



OPEN TO
OPPORTUNITY.

DEFINITIVE: A Key Bridge to Broader Atherectomy Usage

Core User Group:
"Hawkers"

CLINICAL DATA

Peripheral Endovascular
Specialists





DEFINITIVE Ca⁺⁺ | DEFINITIVE LE



DEFINITIVE Ca⁺⁺

DEFINITIVE Calcium

Expand indications for SilverHawk® LS-C (RockHawk) and SpiderFX™

- **Challenge**
 - Calcified lesions remain a significant clinical issue
 - In the US, no embolic protection device is approved in the leg
- **Solution**
 - RockHawk + SpiderFX looking at safety and definitive reduction of calcium

DEFINITIVE LE

DEFINITIVE Lower Extremity

“Real world” all-comers study designed to support and inform physician day to day decision making

- **Challenge**
 - Robust, multi-center SilverHawk performance data has yet to be generated
- **Solution**
 - Robust 800 subject, global, multi-center study with core lab adjudication as well as IVUS and plaque analysis sub-studies and sub-population analyses

DEFINITIVE IS UNDERWAY.

Review of Key Data Collected to Date

Highlighted on
following pages

<u>Study</u>	<u>Patients</u>	<u>Results</u>
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McKinsey ¹	275	<ul style="list-style-type: none">• 62.2% primary patency at 1 year• 93.1% limb salvage
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Zeller ²	84	<ul style="list-style-type: none">• Primary patency at 1 year:<ul style="list-style-type: none">– 84% in de novo lesions– 54% in restenotic lesions and in-stent restenosis
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Keeling ³	60	<ul style="list-style-type: none">• 61.7% primary patency at 1 year; 90+% in TASC A/B and claudicants• 86.2% limb salvage
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Kandzari ⁴	69	<ul style="list-style-type: none">• 99% procedural success and 82% limb salvage at 6 months
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TALON ⁵	601	<ul style="list-style-type: none">• 80% freedom from TLR at 1 year• 97.6% procedure success
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¹ McKinsey et al. Ann Surg. 2008 Oct;248(4):519-28.

² Zeller et al. J Am Coll Cardiol. 2006 Oct 17;48(8):1573-8. Epub 2006 Sep 26.

³ Keeling et al. J Vasc Surg. 2007 Jan;45(1):25-3.

⁴ Kandzari et al. J Endovasc Ther. 2006 Feb;13(1):12-22.

⁵ Ramaiah et al (TALON). J Endovasc Ther. 2006 Oct;13(5):592-602.



SILVERHAWK[®]



SILVERHAWK[®]
PLAQUE EXCISION SYSTEM

COMMITTED TO CLINICAL LEADERSHIP

New York Presbyterian Experience¹ Dr. James F. McKinsey, M.D., Site Chief of Vascular Surgery

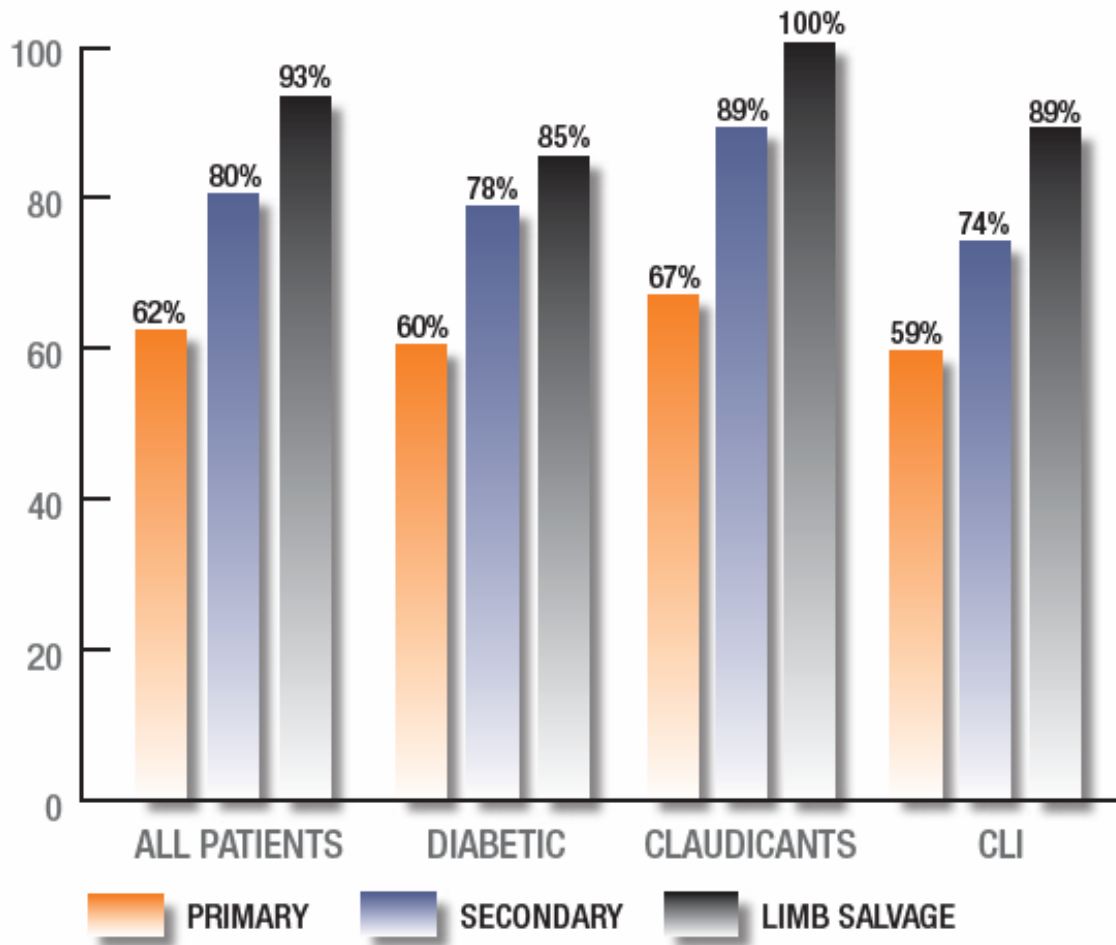
DATA HIGHLIGHTS

- Diseased population: Diabetic = 68%, Claudication = 37%, CLI = 63%, (*Tissue Loss = 52%*)
- Primary patency at 12 months = 62%, secondary patency at 12 months = 80%
- Limb salvage 93% at 12 months
- 65% of cases were free of adjunctive therapy (*77% = PTA*)
- Consistent duplex, angiography, and long-term follow up
- Clinical outcomes reviewed by independent research team
- Keeling reported similar results (*62% primary patency at 12 months*) in challenging lesions (*n = 70 lesions; 73% TASC C, D*)²
- Average lesion length of 71 mm, 90% average stenosis

¹ Ann Surg. 2008 Oct; 248(4):519-28.

² J Vasc Surg. 2007 Jan;45(1):25-31.

% PATENCY AND LIMB SALVAGE AT 12 MONTHS



PATIENT INFORMATION

Diabetic = 68%
Claudication = 37%
CLI = 63%
Tissue Loss = 52%
n = 579 lesions
n = 275 patients





Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. This indication is limited by Federal law to investigational use. CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician. The study of RockHawk and SpiderFX for endovascular treatment of moderate to severe calcified lesions of the lower extremity is being performed in an IDE trial. This indication is limited by Federal law to investigational use. SilverHawk is a registered trademark of FoxHollow Technologies, Inc. d/b/a ev3, Inc. SpiderFX is a trademark of ev3, Inc.

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