AVANOS

TECHNICAL BULLETIN

HOMEPUMP* AMBULATORY INFUSION SYSTEM

The use of Homepump* in the Magnetic Resonance (MR) environment

This technical bulletin is intended to verify the safety profile of the Homepump* in the MR environment.

The term "MR safe" as defined by the American Society for Testing and Materials (ASTM), means: "The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information."

Testing Methods:

Testing for magnetic field interactions was conducted by an outside laboratory according to ASTM guidelines F 2052-02 to determine translational attraction and torque using a 3-Tesla MR system (General Electric Medical Systems, Milwaukee, WI.). Products tested were categorized as MR Conditional, or MR Unsafe.

MR Safe Devices: Homepump Eclipse* and Homepump C-Series* Elastomeric Pumps.

These devices do not contain metal. Through non-clinical testing, these products have been shown to be MR safe for patients undergoing examinations using MR systems operating at static magnetic field strengths of 3-Tesla or less. There are no magnetic field interactions (i.e., magnetically induced displacement force and magnetically induced torque) and no MRI-related heating. Testing has not been performed at field strengths higher than 3-Tesla.

MR Unsafe Devices: E-Clip Accessory and Carry Case.

The E-clip exhibits substantial magnetic field interactions in a 1.5-Tesla MR environment. **Therefore, the E-Clip must be removed from the pump before entering the MR environment.**

Additional Note: The carrying case that is available as an accessory for the Homepump was not tested for MR safety. This pouch contains a metal grip on the zipper, and therefore should be removed prior to MR testing.

Conclusion:

Avanos Homepump Eclipse* and Homepump C-Series* elastomeric pumps, excluding the E-Clip and the carrying case accessories, are deemed MR safe up to a 3-Tesla MR system. The E-Clip and carrying case, if present, must be removed from the pump prior to MR testing.

Note: The function of the pumps before and after exposure to MR was not a part of this safety testing.

 MR SAFE	 MR CONDITIONAL	 MR UNSAFE
An item that poses no known hazards in all MR environments.	An item that has demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.	An item that is known to pose hazards in all MR environments.

There are inherent risks in all medical devices. Please refer to the product labeling for **Indications, Cautions, Warnings** and **Contraindications**. Failure to follow the product labeling could directly impact patient safety. Physician is responsible for prescribing and administering medications per instructions provided by the drug manufacturer. Refer to **www.avanosmedicaldevices.com** for additional product safety **Technical Bulletins**.

Please contact the Clinical Services Department at 800-444-2728 or 949-923-2400 if you have any questions regarding this information.

AVANOS

avanosmedicaldevices.com

MK-00028 rev1 07/15