

# ACIST CVi®

Contrast Delivery System

## KNOW and CONTROL

how much contrast is used.

CVi delivers the power to improve patient safety, minimizing the risk of contrast-induced acute kidney injury (CI-AKI) for coronary catheterizations when compared to manual injection of contrast media.<sup>1</sup>

ACIST CVi® is a sophisticated system providing precise control of contrast injections for all your interventional and diagnostic angiographic procedures. From small injections in the coronaries to large volumes in the ventricles and peripheral vasculature. It's the advanced technology that physicians and staff can rely on for controlled delivery of contrast.<sup>3</sup>

As interventional procedures become more complex, it's important to take steps to reduce the incidence of CI-AKI<sup>2</sup> and also reduce the radiation exposure in clinicians.<sup>3</sup>

The **All-In-One** system that simplifies contrast injection for all your interventional and diagnostic procedures.



The unique **AngioTouch® Hand Controller** allows real time variable-flow control of the contrast injection rate for precise and consistent contrast administration.

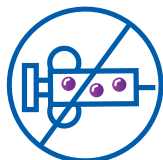
# CVi increases safety and operational efficiency.

## Increase **Patient Safety**



### **Kidney Protection**

**Up to 30% reduction** in CI-AKI vs. manual injection.<sup>1,4</sup>



### **Air Embolism**

The following 5 key design elements were included in the CVi System to mitigate air injection:

- Air column detect (ACD) sensor
- Auto-purge/auto-refill
- Syringe angle facilitates air purge
- Bottom syringe port injection
- Clear components

## Increase **Workplace Efficiency**



**Up to 50% reduction** in clinician radiation exposure by stepping back.<sup>3</sup>

## Increase **Operational Efficiency**



**45 mL decrease** per case when injector used.<sup>1</sup>

Contact your ACIST sales representative or ACIST Customer Support for more information.

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Prior to use, reference Instructions for Use, inside the product carton (when available) or at [www.acist.com](http://www.acist.com) for more detailed information on safe use of the device.

**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 Info:** 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.

1. Minsinger KD, Kassis HM, Block CA. Meta-analysis of the effect of automated contrast injection devices versus manual injection and contrast volume on risk of contrast-induced nephropathy. *Am J Cardiol.* 2014;113(1):49-53.

2. Tsai T, et al., Contemporary Incidence, Predictors, and Outcomes of Acute Kidney Injury in Patients Undergoing Percutaneous Coronary Interventions. *JACC*, Vol. 7, Jan. 2014.

3. Data on file, TRCO-18910.

4. Call J, Sacrinty M, Applegate R, Little W, Santos R et al. (2006) Automated contrast injection in contemporary practice during cardiac catheterization and PCI: effects on contrast-induced nephropathy. *J Invasive Cardiol* 18 (10): 469-474.

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