Introduction to IVUS Technology
Intravascular Ultrasound
Clinical Applications

A Tool with Many Apps

- Diagnostic IVUS Assessment
- Assessment of Lesion Significance
- Assessment of Angiographically Indeterminate Lesions
- Guidance for Plaque Modification
- Guidance for Stenting
- Thrombosis and Restenosis
- Assessment of Complex Patients/Lesions
- Assessment For Complications
- Guidance in Peripheral Interventions
- Additional Clinical Applications
  - Assessment in Disease Progression/Regression
  - IVUS Assessment in Cardiac Transplants
  - IVUS use in Clinical Studies/Research

Image property of Boston Scientific Corp
Progression of IVUS Usage in PCI
Use in United States Through 2009

US IVUS Procedure Usage in PCI

- IVUS Penetration %
- PCI

- Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4
- 2004 2005 2006 2007 2008 2009

- IVUS Penetration
- PCI

Boston Scientific Corp Internal Market Model
IVUS Technology

Review of Ultrasound Principles

- Developed by Bom (Rotterdam, 1971)
- Mid-1980s: Development of Technology
- 1988: First Image of a Human Vessel

Electrical Impulse

System electronics process the signal

Reflection

Tissue

Electrical Current (Piezoelectric Crystal)
- Expansion – Contraction
- Sounds Wave Production

High frequency sound waves echo off vessel walls and are sent back to system

Images by Mintz, Gary, MD., Intracoronary Ultrasound 2005
Transducer Technology

**Mechanical Transducer**
Single transducer rotates on a drive shaft, 1900 rpm

**Phased Array / Solid State Transducer**
Multiple (64) stationary transducers

Images property of Boston Scientific, Corp.
Phased Array Transducers use flashing ultrasound sources. With Phased Array catheters, interference occurs around the catheter and an area of “no information” is created; this is called ringdown.

Mechanical Transducer catheters use rotating ultrasound sources. With Mechanical Transducer catheters, the ultrasound signal covers the entire vessel, with no vessel signal interference.

Ringdown Comparison *(Images not scaled)*

**40 MHz Atlantis® SR Pro Catheter**

- No ring down

**20 MHz Eagle Eye® Gold Catheter**

- Ringdown 1–2 mm²

The ring down associated with Phased Array transducers may limit your field of view in comparison to Mechanical Transducers.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary. IVUS images courtesy of Jeffery Clevenger, MD Forsyth Medical Center Winston Salem, NC. Eagle Eye is a trademark of Volcano Corporation.
Ultrasound Principles

Basic principles

1. The beam remains fairly parallel for a distance (near field) and then begins to diverge (far field)

2. The quality of ultrasound images is better in the near field because the beam is more parallel and the resolution greater

3. Therefore, larger transducers with lower frequencies are used for examination of large vessels because they create a deeper near field
Ultrasound Principles

Image Quality

Image quality can be described by two important factors

- **Spatial resolution**
  - Ability to discriminate small adjacent objects within the image
  - For a 30–40MHz IVUS transducer the typical resolution is 80–100 microns axially and 200–250 microns laterally

- **Contrast resolution or dynamic range** = the distribution of the grayscale of the reflected signal
  - Low dynamic range images appear “black and white” with only a few “in-between” grayscale levels
  - High dynamic range images have more shades of gray, are often “softer,” and have more preserved subtleties in the image presentation
Image Quality

Spatial Resolution

40 MHz Rotational Catheter

20 MHz Phased Array Catheter

45 MHz Rotational Catheter

Image Quality

Contrast Resolution

Low Dynamic Range

High Dynamic Range

Images by Boston Scientific, Corp.
Image Quality
Axial and Lateral Resolution

**Axial**
Measured along the ultrasound beam

**Lateral**
Measured along the sweep of the IVUS image

A = Axial Resolution
L = Lateral Resolution
Clinical Importance

Axial and Lateral Resolution

The Importance of Axial Resolution
Detecting Stent Apposition

The Importance of Lateral Resolution
Detecting Edge Dissection

Images by Boston Scientific, Corp.
Impact of MHz
Axial and Lateral Resolution

40 MHz
Rotational Catheter

20 MHz
Phased Array Catheter

45 MHz
Rotational Catheter

To test Axial Resolution: Look for stent strut thickening
To test Lateral Resolution: Look for stent strut separation

Images of Eagle Eye Gold excerpted from product Directions for Use. Images taken by Boston Scientific, Corp.
Resolution of Current Catheters
Axial and Lateral

Smaller Resolution
Increased level of detail in the image

Testing completed by Boston Scientific Corp. Data on file. Bench test results may not necessarily be indicative of clinical performance. n=4
Other IVUS Catheter Features

Hydrophilic Coating

Bioslide™ Hydrophilic coating to reduce push force

![Graph showing Catheter Average Push Force (grams)]

- Atlantis® SR Pro Coronary Imaging Catheter
- iCross® Coronary Imaging Catheter

IVUS Pullback –
Motorized and Manual Interrogation

**Motorized Transducer Pullback**
- Intended Advantages
  - Steady catheter withdrawal
  - Creates length and volumetric measurements
  - Uniform images
  - Reproducible images
- Disadvantages
  - May provide inadequate examination in regions of interest due to preset speed

**Manual Transducer Pullback**
- Intended Advantages
  - Ability to concentrate on a specific region of interest
- Disadvantages
  - Possibility of skipping over significant pathology by irregular pullback
  - Potential inaccuracies in length and volume measurements
IVUS Systems –

Integrated System or Cart System

**IVUS Integrated System**
- Intended Advantages
  - May reduce procedure time
  - Immediate access
  - Tableside control with sterile field
  - Eliminate transporting system between rooms
  - Save procedure room space
  - May serve as a platform for other/new technology
  - Workflow improvements

- Disadvantages
  - Not mobile
  - Installation required
IVUS Cart System

Cart System

- Intended Advantages
  - Mobility
  - No installation requirements
  - Table side controller

- Disadvantages
  - May increase procedure time
  - Transporting between rooms
  - Space
  - Availability
  - Start up time

Image property of Boston Scientific Corp
**IVUS Integration**

*Impact on Workflow*

**Historical IVUS Workflow**

1. Locate IVUS Console in neighboring labs
2. If not in use, unplug and transport 400 lb. system
3. Plug in console and ECG lead to power up
4. Enter Patient information manually via keyboard
5. Plug in catheter and begin imaging
6. Trace borders
7. Make measurements by hand

**IVUS Integrated System Workflow**

1. Enter Patient information manually via keyboard
2. Plug in catheter and begin imaging
3. Confirm automatic borders & measurements

Adapted from Mintz, Gary, CRT 2008,
Software developments continually add features to improve image quality and interpretation, promote ease of use, time efficiencies, consistency in process and workflow. Examples of software features

**Volumetric Analysis**
With the volumetric analysis feature clinicians can gather total plaque volume measurements based on lumen and media borders.

**Modality Worklist**
iLab® System Software 2 Interfaces with Modality Worklist servers to conveniently pull daily patient information onto the iLab® Ultrasound Imaging System.

**Advanced Export**
In addition to DICOM and iLab® formats physicians can now export IVUS information as a native RF file, as screenshots or as video files.

**iMap – Tissue Characterization** (Not approved in U.S., available internationally)
A pattern recognition concept that characterizes tissue within the plaque using the full spectrum of radiofrequency (RF) signals of IVUS
TC looks at a region of interest (ROI) and pick out the underlying **radiofrequency (RF) signal** …

… which is immediately converted to the mathematically more tractable **frequency spectrum**

The algorithm characterizes the ROI as the tissue type associated with the most similar spectrum assessed from previous analysis of different cadaver hearts

The algorithm also states the confidence of its characterization based on the degree of similarity.

Not currently available in the U.S. Images not indicative of product performance. Images by Boston Scientific, Corp.
IVUS Possibilities for the Future

Transducer Advancements For Image Improvements
  Increasing Resolutions
  Improvements in Image Interpretation
  Multi-frequencies
System Improvements for Increasing Ease Of Use
Continuing Software Enhancements
New Functionalities
  Forward Looking IVUS
  IVUS on a Guidewire
  IVUS and Angiography Coregistration

Images property of Boston Scientific Corp.
INDICATIONS: The iLab® Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy. Refer to the Directions for Use provided with all Boston Scientific ultrasound imaging catheters to determine compatibility with the iLab® System. The imaging catheters generate ultrasound images and are intended for patient examination of vascular and cardiac anatomies. Boston Scientific manufactures a wide variety of imaging catheters for different applications. The recommended use of each of these catheters may vary depending on the size and type of catheter.

INDICATIONS FOR AUTOMATIC PULLBACK USE: Automatic Pullback is indicated when the following occurs: The physician/operator wants to standardize the method in which intravascular ultrasound images are obtained and documented: procedure-to-procedure, operator-to-operator. • The physician/operator wants to make linear distance determinations post-procedurally, which requires the imaging core of a catheter to be pulled back at a known uniform speed. • Two-dimensional, longitudinal reconstruction of the anatomy is desired.

CONTRAINDICATIONS: Use of Automatic Pullback is contraindicated where introduction of any catheter would constitute a threat to patient safety. Use of the imaging catheter is contraindicated where introduction of any catheter would constitute a threat to patient safety. This instrument is contraindicated for fetal imaging. The contraindications include the following patient characteristics: • Bacteremia or sepsis • Coronary artery spasm • Intra-arterial or intra-ventricle thrombosis • Life-threatening rhythm disorders • Major coagulation system abnormalities • Mechanical heart valves that would be crossed by the imaging catheter • Myocardial infarction • Severe hemodynamic instability or shock • Total occlusion • Unsuitability for balloon angioplasty (PTCA) • Unsuitability for coronary artery bypass surgery.

COMPLICATIONS OF VASCULAR IMAGING: The risks and discomforts involved in vascular or cardiac imaging include those associated with all catheterization procedures. These risks or discomforts may occur at any time with varying frequency or severity. Additionally, these complications may necessitate additional medical treatment including surgical intervention and, in rare instances, may result in death: Abrupt closure • Angina • Cardiac arrhythmias including, but not limited to, ventricular tachycardia, ventricular fibrillation and complete heart block • Catheter/guide wire/pressure wire entrapment • Embolism • Emergent coronary artery bypass graft (CABG) surgery • Infection • Myocardial infarction, ischemia and/or perforation • Stent strut damage • Stroke (including cerebral vascular accident and transient ischemic attack) • Thrombus formation • Total vessel occlusion • Valvular injury • Vessel dissection, injury, spasm or perforation.

WARNINGS/CAUTIONS/PRECAUTIONS: Federal law restricts this device to sale by or on the order of a physician. For further information, please consult the iLab® Ultrasound Imaging System Users Guide.
**Intended Use/Indications:**
- This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

**Contraindications:**
- Use of this imaging catheter is contraindicated where introduction of any catheter would constitute a threat to patient safety. Contraindications include: Bacteremia or sepsis, Major coagulation system abnormalities, Patients disqualified for CABG surgery, Patients disqualified for PTCA, Severe hemodynamic instability or shock, Patients diagnosed with coronary artery spasm, Total occlusion.

**Complications:**
- The following complications may occur as a consequence of intravascular ultrasound imaging: Arterial dissection, injury or perforation; Total occlusion; Death; Abrupt closure; Acute myocardial infarction; Ventricular fibrillation; Unstable angina. Air embolism.

**Warnings:**
- Do not advance the catheter if resistance is encountered. The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis. If resistance is met upon withdrawal of the catheter, verify resistance using flouroscopy, then remove the entire system simultaneously.

**Precautions:**
- Contents supplied sterile using a gamma radiation (Cobalt 60) process. Do not use if sterile barrier is amaged. If damage is found call your Boston Scientific representative. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Store in a cool, dark place. During the procedure, inspect the catheter carefully for any damage which may have occurred during use. The catheter has no user serviceable parts. Do not attempt to repair or to alter any component of the catheter assembly as provided. Do not attempt to connect the catheter to electronic equipment other than the designated systems. Never attempt to attach or detach the catheter while the motor is running. To do so may damage the connector. Avoid any sharp bends, pinching or crushing of the catheter. Do not kink or sharply bend the catheter at any time. This can cause drive cable failure. An insertion angle greater than 45 degrees is considered excessive. Care should be taken when a guidewire is exposed in a stented vessel. Catheters that do not encapsulate the guidewire may engage the stent between the junction of the catheter and guidewire. Care should be taken when readvancing a guidewire after stent deployment. A guidewire may exit between stent struts when recrossing a stent that is not fully opposed to the vessel wall. Subsequent advancement of the catheter could cause enlargement between the catheter and the stent. Care should be taken to slowly remove the catheter from a stented vessel. Turn the MDU “off” before withdrawing the imaging catheter.

**Caution:**
- Federal (USA) law and governing law outside the USA restricts these devices to sale by or on order of a physician.
**Intended Use/Indications:**

- This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.
- **Contraindications:**
- Use of this imaging catheter is contraindicated where introduction of any catheter would constitute a threat to patient safety. Contraindications include: Bacteremia or sepsis, Major coagulation system abnormalities, Patients disqualified for CABG surgery, Patients disqualified for PTCA, Severe hemodynamic instability or shock, Patients diagnosed with coronary artery spasm, Total occlusion.
- **Complications:**
- The following complications may occur as a consequence of intravascular ultrasound imaging: Arterial dissection, injury or perforation; Total occlusion; Death; Abrupt closure; Acute myocardial infarction; Ventricular fibrillation; Unstable angina; Air embolism.
- **Warnings:**
- Do not advance the catheter if resistance is encountered. The catheter should never be forcibly inserted into lumens narrower than the catheter body or forced through a tight stenosis. If resistance is met upon withdrawal of the catheter, verify resistance using flouroscopy, then remove the entire system simultaneously.
- **Precautions:**
- Contents supplied sterile using a gamma radiation (Cobalt 60) process. Do not use if sterile barrier is amaged. If damage is found call your Boston Scientific representative. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Store in a cool, dark place. During the procedure, inspect the catheter carefully for any damage which may have occurred during use. The catheter has no user serviceable parts. Do not attempt to repair or to alter any component of the catheter assembly as provided. Do not attempt to connect the catheter to electronic equipment other than the designated systems. Never attempt to attach or detach the catheter while the motor is running. To do so may damage the connector. Avoid any sharp bends, pinching or crushing of the catheter. Do not kink or sharply bend the catheter at any time. This can cause drive cable failure. An insertion angle greater than 45 degrees is considered excessive. Care should be taken when a guidewire is exposed in a stented vessel. Catheters that do not encapsulate the guidewire may engage the stent between the junction of the catheter and guidewire. Care should be taken when readvancing a guidewire after stent deployment. A guidewire may exit between stent struts when recrossing a stent that is not fully opposed to the vessel wall. Subsequent advancement of the catheter could cause enlargement between the catheter and the stent. Care should be taken to slowly remove the catheter from a stented vessel. Turn the MDU “off” before withdrawing the imaging catheter.
- **Caution:** Federal (USA) law and governing law outside the USA restricts these devices to sale by or on order of a physician.