

IVL, the gold standard?

Disclosures

Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Consulting / speaker honoraria: **Shockwave Medical**, Boston Scientific, Teleflex, Asahi Intecc

I use IVL balloons

I use cutting balloons

I use balloons

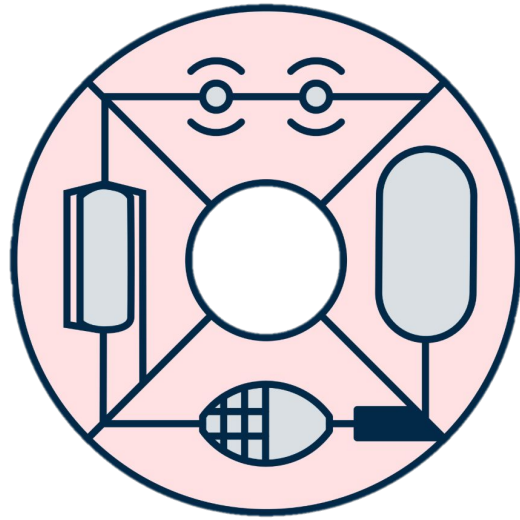
I use rotational atherectomy

What is meant by 'Gold Standard'?

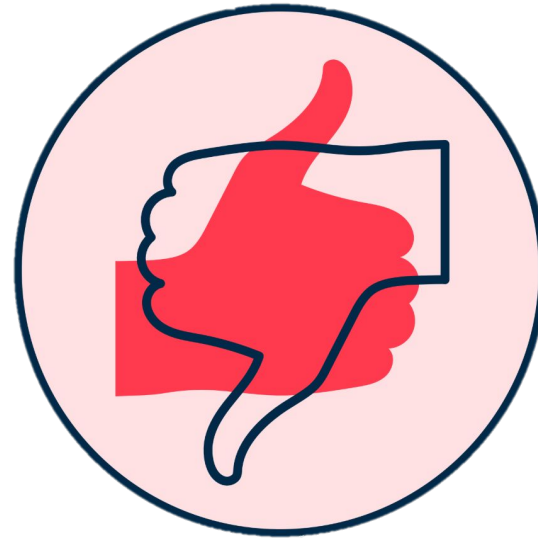
The Gold Standard requires...



Safety



Efficacy

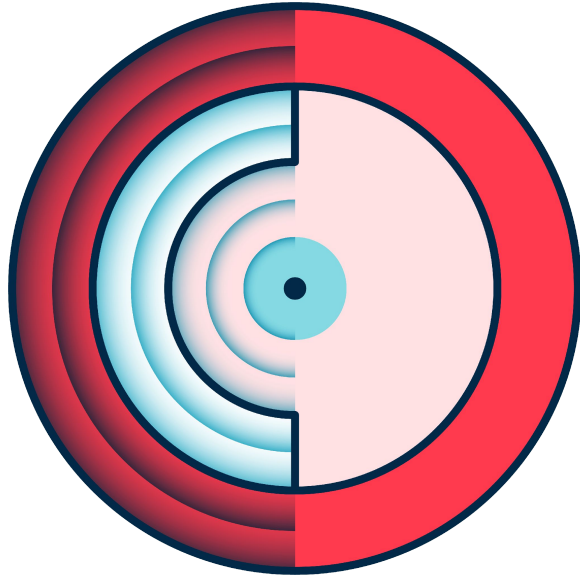


Selectivity

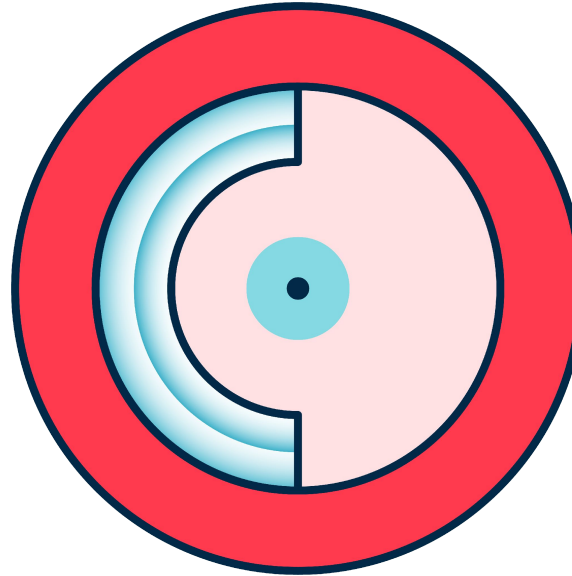


Ease of use

What does selectivity mean?



Target-orientated
Force applied is **always**
orientated to the target



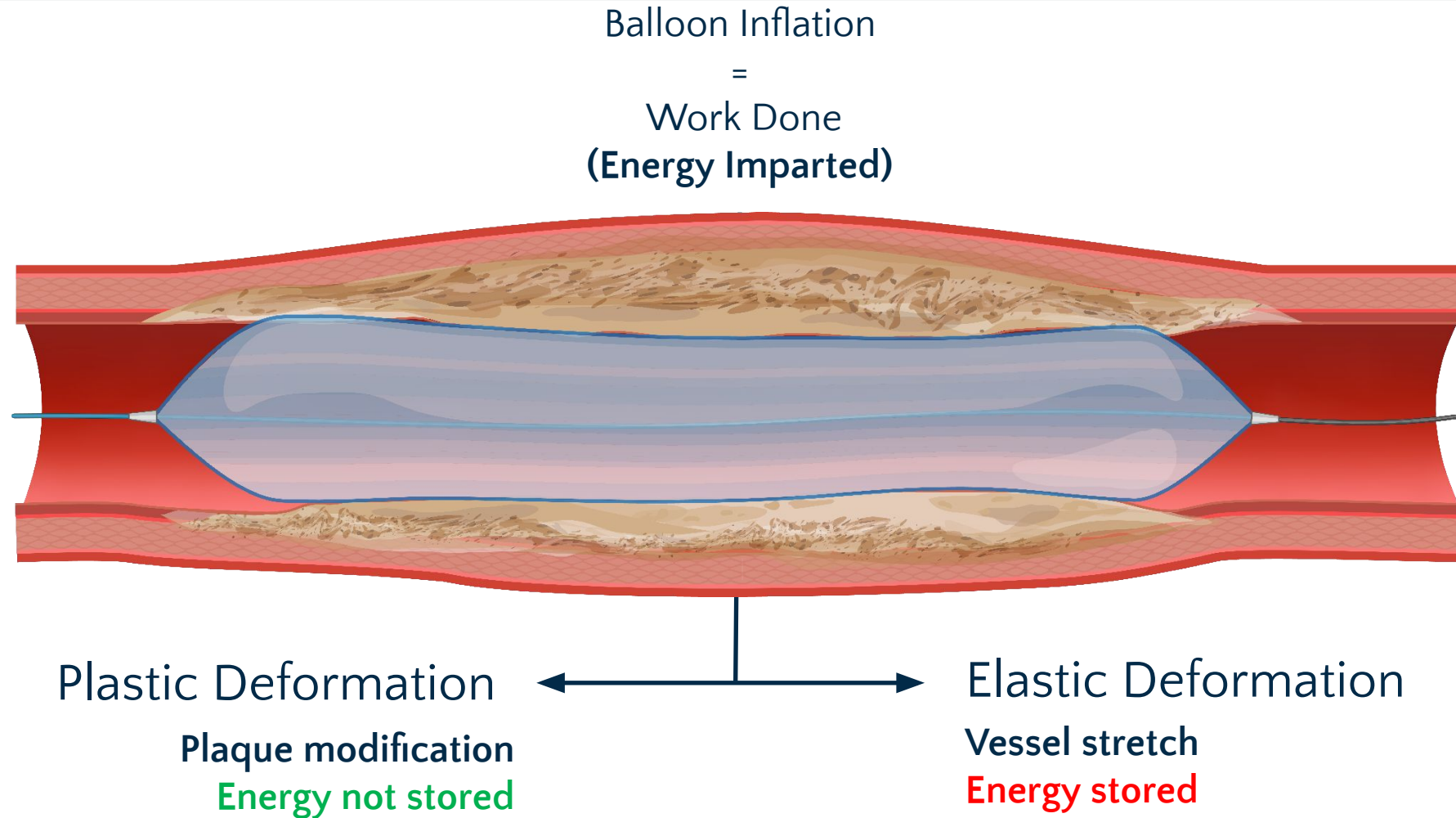
Target-focused
Force is **only** applied
to the target



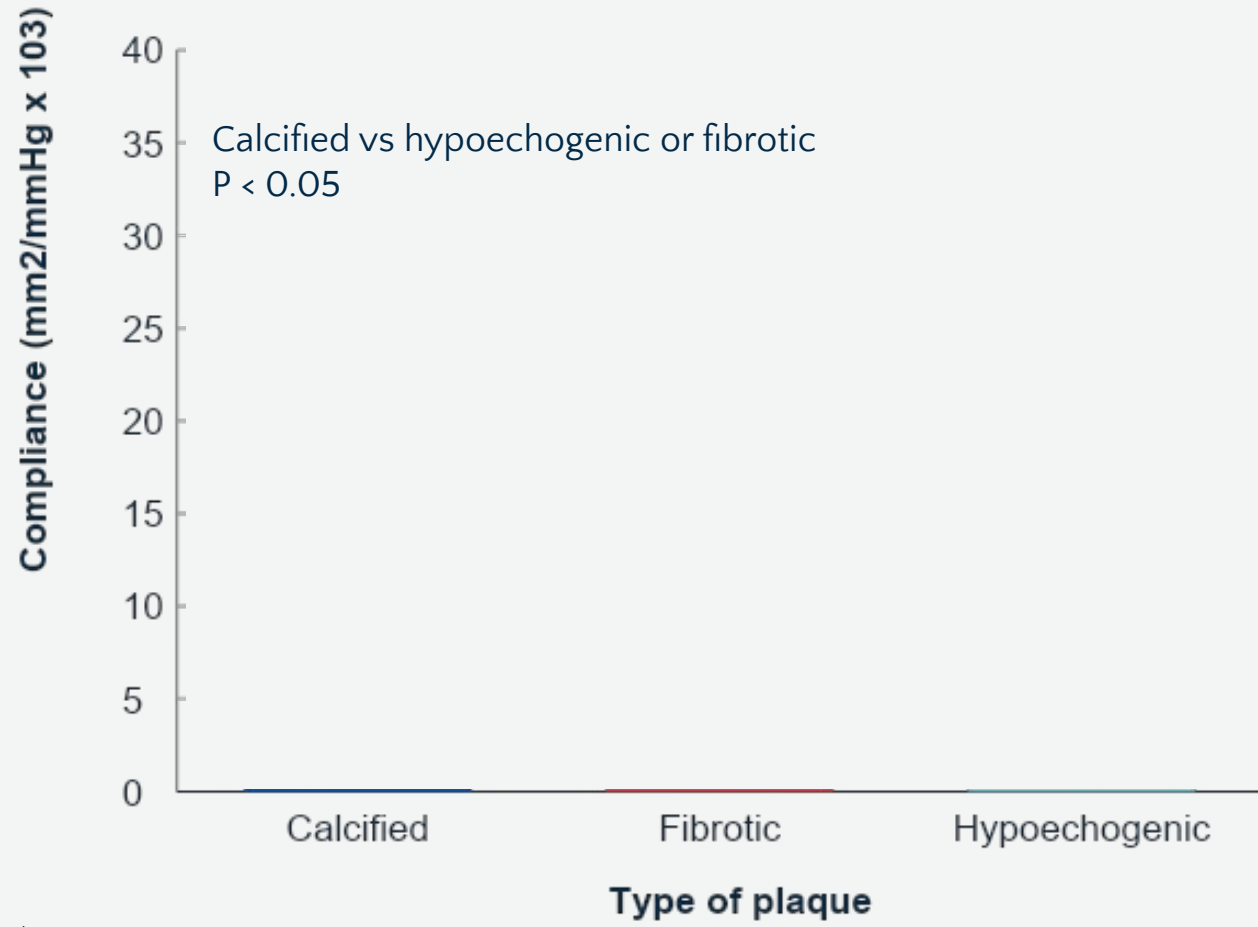
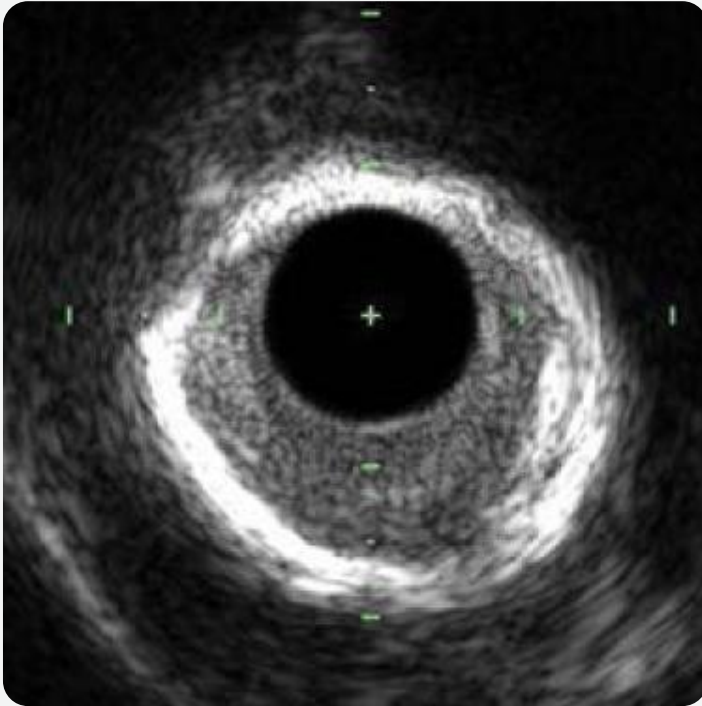
Low risk to vessel
Force applied is safe

How is luminal gain achieved?

Non-calcific disease: Mechanism of luminal gain?



Calcific plaque is non-compliant

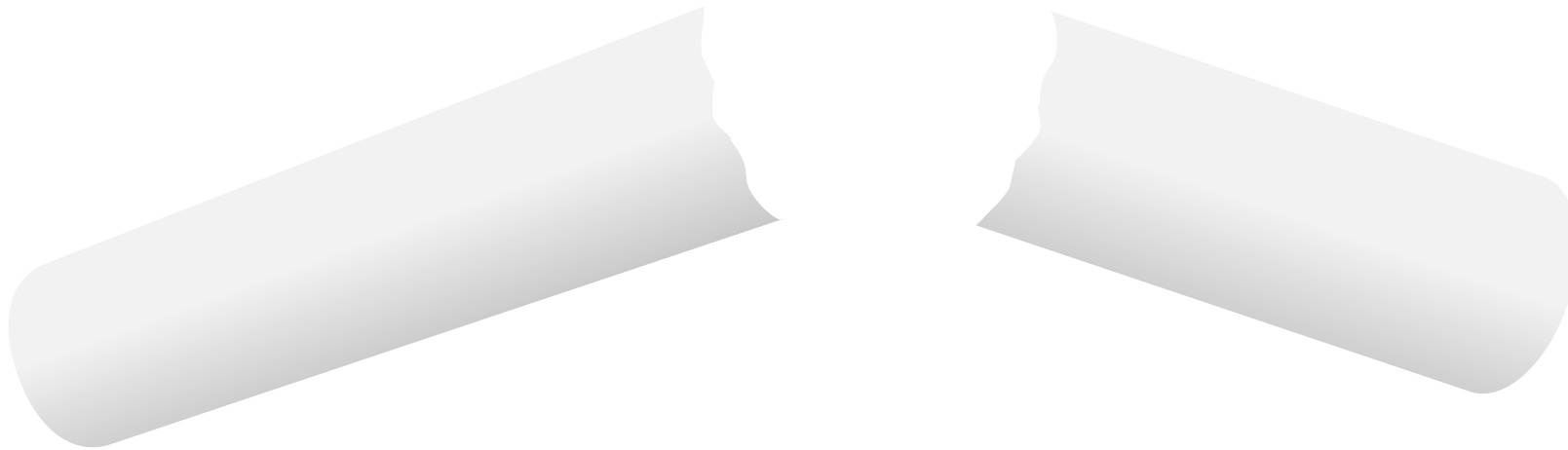


Alfonso F et al, JACC 1994.

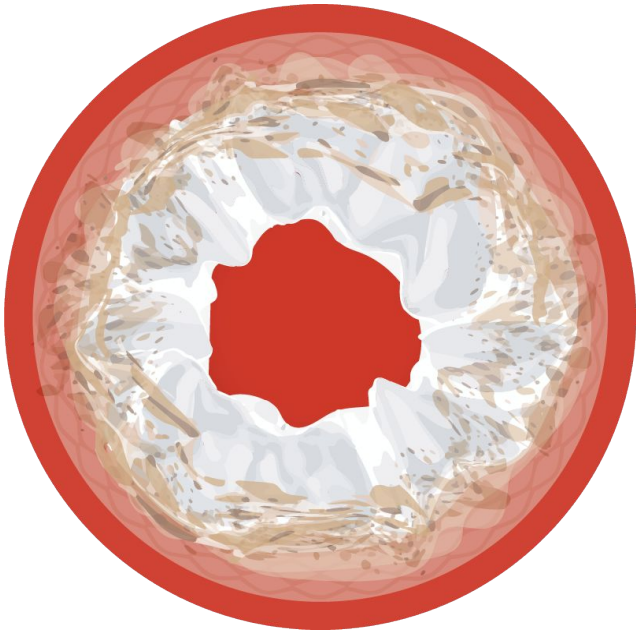
Calcium does not stretch...



Or deform!

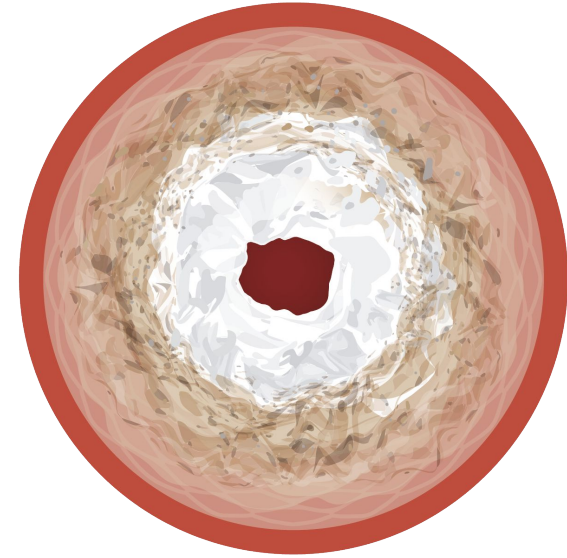
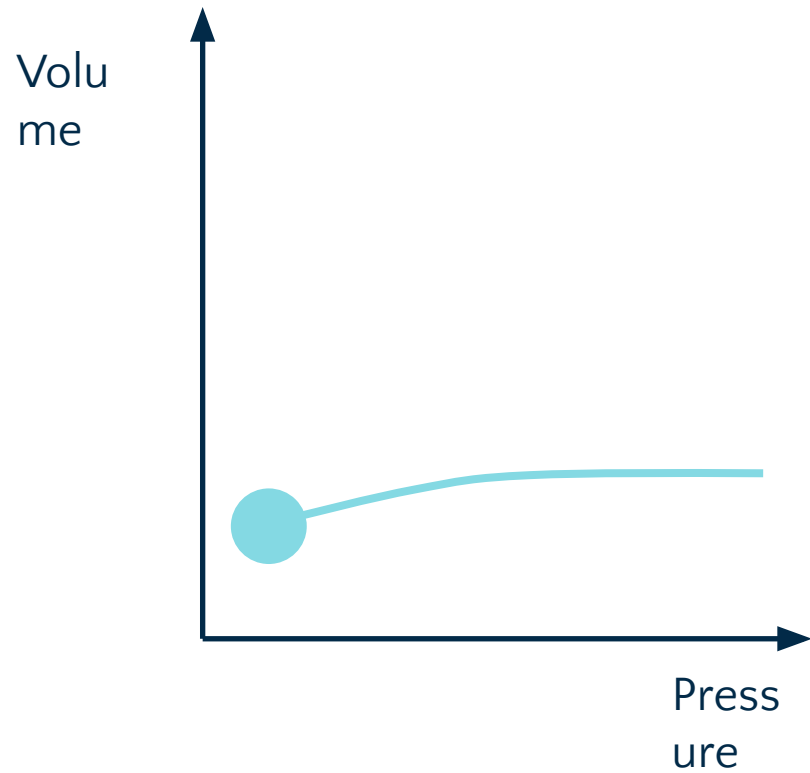


Why does Calcium phenotype matter?

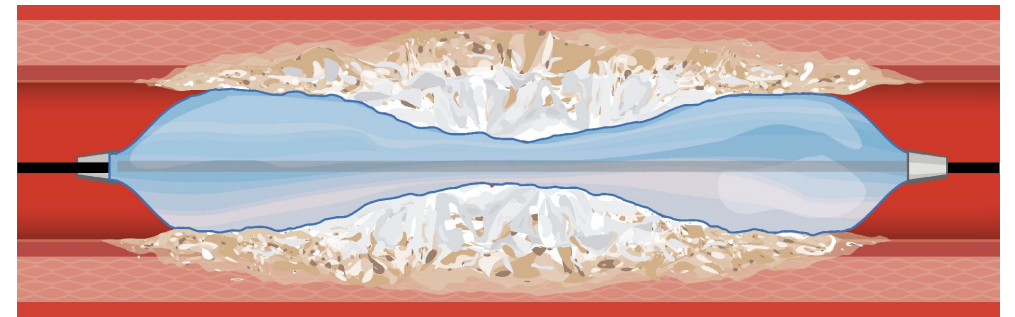
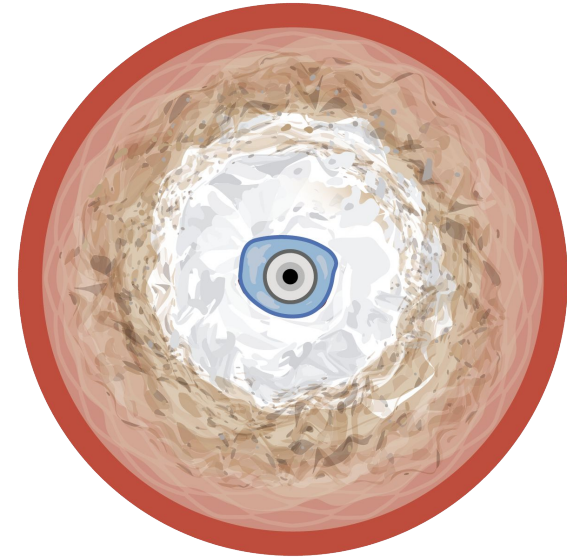
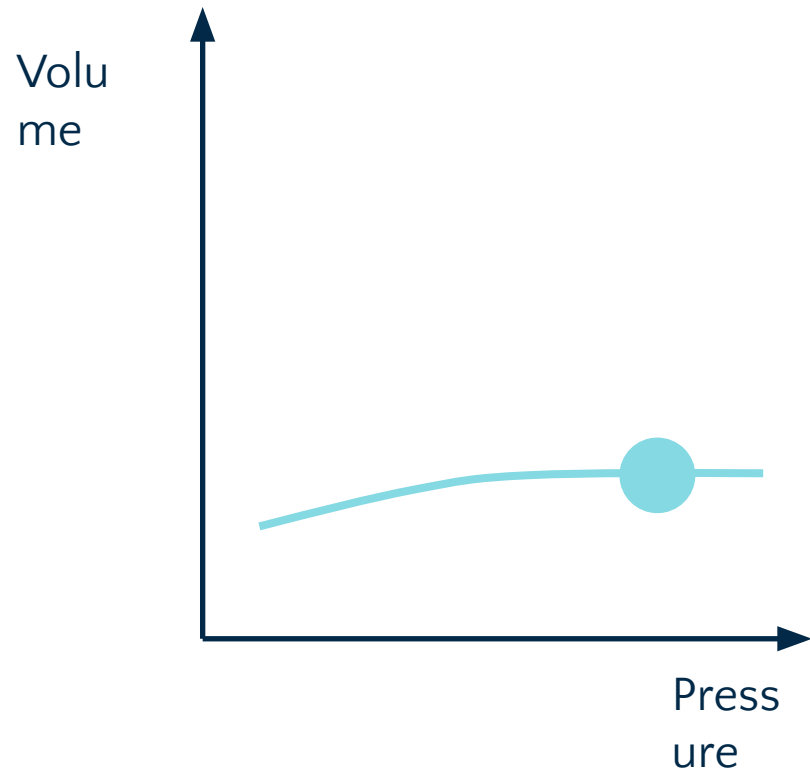


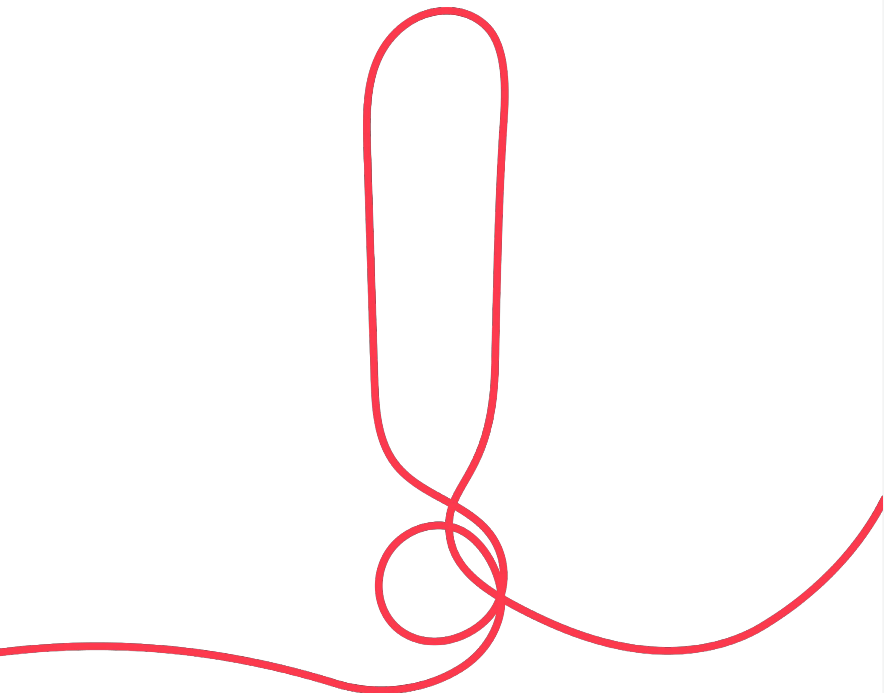
Concentric

Concentric calcium decreases vascular compliance



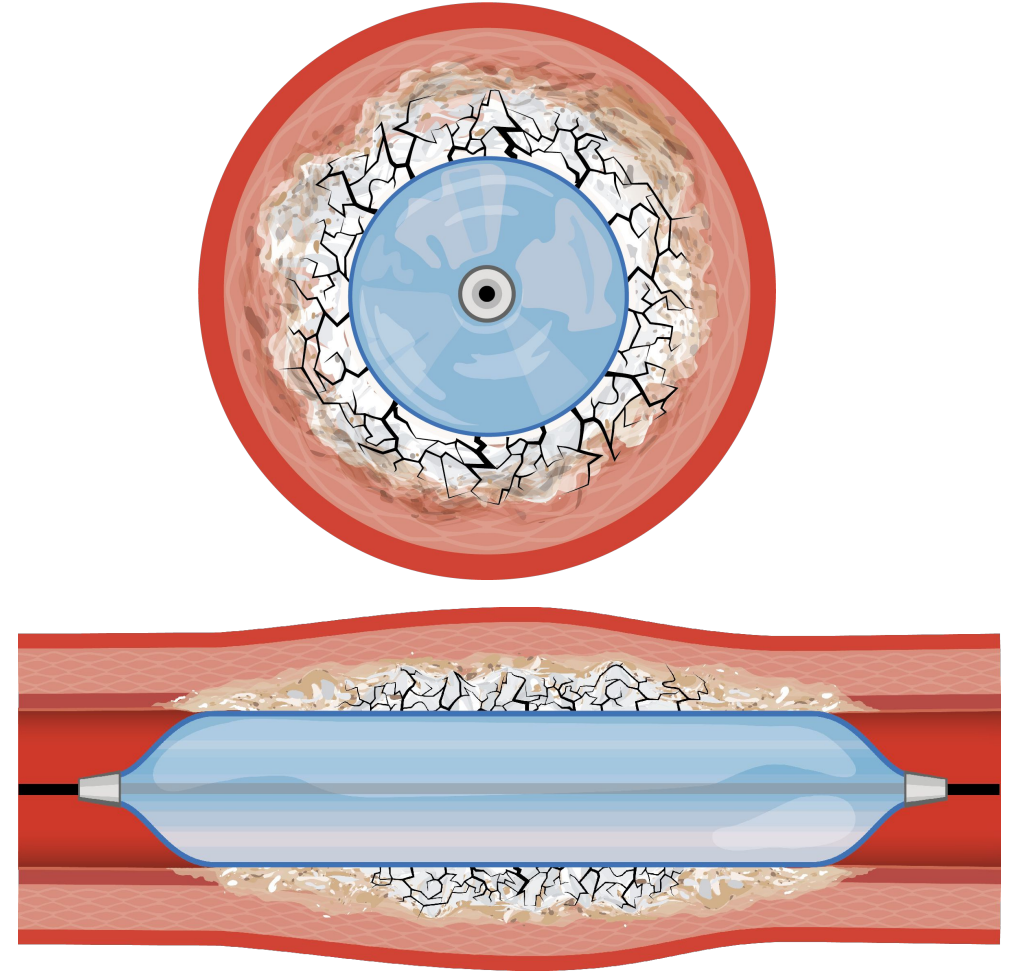
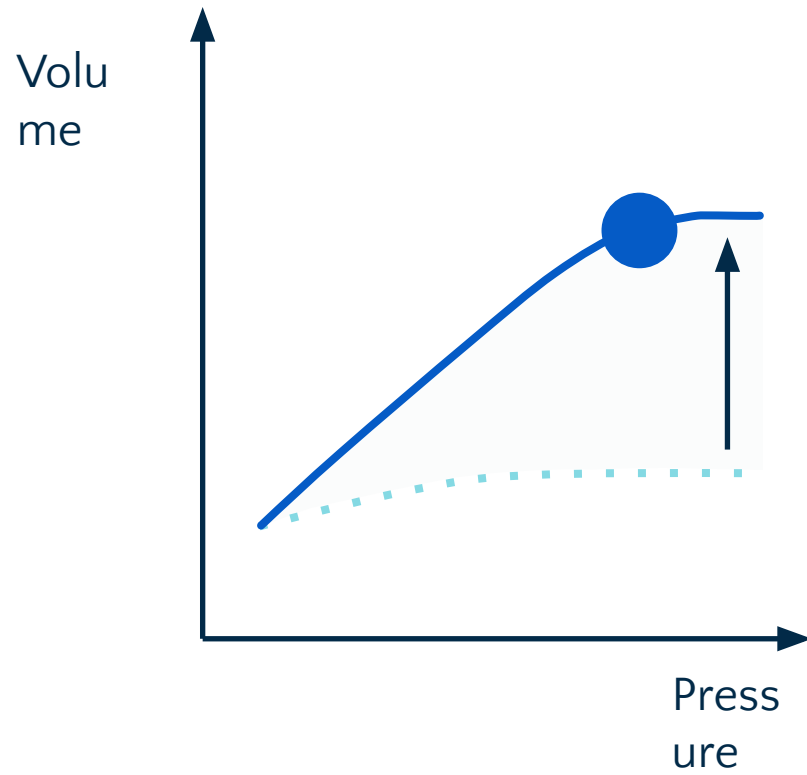
Concentric calcium decreases vascular compliance





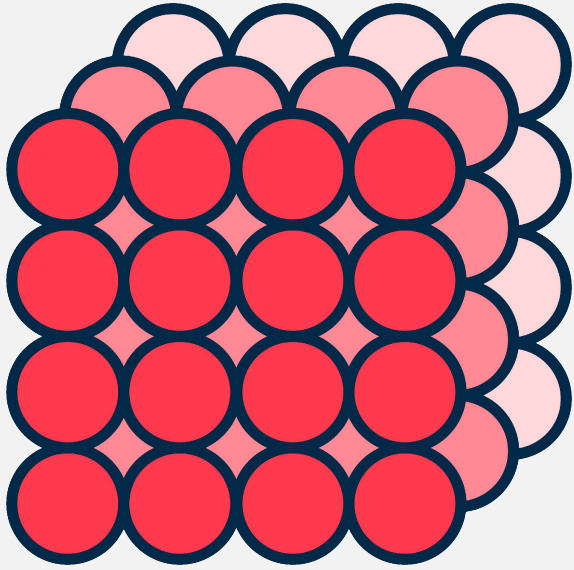
Fracturing confluent
calcium **allows** vessel
stretch

Fractures allow vessel stretch

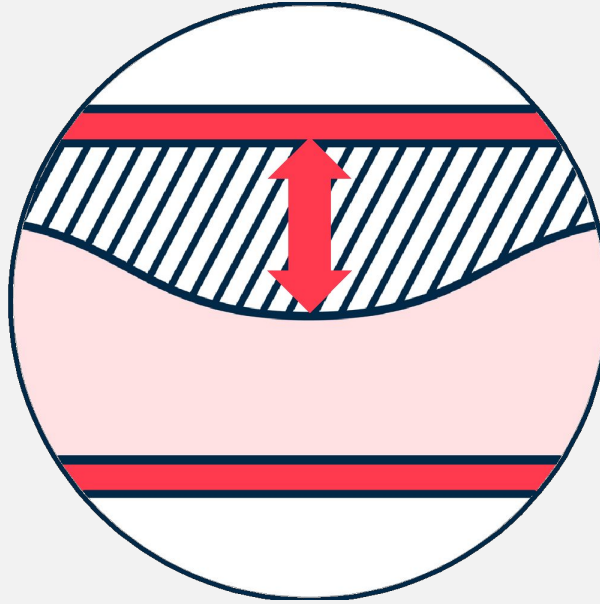


Concentric calcium:
If force applied >
intrinsic resistance =
fractures

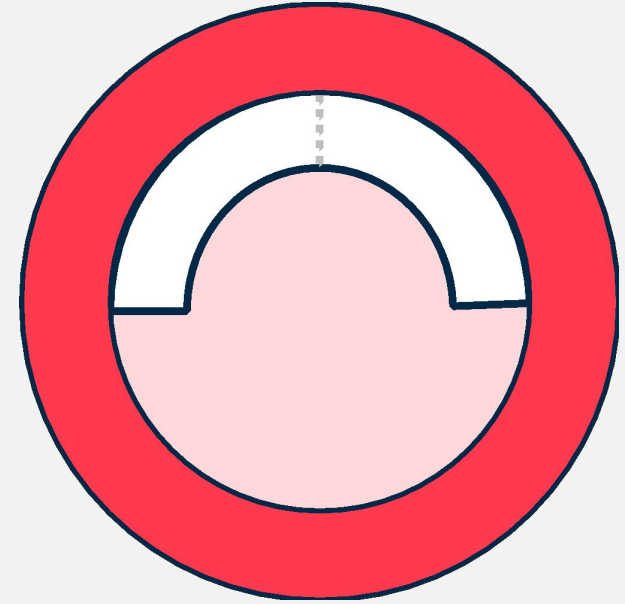
Calcium characteristics may prevent modification by pressure



Density

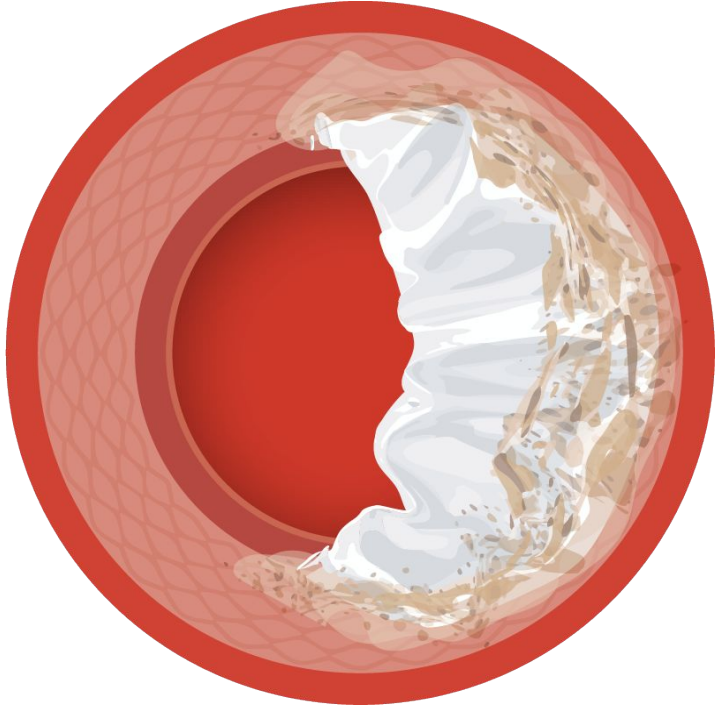


Thickness / Depth



Eccentricity

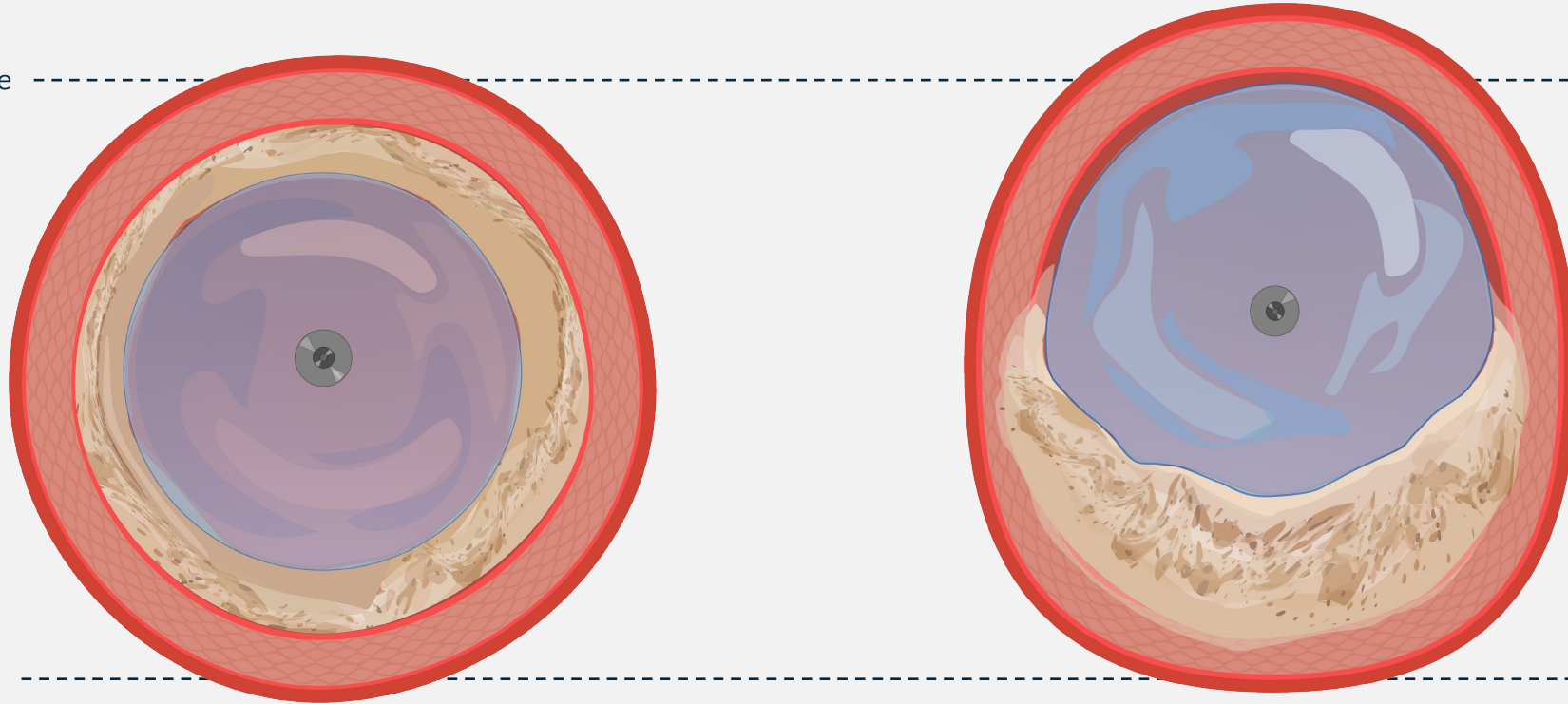
Device Selectivity is most relevant in eccentric calcium



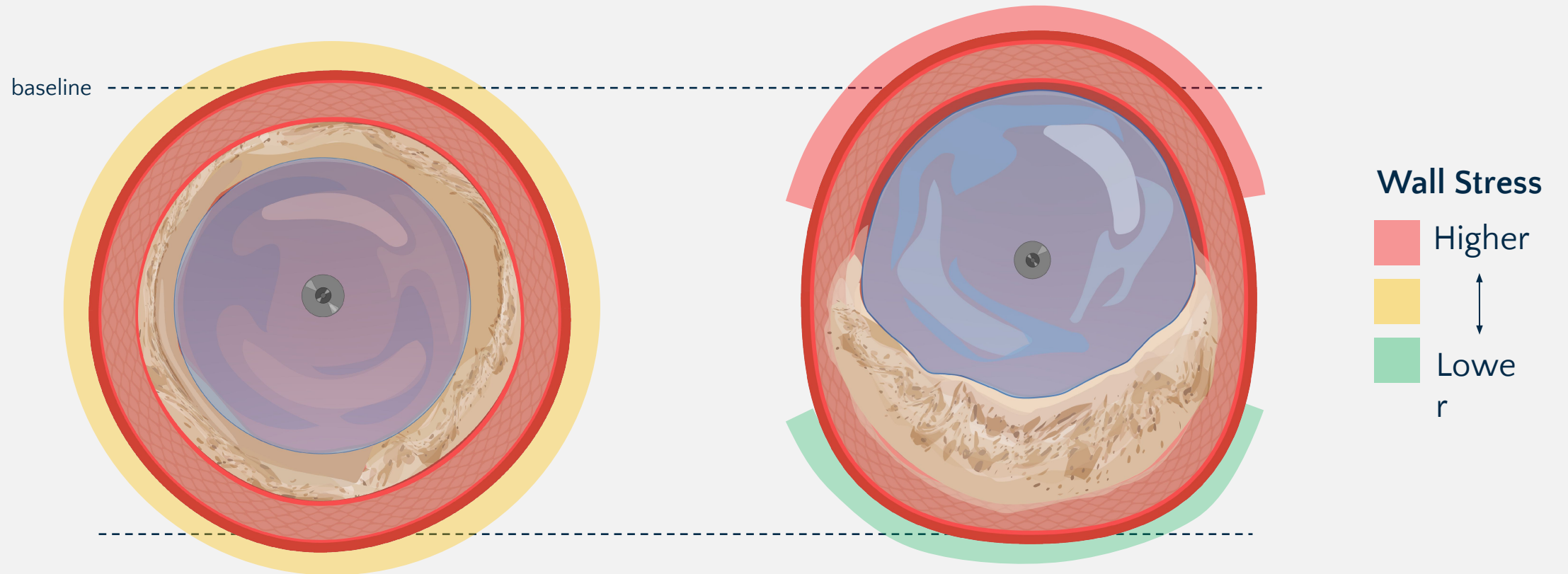
Eccentric

Eccentricity and wall stress

baseline

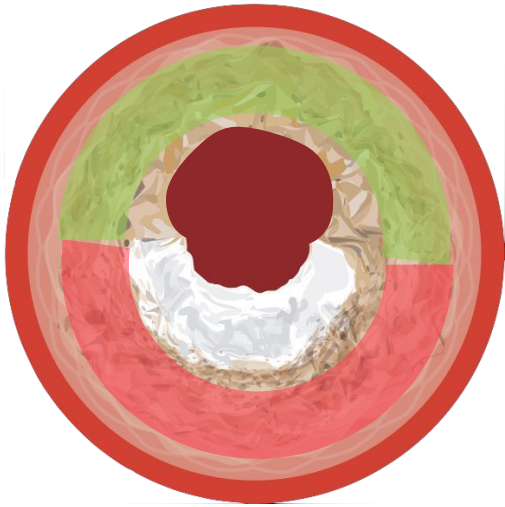


Eccentricity and wall stress

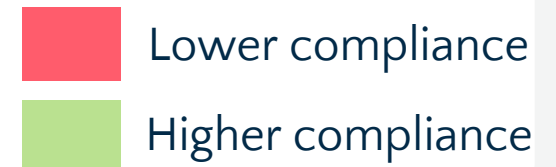
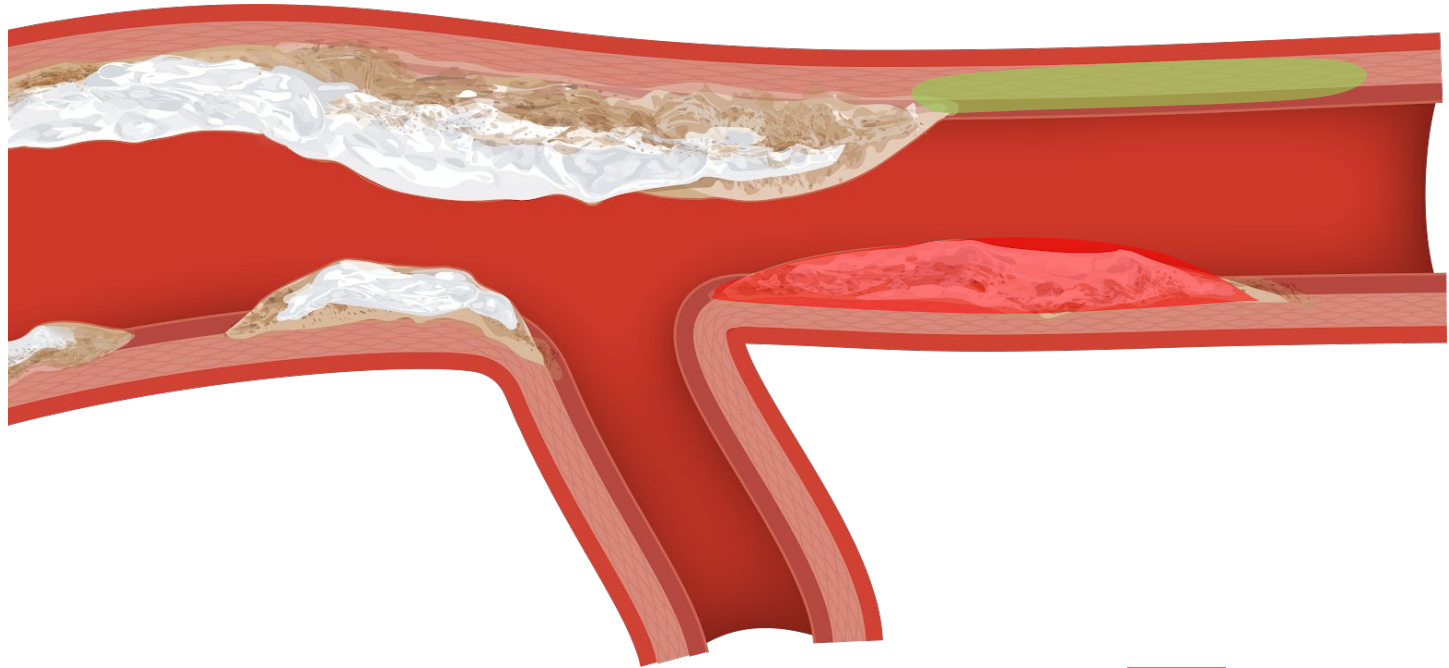


Non-uniform circumferential compliance

Eccentric calcium



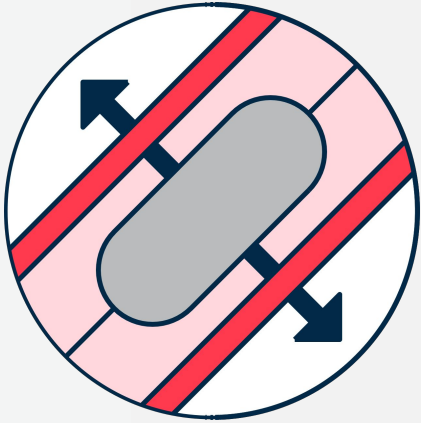
Non-uniform circumferential compliance



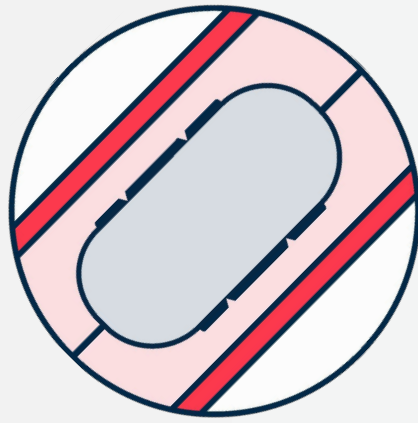
What devices are available?

What are the options?

Balloon-Based Barotrauma

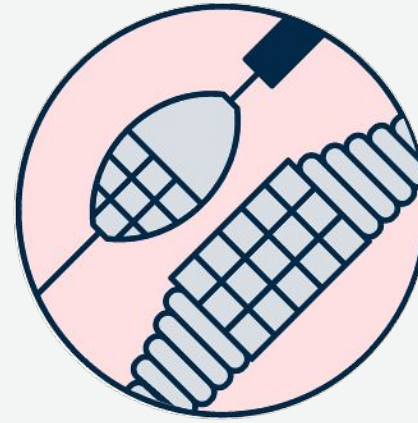


Balloon
Circumferential force



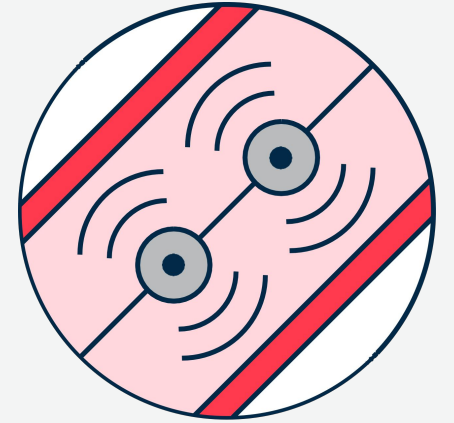
Cutting Balloon
Focused circumferential
force

Atherectomy



Ablative technologies
Rotating drills

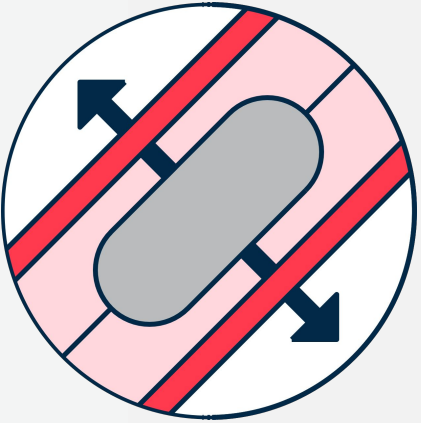
Intravascular Lithotripsy



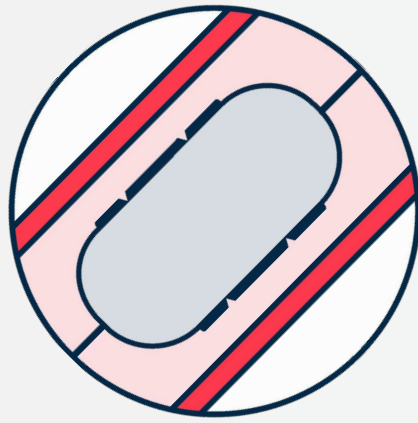
Acoustic Energy
IVL – acoustic
waveform

Balloons

Balloon-Based Barotrauma

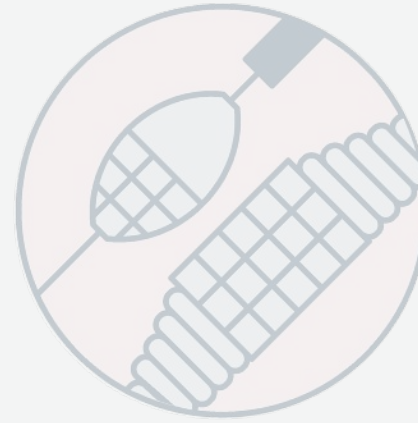


Balloon
Circumferential force



Cutting Balloon
Focused force

Atherectomy



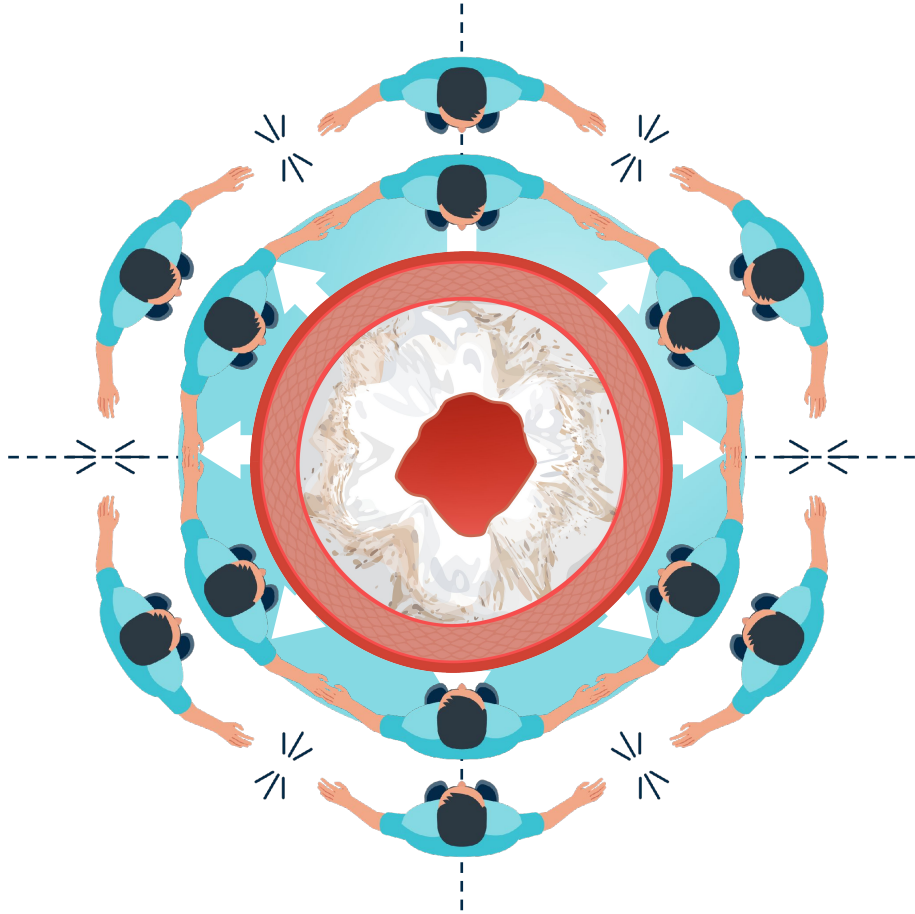
Ablative technologies
Rotating drills

Intravascular Lithotripsy



Acoustic Energy
IVL – acoustic
waveform

MOA of all balloons is the same...

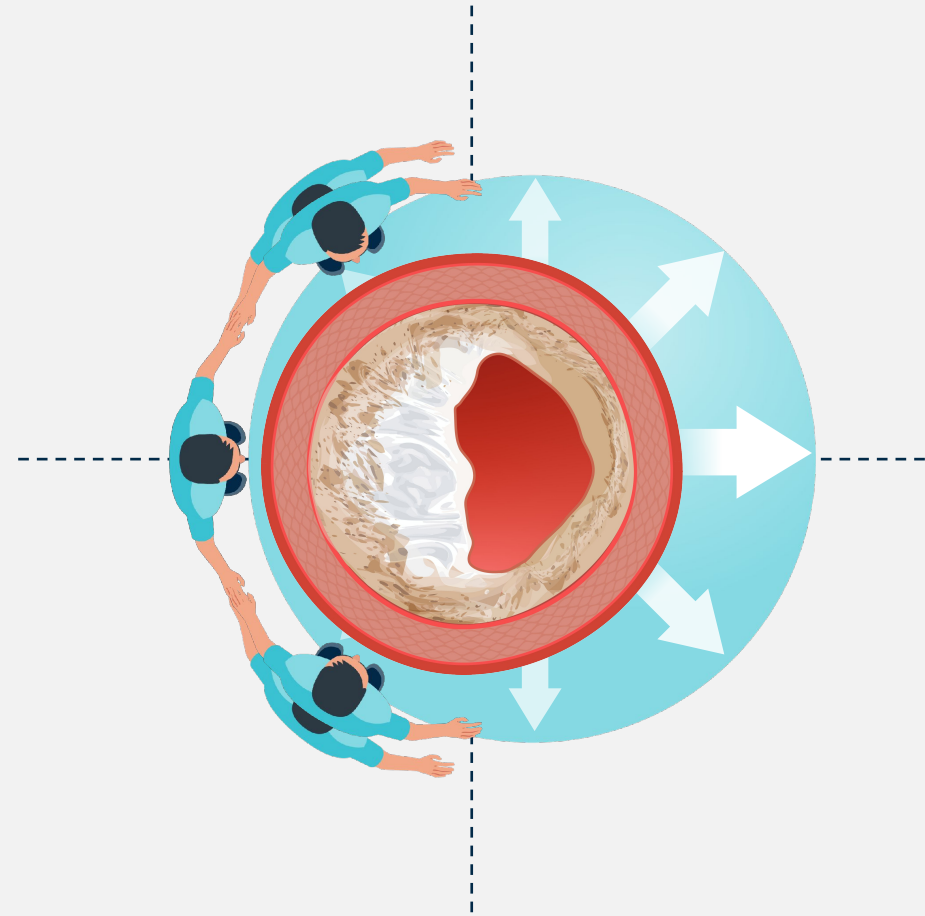
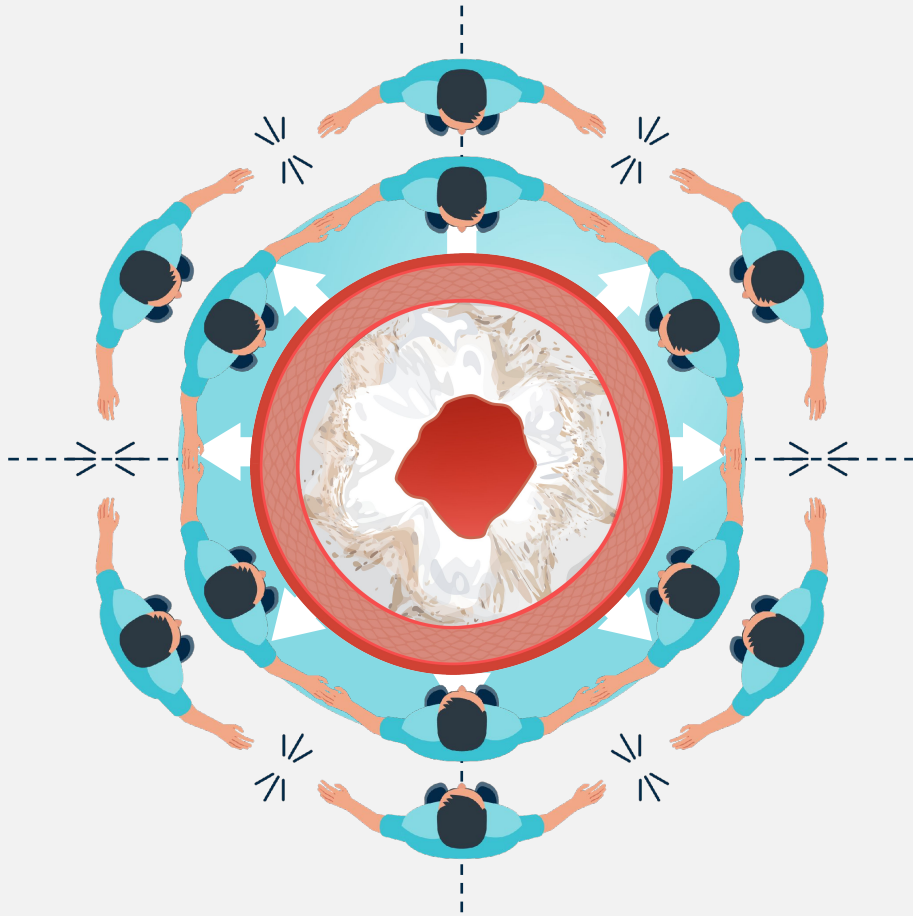


Force delivered by balloon pressure

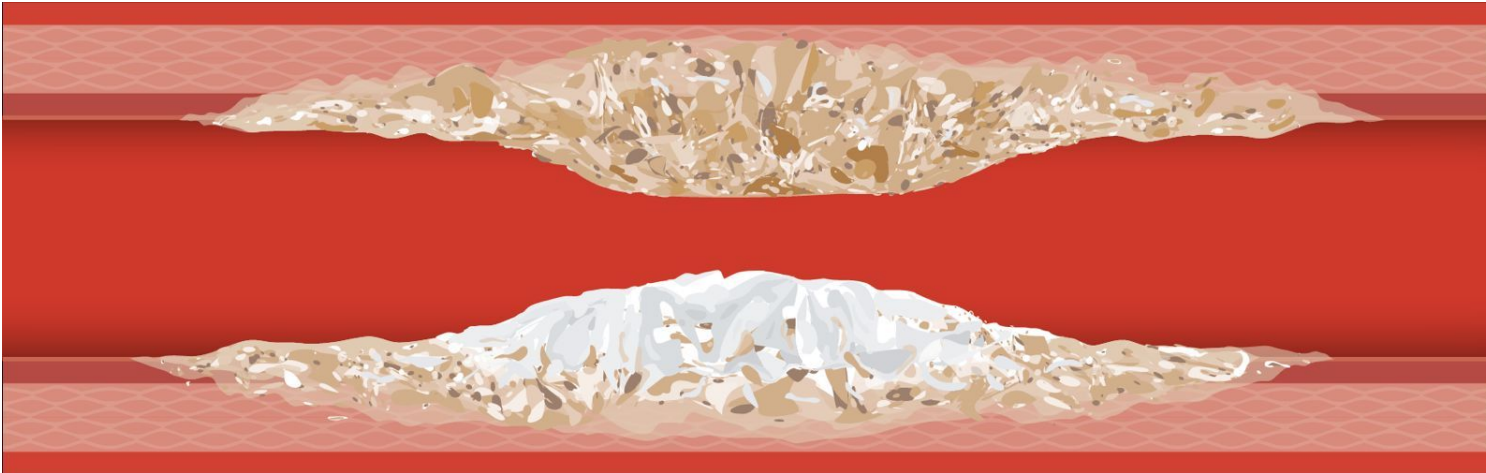
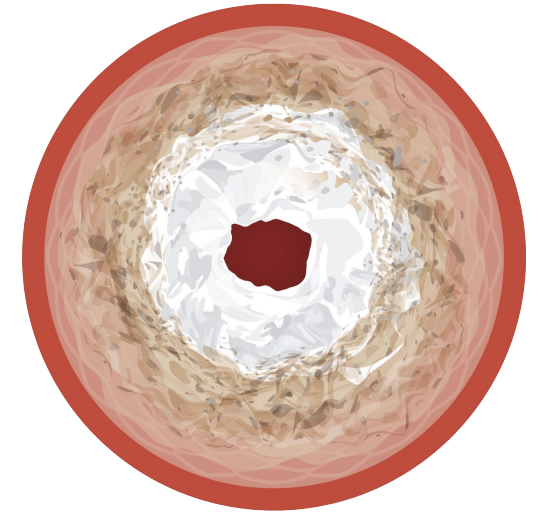
overcomes

Fracture resistance

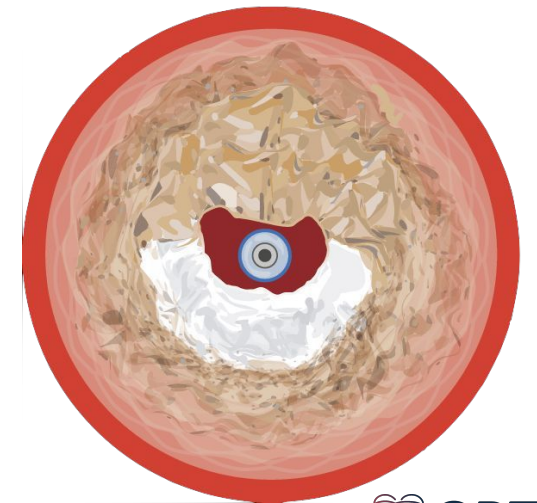
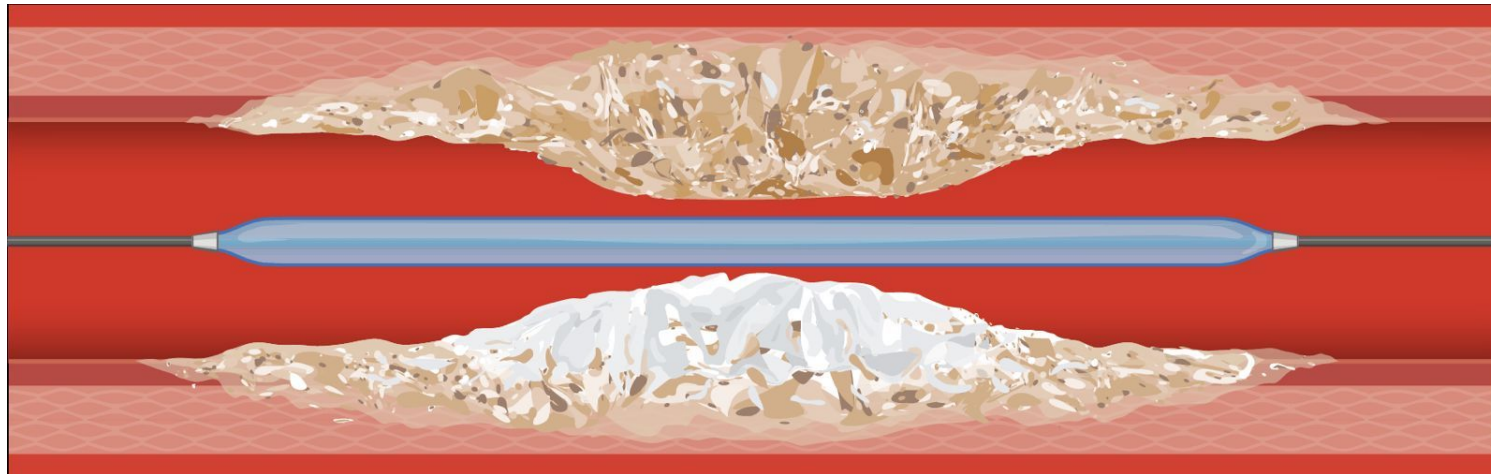
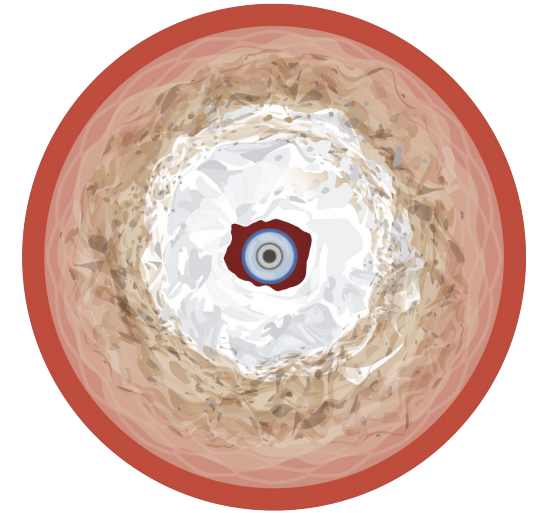
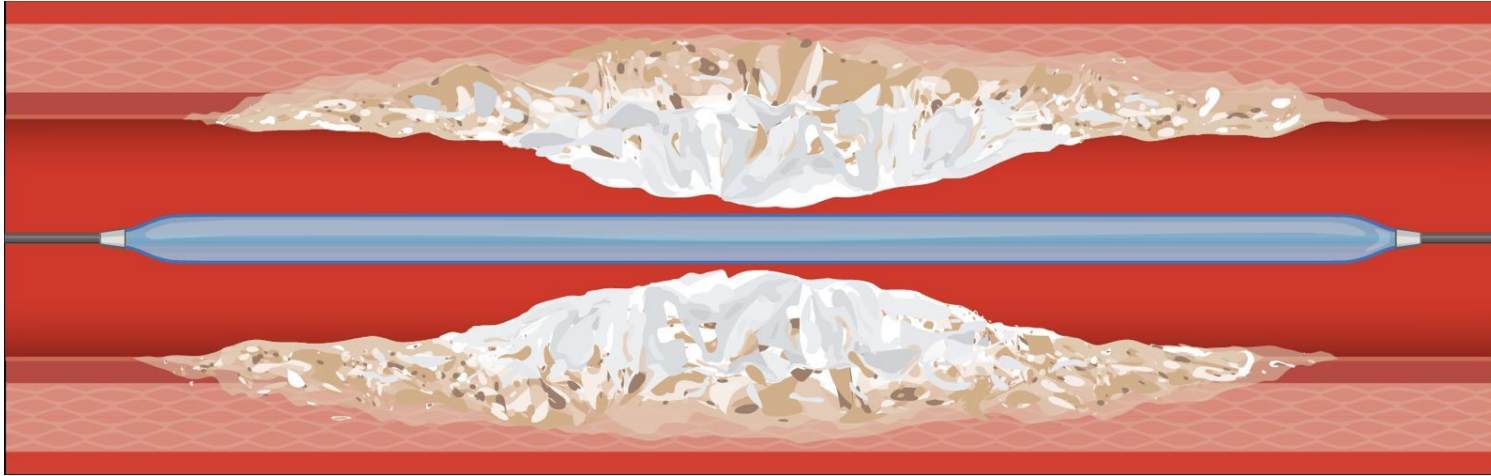
Balloons don't modify eccentric calcium



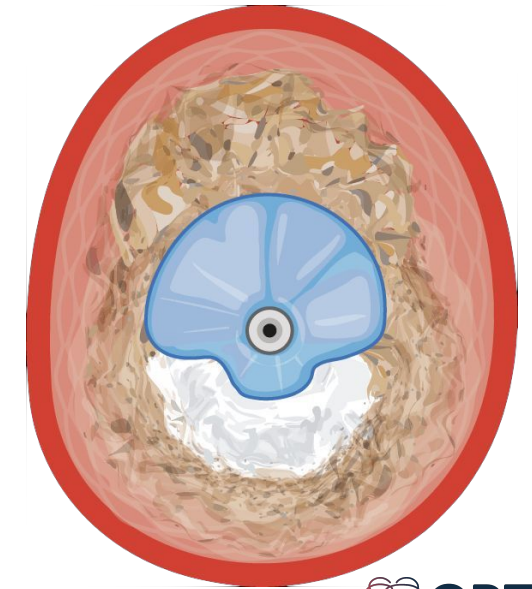
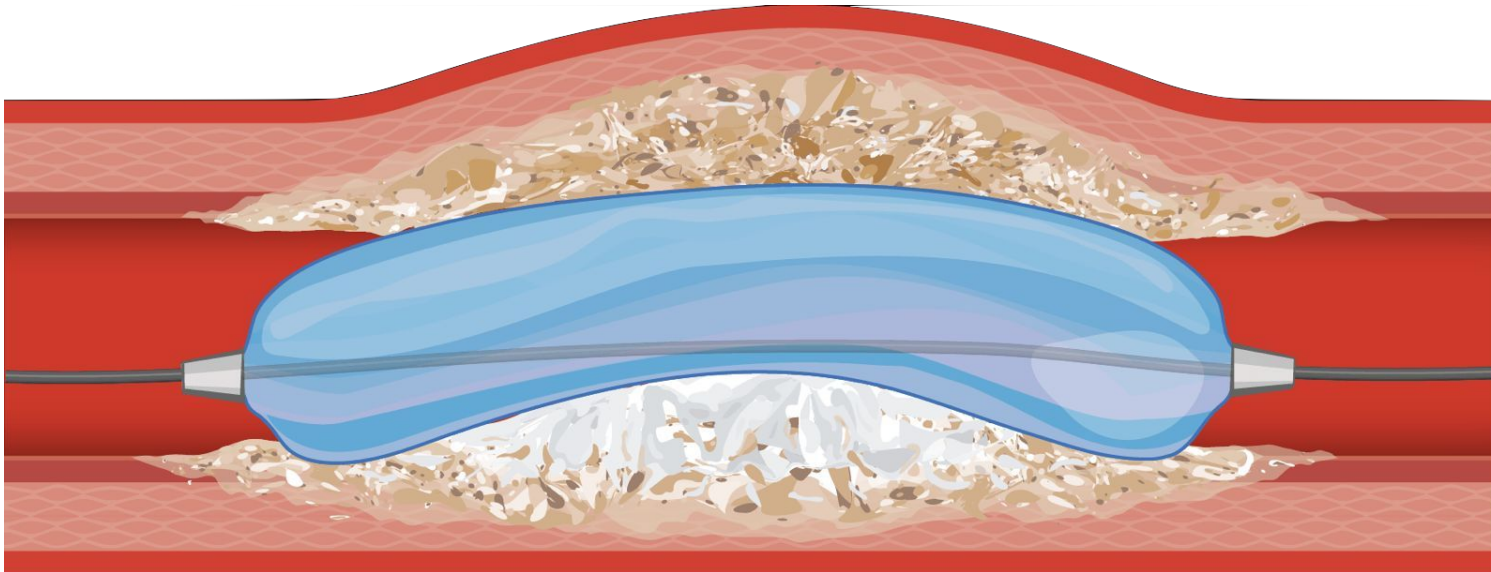
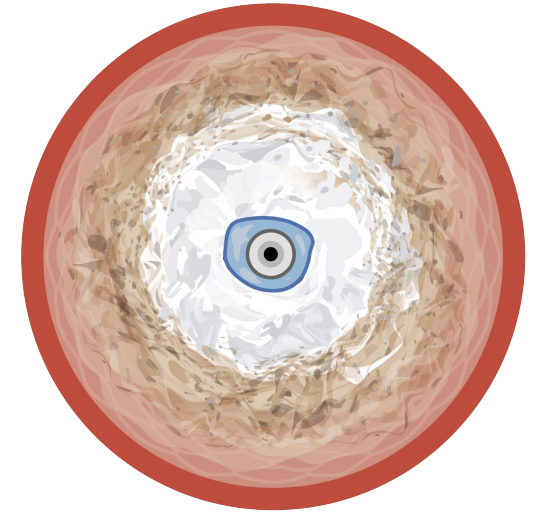
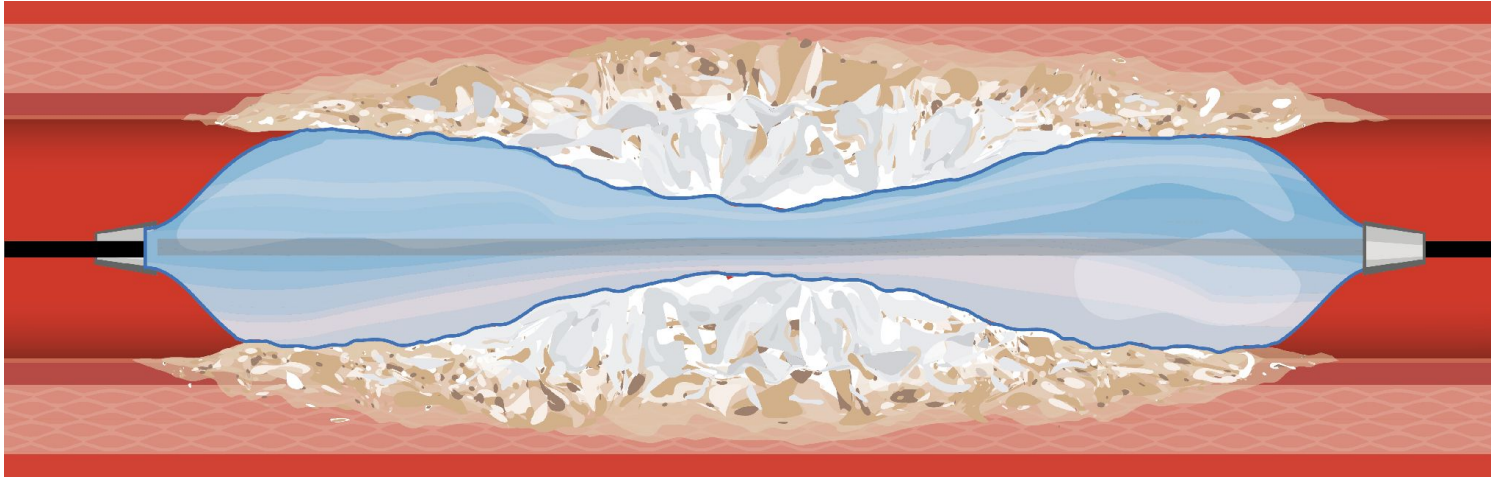
Balloon expansion in concentric vs eccentric calcium



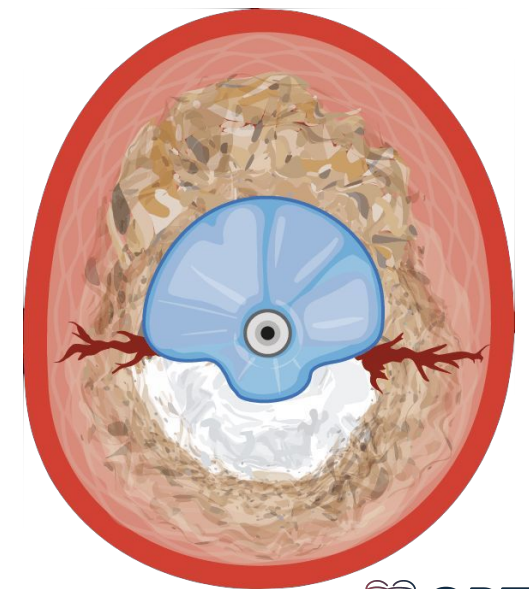
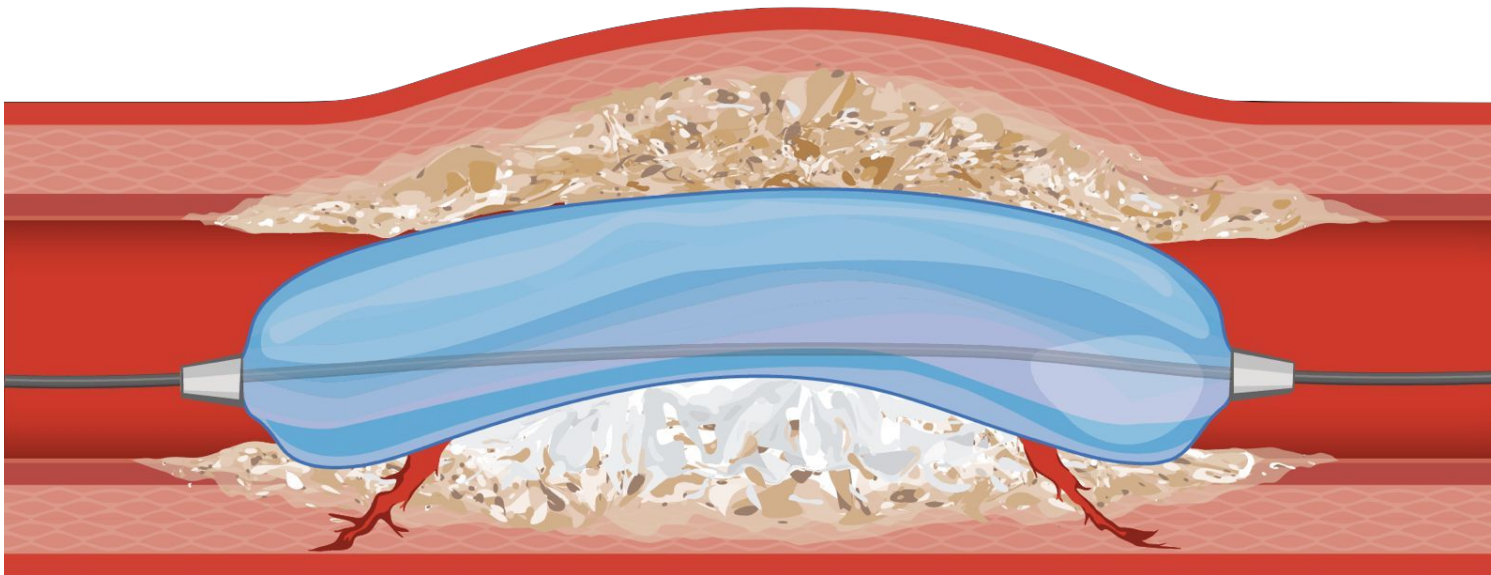
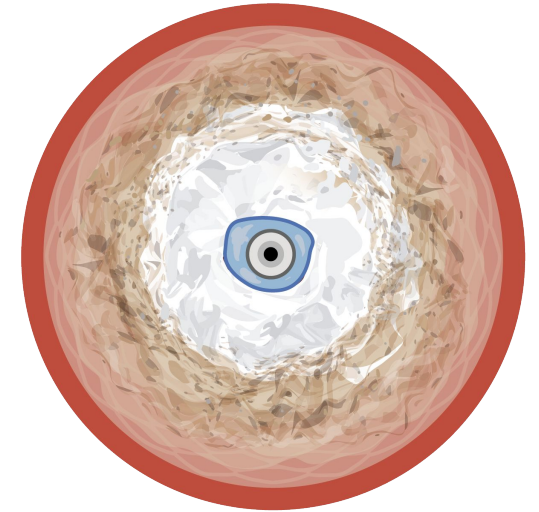
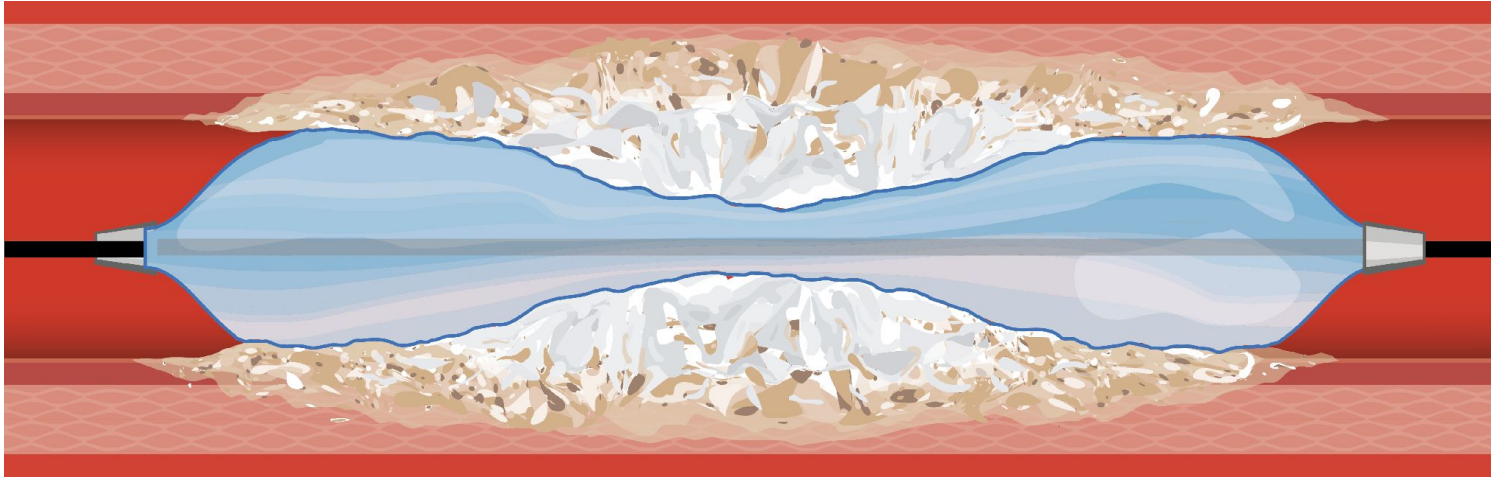
Balloon expansion in concentric vs eccentric calcium



Balloon expansion in concentric vs eccentric calcium

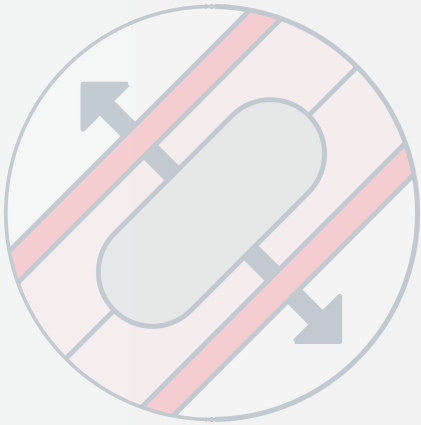


Balloon expansion in concentric vs eccentric calcium



Can IVL provide a solution?

Balloon-Based Barotrauma

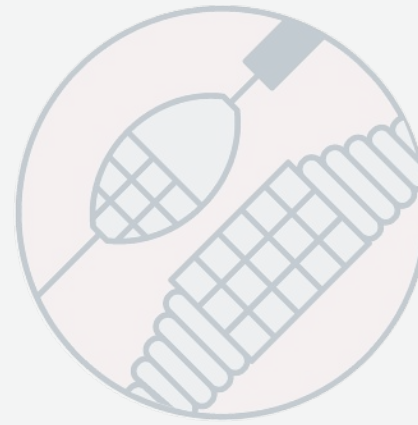


Balloon
Circumferential force



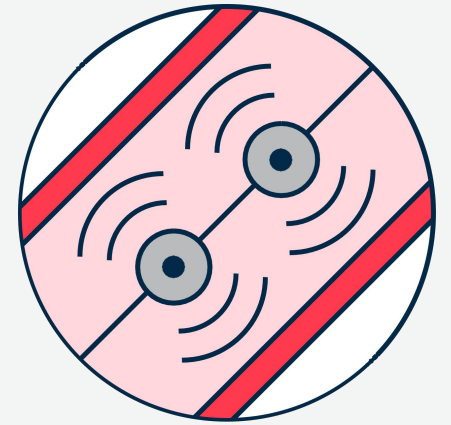
Cutting Balloon
Focused circumferential
force

Atherectomy



Ablative technologies
Rotating drills

Intravascular Lithotripsy

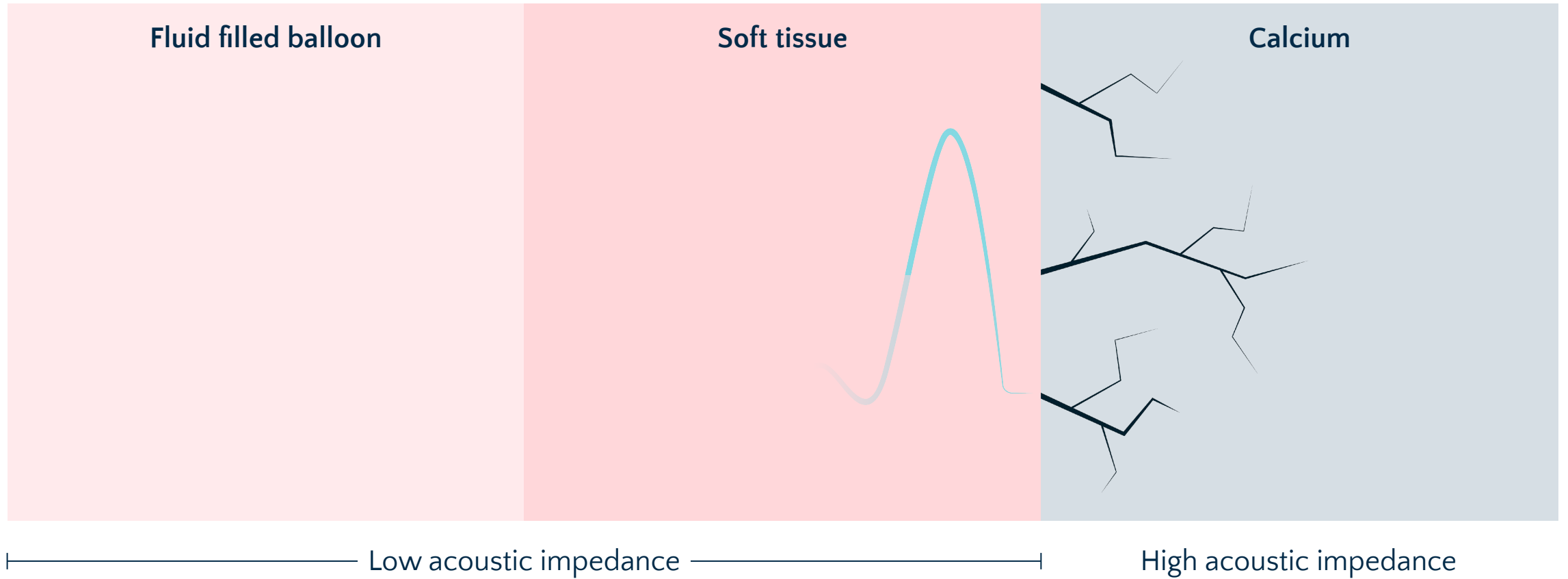


Acoustic Energy
IVL – acoustic
waveform

03

Why are shockwaves selective for calcium?

Shockwaves only generate disruptive forces when they encounter a large **change** in acoustic impedance



IVL induces fractures in multiple planes

Balloon-only

Compressive force only

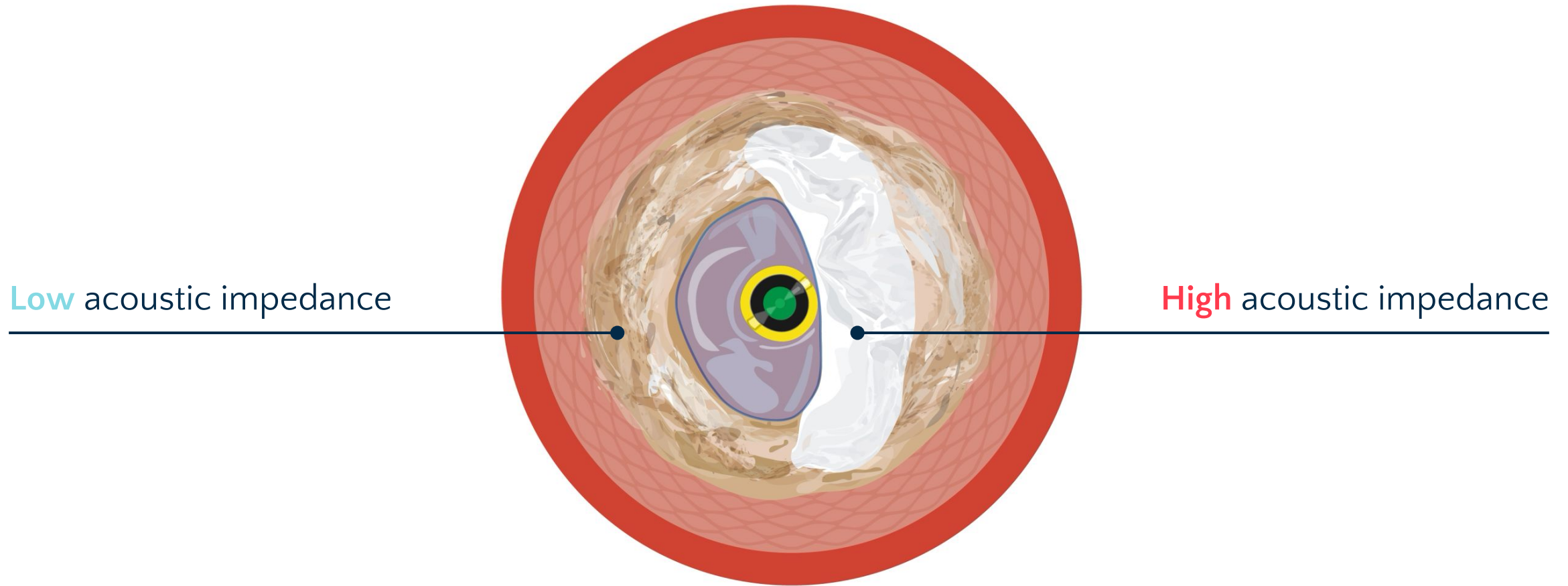


IVL

Multiple mechanisms of fracture

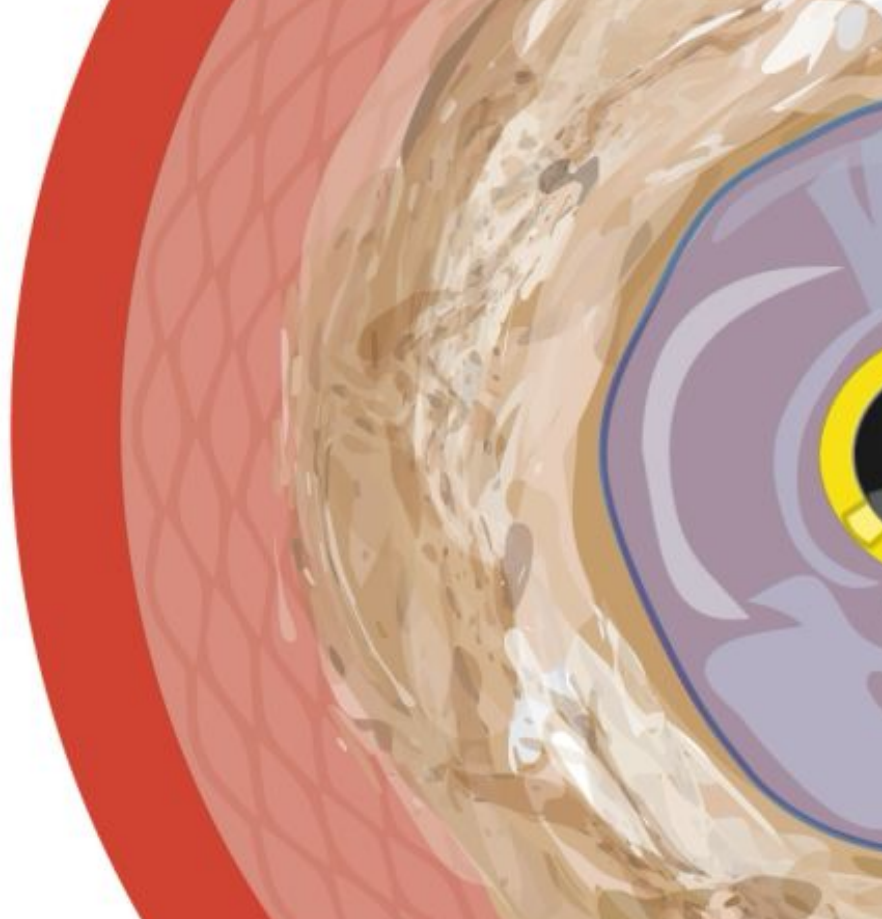


Shockwaves only generate disruptive forces when they encounter a large change in acoustic impedance

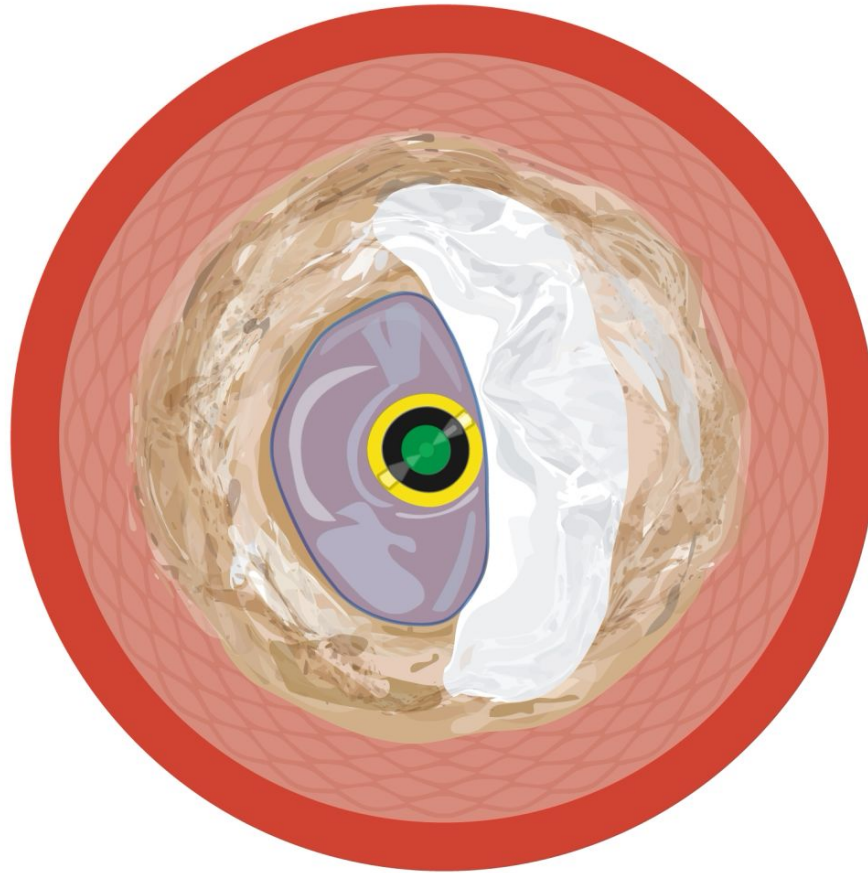


Shockwaves only generate disruptive forces when they encounter a large change in acoustic impedance

Pass harmlessly
through normal vessel



Shockwaves only generate disruptive forces when they encounter a large change in acoustic impedance

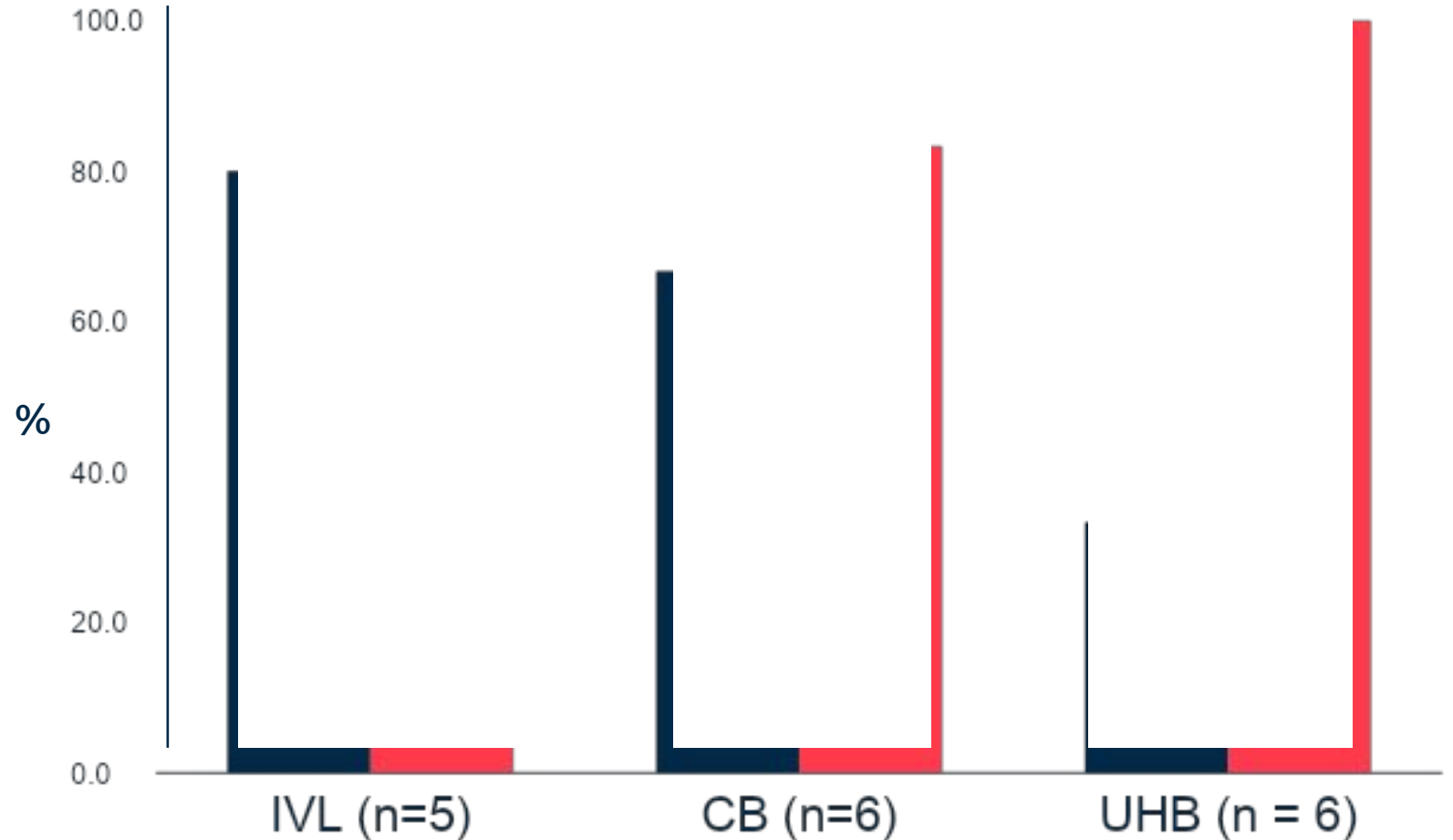


Why does this matter?

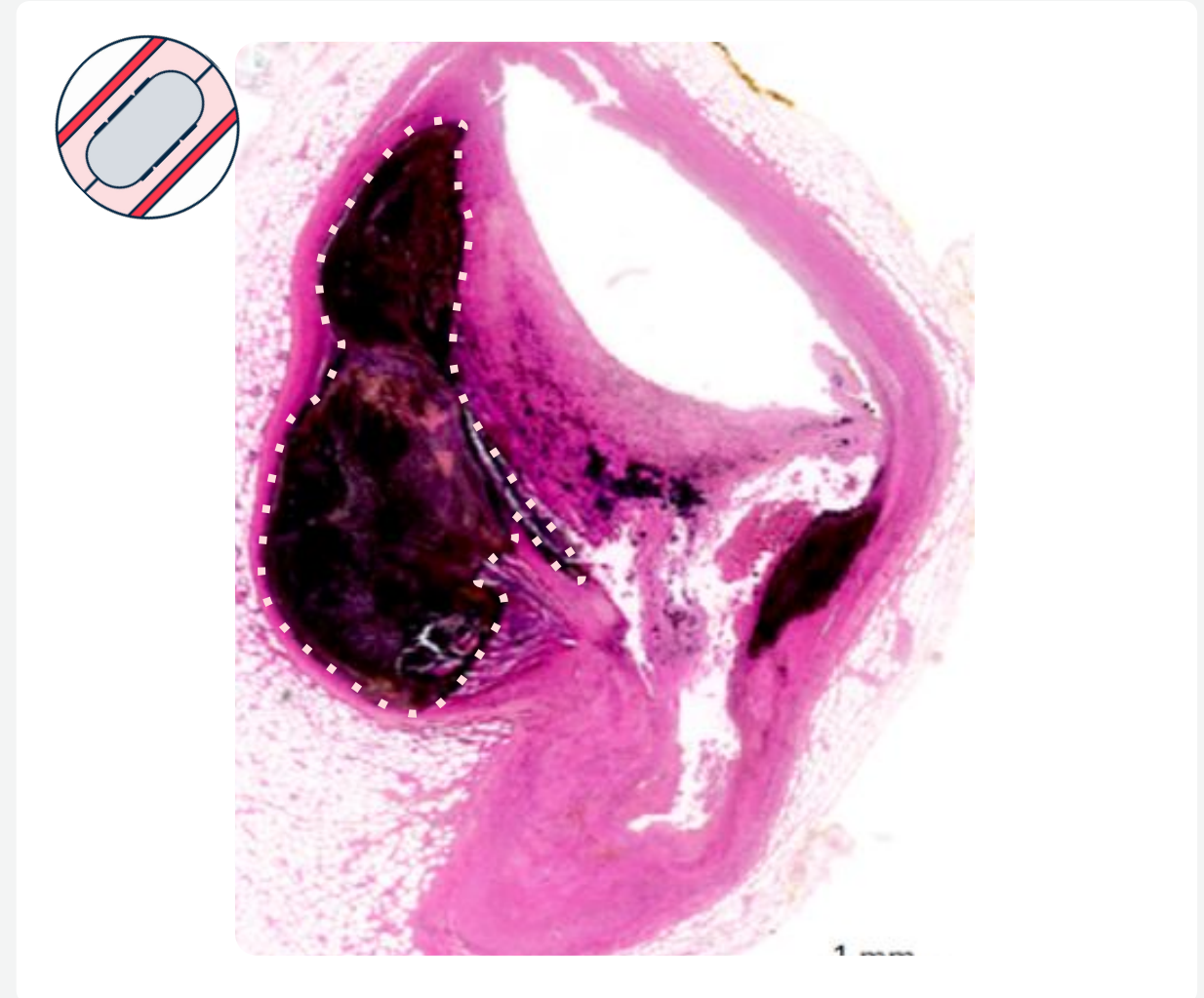
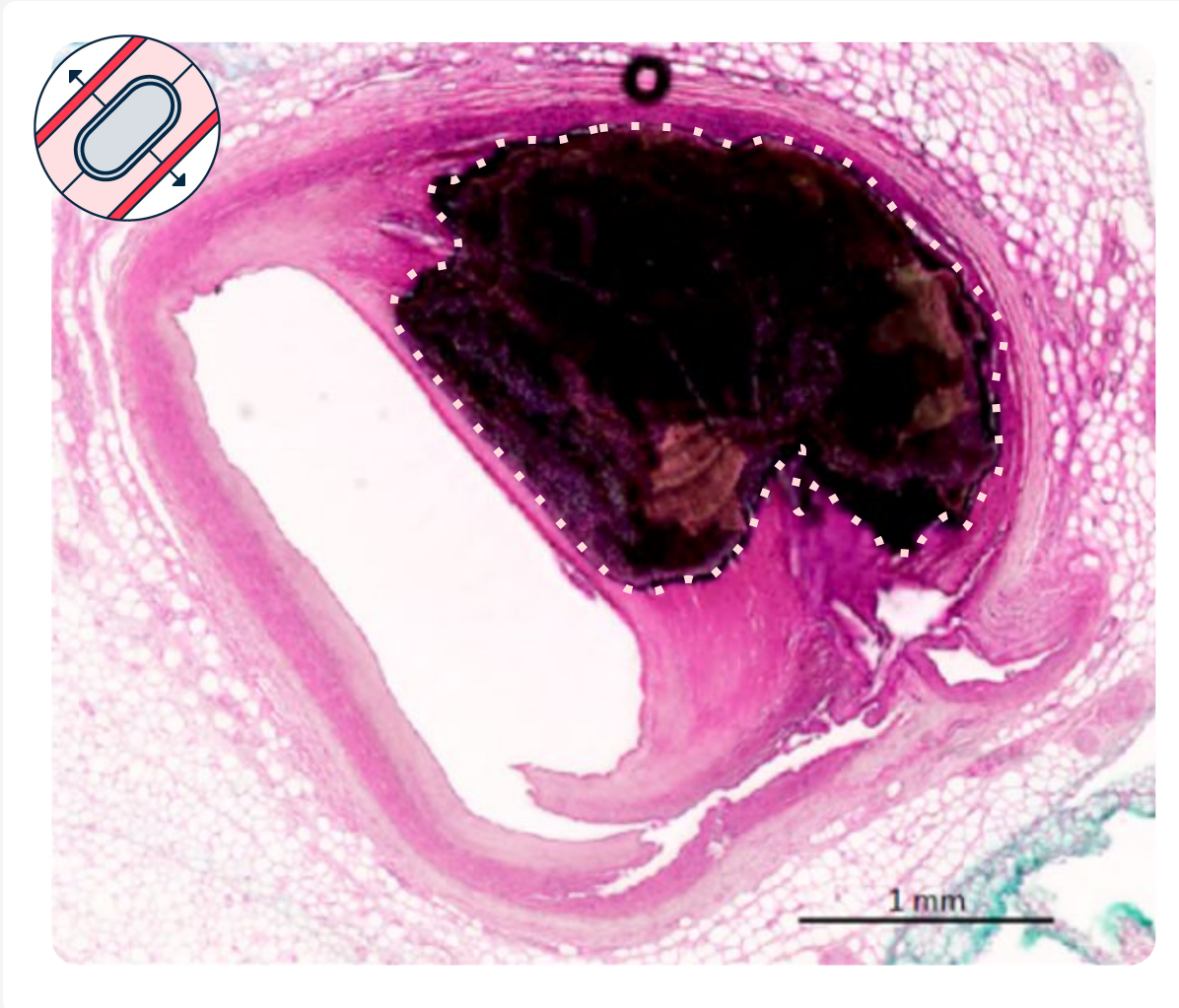
Higher efficacy, Lower injury

Fracture
(Micro-CT and Histology)
Overall: $p = 0.350$

Medial Injury
Overall: $p = 0.012$
IVL vs CB: $p = 0.080$
IVL vs UHB: $p = 0.015$
CB vs UHB: $p = 1.000$

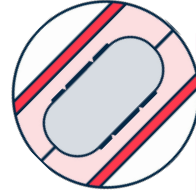
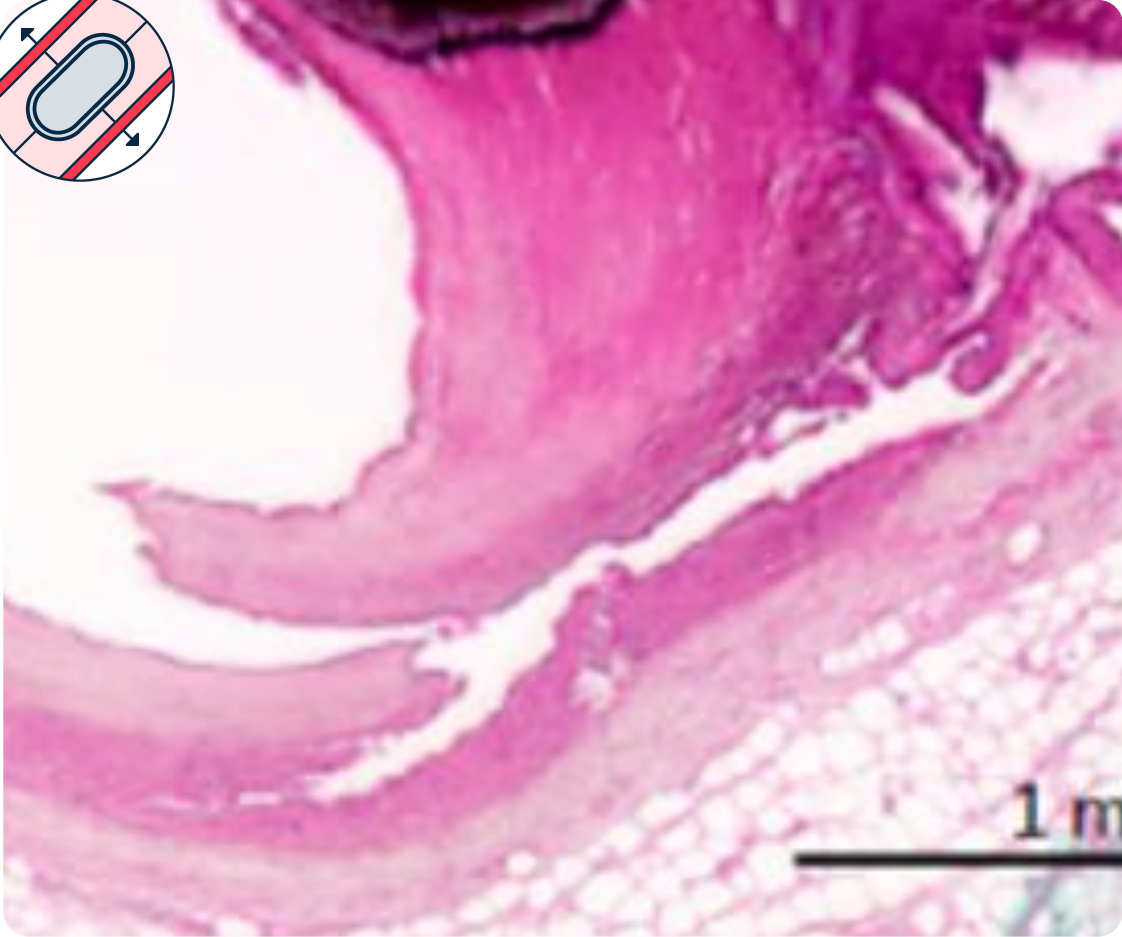
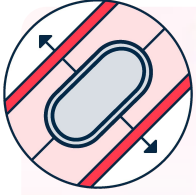


OPN / CB in eccentric calcium... 0 calcium fractures



No fractures

OPN or CB in eccentric calcium... eccentric force



Vascular injury

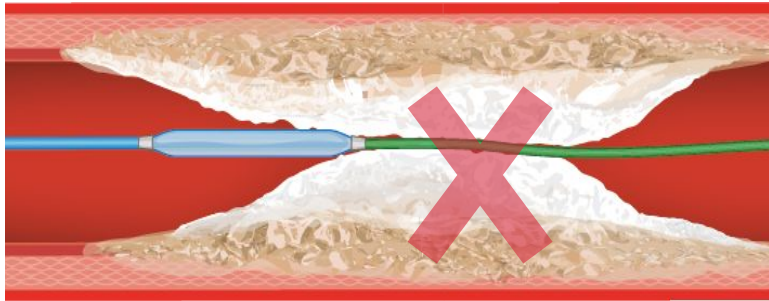
IVL MOA explains safety



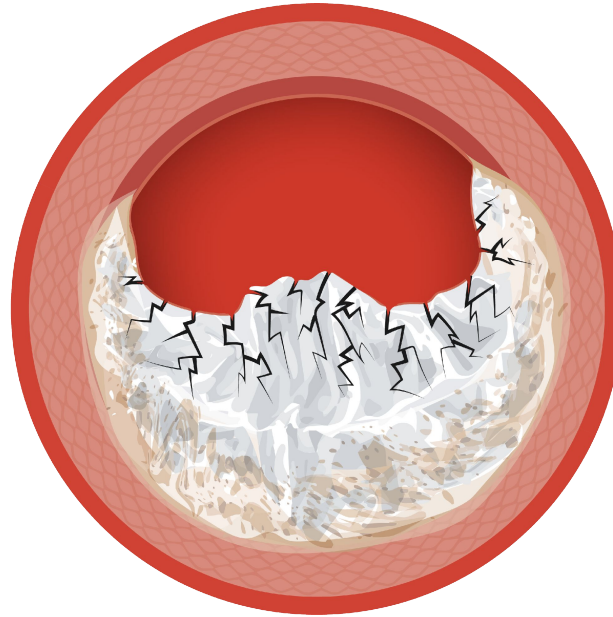
Major Dissection	0%	0 – 2.4%
Acute Vessel Closure	0%	0 – 1%
Side-Branch Occlusion	0%	0 – 0.7%
Slow flow / No reflow	0%	0 – 0.2%
In-hospital MI	5.8 – 6.7%	0 – 1.4%
Perforation	0%	0 – 0.7%

IVL is simple to use

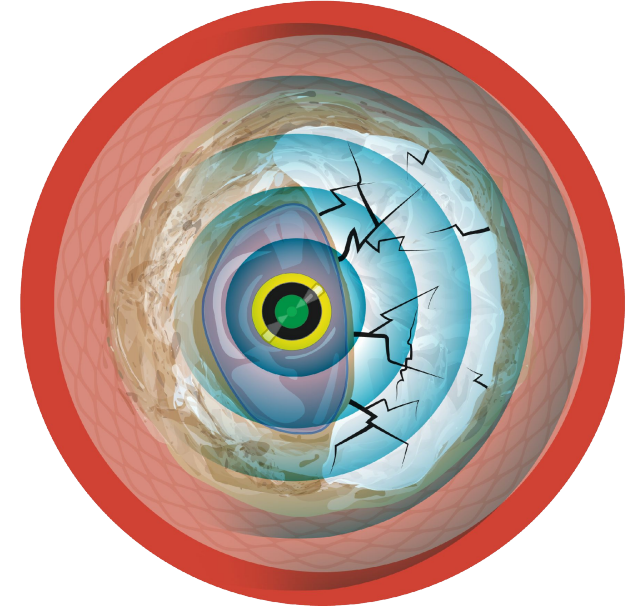
Limitations of IVL



Deliverability



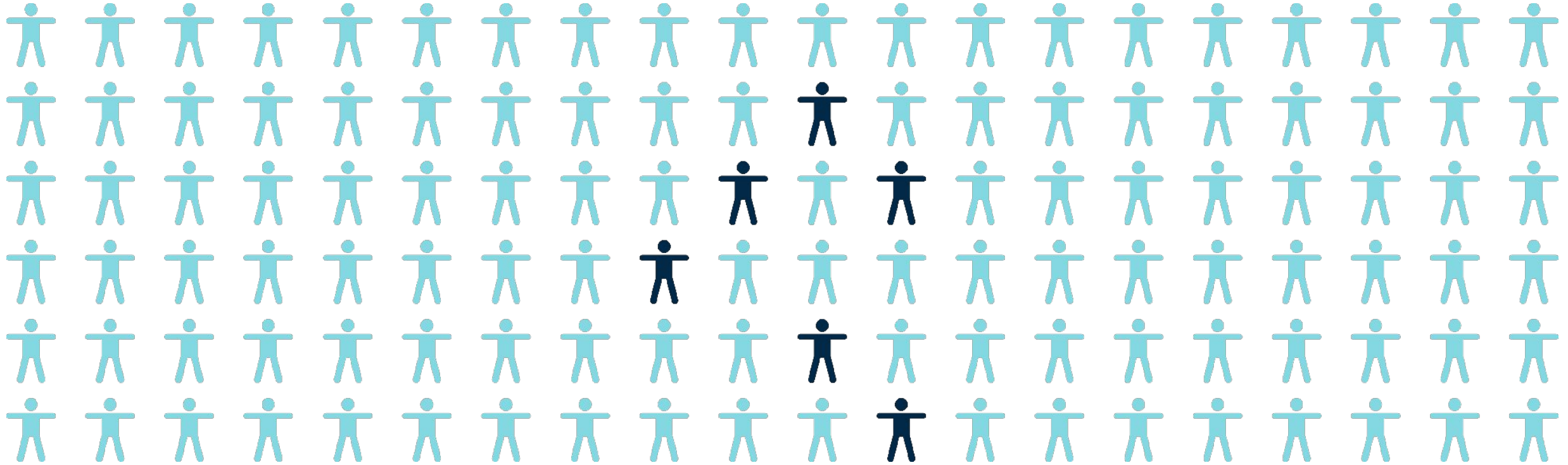
Volume reduction



Threshold effect

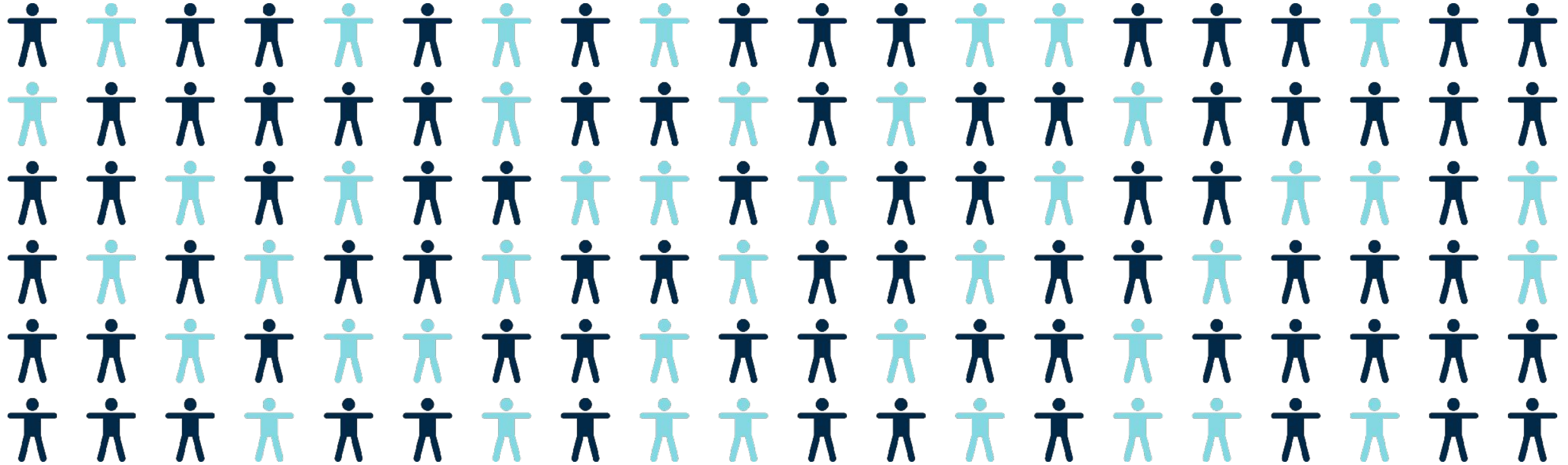
The problem

Atherectomy is rarely used



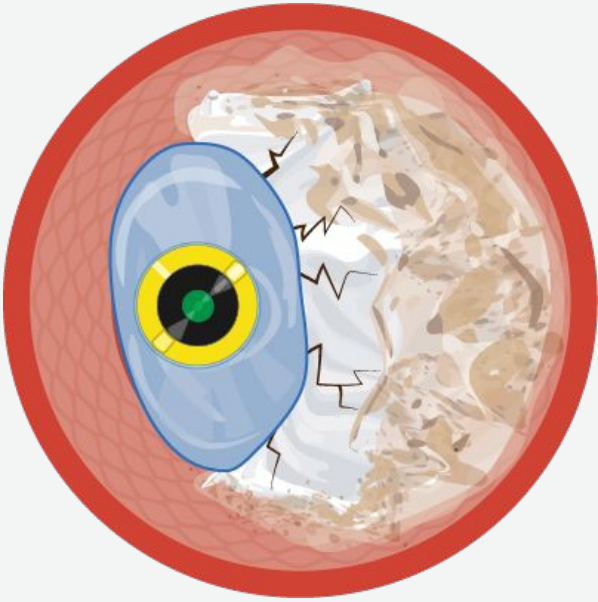
The solution

Democratise the solution

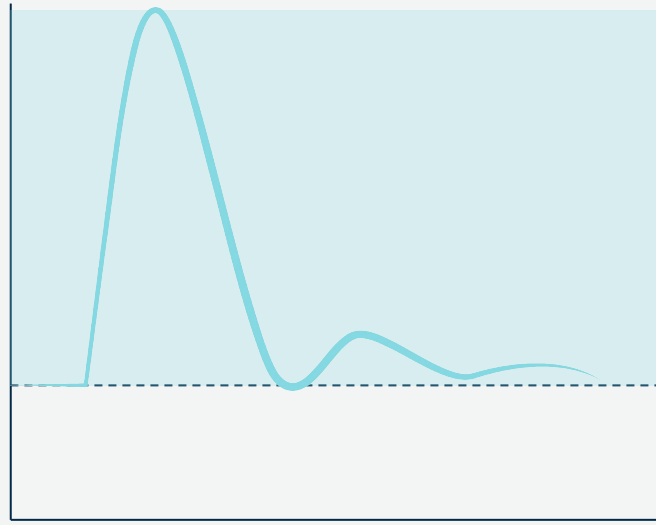


Summary

IVL is the gold standard



IVL is **safe** and **effective**
across calcium
morphologies



Acoustic pressure wave
maximize safety with
efficacy



IVL is **easy** to **use**

Thank you