limit at 1.5T	This situation is closely analogous to that for AMS penile prostheses Frank Shellock: "In the case of the labeling for the AMS 800, the SAR values indicated in the labeling were based on the values used for the MRI-related heating assessments, not because of a concern for excessive heating. Notably, the metallic part is insulated and isolated from the patient by silicone." "Additionally, MRI-related heating is not an issue for those particular implants." Emanuel Kanal: "Part of what I teach in my courses is that at least in the past the FDA-approved product labeling may have been based on and ONLY based on the testing data that was submitted by the device manufacturer to the FDA for their review and approval. Thus, these may represent nothing more than the conditions that were found at the time that this device was tested for/by this device manufacturer in the specific 1.5T and 3T MR scanners that they happened to have access to and use for testing purposes. It is CRITICAL for all of us to recognize that we, the

		end users, do not know if the approved device labels represent merely the conditions under which the device was tested and found to be safe OR the actual limits of safety and shortly beyond those conditions it would indeed be unsafe. The FDA today WANTS to have devices labeled to safety thresholds. However, there are hundreds or thousands or tends [sic] of thousands of devices that are historically already labeled in a manner that merely reflects the conditions under which those devices were tested and found to be safe. This is a MOST unfortunate circumstance due to the clinical confusion and uncertainty that it generates. It is single-handedly responsible for SOOOO many patients being denied access to requested MR studies that they may have otherwise been able to safely undergo had we only understood more about the labeling circumstances associated with that particular device"
18/02/17	X-ray image of unknown penile prosthesis implant presented, question as to whether safe to scan in MRI	Response suggests using radiographic atlas in Ref [havsepian1989] to exclude possibility of Dacomed Omniphase/Duraphase. Poster updates to state handheld magnet also used to test for ferrous forces – none detected. Scan proceeded without incident.
09/07/20	MRI safety of unidentified penile prosthesis	Replies suggest need to exclude Dacomed Omniphase/Duraphase, by x-ray or by discussing device function with patient – any form of 'pump' implies inflatable penile prosthesis, all of which are considered 'safe' for MRI. Use of ferromagnetic detector also discussed, to exclude possibility of ferrous components.
06/12/22	Use of x-rays to identify penile prostheses ahead of MRI	With respect to Dacomed Omniphase/Duraphase, Frank Shellock: "Even though those penile implants are labeled MR Unsafe, if the MRI exam is vital for patient management, it's possible to implement procedures to substantially mitigate risks" "MRI-related heating is not a concern for any penile implant. Force and torque are the potential issues. In addition to securely applying a wrap, if possible, the patient may be placed in a prone position for the MRI exam."

10/11/21	Question regarding MRI of unidentified penile prosthesis	Frank Shellock: "I've tested many penile implants over the years and know that they are all low risk for MRI safety issues. That includes the ones that are labeled MR Unsafe for which possible issues with magnetic field interactions (force and torque) can be mitigated by applying some means of stabilization, such as securing the device with an elastic bandage. MRI-related heating is a non-issue." Wes Carter: "If a xray shows the implant isn't a Duraphase or Omniphase, our facilities will proceed with scanning any type of MRI exam."
20/06/24	Question: are there any penile prostheses that are unsafe for MRI?	Jane Sammons: "We had one case in the early 1990s and the radiologist investigated it and he said no scan because it had something electronic in it." Frank Shellock contests this anecdote, claiming he has never encountered a penile prosthesis with electronic components, least of all from the 1990s, and suggests it might be an inflatable mechanism. Jane maintains the accuracy of her claim, but provides no further details when asked to do so.
UK MRI SAFETY GROUP		
20/11/20	Barbara Nugent shares AMS MRI Safety Letter	Emanual Kanal: "As we discussed a few days ago in my most recent MRMD/MRSO MR Safety Training Course, at least part of this product labeling (AMS 700 ™ and AMS Ambicor ™ Inflatable Penile Prostheses Additional Data) is an example of MR safety labeling that is dated, contradictory, and unnecessarily confusing for end users. From a purely static field, torque-and-translation-concern point of view, a product that has been found to be safe at 3 Tesla and 720 gauss per cm is also de facto (from a purely static field, torque-and-translation-concern point of view) safe at 1.5T and 450 g/cm. and also at 1.5T and 720 g/cm. And, in fact,(from a purely static field, torque-and-translation-concern point of view) is safe at 720 g/cm at EVERY Bo static field value up to 3T. Of course I recognize that they listed different Bo fields due to the concerns regarding potential RF-related heating. But that is precisely what they should have done and did NOT do - list different Bo

		static magnetic fields only insofar as potential heating is concerned, and explain that at 1.5T the SAR limit is different from what they tested and found to be safe SAR limits at 3T. Listing ANYTHING for dB/dx (i.e.. the spatial field gradient) other than 720 g/cm is unnecessary and confusing to the typical end user. Indeed, by this label, one might wonder if scanning a patient in whom this device was implanted at 1.5T and 720 g/cm might be considered off label! This is yet one more reason why it is so important to truly *** understand *** MR safety, and not try to blindly follow product labels which were never intended to define the practice of medicine in the first place and whose only legal authority (at least in the US!) is limited to restarting what device manufacturers can *** CLAIM *** in their marketing literature and statements about a device (or drug) that they wish to sell to us."

Regulatory Medical Device Databases

Source: MAUDE (Manufacturer & User Facility Device Experience) Database

Date of Query: 01/04/2025

Comments: The MAUDE database was searched using key words "penile" AND "MRI".

Results: The search returned 84 results. However multiple entries were regarding other implanted devices such as the AMS 800, or Boston Scientific SpaceOAR Hydrogel. All records were viewed and all involved post-surgery complications or device malfunctions where MRI was part of the investigation, rather than MRI-induced issues.

Source: MDR Database

Date of query: 25/03/2025

Comments: The Medical Device Reporting (MDR) database was searched using key words "penile prosthesis" which returned >500 records *per year* for 1990-1996 inclusive, and >200 records from the period 1985-1989, inclusive.

Results: It is not practically feasible to review all of the records to rule out MRI as a cause, but a sample were inspected and were found to all relate to device malfunction or post-implantation infection. There are no records within the search terms between 1997 and the time of writing (May 2025).

Source: Clinical Trials Database (www.clinicaltrials.gov)

Date of query: 09/05/2025

Comments: A search of www.clinicaltrials.gov using key words "penile prosthesis" revealed 49 entries. All of these trials involved existing devices discussed elsewhere in this document.

Regulatory Professional and Standards bodies

A search of the MHRA database was not requested as it was felt there was enough existing evidence for the procedure.

Anecdotal evidence

An email was sent to the UK national JISC mailbase 'MRI Physics', inviting the community to:

- advertise any local procedures in use for MR scanning of penile prostheses
- contribute any experiences of adverse events relating to MRI scanning of penile prostheses
- raise any concerns with the production of a GISP for this implant category
- share experiences of MR scanning of the Dacomed Omniphase/Duraphase devices

Responses are summarised below:

- Guy's and St Thomas' NHS Foundation Trust

A local GISP has been in place for several years, with a couple of patients scanned per year. Normal Mode for RF (First Level for head imaging, if required) is permitted for field strengths up to 3T. Dacomed implants are excluded by having the patient cautiously self-test with a handheld magnet to ensure no ferrous forces are detected.

- The Royal Marsden NHS Foundation Trust

A GISP was introduced in March 2025, with no patients yet scanned. Consideration was given to how to exclude Dacomed implants – x-ray identification was not selected due to similarities in design between the Dacomed Duraphase and its successor, the MR Conditional Dura II. Date and location of implantation was also not selected, due to a lack of concrete evidence to inform selection criteria. Instead, all patients scanned under the GISP with non-identified malleable implants give their consent to proceed with the scan with the possibility of discomfort due to ferrous forces. The Trust does not believe that there is a risk of actual injury due to these forces. Mitigations are employed: "position the patients with the penis in the midline and either stabilise it with a coil if they are having pelvic imaging or use tape if a pelvic coil is not needed."

- Leeds Teaching Hospitals NHS Trust

A GISP is in place which permits scanning of penile prostheses at 1.5T, in Normal Mode for RF. Dacomed devices are excluded from the procedure, and patients with devices implanted between 1986 and 1998 are investigated individually. Patients with implants from this date range would have their device identified, or would be invited to self-test with a handheld magnet. Dacomed devices would be considered for scanning with appropriate mitigation strategies to counter ferrous forces.

Discussion (optional)

- **Trademark register search**

A search of the trademark register showed that the 'Omniphase' penile prosthesis trademark was registered in 1985, extended after 6 years in 1991, and subsequently expired in 2006.

The 'Duraphase' penile prosthesis trademark was registered in 1988, and was cancelled after the first 6 years, in 1995.

Given the Duraphase was the successor to the Omniphase, it is therefore apparent that neither of these devices would be commercially available after 1995. This could provide a conservative estimate of the implant cutoff date for the Dacomed implants.

Summary

With the exception of the Dacomed Omniphase and Duraphase devices, this review has shown that MRI is not believed to present a risk to patients with penile prosthesis devices in-situ, when the following conditions are adhered to:

- 1.5 or 3T
- Normal Operating Mode for RF (maximum whole body average SAR of 2 W/kg)

It is noted that these conditions make no mention of maximum static spatial gradient or polarization mode. This is based on the fact that any such conditions stated by device manufacturers reflect limits of testing, rather than limits of safety. Additionally, these conditions exceed the quoted SAR limits for certain devices (the AMS Ambicor, at 1.5T), which are again understood to reflect the limits of testing, and also lead to quoted temperature rises that demonstrate that Normal Mode would not lead to unsafe heating of the device.

The lack of reported adverse incidents arising from exposure of penile prostheses to MRI further justifies the claim that MRI does not pose a significant risk to this class of implants. It is noted that reviews of possible future penile prosthesis technologies contain multiple potential design advances that would have implications for MRI safety, and so the state of the art must be continually reviewed with care. For example, prototype products have been designed with reservoirs activated by active electronic components, thermally activated devices which rely on external magnetic induction mechanisms, and piezoelectric pumps which would be magnetically operated.

While it is believed that exposure of either a Dacomed Omniphase or Duraphase device to MRI would pose a risk of discomfort to a patient, rather than more serious clinical consequences, best practice for these devices would involve risk assessment, patient consent, and mitigating measures prior to performing an MRI scan. For this reason, these two devices are explicitly excluded from this GISP.

Multiple strategies could be considered to exclude the Dacomed Omniphase and Duraphase devices, such as one or more of the following approaches:

- Date of implantation (between 1985 and 1995 could be a conservative range where the Dacomed devices could be present)
- Testing with a handheld magnet (the presence of significant forces would only be expected for the Dacomed devices)

- Questions regarding the mode of operation of the prostheses (e.g., any mention of ‘pumping’ would indicate the presence of an IPP and hence exclude the Dacomed devices)
- Inspection of existing or newly obtained x-ray imaging (care would need to be taken to distinguish the Dacomed devices from their successor, the Dura II, which does not present the same MR safety concerns)

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4 Risk Assessment

4.1 Hazards

Penile prosthesis designs come in two main variants: malleable and inflatable.

Malleable penile prostheses tend to be primarily composed of silicone, but contain central metal cores, or cables.

Inflatable penile prostheses tend to contain smaller metal components within their construction, particularly within the pump valves or tubing connections.

The presence of metal components means that safety concerns relating to these implants include:

- Projectile force or torque arising from the interaction of the static magnetic field with the implant may cause displacement or rotation of the device.
- RF fields can lead to heating of metallic components.

4.2 Description of Risk

Many malleable and inflatable designs have undergone MRI safety testing which demonstrates RF-induced heating and significant forces due to B0 interactions are not borne out in practice. It is noted that these devices are designed to withstand considerable forces encountered during intercourse.

There are no convincing reports of adverse events relating to MRI scanning of penile prostheses. This review identified just one instance of a malleable penile prosthesis purported to have rotated due to exposure to an MRI scan, with no clinically significant consequences.

Exceptions to these statements are limited to the Dacomed Omniphase and Duraphase malleable implants, which were commercially available between around 1986 and 1992. MRI safety testing of these devices demonstrated the presence of significant deflections during B0 interaction. It is reported that these forces would not be expected to lead to clinical risk, but rather the risk of patient discomfort. These forces could be mitigated via the application of appropriate immobilization or strapping, and so the devices are not considered an absolute contraindication to MRI scanning. However, due to the need to perform an additional risk assessment prior to MRI scanning of these devices, they are explicitly and specifically excluded from this GISP.

4.3 Existing precautions

Upon referring a patient for an MRI scan the referrer is required to complete a safety checklist where they should declare any patient implants. The patient is also taken through an MRI safety checklist upon arrival to the MRI department. Due to the format of the safety questionnaires used, patients are typically asked about implants three times in different ways, therefore the risk of misidentification is negligible.

4.4 Level of Risk

Risk Description	Likelihood	Consequence	Risk
Patient with an undeclared penile prosthesis is exposed to MRI	Unlikely	Negligible	Low
A penile prosthesis brought to the market is MR Unsafe	Rare	Minor	Low

Risk Matrix

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 only be created where the risk is low