Indigo™ System
Coronary Mechanical Thrombectomy

CAT™ RX

Coronary Data Overview

Penumbra

	Initial Experience	Stony Brook Experience	UH Cleveland Experience[c]	CHEETAH
Patients	72	34	123	400
Study Design	Retrospective | Multicenter Investigator Initiated	Retrospective | Single-center Investigator Initiated Stony Brook University, NY	Retrospective | Single-center Investigator Initiated University Hospitals Cleveland, OH	Prospective | Multicenter **Frontline use of CAT RX** Penumbra Sponsored
Primary Vessels Treated	RCA, LAD, LCx	RCA, LAD, LCx, SVG, Ramus	RCA, LAD, LCx, SVG, LM, OM	RCA, LAD, LCx
Post CAT RX TIMI 3 Flow	86.1%	88%	—	85% (TIMI 2–3 flow)
Final TIMI 3 Flow	97.2%	—	90.2% 70% of patients who did not achieve TIMI 3 flow received balloon dilatation prior to CAT RX	97.5%
Ischemic Stroke	0[a]	0[b]	0[d]	0[e] device-related
Key Takeaways	"In our initial experience, aspirating thrombus from ACS patients using the Indigo CAT RX Aspiration System before PCI was safe and effective for reducing thrombus burden and restoring flow."	"Penumbra CAT RX system appears to be safe and highly effective at thrombus removal in the acute setting without increased stroke risk seen with manual aspiration."	"We strongly believe that the Penumbra CAT RX device should be used before any balloon angioplasty in patients with high thrombus burden..."	Sustained power aspiration with CAT RX is safe for the removal of high thrombus burden with low rates of distal embolization and improved myocardial perfusion.

a. There was 1 (1.4%) incident of hemorrhagic stroke reported. Timeframe: 30 days post-procedure.
Mathews SJ, et al. Initial experience with a continuous mechanical aspiration system for thrombus removal before percutaneous coronary intervention. *Catheter Cardiovasc Interv.* 2022 Nov;100(6):950–954. doi:10.1002/ccd.30389. Epub 2022 Oct 2.

b. Timeframe: post-procedure.
Gilchrist Jr IC, Fordham MJ, Pyo R, et al. Mechanical aspiration thrombectomy using the penumbra CAT RX system for patients presenting with acute coronary syndrome. *Cardiovasc Revasc Med.* 2021 Jul 2;S1553–8389(21)00501–7. doi:10.1016/j.carrev.2021.06.130.

c. 11 patients (8.9%) experienced an adverse cardiovascular event (3 MI, 8 heart failure) and there were 14 patient (11.3%) deaths within 6 months.
d. Timeframe: not specified.
Tashtish N, Chami T, Dong T, et al. Routine use of the "Penumbra" thrombectomy device in myocardial infarction: a real-world experience–ROPUST study. *J Interv Cardiol.* 2022 Mar 26;2022:5692964. doi:10.1155/2022/5692964.

e. There were 3 (.77%) incidence of non-device related strokes as adjudicated by Independent Medical Reviewer. Timeframe: 30 days post-procedure.
Mathews SJ, Parikh SA, Wu W, et al. Sustained mechanical aspiration thrombectomy for high thrombus burden coronary vessel occlusion: the multicenter CHEETAH study. *Circ Cardiovasc Interv.* 2023 Feb;16(2):e012433. doi:10.1161/CIRCINTERVENTIONS.122.012433. Epub 2023 Feb 21.

The safety and effectiveness of this device for use in the treatment of ST-Elevation Myocardial Infarction (STEMI) has not been established. Complications from the use of this device in this manner could lead to death, permanent impairment, and/or the need for emergency medical intervention. Penumbra ENGINE™ and Penumbra Pump MAX™ were both used during CHEETAH Study.

Maximized Clot Removal

Large .044" (1.12 mm) Lumen

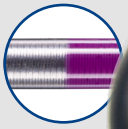
Penumbra ENGINE™

Rapid Exchange

.014" (.356 mm) Wire Compatibility

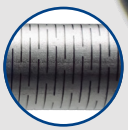
Advanced Trackability

with Neuro-Tracking Technology

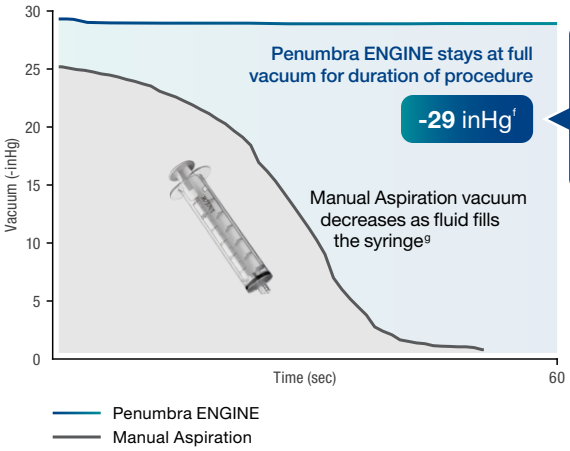


Enhanced Deliverability

Proximal Laser-Cut Hypotube



Sustained Power Aspiration vs. Manual Syringe-Based Aspiration



112% more aspiration efficiency compared with a syringe[h]

Watch the Video Now to see Sustained Power Aspiration with Penumbra ENGINE

f. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance.
g. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance. Data obtained using a 30 cc syringe connected to manual aspiration catheter with vacuum gauge attached to proximal barrel of syringe and continuous filling of syringe.
h. Aspiration efficiency defined as volume under graph.

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For the complete Penumbra IFU Summary Statements, please scan QR code or visit: peninc.info/risk

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Product availability varies by country. Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. Prior to use, please refer to the Instructions for Use for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use. Please contact your local Penumbra representative for more information.