Key Questions

1. Does the evidence demonstrate that Intravascular Lithotripsy (IVL) is effective for the treatment of severely calcified coronary vessels?[1-11] Is there evidence for use in moderately severe calcified coronary vessels?[12]

2. How do we classify the severity of plaque (such as moderate or severe- e.g. calcium angles, plaque without motion)? What definition should be used, and does it make a difference in the outcomes?[11-19]

3. What is the best success measurement for this procedure as it does not seem to be measured consistently in literature? e.g. flow, pressure across the width of the stent, residual diameter stenosis less than 50%, 30%, 20%?

4. What is the best method to evaluate the lesion needed for Intravascular Lithotripsy? E.g. Fractional Flow Reserve (FFR) by CT or invasive, optical coherence tomography, intravascular ultrasound. This is measured by different techniques in many of these articles and does it make a difference in the results?

5. The evidence does not necessarily compare the same artery to the same artery- are there standards on which arteries are appropriate for treatment based on the current evidence?

6. Are there standards set on the techniques for current standard of care procedures (such as rotational or laser atherectomy, cutting balloons, high-pressure balloons, etc.), and do these standards affect the outcomes of these procedures?

7. Please define the a) patient population and b) angiographic criteria for which lithotripsy would be the preferred procedure or alternative to the current procedures (rotational or laser atherectomy, cutting balloons, high pressure ballons, etc.) for calcified coronary artery lesions. Please opine in context to these issues:

   Shockwave Coronary Lithotripsy (IVL) System with Shockwave C2 Coronary Intravascular Lithotripsy (IVL) Catheter PMA was approved based on the DISRUPT CAD III trial. PMA # P200039. Clinical Trials# NCT03595176. IDE# G180146 (2019). Approval for this device and procedure is indicated for lithotripsy-enabled, low-pressure balloon dilatation of **severely calcified**, stenotic **de novo** coronary arteries prior to stenting. This PMA has very detailed inclusion and exclusion criteria (e.g. lesion site, no ostial lesions, no LM, no totally occluded lesions, target vessel diameter and length, patients without YHA Class III or IV CHF, no chronic dialysis, or creatinine >2.5 , etc.)

FDA S008. 12.13.2022. Approval for the addition of a sterile sleeve and labeling modifications, including an increase in the maximum pulse count from 80 to 120. There is limited data regarding outcomes, safety, or MACE with this increase to 120 maximum pule count.?[1,20]

8. Will lithotripsy be an alternative or adjunct to the established current procedures at the same time of the initial procedure for these severely calcified, stenotic de novo coronary artery lesions?

9. Are there different considerations for treatment depending on the location of the Coronary Artery calcification (CAC) aka which artery is affected? How does IVL compare to the Coronary Artery Bypass Grafting (CABG) for left main CAC? Is there evidence to show IVL is safe for use in left main disease?[3,13,14,16,21-23]

10. Is there long -term outcome data regarding IVL sufficient to support this procedure? Please opine on any long-term outcome data regarding restenosis rates, frequency or need for repeat cardiac intervention procedures or CABG, or MACE compared to the current standard of care procedures (rotational or laser atherectomy, cutting balloons, high pressure ballons, etc.) for calcified coronary artery lesions? How does the safety profile compare to other calcium modification interventions? [11-14,16-19,24,25]

11. Based on the evidence what (if any) measures that should be used to improve safety (eg. Intravascular ultrasound)? US and point system?[21,26,27]

12. How does intravascular lithotripsy compare to other calcium modification techniques for management of this condition?[11-14,16-19,25,28] Are there certain factors/criteria that is considered when choosing the calcium modification technique that will be used?

13. The comparators vary in the studies for instance some articles use rotational atherectomy or orbital atherectomy as the comparator while others do not- how does this impact the outcomes?

14. The technology is FDA approved for severely calcified de novo coronary lesions prior to stenting. There are many reports of off-label use. Based on the evidence what limitations should be considered for this technology?[12-14,18,19,22-24,28-32]
    a. Combined with other calcium modification devices[18]
    b. Used peri-procedure with stent in place[29]
    c. Anatomical locations[13,21,30] (eg. bifurcation, LM)

d. Acute coronary syndrome[18,23,24,29,33,34]
e. Lesions size
f. Total occlusion[12]

15. Does the use of calcium modification devices improve Percutaneous Coronary Intervention (PCI) outcomes? For what duration is outcome data available?[17,22,24,31]

16. Are there different considerations for treatment depending on the location of the CAC aka which artery is affected? How does IVL compare to the CABG for left main CAC? Is there evidence to show IVL is safe for use in left main disease? What are the percentage failures at 1, 5, 10 years?

17. What are the contraindications for Intravascular Lithotripsy? [34]

18. Is it appropriate to perform these procedures in Ambulatory Surgery or Office-Based centers without surgical back-up and if so who (if any) would or would not be eligible?[20]

19. Please opine the additional training and certification requirements for physicians and medical staff (radiology or imaging technicians and RNs, etc.)?

20. What ICD-10 codes do you think are appropriate for this technology?

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