

Infusomat® Space, Perfusor® Space, and Perfusor® Space PCA

Supplement MR Conditional Information



Rx only

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**Supplement MR Conditional Information to Instructions for Use
 Infusomat® Space, Perfusor® Space, and Perfusor® Space PCA**


YOU NEED ONE COPY PER INSTRUCTIONS FOR USE. PLEASE COPY IF NECESSARY.

**Supplement to Infusomat Space, Perfusor Space, and Perfusor Space PCA Instructions for Use (IFU):
 Information about MR safety of the devices.**

Read the following information and instruct all users in your organization. Add this supplement to your Instructions for Use.

This supplement only contains information that is changed. For complete descriptions, refer to the existing IFUs for Infusomat Space, Perfusor Space, and Perfusor Space PCA.

The following information is added to the **Symbols on Product** section:

IEC TR 60878: Technical Report Graphical symbols for electrical equipment in medical practice			
Symbol	Title	Reference-number	Explanatory text or meaning
	MR Conditional	62570-7.3.2	To identify an item which poses no unacceptable risks within defined conditions to the patient, medical staff or other persons within the MR environment. *See Warning statement regarding MR information in Patient Safety section for further information.

The following statement is added to the **Patient Safety** section:



WARNING: The Infusomat® Space, Perfusor® Space, and Perfusor® Space PCA Infusion Pumps are unsafe when used as a standalone device in proximity to magnetic resonance imaging (MR) equipment. The pumps, when within the SpaceStation MRI, can be used conditionally in the MR environment when complying to the SpaceStation MRI Instructions for Use. Do not remove the pump from the SpaceStation MRI in proximity to MRI equipment.

which replaces the following statement, if present, from the **Patient Safety** section:

The Infusomat® Space and Perfusor® Space System is unsafe to use in proximity to Magnetic Resonance Imaging (MR) equipment.