CLC2000® Positive Displacement Connector Use in MRI with Power Injectors

The CLC2000 is FDA cleared {510(k)100576} as a standalone device and, in connection with pressure-rated tubing sets, for use in MRI and Power Infusion procedures.

The CLC2000 will tolerate a maximum of 400 psig or a flow rate of 10 mL/sec of room temperature contrast media (Omnipaque™ 300 Injection, GE Healthcare). The dead-space of the CLC2000 is low (.04 mL), and the fluid path has an average flow rate of a 16G needle. This presents minimal restriction and very low internal compliance. Actual infusion pressures required to deliver the desired volume of contrast media are typically far less than the maximum 400 psig through the standalone connector; however, pressures will increase when used in conjunction with an extension set and will vary depending on the internal diameter and length of that tubing.

The CLC2000 incorporates a stainless steel spring that does not have any ferromagnetic properties to cause a magnetic or heat reaction during the MRI procedure. However, these materials do have the potential to cause an artifact; therefore, care should be taken to ensure that the transducer and cable are away from the field of view at the time of imaging. These types of devices are classified as “MR-conditional” according to the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. This standard describes a series of testing for ferromagnetic reaction and a review of materials. A technical review of the CLC2000 materials indicate that MR Conditional is an appropriate classification for this device.

If there are further questions or concerns, please visit our website at www.icumed.com or contact the corporate offices at 949-366-2183 or 800-824-7890.

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