

# Coronary Intravascular Lithotripsy (IVL)

## ICD-10-PCS Code Application

Rob Fletcher

Vice President of Marketing & Reimbursement



# Patient Population

- Percutaneous coronary intervention (PCI) of heavily calcified lesions is associated with early complications and / or late adverse events
- Coronary artery calcification (CAC) impedes stent delivery and deployment, leading to under expansion, malposition or stent surface damage potentially impairing drug delivery
- Suboptimal stent expansion is the strongest predictor of stent thrombosis and restenosis
- Atherectomy facilitates stent expansion, but CAC modification is limited by guidewire bias and may be associated with peri-procedural complications
- Moderate-severe CAC presents in approximately one-third of patients presenting with stable coronary artery disease or acute coronary syndrome, and severe CAC is found in approximately 15% of patients undergoing PCI

# Potential Complications in Treating Calcified Atherosclerosis

Current Therapy	Potential Complication
Standard Balloons	<ul style="list-style-type: none"><li>• Dissection</li><li>• Perforation</li><li>• Restenosis (from tissue damage)</li></ul>
Specialty Balloons (cutting and scoring)	<ul style="list-style-type: none"><li>• Dissection</li><li>• Perforation</li><li>• Restenosis (from tissue damage)</li></ul>
Atherectomy	<ul style="list-style-type: none"><li>• Embolism</li><li>• Dissection</li><li>• Perforation</li><li>• Restenosis (from tissue damage)</li></ul>

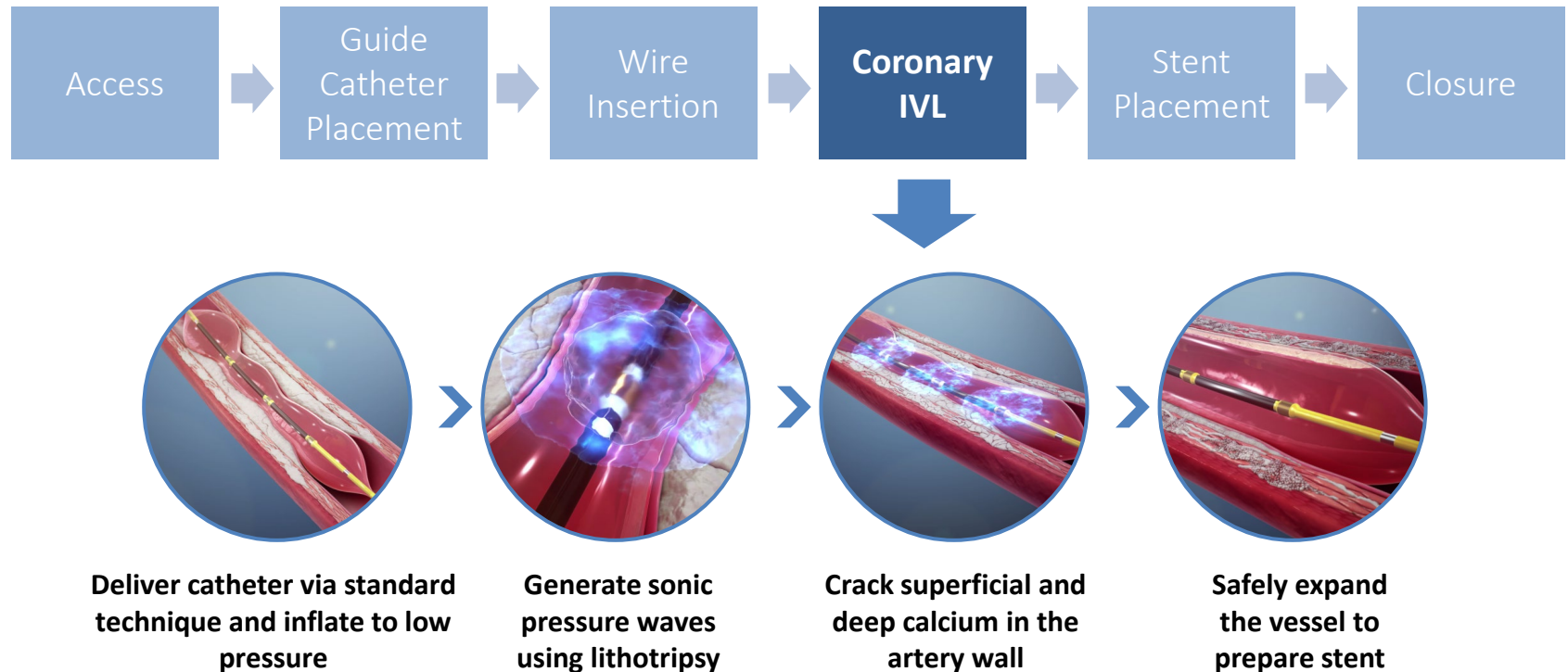
# Coronary IVL – Shockwave IVL System

## Components:

- Generator – portable, rechargeable, non-sterile, reusable
- Connector Cable – non-sterile, reusable
- IVL Catheter – single use, sterile catheter that delivers intravascular lithotripsy



# Coronary IVL Procedure



- Coronary IVL is performed in addition to the procedural steps to deliver and place a coronary stent

# Coronary IVL Procedure

- In the pivotal trial, the number of coronary IVL catheters utilized per case was 1.2
- Coronary IVL has a great safety profile with an overall procedural success rate of 92%
  - Minimal Complications reported (.5%) in the CAD III Trial include:
    - Severe dissection
    - Perforation
    - Abrupt closure
    - Slow Flow
    - No Re-Flow

*Coronary IVL prior to DES implantation is well tolerated with a low rate of major peri-procedural clinical and angiographic complications*

# Regulatory Status

- FDA awarded coronary IVL with Breakthrough Device Designation on September 3, 2019
- FDA PMA approval is expected in Q1, 2021
- Indications for Use (Anticipated)
  - The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C2 Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of calcified, stenotic *de novo* coronary arteries prior to stenting.

# Summary

- Coronary artery calcification (CAC) impedes stent delivery and deployment, leading to under expansion, malposition or stent surface damage potentially impairing drug delivery
- Coronary IVL is a novel technology specifically designed to address calcified lesions prior to the placement of coronary stents
- Current ICD-10-PCS codes do not uniquely identify the use of the coronary IVL, and does not allow for accurate reporting and outcomes tracking