



# High Rates of Technical Success Indigo System for Acute Limb Ischemia

## STRIDE Study<sup>1</sup>

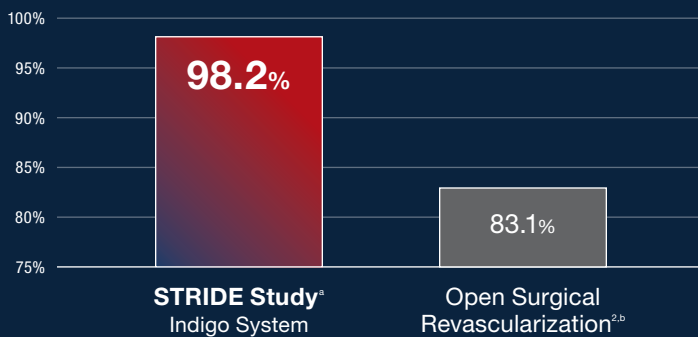
Objective: To collect safety and performance data on the Indigo Aspiration System in a patient population with lower extremity acute limb ischemia (LE-ALI)

Design: Prospective | Single-arm | Multicenter, 16 Sites | 119 Patients Enrolled

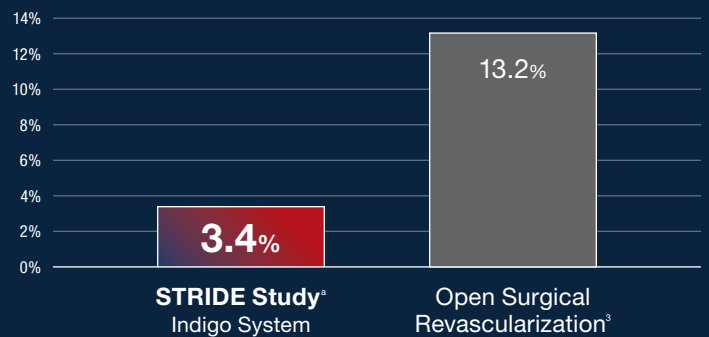
VIEW STUDY  
DETAILS



### Target Limb Salvage at 30 days



### Mortality at 30 days



22 minutes Median Indigo Aspiration Time	Baseline Characteristics	% (n/N) or Mean ± SD Median [IQR]
	Target Thrombus Length, mm	125.7 ± 124.7 (N=113)
	Rutherford IIa and IIb	89.1% (106/119)
	Tandem Lesion	18.5% (22/119)

Lightning  
usage was  
**43.7%**  
(52/119)

Penumbra ENGINE™

Patients with firstline use of the **Indigo Aspiration System** had excellent limb salvage rates and low peri-procedural complications.

*In this study, Indigo Aspiration System provided a safe and effective clot removal option for LE-ALI patients.*

a. STRIDE study was not a randomized or head-to-head study. Please refer to specific publications to review source for detailed patient and data collection methods for open surgical revascularization.

b. Composite limb salvage rate at 30 days calculated and data on file at Penumbra, Inc.

1. Maldonado TS, Powell A, Wendorff H, et al. Safety and efficacy of mechanical aspiration thrombectomy for patients with acute lower extremity ischemia. *J Vasc Surg.* 2024;79(3):584–592 e5. doi:10.1016/j.jvs.2023.10.062.

2. Veenstra EB, van der Laan MJ, Zeebregts CJ, et al. A systematic review and meta-analysis of endovascular and surgical revascularization techniques in acute limb ischemia. *J Vasc Surg.* 2020 Feb;71(2):654–668.e3. doi:10.1016/j.jvs.2019.05.031.

3. Taha AG, Byrne RM, Avgerinos ED, et al. Comparative effectiveness of endovascular versus surgical revascularization for acute lower extremity ischemia. *J Vasc Surg.* 2015 Jan;61(1):147–54. doi:10.1016/j.jvs.2014.06.109.

The clinical results presented herein are for informational purposes only, and may not be predictive for all patients. Individual results may vary depending on patient-specific attributes and other factors. Please refer to the Instructions for Use (IFU) for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use.



# Historical Surgical Outcomes vs. STRIDE Study Data

Outcome	Open Surgery	STRIDE <sup>1,a</sup>
Target Limb Salvage at 30 days	83.1% <sup>2,b</sup>	98.2% (109/111)
Patency at 30 days	78.6% <sup>4</sup>	89.4% (101/113)
Mortality at 30 days	13.2% <sup>3</sup>	3.4% (4/119)
Major Bleeding <sup>c</sup>	21.0% <sup>5</sup>	4.2% (5/119)

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b. Composite limb salvage rate at 30 days calculated and data on file at Penumbra, Inc.

c. Major bleeding definitions may vary across studies. Please refer to specific publications for details.

1. Maldonado TS, Powell A, Wendorff H, et al. Safety and efficacy of mechanical aspiration thrombectomy for patients with acute lower extremity ischemia. *J Vasc Surg.* 2024;79(3):584–592.e5. doi:10.1016/j.jvs.2023.10.062.

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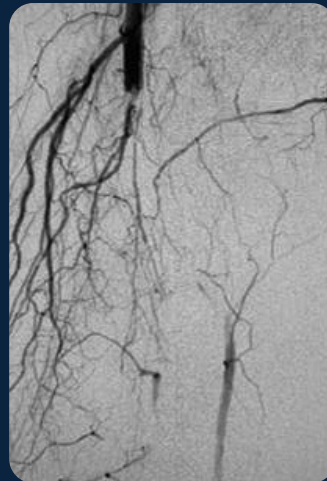
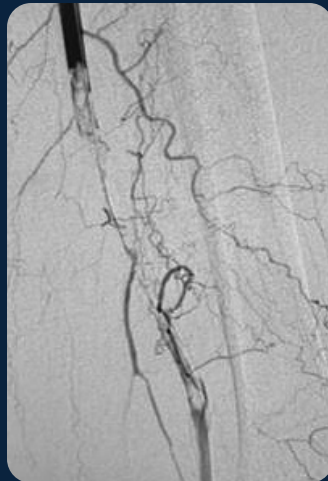
3. Taha AG, Byrne RM, Avgerinos ED, et al. Comparative effectiveness of endovascular versus surgical revascularization for acute lower extremity ischemia. *J Vasc Surg.* 2015 Jan;61(1):147–54. doi:10.1016/j.jvs.2014.06.109.

4. Grip O, Wanhaiainen A, Michaëlsson K, Lindhagen L, Björck M. Open or endovascular revascularization in the treatment of acute lower limb ischaemia. *Br J Surg.* 2018 Nov;105(12):1598–1606. doi:10.1002/bjs.10954.

5. Kolte D, Kennedy KF, Shishebor MH, et al. Endovascular versus surgical revascularization for acute limb ischemia: a propensity-score matched analysis. *Circ Cardiovasc Interv.* 2020;13(1):e008150.

## Removal of Thrombus from Tibial Artery

Dr. Paul Isenbarger  
Cleveland Clinic, FL, USA



**Penumbra, Inc. USA**  
One Penumbra Place  
Alameda, CA 94502  
USA  
1.888.272.4606  
T 1.510.748.3200  
F 1.510.748.3232  
order@penumbrainc.com  
info@penumbrainc.com

**Penumbra Europe GmbH**  
Am Borsigturm 44  
13507 Berlin  
Germany  
T +49 30 2005 676-0  
F +49 30 2005 676-10  
de-order@penumbrainc.com  
de-info@penumbrainc.com

**Penumbra Neuro Australia Pty Ltd**  
55 Kirby Street  
Rydalmere NSW 2116  
Australia  
T +61-1300 817 025  
F +61-1300 817 026  
order.anz@penumbrainc.com

**Penumbra Latin America  
Distribuidora de Equipamentos  
e Produtos Médicos Ltda**  
Av. Brigadeiro Faria Lima 1336  
Cj 82, CEP 01451-001  
São Paulo/SP, Brazil  
T +55 11 2883-5825  
order.la@penumbrainc.com



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