

## **Heart Connect™ System**

### **Intended Use**

The Heart Connect System is an optional data-sharing system intended to display and share physiological and/or other medical data from connected medical equipment. The Heart Connect System provides health care providers and Boston Scientific personnel with means to establish an online meeting and share the video display from the connected medical equipment with individuals in a remote location.

### **Contraindications**

The Heart Connect System is contraindicated for use with medical equipment that is not compatible with system characteristics as defined in these Instructions For Use.

### **Warnings**

The use of any cables or accessories with the Heart Connect System, other than those included with the Heart Connect may result in increased emissions or decreased immunity of the system. Do not connect an extension cord or portable multiple socket outlet to the Heart Connect System. The Heart Connect System must be kept outside the patient environment (at least 1.5 m [4.9 ft]) away from the patient or as specified in the instructions for the connected medical equipment). The Heart Connect System is MR unsafe and must remain outside the magnetic resonance imaging (MRI) site Zone III (and higher). The System is non-sterile and cannot be sterilized.

### **Precautions**

Patient data should only be accessed by authorized healthcare providers and Boston Scientific personnel. Ensure that any changes to the settings of the Heart Connect System are made per guidance from authorized Boston Scientific personnel or authorized health care providers. USB drives should only be connected to the Heart Connect Tablet by authorized personnel. Any USB drives that are to be connected to the Heart Connect Tablet must be controlled to help prevent unauthorized modifications to the Heart Connect System. The Local User should store the Heart Connect System in a secure location when not in use to help prevent theft or unauthorized access. If unexpected behavior is seen with the Heart Connect System, restart the system. If issues continue to be seen or if the system appears to be compromised, discontinue use and contact Boston Scientific Technical Services for assistance, using information from the back cover of this manual.

### **Adverse Effects**

There are no known adverse effects.

*Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events.*

*Rx only. (Rev A) 046774 AI*