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MRI Information

Several Magnetic Resonance Imaging (MRI) studies have concluded that the Boston Scientific products listed below will not produce additional risks to patients in association with MRI procedures under the conditions used for testing. In these investigations, Boston Scientific products underwent evaluations for magnetic field interactions at 1.5 and/or 3.0 Tesla. No unsafe magnetic field interactions were identified by this research.[1]

MRI Safe
The following product does not contain metallic components and therefore is considered **MRI Safe**.

- AdVance™ Male Sling System
- AdVance XP Male Sling System

MRI Conditional ("MR Conditional")
Some Boston Scientific products are **MRI Conditional** up to 3.0 Tesla. These products include:

- AMS 800™ Urinary Control System
- Inflatable Penile Prostheses: AMS 700™ CX, CXM, CXR, Ultrex, Ultrex Plus, AMS 700 LGX™
- AMS Ambicor™ Inflatable Penile Prosthesis
- Spectra™ Penile Prostheses
- Tactra™ Malleable Penile Prosthesis

MR parameters for these products are provided in the individual device's instructions for use as well as on pages 3-5 of this document.

Additional MRI testing was conducted on some Boston Scientific devices at 1.5 and 3.0 Tesla to evaluate the impact of MR imaging on the devices that contain metallic components. Testing conducted at 1.5 Tesla concluded that torque, deflection angle, and heating/temperature change results for the following products were found acceptable:

- AMS Artificial Urinary Sphincters 791™ and 792™
- InVance™ Male Incontinence Sling System
- Malleables: Dynaflex™ / Hydroflex™
- Malleables: AMS 600™ / 600M™ / 650™ / Dura II™; and Spectra
- UroLume™ Endoprosthetic Stent
- AMS Mainstay™ Urologic Soft Tissue Anchor

1. Data on file with Boston Scientific.

Testing conducted at 3.0 Tesla concluded that torque and deflection angle results for the following products were found acceptable:

- AMS Artificial Urinary Sphincters 791™ and 792™
- InVance™ Male Incontinence Sling System
- Malleables: Dynaflex™ / Hydroflex™
- Malleables: AMS 600™ / 600M™ / 650™ / Dura II™
- UroLume™ Endoprosthetic Stent
- AMS Mainstay™ Urologic Soft Tissue Anchor

Boston Scientific Company Contact: Patient Liaison at 1-800-328-3881, option 2, or 952-930-6261, or Email at Patient.Liaison@bsci.com, Monday-Friday 7:00am until 4:00pm Central Time.

AMS 700™ and AMS Ambicor™ Inflatable Penile Prostheses Additional Data

Magnetic Resonance Imaging (MRI) Important Safety Information
Non-clinical testing has demonstrated the penile prostheses AMS 700 / AMS Ambicor product line is MR Conditional. The device can be scanned safely under the following conditions:

Static Magnetic Field	1.5 Tesla[a]	3.0 Tesla[b]
Spatial Gradient Field	450 Gauss/cm or less	720 Gauss/cm or less
Maximum whole body averaged Specific Absorption Rate (SAR)	1.5 W/kg for 15 minutes of scanning as assessed by calorimetry	2.9 W/kg for 15 minutes of scanning as assessed by calorimetry
(a) 1.5T - 64 MHz MR System (General Electric Healthcare, Milwaukee, WI) (b) 3.0T MR Excite, General Electric Healthcare, software version 14X.M5		

MRI-Related Heating
Non-clinical testing has demonstrated the penile prostheses AMS 700 / AMS Ambicor product line produced the temperature rises during MRI performed for 15 minutes of scanning in the respective MR systems which would not pose a hazard to the human subject.

Static Magnetic Field	1.5 Tesla[a]	3.0 Tesla[b]
Highest Temperature Change	≤ +0.4°C	≤ +1.9°C
(a) 1.5T - 64 MHz MR System (General Electric Healthcare, Milwaukee, WI) (b) 3.0T MR Excite, General Electric Healthcare, software version 14X.M5		

Artifact Information
Non-clinical testing has demonstrated that the penile prostheses AMS 700 / AMS Ambicor product line may compromise the MR image quality if the area of interest is relatively close to the position of the implant. The maximum image artifact produced by a MR gradient echo pulse sequence was a "moderate" localized signal void in size and shape of the implant. Optimization of MR imaging parameters to compensate for the presence of the device may be necessary.

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

AMS 800™ Urinary Control System Additional Data

Magnetic Resonance Imaging (MRI) Important Safety Information
Non-clinical testing has demonstrated the AMS 800 Urinary Control System product line is MR Conditional. The device can be scanned safely under the following conditions:

Static Magnetic Field	1.5 Tesla[a]	3.0 Tesla[b]
Spatial Gradient Field	450 Gauss/cm or less	720 Gauss/cm or less
Maximum whole body averaged Specific Absorption Rate (SAR)	1.5 W/kg for 15 minutes of scanning as assessed by calorimetry	2.9 W/kg for 15 minutes of scanning as assessed by calorimetry
(a) 1.5T - 64 MHz MR System (General Electric Healthcare, Milwaukee, WI) (b) 3.0T MR Excite, General Electric Healthcare, software version 14X.M5		

MRI-Related Heating
Non-clinical testing has demonstrated the AMS 800 Urinary Control System product line produced the temperature rises during MRI performed for 15 minutes of scanning in the respective MR systems which would not pose a hazard to the human subject.

Static Magnetic Field	1.5 Tesla[a]	3.0 Tesla[b]
Highest Temperature Change	≤ + 0.4° C	≤ + 2.0 ° C
(a) 1.5T - 64 MHz MR System (General Electric Healthcare, Milwaukee, WI) (b) 3.0T MR Excite, General Electric Healthcare, software version 14X.M5		

Artifact Information
Non-clinical testing has demonstrated that the AMS 800 Urinary Control System product line may compromise the MR image quality if the area of interest is relatively close to the position of the implant. The maximum image artifact produced by a MR gradient echo pulse sequence was a "moderate" localized signal void in size and shape of the implant. Optimization of MR imaging parameters to compensate for the presence of the device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	5,800 mm^2	1,956 mm^2	6,096 mrn^2	2,650 mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Spectra™ Concealable Penile Prosthesis Additional Data

Magnetic Resonance Imaging (MRI) Important Safety Information
Non-clinical testing has demonstrated the Spectra Concealable Penile Prosthesis product line is MR Conditional. The device can be scanned safely under the following conditions:

Static Magnetic Field	≤ 3.0 Tesla[a]
Spatial Gradient Field	720 Gauss/cm or less
Maximum whole body averaged Specific Absorption Rate (SAR)	2.9 W/kg for 15 minutes of scanning as assessed by calorimetry
(a) 3.0T 128MHz, General Electric Healthcare, Excite software version G3.0-052B	

MRI-Related Heating
Non-clinical testing has demonstrated the Spectra Concealable Penile Prosthesis ABS product line produced the temperature rises during MRI performed for 15 minutes of scanning in the respective MR systems which would not pose a hazard to the human subject.

Static Magnetic Field	≤ 3.0 Tesla[a]
Highest Temperature Change	≤ +1.6°C
(a) 3.0T 128MHz, General Electric Healthcare, Excite software version G3.0-052B	

Artifact Information
Non-clinical testing has demonstrated that the Spectra Concealable Penile Prosthesis product line may compromise the MR image quality if the area of interest is relatively close to the position of the implant. The maximum image artifact produced by a MR gradient echo pulse sequence was a "moderate" localized signal void in size and shape of the implant. Optimization of MR imaging parameters to compensate for the presence of the device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	7,193 mm^2	1,553 mm^2	1,160 mrn^2	7,030 mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

Tactra™ Malleable Penile Prosthesis Additional Data

Magnetic Resonance Imaging (MRI) Important Safety Information
Non-clinical testing demonstrated the Tactra device is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

Static Magnetic Field 1.5 and 3.0 Tesla only	1.5 and 3.0 Tesla only
Maximum Spatial Gradient	13,000 G/cm (130 T/m)
Maximum Force Product	235,000,000 G^2/cm (235 T^2/m)
Theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR)	2 W/Kg in the Normal Operating Mode

MRI-Related Heating
Under the scan conditions defined, the Tactra Penile Implant is expected to produce a maximum temperature rise of

- 1.1°C (2W/kg, 1.5 Tesla) RF-related temperature increase with a background temperature increase of ~ 1.0 °C (2 W/ kg, 1.5 Tesla)
- 0.6 °C (2 W/kg, 3 Tesla) RF-related temperature increase with a background temperature increase of ~ 0.5 °C (2 W/ kg, 3 Tesla)

after 15 minutes of continuous scanning.

Artifact Information
In non-clinical testing, the image artifact caused by the Tactra Penile implant extends approximately 29.5 mm from this implant when imaged using a gradient echo pulse sequence and a 3 Tesla MR system. Optimization of MR imaging parameters to compensate for the presence of the device may be necessary.

This letter contains important safety information on the use of magnetic resonance imaging with Boston Scientific's products. For additional product information on indications for use, contraindications, warnings, precautions, and adverse events, please refer to the product's instructions for use.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

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