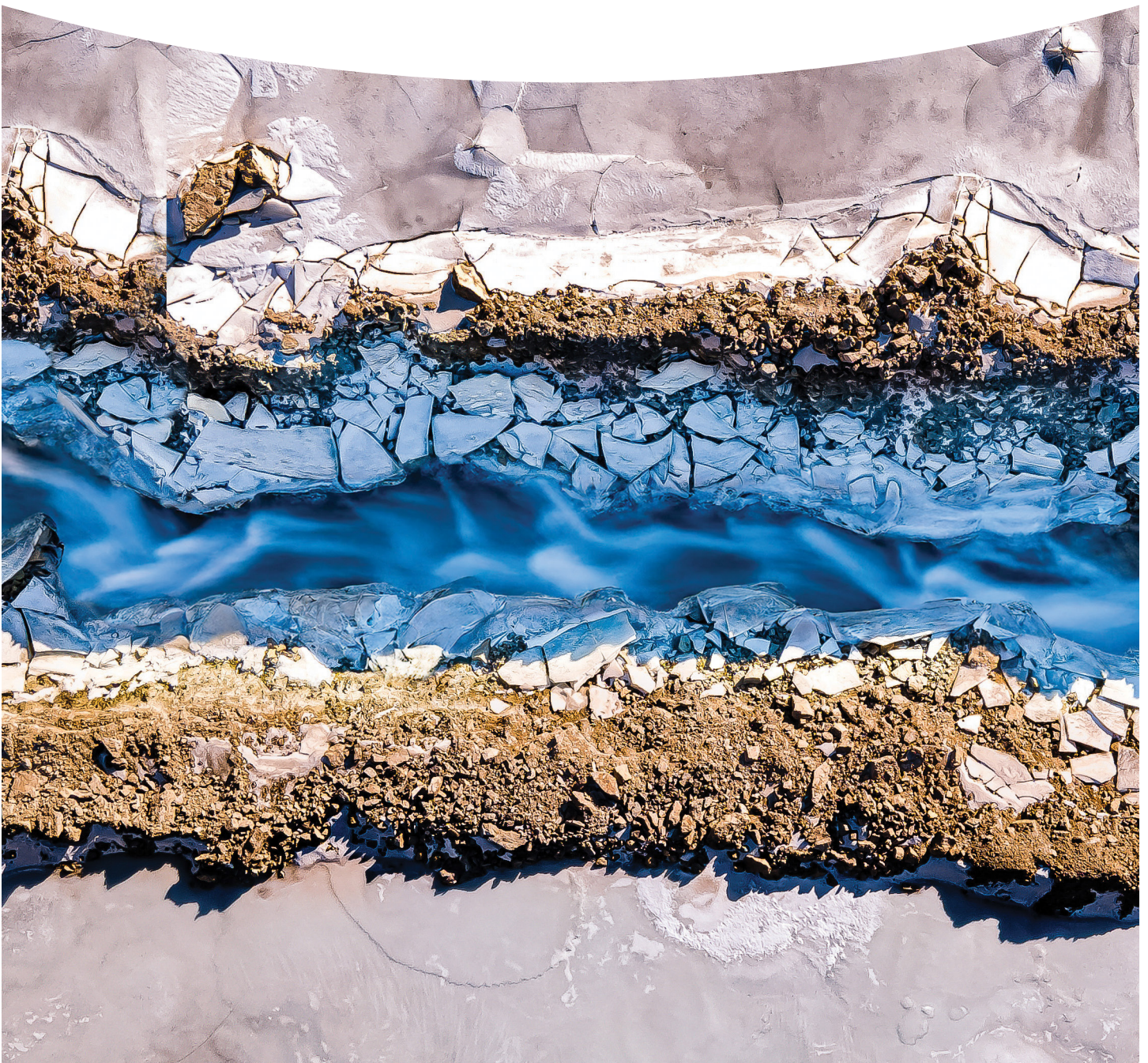




HERTZ CONTACT INTRAVASCULAR LITHOTRIPSY

BREAK FREE





TRANSLATING FORCE

INTO ENERGY

LithiX Hertz Contact Intravascular Lithotripsy (HC-IVL) creates deep, wide cracks in lesions with eccentric, concentric, or nodular calcium without damaging soft tissue.



And while we make it look easy, the technology has been crafted and engineered to achieve highly effective outcomes. LithiX operates like a familiar balloon catheter but accelerates and maximizes **mechanical lithotripsy outcomes without requiring an external energy console.**

SAFE AND EFFECTIVE

1.7% in-hospital and 30-day MACE¹
<30% residual diameter stenosis achieved in 100% of lesions¹

SIMPLE

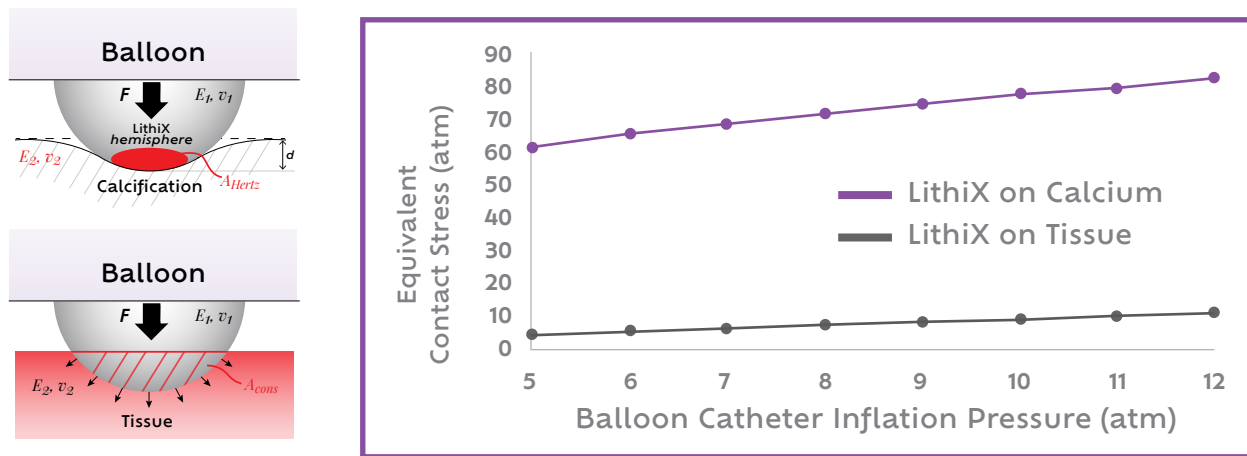
Seamless integration and expedited workflow

VERSATILE

Optimize stent expansion regardless of calcium morphology

SAFE AND EFFECTIVE
HARD ON CALCIUM. SOFT ON TISSUE.

Hertz Contact Stress: Discrete and high stress for calcium fragmentation*



*Calculated forces: Hertz Contact stress formula

In the PINNACLE I study, LithiX achieved excellent clinical success.*

100% + **No**
 Angiographic success¹ Angiographic complications¹

Target lesion failure**
1.7%
 Out to 6 months¹

CV death
0.0%
 Out to 6 months¹

SIMPLE
GETTING TO THE LESION SHOULDN'T BE TORTURE.

The votes are in.
 Operator Post-Market Feedback²
 (n = 172)

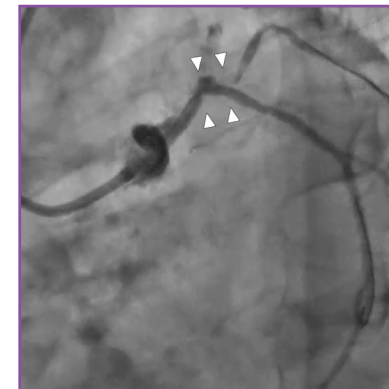


System track and flexibility: 4.7 average



Ease of crossing the lesion: 4.5 average

Case Example: LM/LCx severe angulation into and through calcific lesion

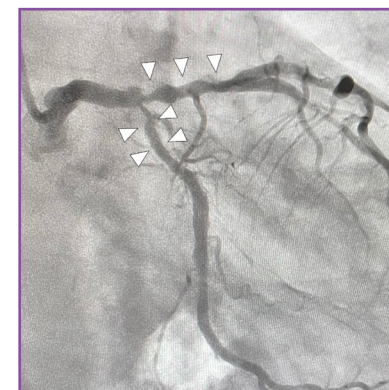


Pre-LithiX



Final Result

Case Example: severe calcification in multiple vessels treated with single LithiX device



Pre-LithiX

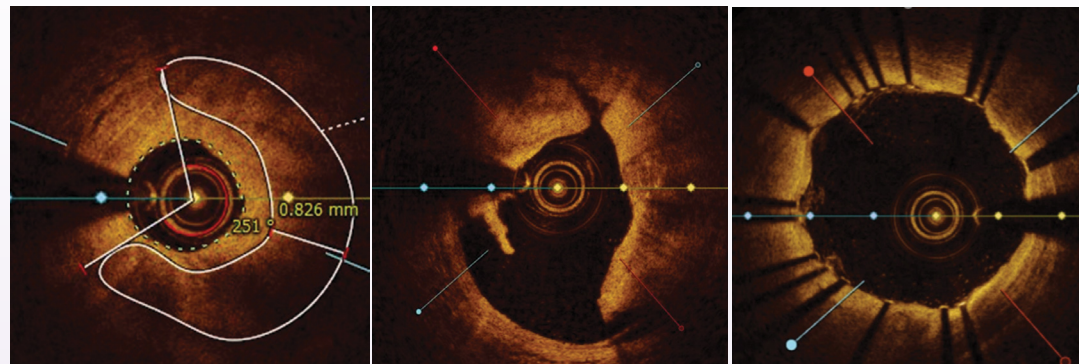


Final Result

VERSATILE
LITHOTRIPSY WITHOUT LIMITS

LithiX can be used in **lesions with eccentric, concentric, and nodular calcium**, producing a multitude of visible cracks.

Eccentric calcified lesions

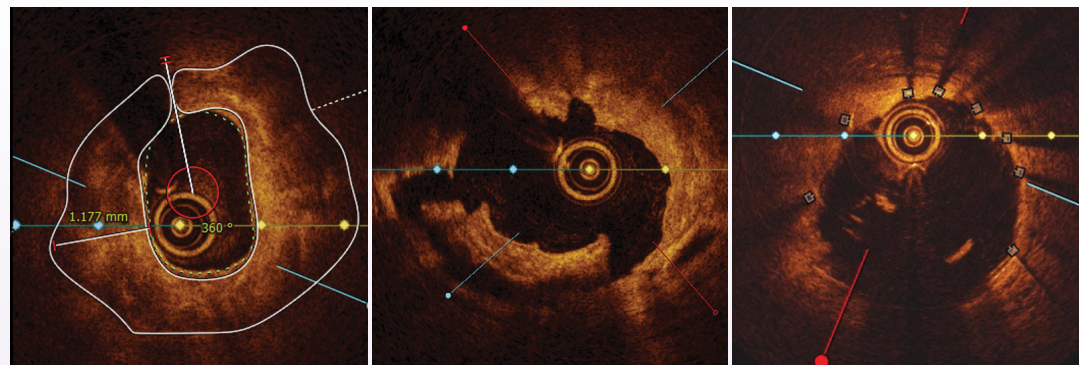


Pre-procedure

Post-LithiX HC-IVL

Final Post-stent

Concentric calcified lesions

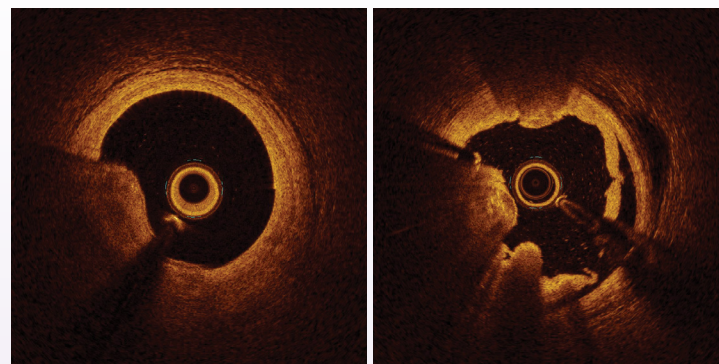


Pre-procedure

Post-LithiX HC-IVL

Final Post-stent

Lesions with nodules



Pre-procedure

Post-LithiX HC-IVL

LithiX provides ultimate freedom and flexibility — to consistently **achieve maximum stent expansion**.

EAPCI Consensus Document: Target minimum stent area (MSA) >80% relative to average reference lumen area following stent optimization³

Eccentric calcified lesions

Final stent expansion
101.38%
At Minimum Stent Area⁴

Fracture depth⁴
0.76 mm

Fracture width⁴
0.51 mm

Concentric calcified lesions

Final stent expansion
93.95%
At Minimum Stent Area⁴

Fracture depth⁴
0.85 mm

Fracture width⁴
0.75 mm

Lesions with nodules

Final stent expansion
91.40%
At Minimum Stent Area⁵

Fracture depth⁵
0.81 mm

Fracture width⁵
0.57 mm

Fracture depth and width were measured by an independent core lab of OCT images post-LithiX HC-IVL and prior to stenting.^{4,5}

TECHNICAL SPECIFICATIONS

LithiX HC-IVL Catheter	
Available Balloon Nominal Diameters	2.0, 2.5, 3.0, 3.5 mm
Balloon Nominal Length	14 mm
Catheter Working Length	140 cm
Catheter Design	Rapid Exchange
Distal Outer Shaft OD	2.7 FR / 0.89 mm
Intermediate Shaft OD	2.5 FR / 0.85 mm
Hypotube OD	1.95 FR / 0.65 mm
Guiding Catheter Compatibility	6 French (\geq 0.071 in ID or 1.8 mm ID)
Guidewire Compatibility	0.014 in or 0.36 mm
Tip Entry Profile	0.017 in / 0.43 mm
Crossing Profile	0.046 in – 0.057 in / 1.17 mm – 1.45 mm / 3.5 FR – 4.3 FR

COMPLIANCE CHART

Inflation	Balloon Outer Diameter (mm)				
	ATM	2.0 mm	2.5 mm	3.0 mm	3.5 mm
5 [NOM]		2.06	2.57	2.99	3.59
6		2.09	2.61	3.04	3.65
7		2.12	2.65	3.09	3.70
8		2.15	2.69	3.14	3.76
9		2.18	2.72	3.18	3.80
10		2.20	2.75	3.21	3.83
11		2.22	2.77	3.24	3.86
12 [RBP]		2.24	2.79	3.27	3.88

LithiX Diameter			
2.0 mm	2.5 mm	3.0 mm	3.5 mm
DAR2014	DAR2514	DAR3014	DAR3514

Not all sizes available in all geographies.

References

- Paradies V. TCT 381: Safety and Effectiveness of a Novel Intravascular Lithotripsy Device Using the Hertz Contact Stress Mechanism for Calcium Fragmentation: PINNACLE I Clinical Trial Six-Month Outcomes. Presented at TCT 2024 on behalf of the PINNACLE I Investigators.
- LithiX HC-IVL Post-market Case Survey. Data on file.
- Räber L, et al. Clinical use of intracoronary imaging. Part 1: guidance and optimization of coronary interventions. An expert consensus document of the European Association of Percutaneous Cardiovascular Interventions. EuroIntervention. 2018.
- Bennett J. TCT 383: Mechanistic Effects of Coronary Hertz Contact Intravascular Lithotripsy (HC-IVL) on Treatment of Calcified Lesions: PINNACLE I OCT Sub-study Procedural Imaging Outcomes. Presented at TCT 2024 on behalf of the PINNACLE I Investigators.
- PINNACLE I Clinical Trial. Data on file.

Notes: *Clinical success is defined as achieving the primary effectiveness and safety endpoint: residual stenosis <50% with no in-hospital MACE. **One subject with TVMI (peri-procedural, non Q-wave)