ACIST®

ACIST informs interventional decisions during peripheral, cardiovascular disease and structural heart procedures.

Physicians worldwide rely on our diagnostic technologies to give them the power to visualize, assess and inform patient treatment. Economic decision-makers appreciate our ability to demonstrate the value of therapeutic intervention.

How much contrast have I delivered?

ACIST **CVi**®

Is an intervention needed?

ACIST **RXi**®

Have I optimized my intervention?

ACIST **HDi**®

ACIST. It's how you know.

Over the last **20 years**, we've helped improve the lives of **35 million** patients and counting in over **75 countries** around the world

Since then, ACIST has become a knowledge catalyst, helping interventional cardiologists quickly visualize, assess and improve patient treatment globally with over 400+ employees worldwide.

Acquired in 2001 and backed by the power of Bracco, a world-class leader in diagnostic imaging, our expanding product and service offering delivers the flexibility clinicians want to get the insights they need.

ACIST CVi

Prior to use, reference Instructions for Use, inside the product carton (when available) or at 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.

ACIST RXi

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

Indications for Use: The ACIST RXi System is indicated for obtaining intravascular pressure measurements for use in the diagnosis and treatment of coronary and peripheral artery disease. The ACIST Navvus & Navvus II MicroCatheter is intended for use with the entire family of ACIST RXi Systems.

Contraindications: The ACIST Navvus Catheters are contraindicated for use in the cerebral vasculature.

Important Safety Info: The RXi System is to be used only on order of a physician by medical professionals with adequate training and experience in the operation of the RXi System and angiographic procedures and techniques. Additionally, individuals using this device must be alert and attentive to the operation of the system while it is connected to the patient catheter. Diligence on the part of the user is an essential requirement of overall device safety. The RXi system is not intended for use as a blood pressure monitoring system. Prior to use and whenever possible during the procedure, carefully inspect the Navvus Catheter for kinks or any other damage. Do not use a kinked or damaged catheter because vessel damage and/or inability to advance or withdraw the catheter may occur. When delivering the Navvus Catheter over the guidewire, ensure that the guidewire and the Navvus Catheter are freely moving within the vessel wall. Failure to do so may traumatize the vessel. The Navvus Catheter is not designed to be torqued. Do not excessively torque the catheter. Never advance or withdraw the Navvus Catheter against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in separation of the catheter or guidewire tip, damage to the catheter, or vessel perforation. This product should not be used in rooms containing magnetic resonance imaging (MRI) equipment. To avoid inaccurate arterial pressure measurements, the use of guide catheters larger than 8F or guide catheters with side holes are not recommended. The Navvus Catheter is not compatible with 4F guide catheters. Do not perform high pressure (> 600 psi) fluid injections while the Navvus Catheter tip is inside a guide catheter. Potential complications that may be encountered during all catheterization procedures include, but are not limited to: vessel dissection or occlusion, perforation, embolus, spasm, local and/or systemic infection, intimal disruption, distal embolization of blood clots and plaque, myocardial infarction, serious arrhythmias, or death.

ACIST HDi

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

Indications for Use: The ACIST HDi® System is intended to be used for the ultrasound examination of coronary and peripheral intravascular pathology. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures. The ACIST Kodama Intravascular Ultrasound Catheter is intended for use with the ACIST HDi System.

Contraindications: Contraindicated for patients with: bacteremia or sepsis; arterial spasm; major coagulation system abnormalities; mechanical heart valves that would be crossed by the catheter; severe hemodynamic instability or shock; total vessel occlusion (prior to initial stages of revascularization). Contraindicated for use in the cerebrovascular arteries. In coronary procedures, the product is also contraindicated for patients who are: disqualified for revascularization surgery; disqualified for balloon angioplasty (PTCA).

Important Safety Info: Intravascular ultrasound studies using this product should be performed only by physicians and other medical professionals fully trained in the required techniques and procedures. The Kodama catheter contains a short monorail guidewire engagement system. As such, it is susceptible to guidewire entanglement and/or prolapse during catheter deployment and withdrawal. Before use and when possible during use, inspect the Kodama catheter carefully for kinks or any other damage. Do not use a kinked or damaged catheter because vessel damage and/or the inability to advance or withdraw the catheter may occur.

Never advance or withdraw the Kodama catheter against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the catheter or guidewire against resistance may result in elongation or separation of the catheter or guidewire tip, damage to the catheter, or vessel perforation.

When advancing the Kodama catheter through a stented vessel, short monorail catheter designs are susceptible to guidewire/ catheter entrapment, catheter tip separation, and/or stent dislocation.

Adverse events that may occur as a consequence of intravascular ultrasound imaging include (but are not limited to): vessel occlusion and/or abrupt closure; air embolism; vessel dissection, injury, or perforation; vessel rupture, injury, or perforation; acute myocardial infarction; cardiac arrhythmias including but not limited to ventricular tachycardia, ventricular fibrillation, and complete heart block; cardiac tamponade; catheter/guidewire entrapment; catheter induced ischemia; death; vessel trauma requiring treatment/surgical intervention, including angioplasty/stent; infection; stent strut damage; stroke (including cerebral vascular accident and transient ischemic attack); thrombus formation or thromboembolism; vasospasm.

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ACIST®

Your Cath Lab **Knowledge Catalysts**

It's how you know.

Bracco Group

ACIST®

From helping to reduce and track contrast delivery[1] to enabling physicians to use their 0.014" guidewire of choice, to optimized imaging.[2]

ACIST gives you the power to make those critical decisions.

Beyond their clinical effectiveness, our diagnostics also validate the appropriateness of therapeutic intervention to improve patient outcomes.

ACIST is **YOUR** diagnostic partner providing you clinical and economic value every day.

ACIST **CVi**®

Contrast Delivery System

Increase safety and operational efficiency

ACIST CVi delivers the power to reduce delivered contrast, minimizing the risk of contrast-induced acute kidney injury (CI-AKI).*

ACIST AT X65 provides a more defined hemodynamic signal, without using a hand manifold.

*When compared to manual injection of contrast media: 22% reduction in contrast use without compromising image quality.[1]

Clinical and Economic Value

CVi

- Up to **30%** reduction in CI-AKI vs. manual injection[1,2]
- **49.4%** of Interventional Cardiologists have experienced at least one orthopedic injury.[3] CVi may reduce repetitive stress injuries that can be caused by manual contrast injection.
- Up to 50% reduction in clinician radiation exposure by stepping back.[5]
- Average **5 min** faster per procedure, which may allow for additional procedures to be performed in a day[6]

CVi Consumable Kits

ATX and ATP Hand Controller Kits
Multi-use Syringe
Automated Manifold
Pressure Monitoring Set

ACIST **RXi**®

Rapid Exchange FFR System with dPR (Diastolic Pressure Ratio), the Non-Hyperemic Index for Coronary Physiology

Efficiently assess, and confirm coronary artery disease, even in the most complex cases

RXi and the ultra-thin Navvus® II MicroCatheter provides you with the power to simplify assessment of complex coronary artery disease using your 0.014"guidewire of choice.

dPR provides a non-hyperemic alternative for physiological assessment of coronary disease. Non-hyperemic pressure ratios, such as dPR, may reduce patient discomfort,* cost** and procedural time.***

* Reduced side effect profile when comparing resting approach (iFR, dPR, Pd/Pa) to FFR with adenosine induced hyperemia.
** Cost savings based on the reduced cost of utilizing a resting approach compared to conventional FFR and respective cost of administration of hyperemic agent (adenosine).
*** When comparing resting index (iFR, dPR, Pd/Pa) to FFR with adenosine induced hyperemia.

ACIST Navvus II Rapid Exchange FFR MicroCatheter

- **13%** reduced lesion entry profile[7,8] to streamline contouring in allowing navigation of complex diseases.
- **28%** improved flexibility[9]
- Maximize control by enabling you to use the **0.014" guidewire of choice** to maintain wire position
- **Consistent and reliable**[10] fiber optic technology may be less susceptible to clinically significant drift compared to traditional pressure wire.*

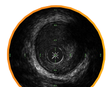
RXi System

- Requires zeroing only once, at initial install, when in stationary mode
- Ready when you are, displaying patient's aortic pressure

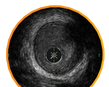
*Difference did not reach statistical significance in clinical trial.

ACIST **HDi**®

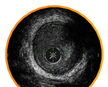
HD IVUS System



LumenView™
For a better defined lumen border visualization*



SilkView™
For a softer gray scale and more defined plaque visualization*



ClassicView™
Utilizes blood speckle to define the intravascular space*

*Data on file - TR-07057 – Internal Testing.

The system of choice for optimized imaging in percutaneous coronary and peripheral interventions

ACIST HDi with advanced imaging modes provides a better defined IVUS image for pre-procedural planning and post procedural assessment.[2]

HDi High-Definition IVUS System with Extended Field of View Kodama IVUS Catheter

- Improved deliverability[11] and optimized imaging[2] with the offset distal tip
- High-speed pullback – **10x** faster pullback; 90%-time reduction[12]
- **Better visualization** of media with 60 MHz IVUS than OCT for optimizing stent sizing[13]
- **Interactive** compact HDi console with touch screen for rapid analysis and small footprint
- 0.014" guidewire compatible; 20 mm max imaging diameter

IVUS Benefits

- IVUS use changed the treatment strategy during the procedure **74% of the time**[13]
- IVUS-guided PCI was significantly associated with lower risk of death, myocardial infarction, revascularization, and stent thrombosis[14]
- IVUS is less expensive and more effective than angiography in **71% of PCI procedures**[15]