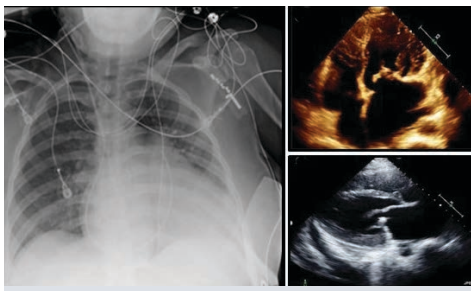
# Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist

CASE REPORT

## Percutaneous Mitral Valvuloplasty for Palliative Management of Severe Mitral Stenosis in a High-Risk Pregnancy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**Abstract**

The management of valvular heart disease in pregnancy is uniquely complex, requiring consideration of both maternal and fetal well-being within the context of the dynamic physiologic changes of pregnancy. As medical and surgical advancements allow more patients with acquired and congenital valvular disease to survive into their reproductive years, the number of patients with pregnancies complicated by valvular heart disease is likely to increase over time.


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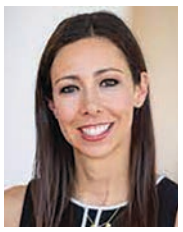
In This Issue

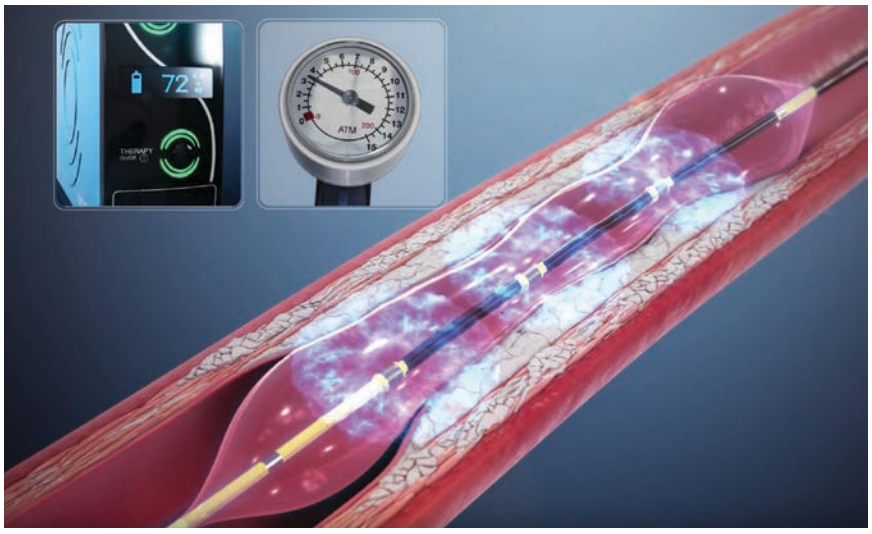


CALCIUM CORNER

## The Impact of Calcium on PCI and the Need for Intravascular Lithotripsy (IVL)

*CLD talks with Nadia R. Sutton, MD, MPH, FACC, FSCAI, Assistant Professor in the Department of Internal Medicine, Division of Cardiovascular Medicine, Section of Interventional Cardiology, University of Michigan Health System, Ann Arbor, Michigan.*





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CASE REPORT

## Radial Access Management of Tortuous Brachiocephalic Artery During STEMI Involving Anomalous Right Coronary Artery


*Sameh Sayfo, MBA, ABVM, MD*
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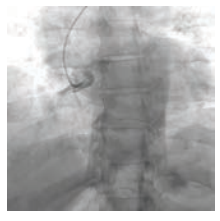

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# The Impact of Calcium on PCI and the Need for Intravascular Lithotripsy (IVL)

*CLD talks with Nadia R. Sutton, MD, MPH, FACC, FSCAI, Assistant Professor in the Department of Internal Medicine, Division of Cardiovascular Medicine, Section of Interventional Cardiology, University of Michigan Health System, Ann Arbor, Michigan.*

**What is the pathogenesis of coronary artery calcium?**

Coronary calcification can either be a reactive or a proactive process. For example, it can be reactive to mechanical strain, such as from hypertension, or to inflammation, or from elevated phosphate levels, such as in patients who are on dialysis or have impaired renal function. Or, coronary calcification can actually be a proactive process, where vascular smooth muscle cells, which are part of the blood vessel wall, actually take on a calcium-producing phenotype. Calcium in the blood vessel wall occurs in different forms. Intimal calcium is most often associated with atherosclerosis, and medial calcium is often seen in patients with hypertension, chronic kidney disease, and in older patients. Sometimes we find nodular calcium, which can protrude into the lumen. Nodules which erupt into the lumen are more likely to be associated with thrombus and cause acute coronary syndrome. It remains poorly understood why calcium nodules form, sometimes even in the mid to distal coronary arteries. Why vascular smooth muscle cells create calcific nodules is unclear, but it is definitely a pathologic process.


**Figure 1.** (A) Intravascular Lithotripsy (IVL). (B) Shockwave Coronary IVL System Components.

**What are the clinical implications?**

Implications depend on the location of the calcium. Medial calcium may not actually cause any obstruction to blood flow, and so the patient may not have any symptoms of angina. Calcification may be detected incidentally or in the course of screening on a computed tomography (CT) scan, but the patient might not even have ischemia. If the calcification actually starts to obstruct blood flow or is associated with a plaque that is obstructing blood flow, these patients might present with symptoms of angina or potentially acute coronary syndrome. We frequently see patients with comorbidities that can lead to coronary artery calcification, including patients on dialysis, patients with hypertension or diabetes, and older patients.

**What treatment options for arterial calcium are available and what are the risks associated with percutaneous coronary intervention (PCI) in calcified arteries?**

We are fortunate to now have several tools for managing calcification, such as rotational atherectomy, orbital atherectomy, laser atherectomy, angioplasty balloons (such as cutting balloons), and most recently, intravascular lithotripsy (IVL). Each of these different tools for modifying calcium work in a slightly different way, and depending on the patient's coronary anatomy or other factors, there is a time and place for each. A risk of inadequate vessel preparation due to not modifying calcium is stent under-expansion. Under-expanded stents lead to recurrent/unresolved symptoms and the need for future interventions. Some risks of intervening on calcified arteries include coronary dissection, perforation, no reflow, and lack of procedural success.

**What is the method of action of intravascular lithotripsy?**

Intravascular lithotripsy (IVL) uses sonic pressure waves to fracture the calcium. Pressure waves are delivered at a balloon inflation pressure of 4 atmospheres (atm), but the effective pressure of

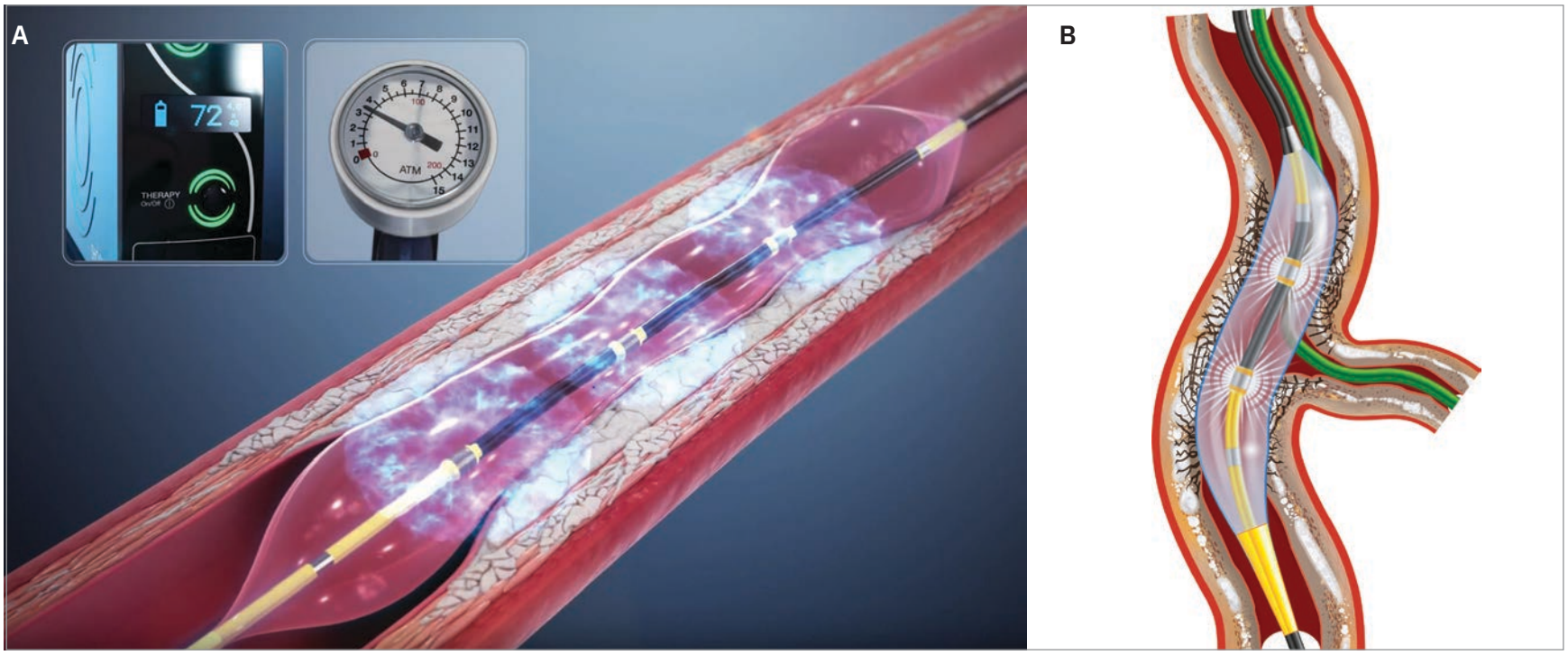



**Figure 2.** **(A) IVL Unique Mechanism of Action. (B) Intravascular Lithotripsy in Coronary Artery Calcium (CAC).**

lithotripsy is 50 atm. Post-treatment angioplasty pressure is 6 atm, and the rated burst pressure (RBP) is 10 atm. With non-compliant angioplasty balloons, we might be going up to 18 or 20 atmospheres. So, intravascular lithotripsy offers a significant amount more impact at a lower inflation pressure for both superficial and deep calcium.

Calcium could be concentric, meaning at that it goes all the way around the inside of the blood vessel, or it could potentially not be concentric, meaning it is less than 360 degrees, perhaps 180 or 270 degrees of circumference. Intravascular lithotripsy works very well when there is concentric calcium, because the sonic pressure waves reflect off of calcium, amplifying the effect and creating fissures. Patients with more nodular calcium or severe stenosis such that an angioplasty balloon cannot be delivered might require rotational atherectomy or a combination of rotational atherectomy plus lithotripsy, termed "RotaTripsy."[1] We need to think about applying the tools available to us, sometimes in sequence. Coronary lithotripsy has been in use in Europe for some time now, and I have found it very helpful to talk to European interventional cardiologists, including Dr. James Spratt and Dr. Claudia Cosgrove, and learn from their experience. It is nice to have IVL as an option, and it is definitely complementary to existing devices.

Another thing I would add is that the role of intravascular imaging cannot be understated when determining the extent, location, length, concentricity, and morphology of calcium. One can easily underestimate the degree of calcification on a diagnostic angiogram. Once you start using intravascular imaging routinely, you will likely find yourself using tools for calcium modification more frequently. That said, imaging catheters can sometimes be difficult to deliver if there is severe calcification. If this occurs, it can still be helpful to image after angioplasty or modifying the calcification.

Without imaging, you may not know if you have actually modified the calcium sufficiently for stent expansion. Lithotripsy creates fissures or fractures in the calcium, and it is possible to see these results either with optical coherence tomography (OCT) or intravascular ultrasound (IVUS) imaging. Lastly, you may not realize you have stent under-expansion unless you are using intravascular imaging. Overall, intravascular imaging is an extremely important aspect of performing high-quality interventions for our patients.

**What are the clinical outcomes associated with intravascular lithotripsy?**

The DISRUPT CAD III trial results were published in 2020.[2] The trial was designed as a prospective single-arm study. There was a primary safety endpoint and a primary effectiveness endpoint. Both endpoints were compared with a pre-specified performance goal, which was based on the outcomes from the ORBIT II trial. What impressed me about the study results was that even though lesion complexity and calcification were greater in DISRUPT CAD III than in ORBIT II, the primary safety (30-day freedom from major adverse cardiovascular events) and primary effectiveness endpoint (procedural success) were not only met, but were exceeded.

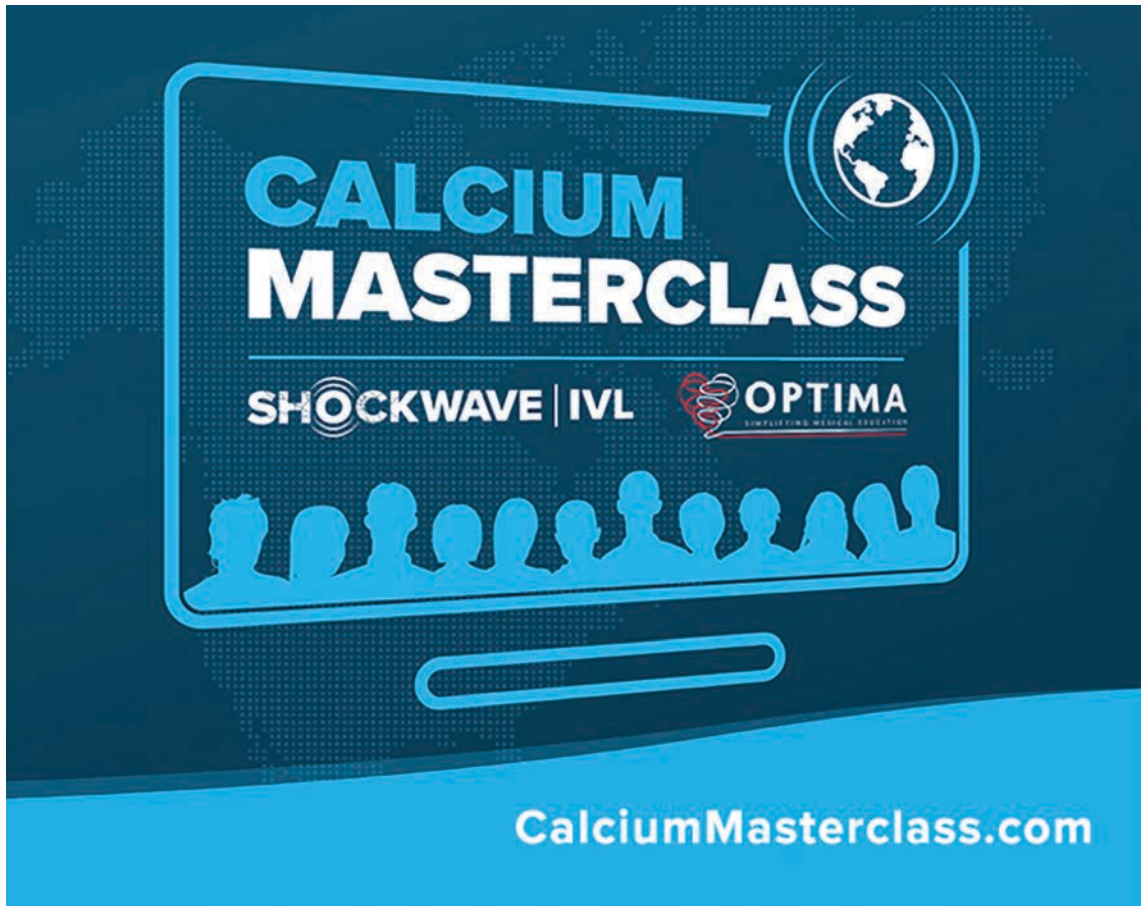
We have had the device at the University of Michigan since this past spring. In my experience, I have found coronary IVL to be very effective and successful. Our patients have done extremely well, including patients with multiple comorbidities and a high burden of calcification. One aspect that sometimes will come up is deliverability of the IVL balloon. If you have a very torturous blood vessel, be aware that the deliverability of the IVL catheter is similar to a non-compliant balloon and should be sized 1:1 to the coronary. We have had good success in delivering the IVL balloon using guide extensions when needed.

**I have found coronary IVL to be very effective and successful. Our patients have done extremely well, including patients with multiple comorbidities and a high burden of calcification.**

**What are the potential advantages of coronary IVL versus other calcium-modifying technologies?**

There does seem to be an impressively low rate of procedural complications with IVL, and it is also very easy to use. This device is very accessible to operators who may not have access to or be comfortable with rotational or orbital atherectomy, though there are still cases where atherectomy will be necessary. IVL may be useful in patients where historically we have shied away from using atherectomy because of patient risk factors, such as in the very elderly, or because of anatomic risk

**Intravascular lithotripsy may be useful in patients where historically we have shied away from using atherectomy because of patient risk factors, such as in the very elderly, or because of anatomic risk factors, such as vessel tortuosity leading to wire bias or proximity to previously placed stents.**




factors, such as vessel tortuosity leading to wire bias or proximity to previously placed stents. Overall, IVL has a safety profile that allows operators to expand vessel calcium modification to more patients. In addition, it may be less time-consuming than atherectomy in some cases. In general, I don't think we will see a significant decline in the use of atherectomy devices now that IVL is available for use in the coronaries. What we will see is that, especially with increasing use of intravascular imaging and availability of IVL, more patients have their coronary calcification treated in a way that it should have been treated all along.

**Any final thoughts?**

Probably one of the greatest things about IVL is that it is just so user friendly. If you can use an angioplasty balloon, you can learn to use this device. There are some minor things that you need to be aware of, such as ventricular ectopics, "shocktopics," especially in patients who have lower heart rates, but it hasn't been much of a problem clinically.[3] I anticipate a growth in IVL use, particularly as increasing use of intravascular imaging will reveal coronary calcification that we have been under-appreciating in the past. ■



*Learn more about coronary intravascular lithotripsy use by visiting Cath Lab Digest's Calcium Corner. Click on the QR Code at right or start at cathlabdigest.com. CLD home page –> Topics –> Calcium Corner*

## References

1. Jurado-Román A, Gonzálvez A, Galeote G, et al. RotaTripsy: combination of rotational atherectomy and intravascular lithotripsy for the treatment of severely calcified lesions. *JACC Cardiovasc Interv*. 2019 Aug 12; 12(15): e127-e129. doi: 10.1016/j.jcin.2019.03.036
2. Hill JM, Kereiakes DJ, Shlofmitz RA, et al; Disrupt CAD III Investigators. Intravascular lithotripsy for treatment of severely calcified coronary artery disease. *J Am Coll Cardiol*. 2020 Dec 1; 76(22): 2635-2646. doi: 10.1016/j.jacc.2020.09.603
3. Wilson SJ, Spratt JC, Hill J, et al. Incidence of "shocktopics" and asynchronous cardiac pacing in patients undergoing coronary intravascular lithotripsy. *EuroIntervention*. 2020 Mar 20; 15(16): 1429-1435. doi: 10.4244/EIJ-D-19-00484

## Suggested Reading

1. Kereiakes DJ, Di Mario C, Riley RF, et al. Intravascular lithotripsy for treatment of calcified coronary lesions: patient-level pooled analysis of the Disrupt CAD studies. *JACC Cardiovasc Interv*. 2021 Apr 20: S1936-8798(21)00715-9. doi: 10.1016/j.jcin.2021.04.015
2. Ali ZA, Nef H, Escaned J, et al. Safety and effectiveness of coronary intravascular lithotripsy for treatment of severely calcified coronary stenoses: the Disrupt CAD II Study. *Circ Cardiovasc Interv.* 2019 Oct; 12(10): e008434. doi: 10.1161/CIRCINTERVENTIONS.119.008434
3. Aksoy A, Salazar C, Becher MU, et al. Intravascular lithotripsy in calcified coronary lesions: a prospective, observational, multicenter registry. *Circ Cardiovasc Interv*. 2019 Nov; 12(11): e008154. doi: 10.1161/CIRCINTERVENTIONS.119.008154
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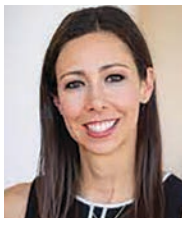
5. Brinton TJ, Ali ZA, Hill JM, et al. Feasibility of Shockwave coronary intravascular lithotripsy for the treatment of calcified coronary stenoses. *Circulation*. 2019 Feb 5; 139(6): 834-836. doi: 10.1161/CIRCULATIONAHA.118.036531

**Use this QR code to access the Calcium Corner directly.**



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**Rx only**
**Indications for Use—** The Shockwave Intravascular Lithotripsy (IVL) System with the Shockwave C2 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 C2 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 non-emergency coronary artery bypass surgery-Emergency or non-emergency 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 warnings, precautions and adverse events. www.shockwavemedical.com/IFU

Please contact your local Shockwave representative for specific country availability and refer to the Shockwave C2 Coronary IVL system instructions for use containing important safety information.