High Rates of Technical Success
Indigo System for Acute Limb Ischemia

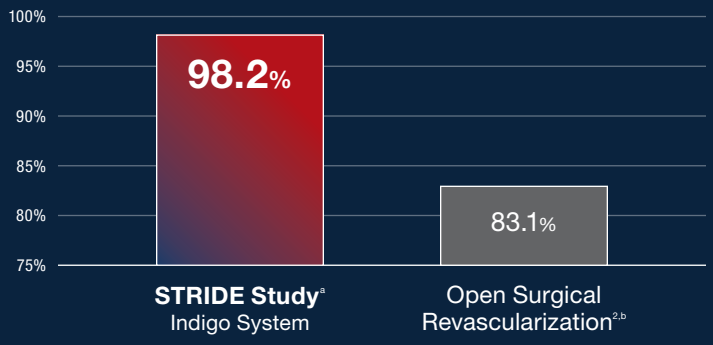
STRIDE Study[1]

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

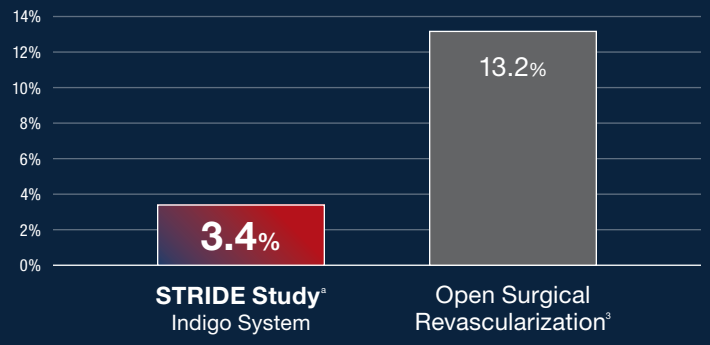
Design: Prospective | Single-arm | Multicenter, 16 Sites | 119 Patients Enrolled

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)

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):147–154. doi:10.1016/j.jvs.2014.06.109.

Historical Surgical Outcomes vs. STRIDE Study Data

Outcome	Open Surgery	STRIDE[a]
Target Limb Salvage at 30 days	**83.1%**[2,b]	**98.2%**[1] (109/111)
Target Limb Salvage at 365 days	**77.3%**[2,b]	**88.5%**[5] (77/87)
Patency at 30 days	**78.6%**[4]	**89.4%**[1] (101/113)
Mortality at 30 days	**13.2%**[3]	**3.4%**[1] (4/119)
Mortality at 365 days	**33.8%**[3]	**12.0%**[5] (12/100)
Major Bleeding[c]	**21.0%**[6]	**4.2%**[1] (5/119)
Access Site Infection Rate	**14.0%**[7]	**0.8%**[1,d]

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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.
d. Data on file at Penumbra, Inc. based on 30-day outcomes. The clinical results presented herein are for informational purposes.

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):147–154. doi:10.1016/j.jvs.2014.06.109.
4. Grip O, Wanhainen 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. Maldonado TS, Powell A, Wendorff H, for the STRIDE Study group. One-year limb salvage and quality of life following mechanical aspiration thrombectomy in patients with acute lower extremity ischemia. *J Vasc Surg.* 2024. doi:10.1016/j.jvs.2024.05.043.
6. Kolte D, Kennedy KF, Shishehbor MH, et al. Endovascular versus surgical revascularization for acute limb ischemia: a propensity-score matched analysis. *Circ Cardiovasc Interv.* 2020;13(1):e008150.
7. Bakshi SC, Fobare A, Benarroch-Gampel J, Teodorescu V, Rajani RR. Lower socioeconomic status is associated with groin wound complications after revascularization for peripheral artery disease. *Ann Vasc Surg.* 2020 Jan;62:76-82. doi:10.1016/j.avsg.2019.05.010. Epub 2019 Jun 12.

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