

ACIST CVi™ Contrast Delivery System

Indications for Use:

The ACIST | CVi® Contrast Delivery System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.

Contraindications:

The ACIST | CVi® Contrast Delivery System (CVi system) is not intended for use as a long-term infusion pump. The system is not intended to be used to inject any agents other than contrast media. The system should not be used to inject substances into nonvascular body cavities. Any applications of the system, other than those described in this manual, are inappropriate and should not be attempted. Do not add any components to the consumable kits or in conjunction with the catheter. No valves or other manifolds may be placed in-line between the ACIST-provided consumable kit and the catheter. ACIST-provided consumable kits are designed, manufactured, and tested for connection to catheters used in angiographic procedures. Do not use the system in the presence of flammable gases.

Important Safety Information:

The CVi System is designed to aid the physician in the injection of contrast media during angiography. It should be used with adequate radiographic imaging and where monitoring equipment for blood pressure and the electrocardiogram is available. Additionally, standard equipment for cardiopulmonary resuscitation and drugs for the treatment of contrast media-induced drug reactions should be present. It is necessary that the CVi system be operated by, or be under the immediate and direct supervision of a physician who is specifically trained in angiography and in the operation of this unit. System operation must be monitored at all times, and specific operational and mechanical integrity must be maintained to ensure patient safety. For proper operation and to ensure equipment compatibility, use only accessories and options provided or specified by ACIST Medical Systems for use with the CVi system. To ensure proper operation of the syringe, viscosity limits must be observed. Do not allow the reusable syringe kit to sit loaded with contrast media longer than the maximum time recommended by the contrast manufacturer. Do not allow the reusable syringe kit to be used for more than five (5) procedures. Replace the automated manifold and hand controller kits after each procedure. Use of the syringe kit for more than five (5) procedures or re-use of the automated manifold and hand controller kits may result in cross contamination, risk of infection or device malfunction, for example, air ingress, leaks, or reduced performance. An air embolism can cause patient injury or death. Operator vigilance and care, along with a defined procedure, are essential to avoid injecting air and causing an air embolism. Before injections, clear all air from the entire patient kit and the angiographic catheter. Make sure that the exterior of the tubing is dry before inserting it into the air column detect sensor. If any fluid is present on the tubing's exterior surface, the sensor may be unable to detect air. High flow rate injections can cause patient injury or death. Use extreme care when setting the flow rate to avoid unintentionally setting a high flow rate injection. When high flow rate injection is

required, be sure to select a pressure setting that does not exceed the rated pressure of the selected catheter.

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