SEISMIQ™ 4CE
Coronary Intravascular Lithotripsy Catheter

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SEISMIQ™ 4CE FIRST-IN-HUMAN STUDY

Laser- and Optics-Based Intravascular Lithotripsy for the Treatment of Calcified Coronary Stenoses: the RESTORE First-In-Human Study[1]

Background

Coronary calcification remains a major challenge during percutaneous coronary intervention (PCI). SEISMIQ 4CE (pronounced 'force') is a novel intravascular lithotripsy (IVL) platform featuring **four coronary emitters (4CE)**. These emitters generate acoustic energy by coupling laser light through fiber optics onto a target located within a semi-compliant balloon. This study explored first-in-human feasibility of this platform for the treatment of severely calcified coronary stenoses.

Methods

RESTORE is a prospective, multicenter feasibility study of 41 PCI patients with a single de novo, severely calcified coronary lesion (RVD 2.5–4.0 mm; length ≤ 60 mm) treated with the SEISMIQ 4CE quad-emitter IVL system and followed for 30 days.

Primary safety endpoint

90.2%

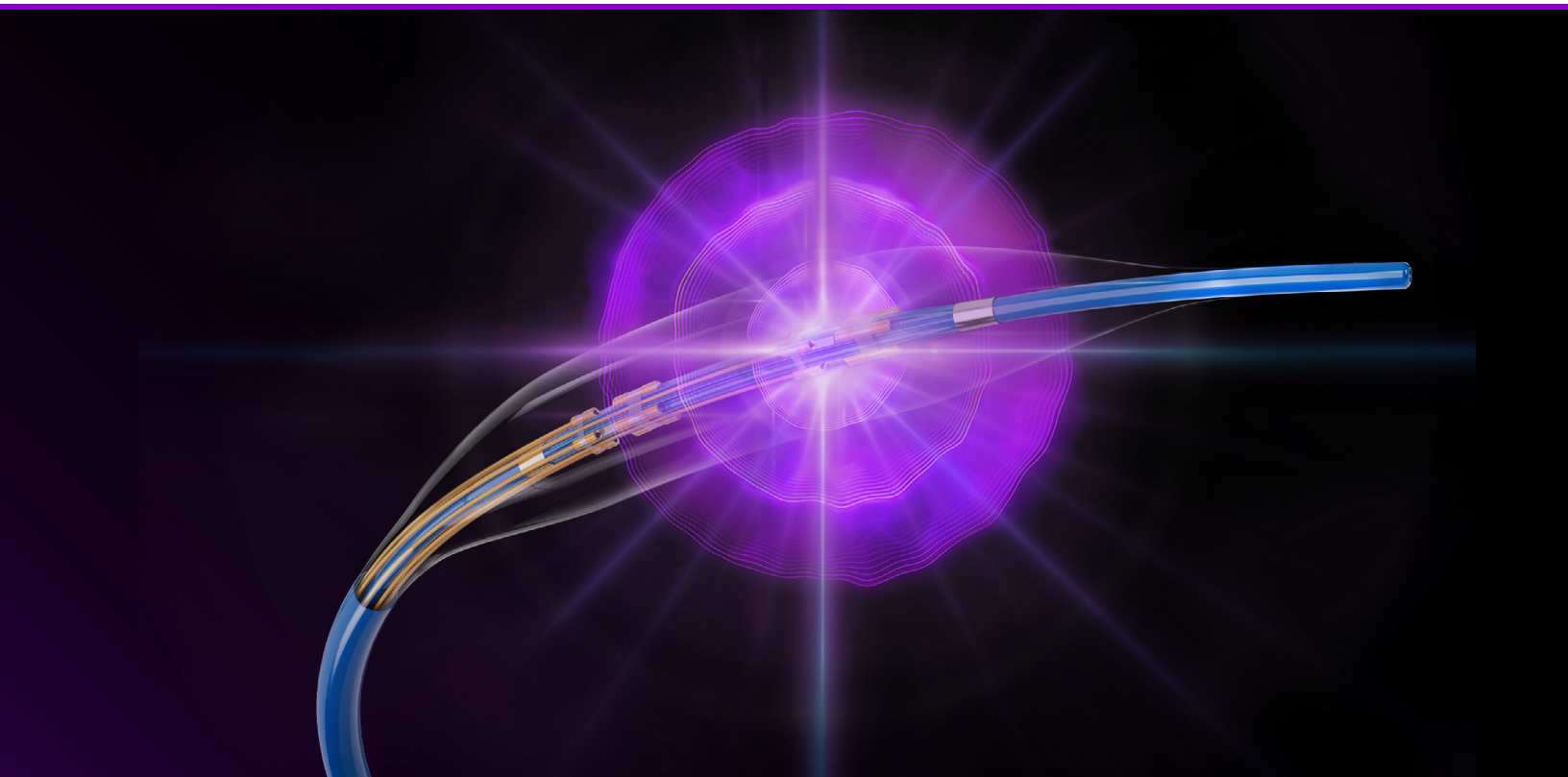
MACE-FREE AT 30 DAYS

Primary effectiveness endpoint

89.5%

PROCEDURAL SUCCESS

See more results on the reverse side.



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Baseline, imaging and procedural outcomes

	Variables	Values
Key Baseline Characteristics	Age, years	71.7 ± 7.7
	Male	27/41 (65.9%)
Baseline Angiographic Characteristics†	Reference vessel diameter, mm	2.9 ± 0.3
	Minimum lumen diameter, mm	0.9 ± 0.3
	Diameter stenosis, %	64.9 ± 11.1
	Lesion length, mm	17.1 ± 8.5
	Calcium length, mm	26.3 (IQR, 18.4-36.7)
IVUS Findings‡	Calcium angle, °	282.3 ± 61.3
	Acute lumen area gain, mm^2	5.4 ± 1.4
	Minimal stent area, mm^2	8.0 ± 1.7
	Stent expansion, %	100 ± 20
Angiographic, Performance and Clinical Outcomes†	**Primary Safety Endpoint:** Freedom from MACE at 30 days	37/41 (90.2%)
	Primary Effectiveness Endpoint: Procedural success§	34/38 (89.5%)
	MACE within 30 days: peri-procedural MI	4/41 (9.8%)
	Residual stenosis < 50%	38/38 (100%)
	Residual stenosis < 30%	38/38 (100%)
	Mean in-stent residual diameter stenosis, %	10.6 ± 4.5
	Device crossing success*	37/38 (97.4%)
	Angiographic success**	38/38 (100%)

Values are presented as n/N (%), median (IQR, Q1-Q3), or mean ± standard deviation.
† *n* = 38.
‡ *n* = 26 patients had baseline and poststent IVUS imaging.
§ Successful stent delivery with a residual stenosis < 50% and without in-hospital MACE.
* Delivery of the IVL catheter across the target lesion and delivery of lithotripsy without serious angiographic complications immediately after IVL.
** Stent delivery with ≤ 30% residual stenosis and without serious angiographic complications.

Conclusions

In the RESTORE feasibility study, SEISMIQ™ 4CE achieved **90.2% freedom from MACE** at 30 days and **89.5% procedural success**. The device facilitated substantial improvements in luminal area and stent expansion, resulting in:

- Final average MSA of 8.0 mm^2
- Average stent expansion of 100%

RESTORE First-In-Human Study provided the initial clinical validation of the SEISMIQ 4CE coronary IVL platform, serving as a key bridge to the FRACTURE IDE pivotal trial to further evaluate safety and effectiveness in a larger, prospective study.

Learn more about **SEISMIQ 4CE:**

1. Price M, Budrys P, Baranauskas A, et al. Laser- and optics-based intravascular lithotripsy for the treatment of calcified coronary stenoses: the RESTORE first-in-human study. *Circ Cardiovasc Interv*, 2026.

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