

Dear Doctor:

September 2003

**Subject: Effect of AMS products on MRI (magnetic resonance imaging)**

Several studies have concluded that the presence of an AMS product will not produce harmful effects during MRI scanning. In these studies, AMS products were subjected to magnetic field strengths up to either 1.5 or 3.0 Tesla.<sup>1,2</sup> No unsafe magnetic interaction was identified by this research. However, it was found that the metallic components in AMS products may distort the uniform magnetic field in the vicinity of the implant. While it is unlikely that these components will interfere with normal MRI, the potential for distortion of imaging should be considered before prescribing treatment based on the MRI. In particular, it was cited that the Malleable™ 600/650 and Dura II™ Penile Prostheses may produce a cylindrical image or a signal void in the vicinity of the implant product. If this is observed under MRI, the penis can be repositioned to minimize the impact on the image.

The AMS products were included in the MRI studies:

- AMS Sphincter 800™ Urinary Control System
- AMS Penile Prostheses (700CX, 700CXM, 700 Ultrex, Ambicor, Malleable 600/650, Dura II, Dynaflex, Hydroflex)
- InVance™ Male Sling System
- InFast™ and InFast Ultra Sling System
- Straight-In™ Sacral Colpopexy System
- Urolume® Endoprosthesis (Male Urethral Stent)
- Acticon® Neosphincter (Bowel Control System)
- Mainstay™ Urologic Soft Tissue Anchor

Thank you for your ongoing interest in American Medical Systems and our products. We appreciate your past business and look forward to serving your needs in the future.

Sincerely,  
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Senior Patient Liaison  
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<sup>1</sup> MR Procedures and Biomedical Implants, Materials and Devices: 1993 Update, Radiology 1993, Vol. 189, 587-599.

<sup>2</sup> Reference Manual for Magnetic Resonance Safety, 2003 Edition.