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MAJESTIC Clinical Trial

12-Month Data[1]

MAJESTIC Stenting of the Superficial Femoral and/or Proximal Popliteal Artery Project with Boston Scientific's (ELUVIA™) Drug-Eluting Stent

OBJECTIVE:

To evaluate the performance of the Eluvia Drug-Eluting Vascular Stent System in the treatment of superficial femoral (SFA) and/or proximal popliteal artery (PPA) lesions.

TRIAL DESIGN:

- Eligible patients with chronic, symptomatic (Rutherford categories 2, 3 or 4) lower limb ischemia and stenotic, restenotic or occlusive lesions in the native superficial femoral artery or proximal popliteal artery (n=57)
- Degree of stenosis ≥ 70% (visual angiographic assessment)
- Vessel diameter ≥ 4 mm and ≤ 6 mm
- Total lesion length ≥ 30 mm and ≤ 110 mm

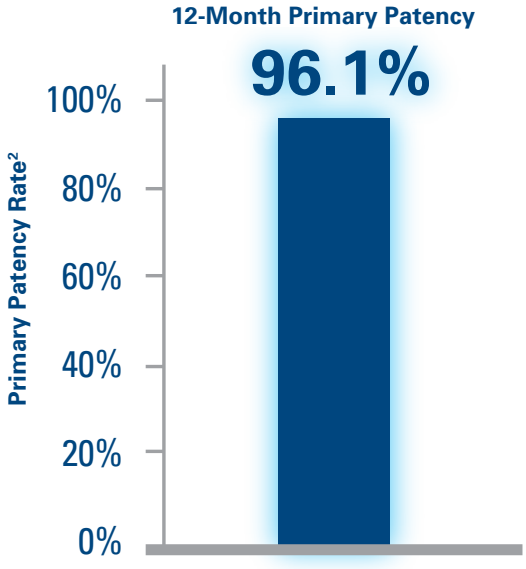
BASELINE CHARACTERISTICS:

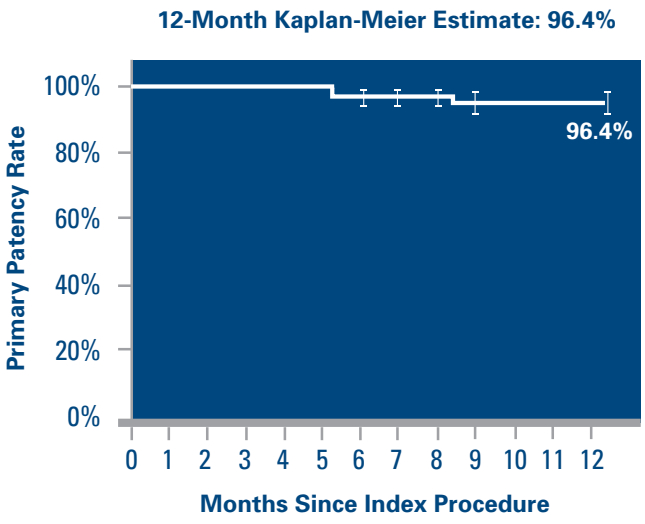
Patient Demographics	n = 57 subjects	Lesion Characteristics (Core Lab)	n = 57 lesions
Age (Years	69.3 ± 9.3	Reference Vessel Diameter	5.2 ± 0.8
Male Gender	82.5%	Target Lesion Length	70.8 ± 28.1
Diabetes Mellitus	35.1%	Severely Calcified	64.9%
History of Smoking	87.7%	Percent Diameter Stenosis	86.3% ± 16.2%
Hypertension	73.7%	Total Occlusions	46.2%
Hyperlipidemia	63.2%	% Extending into Distal SFA	77.2%
Coronary Artery Disease	38.6%	% Extending into PPA	8.8%

EFFICACY RESULTS:

DEFINITION

- Primary patency at 12 months post-procedure assessed by duplex ultrasound as adjudicated by an independent core laboratory





[1]Presented at CIRSE 2015 by Prof. Stefan Müller-Hülsbeck, MAJESTIC Clinical Trial Principle Investigator
[2]Primary patency defined as duplex ultrasound PSVR ≤2.5 and absence of TLR or bypass. Data on file at Boston Scientific.

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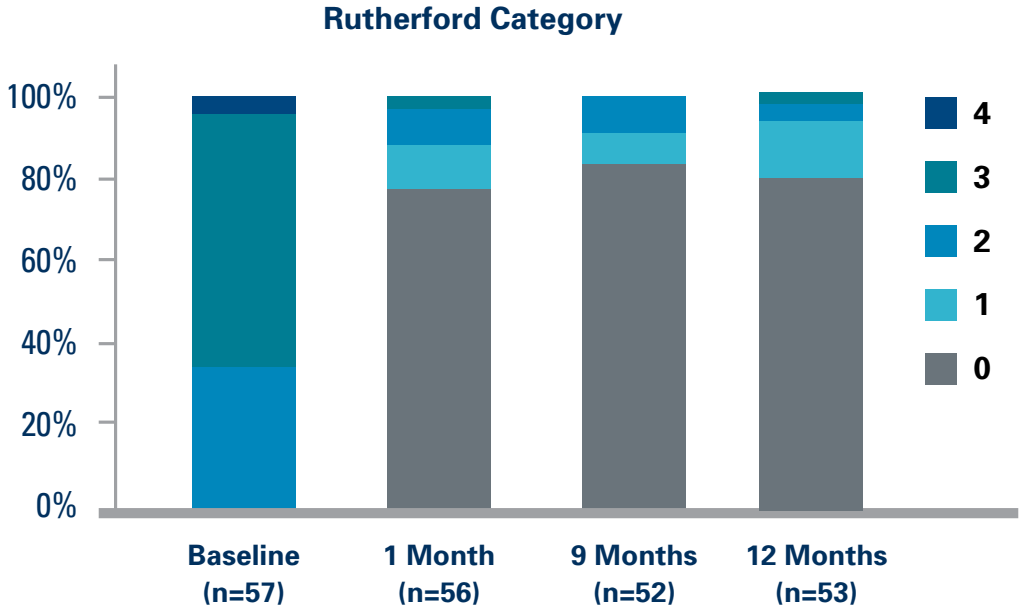
SAFETY RESULTS:
- 3.8% composite major adverse event rate at 12 months
- No deaths or amputations; 2 TLRs (2/53)

	Overall	95% CI
12-Month MAE	3.8%	[0.5%, 13.0%]
All-Cause Death at 1 Month	0.0%	[0.0%, 6.7%]
Target Limb Major Amputation	0.0%	[0.0%, 6.7%]
Target Lesion Revascularization (TLR)	3.8%	[0.5%, 13.0%]

STENT INTEGRITY:
- No stent fractures at 12 months upon angiographic core lab analysis

PATIENT OUTCOMES:
- 94.0% of patients presented with no or minimal claudication (Rutherford 0-1) at 12 months
- Mean ABI improved from 0.73 ± 0.22 at baseline to 1.02 ± 0.20 at 12 months



CONCLUSIONS:
- The Eluvia stent achieved a 96.1% primary patency at 12 months accompanied by a TLR rate of 3.8%.
- The Eluvia stent demonstrated a 12-month composite major adverse event rate of 3.8%, driven by two TLRs, with no deaths or amputations. There were 0 stent fractures at 12 months.
- In the MAJESTIC trial, 94.0% of patients treated with the Eluvia stent had no or minimal claudication at 12 months.

[1]Presented at CIRSE 2015 by Prof. Stefan Müller-Hülsbeck, MAJESTIC Clinical Trial Principle Investigator

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