INTRAVASCULAR IMAGING:
OPTICAL COHERENCE TOMOGRAPHY (OCT)

BASICS OF IMAGE INTERPRETATION
BASICS OF IMAGE INTERPRETATION

OCT is an imaging modality that uses near-infrared light to provide high-definition images of the artery.

5 OCT FUNDAMENTALS

1. Elements of an OCT image view

2. Normal vessel tissue view

3. Most common type of plaque description

OCT Helps to identify different plaque morphologies.

4. Attenuation

To describe images, the term “attenuation” is used in regards to light penetration, or simply “loss of light.”

5. Algorithm for image interpretation

Developed by Ziad Ali, M.D., this quick guide can help to interpret OCT images.
IMPORTANT SAFETY INFORMATION

OPTIS™ INTEGRATED SYSTEM, MOBILE SYSTEM, SOFTWARE

INDICATIONS
The OPTIS Integrated System and Mobile System with OPTIS Software combined with Dragonfly™ DUO or Dragonfly™ OPTIS™ Imaging Catheter are intended for the imaging of coronary arteries and are indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly DUO or Dragonfly OPTIS Imaging Catheter are indicated for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly DUO, or Dragonfly OPTIS Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure.

The OPTIS Integrated System and Mobile System will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.

CONTRAINDICATIONS
The OPTIS Integrated System and Mobile System with OPTIS Software are contraindicated where introduction of any catheter would constitute a threat to patient safety. Contraindications include:

- Bacteremia or sepsis
- Major coagulation system abnormalities
- Patients diagnosed with coronary artery spasm
- Patients disqualified for CABG surgery
- Patients disqualified for PTCA
- Severe hemodynamic instability or shock
- Total occlusion
- Large thrombus
- Acute renal failure

NOTE: The systems have no patient alarm functions. Do not use for cardiac monitoring.

WARNINGS

- Appropriate anticoagulant and vasodilator therapy must be used during the procedure as needed.
- Observe all advancement and movement of the Dragonfly Imaging Catheter under fluoroscopy. Always advance and withdraw the catheters slowly. Failure to observe device movement fluoroscopically may result in vessel injury or device damage.
- Leave the guidewire engaged with the catheter at all times during use. Do not withdraw or advance the guidewire prior to withdrawing the catheter.
- If resistance is encountered during advancement or withdrawal of the Dragonfly Imaging Catheter, stop manipulation and evaluate under fluoroscopy. If the cause of resistance cannot be determined or mitigated, carefully remove the catheter and guidewire together.
- The catheter should never be forced into lumens that are narrower than the catheter body or forced through a tight or heavily calcified lesion.
- The catheter should not be advanced through abnormally tortuous anatomy.
- When advancing or retracting a catheter with a minirail tip through a stented vessel, the catheter may engage the stent between the junction of the catheter and guidewire, resulting in entrapment of catheter/guidewire, catheter tip separation, and/or stent dislocation.
- Refer to the contrast media’s instructions-for-use for general warnings and precautions relating to use of the contrast media.

PRECAUTIONS

- Safety and effectiveness have been established for the following patient population: adult patients undergoing non-emergent percutaneous coronary interventions in lesions with reference vessel diameters between 2.0 to 3.5 mm, which were not located in the left main coronary artery or in a target vessel which has undergone previous bypass procedures.
- All operators must be trained prior to using the OPTIS Integrated System, the OPTIS Mobile System and the Dragonfly Imaging Catheter.
- Only 100% contrast media is approved for human use.
- Store the catheter at ambient temperature in a dry location out of direct sunlight.
- Never attempt to attach or detach a catheter to the DOC while the “lock” LED is lit.
- Do not kink, sharply bend, pinch, or crush the catheter at any time.
- The catheter is for single use only. Do not reuse, re-sterilize, or reprocess.
- The catheter is sterilized by ethylene oxide and is intended for one-time use only. Non-pyrogenic. Do not use if the package is opened or damaged.
- After use, the catheter may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.
- The catheter has no user serviceable parts. Do not attempt to repair or alter any part of the catheter as provided.

POTENTIAL ADVERSE EVENTS

Potential complications which may be encountered during all catheterization procedures include, but are not limited to: acute myocardial infarction or unstable angina, allergic reaction to the contrast media, arterial dissection, injury, or perforation, cardiac arrhythmias, coronary artery spasm, embolism, thrombus formation, or death.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.