FRACTURE IDE Trial

SEISMIQ™ 4CE Coronary Intravascular Lithotripsy Catheter

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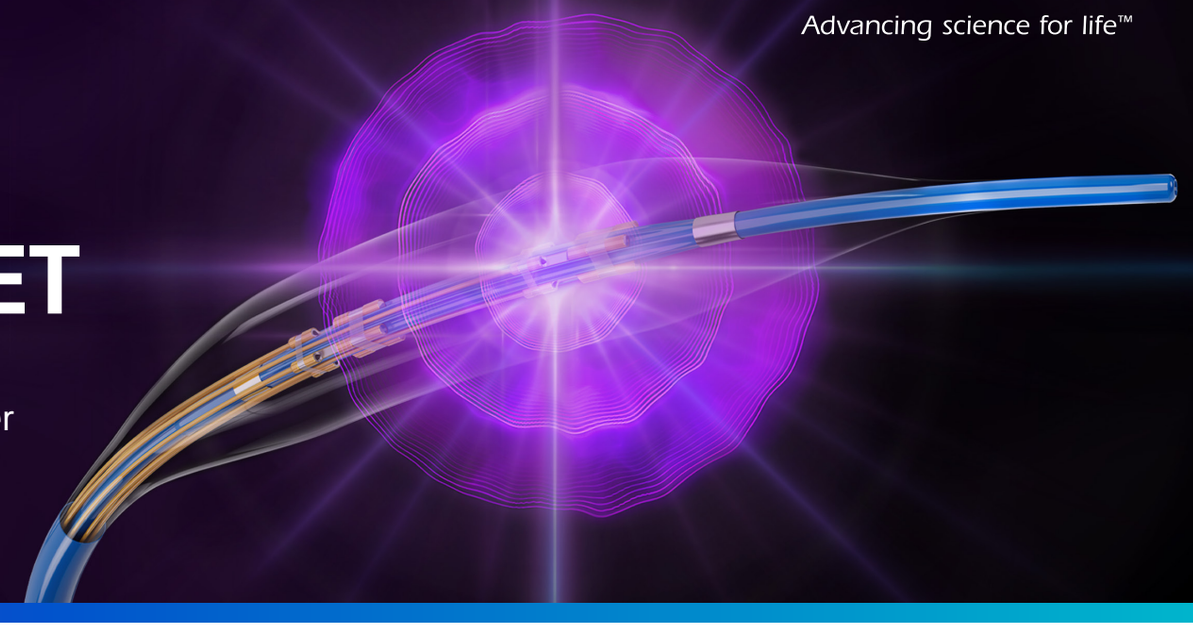


A SEISMIQ shift in coronary IVL:
PRIMARY ENDPOINTS MET

FRACTURE IDE Trial is a pivotal trial designed to determine the safety and effectiveness of SEISMIQ™ 4CE Coronary Intravascular Lithotripsy Catheter in the treatment of severely calcified de novo coronary lesions.

BACKGROUND

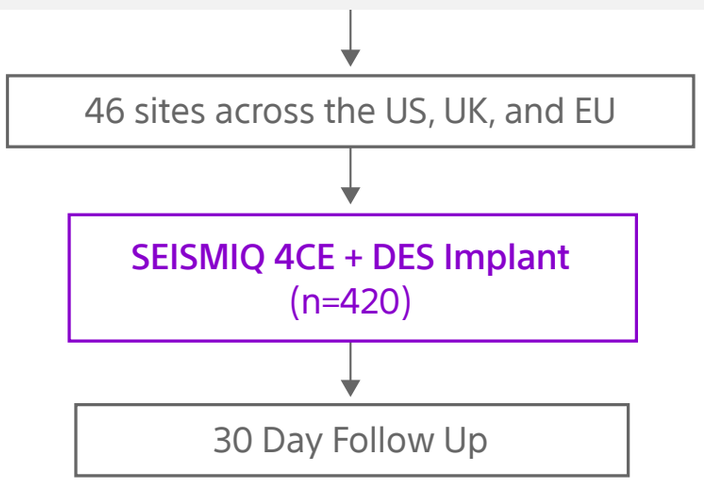
In the treatment of coronary artery disease (CAD), coronary calcification remains a major challenge during percutaneous coronary intervention (PCI). SEISMIQ 4CE (pronounced 'force') is a novel intravascular lithotripsy (IVL) catheter featuring four coronary emitters (4CE). These emitters generate acoustic energy by coupling laser light through fiber optics onto a metallic backstop located within a semi-compliant balloon.

PATIENT CHARACTERISTICS[1]

A highly calcified subset of patients and lesions were studied, including 100% site-reported severe angiographic calcium and OCT measurements of 27.4% nodular and arc of 271.89 ± 77.4° at the site of max calcium. The severely calcified de novo coronary lesions were ≥ 2.5 mm and ≤ 4.0 mm; with a lesion length ≤ 40 mm.

TRIAL DESIGN[1]

The FRACTURE IDE Trial is a prospective, multicenter, single-arm study using SEISMIQ 4CE to treat 420 patients with calcified coronary artery disease (CAD) with primary endpoints assessed at 30 days. Secondary endpoints including long-term safety and effectiveness will be measured through 24 months.



See results on following pages

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Primary safety endpoint MET

93.3%

MACE-free at 30 days[1]

MACE defined as CV death, MI, TVR.

Primary effectiveness endpoint MET

93.7%

Procedural success[1]

Procedural success defined as DES delivery with a final residual stenosis < 50% and freedom from in-hospital MACE.

The FRACTURE IDE Trial met it's primary safety and effectiveness endpoints in the treatment of severely calcified de novo coronary lesions. The device was associated with high procedural success and low complication rate.

BASELINE, IMAGING AND PROCEDURAL OUTCOMES[1]

	Variables	Values
Key Baseline Characteristics	Age	71.2 years
	Male	74.0%
Baseline Angiographic Characteristics†	Reference vessel diameter	3.1 mm
	Diameter stenosis	66.7%
	Lesion length	23.8 mm
	Calcium length	38.0 mm
OCT Findings‡	Calcium angle	271.89°
	Nodular calcium	27.4%
	Minimal stent area	6.52 mm^2
	Stent expansion§	94.2%
Angiographic, Performance and Clinical Outcomes†	**Primary Safety Endpoint: Freedom from MACE at 30 days**	93.3%
	Safety endpoint excluding peri-procedural MI	99.3%
	Primary Effectiveness Endpoint: Procedural success*	93.7%
	Effectiveness endpoint excluding peri-procedural MI	99.8%
	Residual stenosis < 50%	100%
	Residual stenosis ≤ 30%	93.8%

Values are presented as n/N (%), median (IQR, Q1-Q3), or mean.
† *n* = 420.
‡ *n* = 106 patients had baseline and poststent OCT imaging.
§ MSA at site of max calcium relative to proximal and distal references.
* Successful stent delivery with a residual stenosis < 50% and without in-hospital MACE. Insufficient angiographic data for 1 patient.

See conclusions on following page

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CONCLUSIONS

In the FRACTURE IDE Trial, SEISMIQ™ 4CE met its primary endpoints for safety (93.3% MACE-free at 30 days) and effectiveness (93.7% procedural success) and facilitated substantial improvements in luminal area and stent expansion, with low ventricular capture rates, resulting in:

- Safety endpoint excluding peri-procedural MI: **99.3%**
- Effectiveness endpoint excluding peri-procedural MI: **99.8%**
- Final average MSA of **6.52 mm²**
- Average stent expansion of **94.2%**§
- Ventricular capture rate of **16.4%**‖

§ MSA at site of max calcium relative to proximal and distal references.
‖ Ventricular capture is per patient per case.

Learn more about
FRACTURE

1. McEntegart M. et al. Safety and efficacy of novel intravascular lithotripsy system for coronary calcium: FRACTURE study. EuroPCR 2026 LBCT May 19.
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