# SCAI EXPERT CONSENSUS ALGORITHM ON THE MANAGEMENT OF CALCIFIED CORONARY LESIONS[1]


Angiographic Evidence of Calcified Coronary Lesion

Intravascular Imaging to Evaluate Criteria for Calcium Modification*

*Criteria for Ca Modification:
- 360° arc of calcium
- >270° arc of calcium and >5 mm length of calcium

Additional considerations of calcified lesion characteristics:
- Calcified nodule
- Small vessel (Lesion EEL <3.5 mm) or Negative remodeling (Lesion EEL diameter <distal EEL diameter)
- Minimum thickness of calcium >0.5 mm (OCT)

Considerations:
[α]Long, diffuse calcium
[ß]Concentric, eccentric, or nodular calcium
[x]Focal calcium

Intravascular Imaging Not Feasible or Imaging Criteria Not Met

Intravascular Imaging Criteria Met

Unable to Deliver

Atherectomy

1:1 sized NC/Specialty Balloon

Atherectomy[α]
Intravascular Lithotripsy[ß,x]
Specialty Balloons[x]

Intravascular Imaging to Evaluate Criteria for Further Calcium Management
or
1:1 sized NC/Specialty Balloon

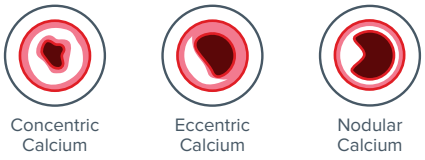
Calcium fractures on intravascular imaging
and/or
Full Expansion of a 1:1 Balloon in 2 Views

Yes

No

Proceed with PCI

## SCAI RECOMMENDATIONS FOR IVL IN CORONARY CALCIUM

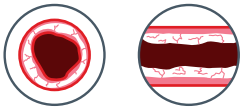



Consider IVL for concentric, eccentric, and nodular lesions and in settings where atherectomy may be relatively contraindicated

IVL can be used synergistically with atherectomy devices, especially in balloon uncrossable lesions or longer lesions where there is often more heterogeneity in vessel size and pattern of calcification

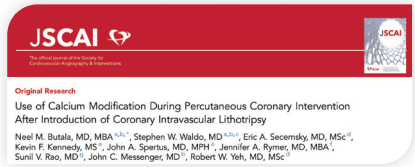
IVL can be used with multiple guide wires in place (bifurcation lesions)

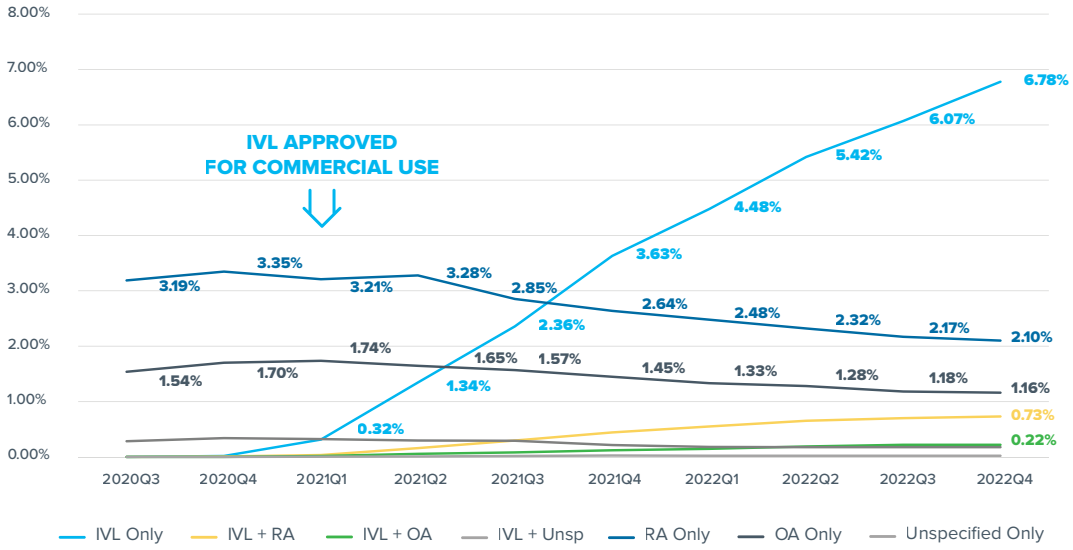
Intravascular imaging is useful determining an IVL pulse strategy



Intravascular imaging demonstrates that IVL results in both superficial and deep, radial and longitudinal, macrofractures, and microfractures

# TRENDS IN USE OF CALCIUM MODIFICATION TOOLS AMONG PATIENTS UNDERGOING PCI[2]




> Interestingly, since the approval of IVL in the United States, the frequency of advanced lesion preparation has increased by 40%, while the use of atherectomy has remained relatively stable, suggesting that IVL has facilitated more widespread adoption of advanced lesion preparation[3]

## THESE TWO PUBLICATIONS...

- Highlight the growing clinical applications of coronary IVL, with an increasing role as the front-line calcium modification tool for balloon crossable lesions.
- Reinforce the proven safety and efficacy of coronary IVL across all types of calcium morphologies: concentric, eccentric, and nodular.
- Emphasize IVL's unmatched safety profile due to its unique mechanism-of-action that differentiates it from other calcium modification technologies.


1. Riley R.F. Patel M.P. Abbott J.D. *et al.* SCAI expert consensus statement on the management of calcified coronary lesions. J Soc Cardiovasc Angiogr Interv. 2024.
2. Butala N. M. Waldo S. W. *et al*. Use of calcium modification during percutaneous coronary intervention after introduction of coronary intravascular lithotripsy. J Soc Cardiovasc Interv. 2024.
3.Ali Z. A. Shin D. *et al*. Between a rock and a hard place: consensus statement on calcified coronary lesions. J Soc Cardiovasc Interv. 2024.


**In the United States: Rx only. Indications for Use —** The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C$^{2+}$ Coronary IVL Catheter is indicated for lithotripsy-enabled, low-pressure balloon dilatation of severely calcified, stenotic de novo coronary arteries prior to stenting. **Contraindications —** The Shockwave C$^{2+}$ Coronary IVL System is contraindicated for the following: This device is not intended for stent delivery. This device is not intended for use in carotid or cerebrovascular arteries. **Warnings —** Use the IVL Generator in accordance with recommended settings as stated in the Operator's Manual. The risk of a dissection or perforation is increased in severely calcified lesions undergoing percutaneous treatment, including IVL. Appropriate provisional interventions should be readily available. Balloon loss of pressure was associated with a numerical increase in dissection which was not statistically significant and was not associated with MACE. Analysis indicates calcium length is a predictor of dissection and balloon loss of pressure. IVL generates mechanical pulses which may cause atrial or ventricular capture in bradycardic patients. In patients with implantable pacemakers and defibrillators, the asynchronous capture may interact with the sensing capabilities. Monitoring of the electrocardiographic rhythm and continuous arterial pressure during IVL treatment is required. In the event of clinically significant hemodynamic effects, temporarily cease delivery of IVL therapy. **Precautions —** Only to be used by physicians trained in angiography and intravascular coronary procedures. Use only the recommended balloon inflation medium. Hydrophilic coating to be wet only with normal saline or water and care must be taken with sharp objects to avoid damage to the hydrophilic coating. Appropriate anticoagulant therapy should be administered by the physician. Precaution should be taken when treating patients with previous stenting within 5mm of target lesion. **Potential adverse effects consistent with standard based cardiac interventions include –** Abrupt vessel closure - Allergic reaction to contrast medium, anticoagulant and/or antithrombotic therapy-Aneurysm-Arrhythmia-Arteriovenous fistula-Bleeding complications-Cardiac tamponade or pericardial effusion-Cardiopulmonary arrest-Cerebrovascular accident (CVA)-Coronary artery/vessel occlusion, perforation, rupture or dissection-Coronary artery spasm-Death-Emboli (air, tissue, thrombus or atherosclerotic emboli)-Emergency or nonemergency coronary artery bypass surgery-Emergency or nonemergency percutaneous coronary intervention-Entry site complications-Fracture of the guide wire or failure/malfunction of any component of the device that may or may not lead to device embolism, dissection, serious injury or surgical intervention-Hematoma at the vascular access site(s)- Hemorrhage-Hypertension/Hypotension-Infection/sepsis/fever- Myocardial Infarction-Myocardial Ischemia or unstable angina Pain-Peripheral Ischemia-Pseudoaneurysm-Renal failure/insufficiency-Restenosis of the treated coronary artery leading to revascularization-Shock/pulmonary edema-Slow flow, no reflow, or abrupt closure of coronary artery-Stroke Thrombus-Vessel closure, abrupt-Vessel injury requiring surgical repair-Vessel dissection, perforation, rupture, or spasm. **Risks identified as related to the device and its use —** Allergic/immunologic reaction to the catheter material(s) or coating-Device malfunction, failure, or balloon loss of pressure leading to device embolism, dissection, serious injury or surgical intervention-Atrial or ventricular extrasystole-Atrial or ventricular capture. **Prior to use, please reference the Instructions for Use for more information on indications, contraindications, warnings, precautions and adverse events. www.shockwavemedical.com/IFU.** Please contact your local Shockwave representative for specific country availability and refer to the Shockwave C$^{2+}$ instructions for use containing important safety information.