ACIST HDi®

HD IVUS System

Your system of choice for

optimized imaging

in percutaneous coronary interventions

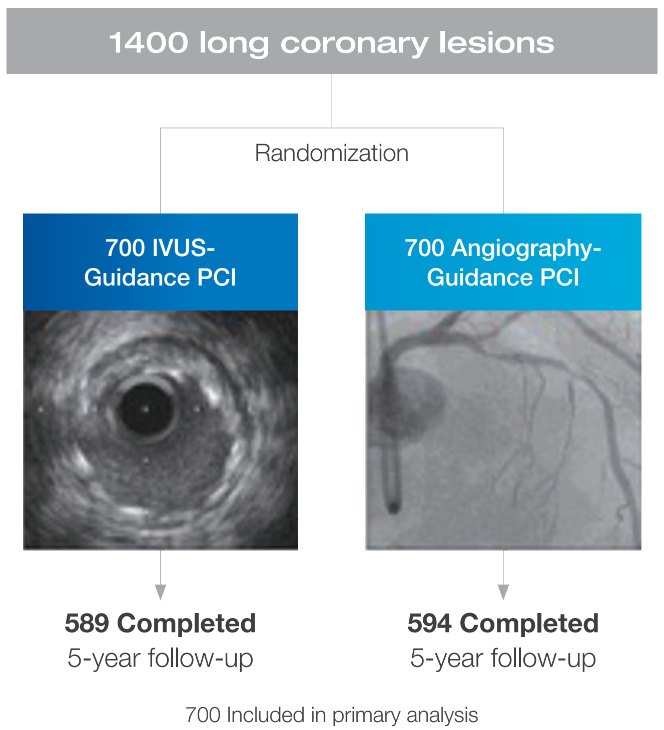
Bracco Group

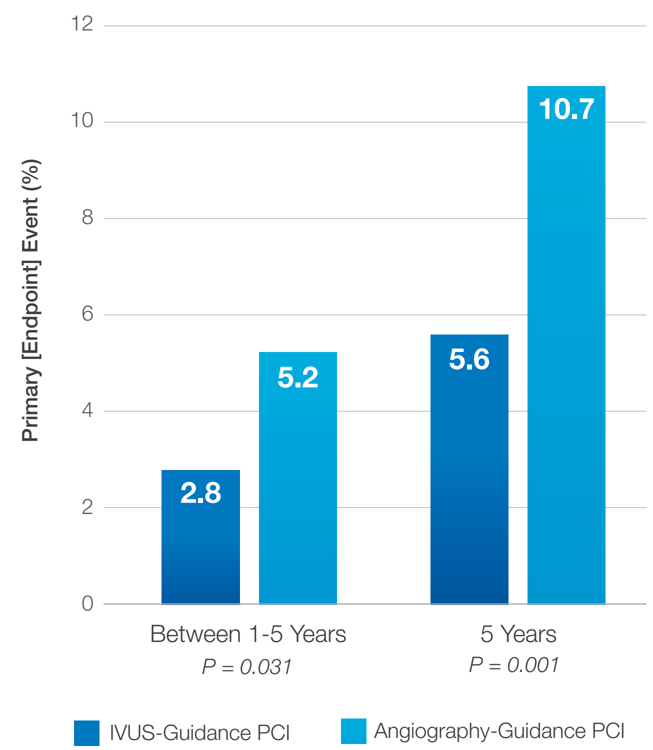
ACIST®

Benefits of IVUS imaging

Improved patient outcomes

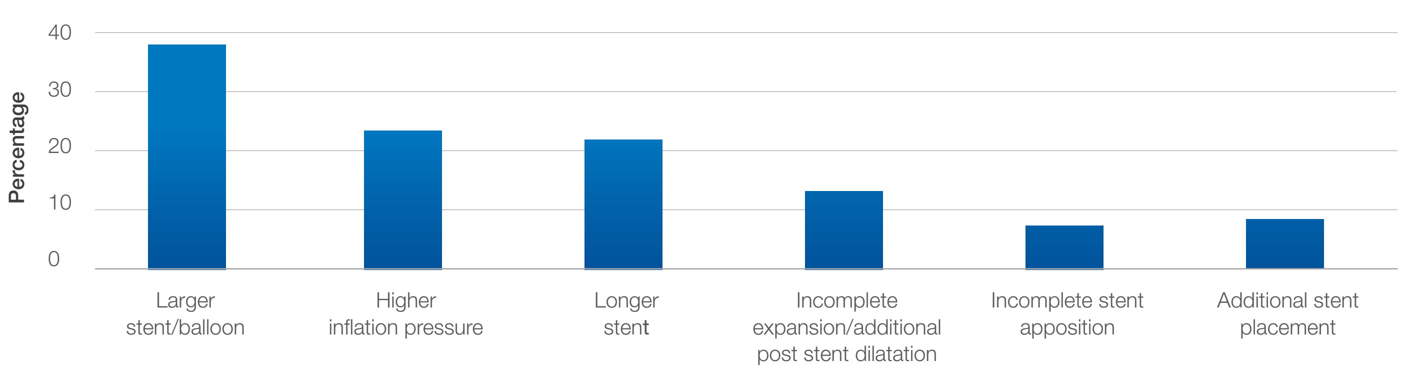
Compared with angiography-guided stent implantation, IVUS-guided stent implantation with long coronary lesions resulted in **48%** reduction in major adverse cardiac events (MACE) up to 5 years[1,2]





Optimized PCI strategy

Based on IVUS evaluation, the operator changed the interventional strategy and optimized the DES implantation procedure **74%** of the time[3]



ACIST HDi®
HD IVUS System

Your solution for High Definition visualization

HDi IVUS system is a fast, user-friendly solution that offers various mounting options to meet your cath lab needs

Benefits of IVUS imaging

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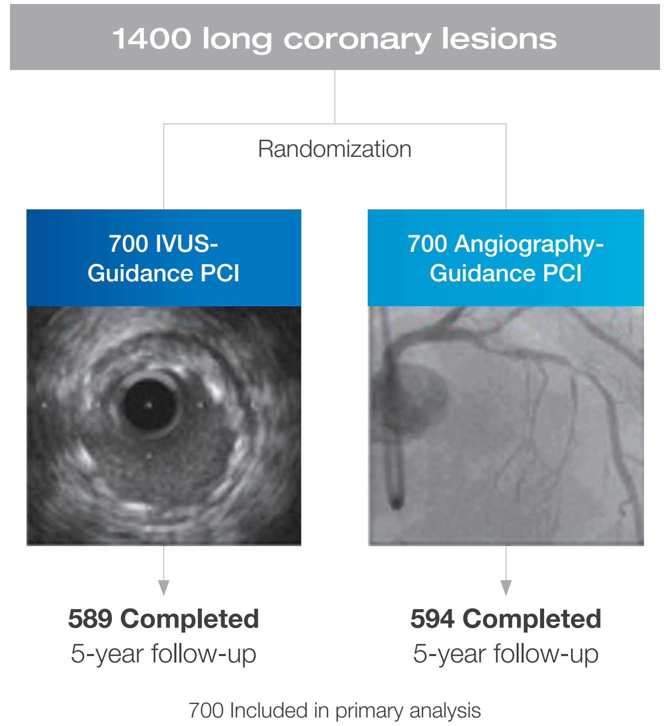

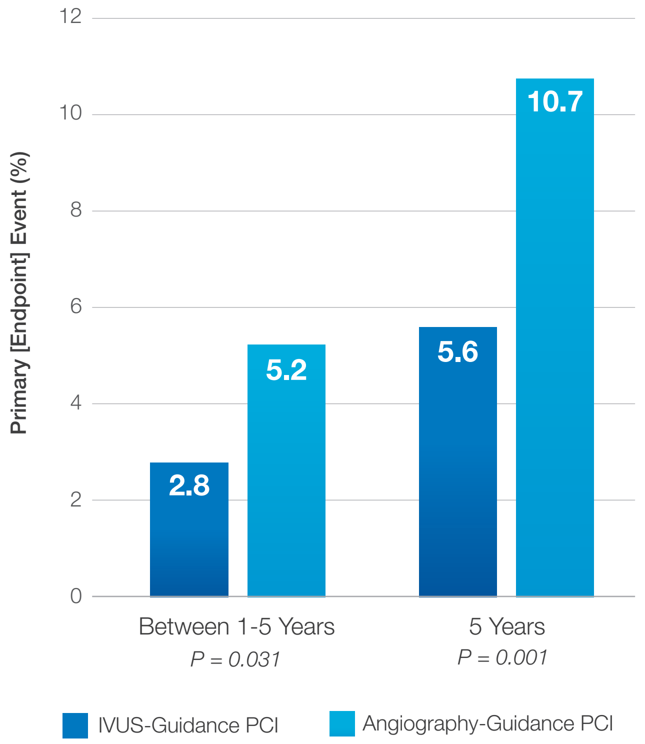

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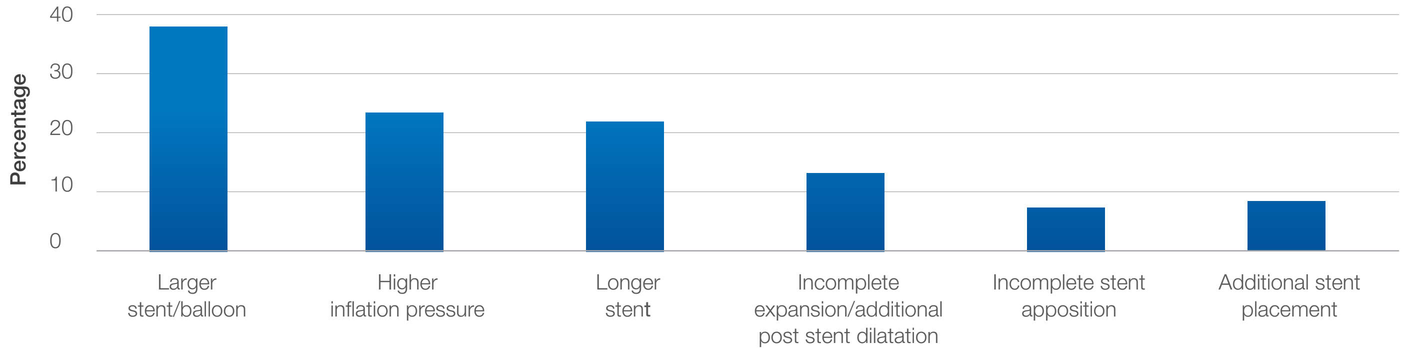
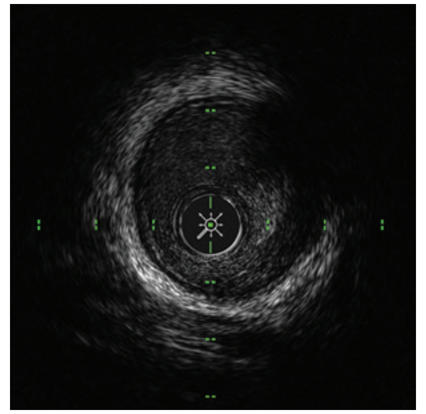


Optimized visualization

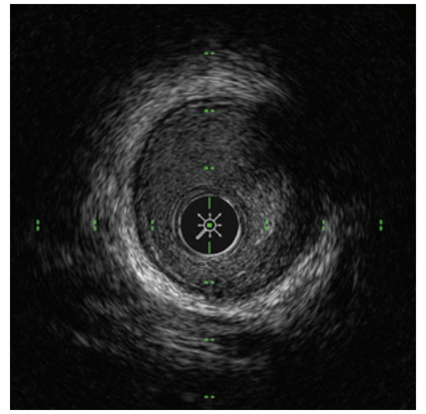
High definition 60 MHz imaging

Enhanced imaging modes

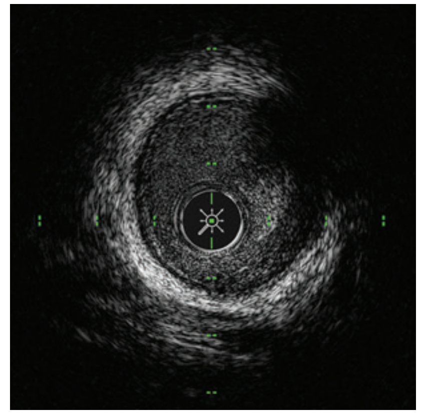
HDi with enhanced imaging modes provides a better defined IVUS image for preprocedural planning and post procedural assessment[4]



LumenView™
For a better defined lumen border visualization



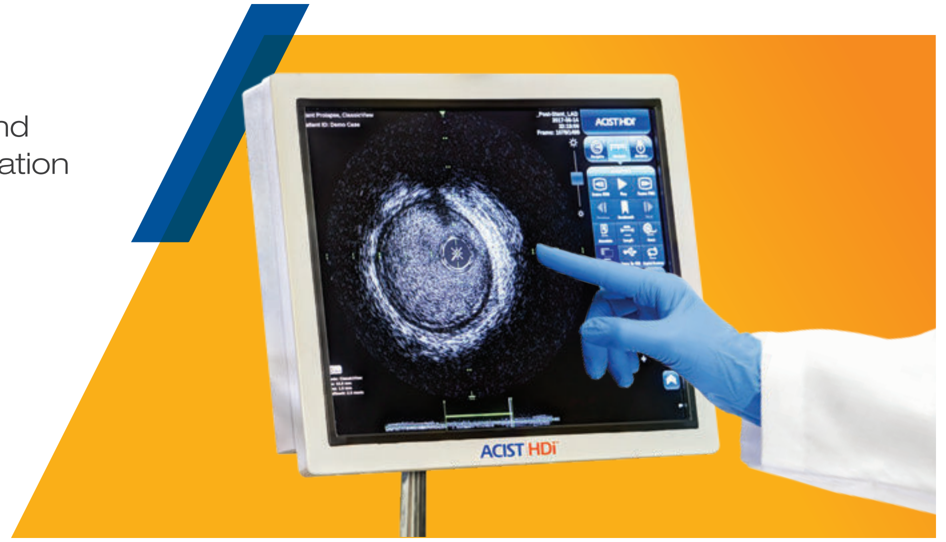
SilkView™
For a softer gray scale and more defined plaque



ClassicView™
Utilizes blood speckle to define the intravascular space

Interactive compact console

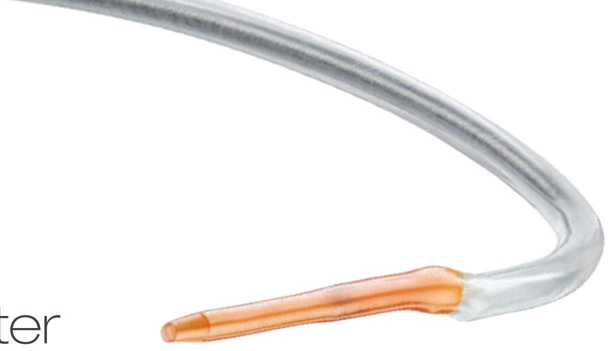
with a touch screen for rapid analysis and a small footprint for easy cath lab integration



Scan the QR code to learn more

ACIST HDi Website

ACIST HDi
HD IVUS System



Kodama®

HD IVUS Catheter

1 Catheter – 2 Frequencies

40 MHz and 60 MHz on the same Kodama catheter

High speed pullback[5]
Up to 10 mm/s

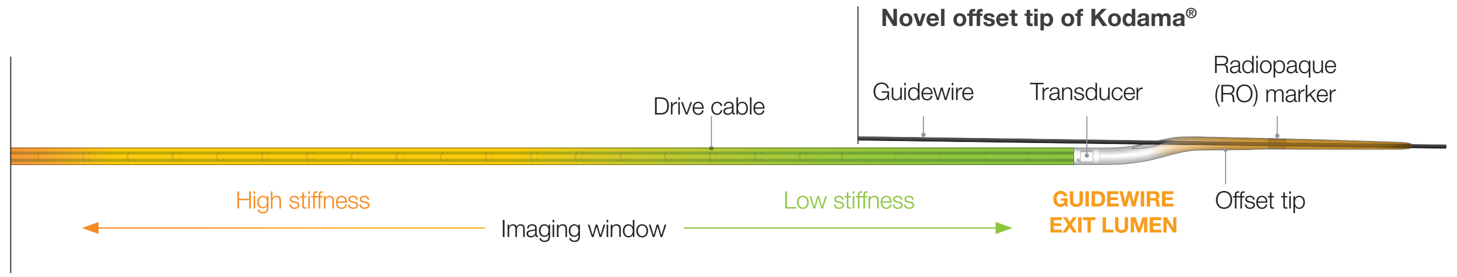
Improved deliverability[6]
- VariFlex imaging window
- Offset distal tip design

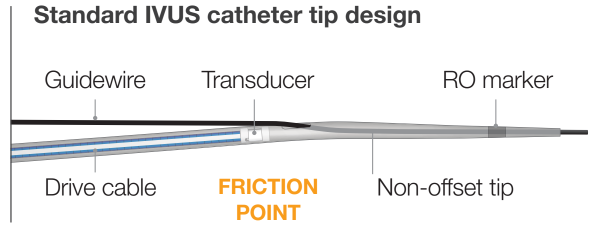
VariFlex™

Differentiated design, optimized imaging[4]

Unique variable-stiffness (VariFlex) imaging window

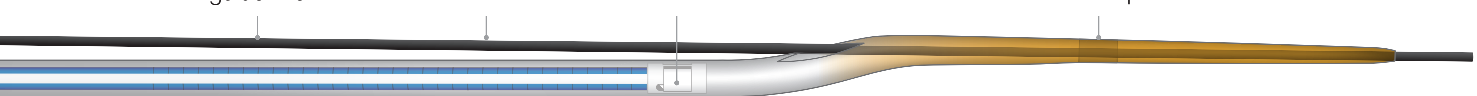
- Designed for variable stiffness along the imaging window length
- Flexible distal end for excellent deliverability
- Stiffer proximal body





ACIST HDi® & Kodama® IVUS Catheter Specifications

Indication	Coronary/Peripheral
Transducer Frequency	Dual 40 & 60 MHz
Enhanced Imaging Modes	Yes (SilkView™, LumenView™, ClassicView™)
Sheath Compatibility (with max wire 0.014")	6F
Guide Catheter Compatibility	6F
Tip Entry Profile	≤1.7F
Crossing Profile	≤3.4F
Catheter Telescoping Length	120 mm
Sled Pullback Length	120 mm
Working Length	≥141 mm
Pullback Speeds	0.5, 1.0, 2.5, 5.0, 10 mm/s
System Design	Mobile Cart or Bed Mount
Screen	Touch Screen or Mouse/keyboard
System Configuration	HDi® Console (SKU# 017986) & Kodama Catheter Case (SKU# 017788 includes 5 catheters)



1. Hong, S.-J. et al. *J Am Coll Cardiol Intv.* 2020;13(1):62-71. **2.** Hong S-J, Mintz GS, Ahn C-M, et al. Effect of intravascular ultrasound-guided drug-eluting stent implantation: five-year follow-up of the IVUS-XPL randomized trial. *J Am Coll Cardiol Intv.* 2019. **3.** IVUS Guided PCI vs Angiography guided PCI - ADAPT DES - 2 Year Follow-up - Maehara A, et al - 16 Nov 2018https://doi.org/10.1161/CIRCINTERVENTIONS.117.006243 Circulation: *Cardiovascular Interventions.* 2018;11:e006243. **4.** Data on file - TR-07057 – Internal testing. **5.** ACIST: Max pull back speed 10 mm/sec; Data on file TR-4013R, 02. **6.** Data on file - TR-4050 – Study Summary for Kodama Catheter performance.

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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