

August 2015

MRI Information

Several Magnetic Resonance Imaging (MRI) studies have concluded that the AMS products listed below will not produce additional risks to patients in association with MRI procedures under the conditions used for testing. In these investigations, AMS 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 AMS product does not contain metallic components and therefore is considered **MRI Safe**.

- AdVance™ Male Sling System

MRI Conditional (“MR Conditional”)

Some AMS products are **MRI Conditional** up to 3.0 Tesla. These products include:

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

MR parameters for these products are provided in the individual device’s instructions for use as well as on pages 3-6 of this document.

Additional MRI testing was conducted on some AMS 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

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

AMS Men's Health 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™ 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 mm 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 mm 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 | $\leq +1.6^{\circ}\text{C}$ |
| (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 mm ² | 7,030 mm ² |
| Plane Orientation | Parallel | Perpendicular | Parallel | Perpendicular |

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



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