Majestic Trial 12 Month Results

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)

- [ ] I do not have any potential conflict of interest

MAJESTIC Clinical Study Overview

Device	Eluvia™ Drug-Eluting Vascular Stent System (Boston Scientific)
Objective	Evaluate the performance of Eluvia DES System when treating Superficial Femoral (SFA) and/or Proximal Popliteal Artery (PPA) lesions up to 110mm in length
Study Design	Prospective, multicentre, single-arm, open label
Subjects	57 patients with femoropopliteal artery lesions
Investigational Centers	14 sites (Europe, Australia, New Zealand) No center to enroll > 20% (11 subjects) of the total study population
Follow-up	Baseline, Procedure, 1 month, 9 months, 1 year, 2 years, 3 years
Primary Endpoint	Primary patency of target lesion at 9 months

- 12-month follow-up is presented here

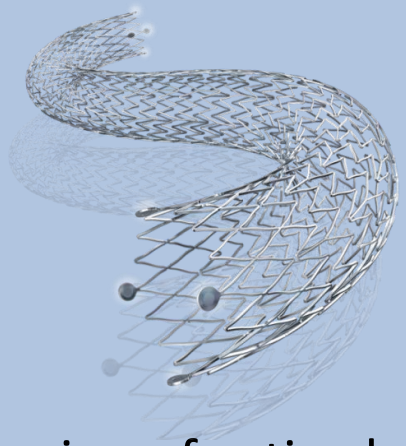
Caution: Investigational Device. Limited by US law to investigational use only. Not available for sale.

Key Eligibility Criteria

- Chronic lower limb ischemia defined as Rutherford categories 2, 3, or 4
- De novo or restenotic lesions (≥70% stenosis) in the native SFA or proximal popliteal artery
- Reference vessel diameter 4-6 mm
- Total lesion length ≥30 mm and ≤110 mm

SFA, superficial femoral artery

Eluvia™ Drug-Eluting Vascular Stent System



- Self-expanding nitinol
- Innova stent platform
- Dual layer coating
  - Primer Layer to promote adhesion of active layer to stent
  - Active Layer (paclitaxel, PVDF-HFP) controls release of paclitaxel and provides sustained release over time
    - Dose: 0.167µg PTx/mm^2 stent surface area

- 6F Tri-axial SDS, 0.035” guidewire compatible
- Blue Tri-Ax shaft is fixed as the clear middle shaft is retracted to release the stent during deployment

PTx, paclitaxel; PVDF-HFP, poly(vinylidene fluoride-co-hexafluoropropylene); SDS, stent delivery system

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Baseline Patient Characteristics (N=57)

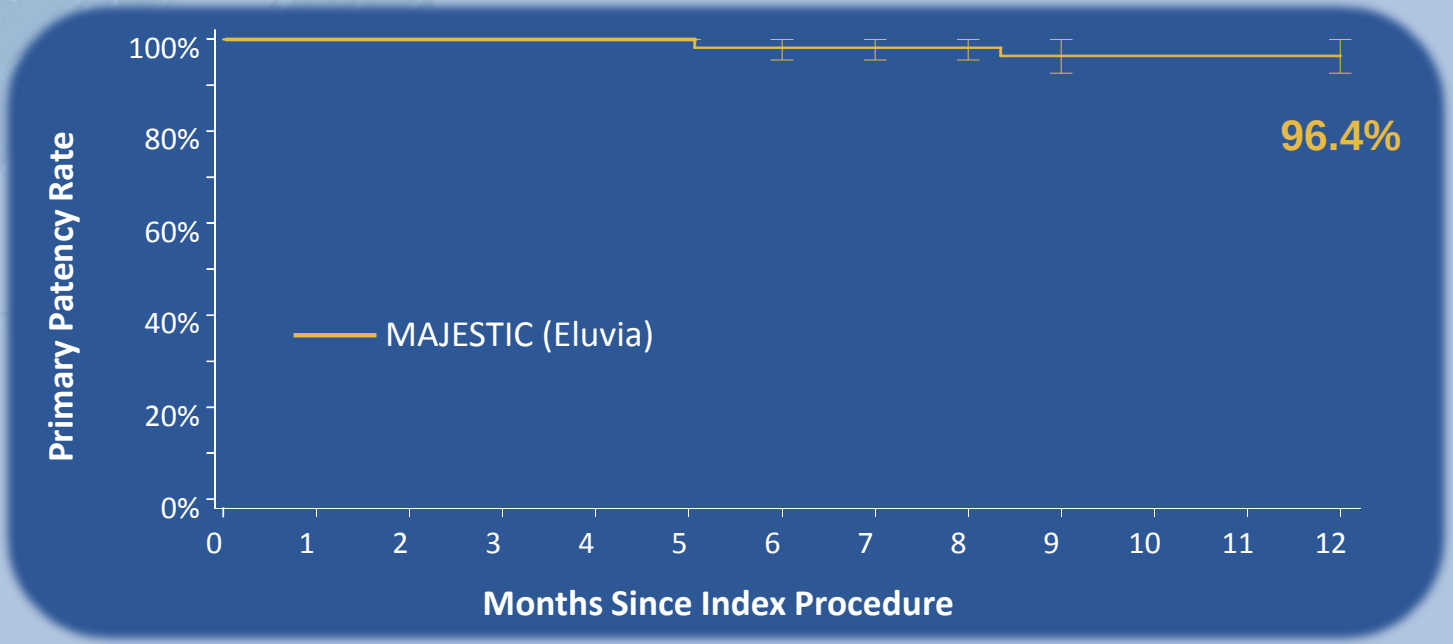
Demographics	
Age (Years)	69.3±9.3
Male Gender	82.5%
Race/Ethnicity	
Caucasian	94.7%
Asian	1.8%
Other	3.5%
General Medical History	
Smoking	87.7%
Current Diabetes Mellitus	35.1%
Hyperlipidemia	63.2%
Hypertension	73.7%
Cardiac History	
Coronary Artery Disease	38.6%
Myocardial Infarction	15.8%
Congestive Heart Failure	5.3%
Peripheral Vascular History	
Peripheral Vascular Surgery	5.3%
Other Peripheral Endovascular Interventions	24.6%
History of Claudication	89.5%

Baseline Lesion Characteristics (core lab)

Arterial Segments	
Ostial	0.0%
Proximal	1.8%
Mid	59.6%
Distal	77.2%
Proximal Popliteal	8.8%
Length (mm)	70.8±28.1
Calcification	
None/Mild	21.1%
Moderate	14.0%
Severe	64.9%
Percent Diameter Stenosis	86.3%±16.2%
Occlusions	46%
Minimum Lumen Diameter (mm)	0.7±0.8
Reference Vessel Diameter (mm)	5.2±0.8
Patency to Foot	
No Infrapopliteal Vessel Patent	5.3%
1 Vessel Patent	28.1%
2 Vessels Patent	31.6%
3 Vessels Patent	22.8%

Patency at 12 Months

- 12-month primary patency rate was **96.1%** (49/51)
- Kaplan-Meier estimate: **96.4%**

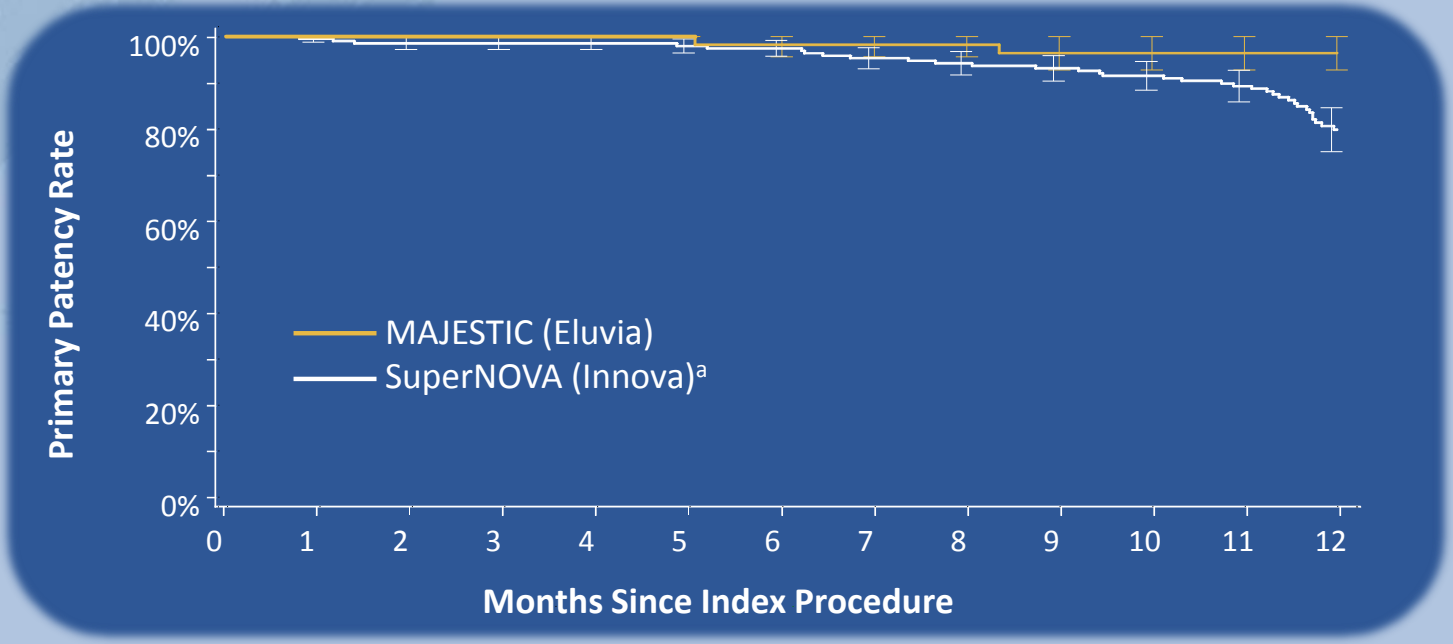


	0	1	2	3	4	6	9	12
Entered	57	57	56	56	56	56	55	53
Events	0	0	0	0	0	1	1	0
Event Rate	0%	0%	0%	0%	0%	1.8%	3.6%	3.6%

Primary patency defined as duplex ultrasound peak systolic velocity ratio ≤2.5 and absence of TLR or bypass. Caution: Investigational Device. Limited by US law to investigational use only. Not available for sale.

Patency at 12 Months: DES vs BMS

- Kaplan-Meier estimate for Eluvia DES: **96.4%**
- Paclitaxel effect suggested by divergence from bare metal platform



Primary patency defined as duplex ultrasound peak systolic velocity ratio ≤2.5 (MAJESTIC) or ≤2.4 (SuperNOVA) and absence of TLR or bypass.

[a]Patients who received 20-120 mm length Innova stents (n=202).

Results from different trials are not directly comparable. Information provided for educational purposes. Caution: Eluvia is an Investigational Device. Limited by US law to investigational use only. Not available for sale.

Safety Profile

	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%]

MAE

- 12-month composite MAE rate was 3.8% (2 TLR events)
- No new TLR events were observed between 9 and 12 months

Stent Integrity

- No stent fractures upon angiographic core lab analysis

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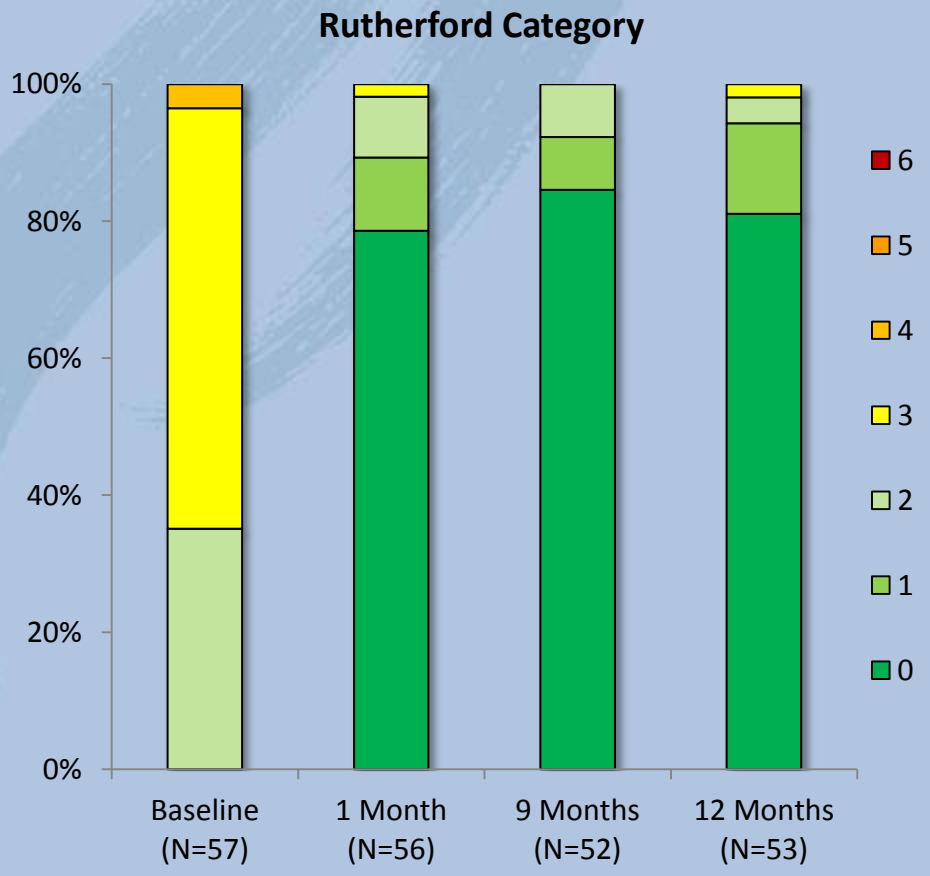
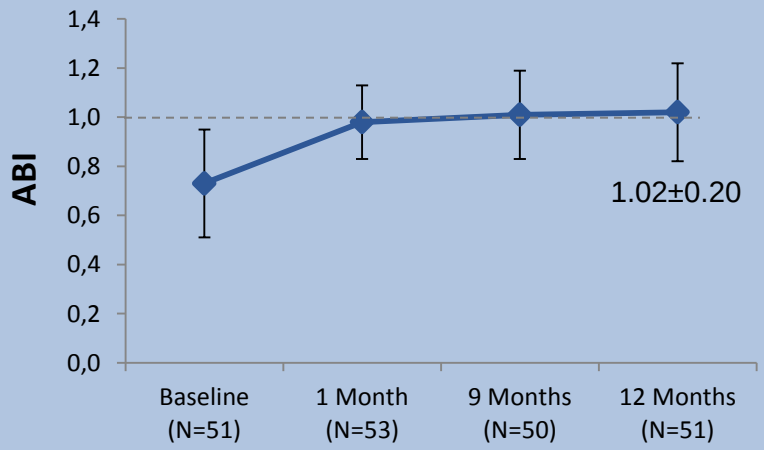
Patient Outcomes



- 94% of patients' symptoms classified as Rutherford Category 0-1 at 12 months
- ABI improvement sustained through 12 months



ABI, ankle-brachial index

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Diabetic Patients (n=20)

- Subgroup with challenging baseline medical and lesion characteristics

Lesion Characteristics	
Arterial Segments	
Proximal	5%
Mid	70%
Distal	75%
Length (mm)	77.7±20.4
Calcification	
None/Mild	15%
Moderate	10%
Severe	75%
Patency to Foot	
No Infrapopliteal Vessel Patent	10%
1 Vessel Patent	35%
2 Vessels Patent	30%
3 Vessels Patent	15%

Patient Characteristics	
Demographics	
Age (Years)	69.6±9.5
Male Gender	95%
Medical History	
Smoking	90%
Hyperlipidemia	85%
Hypertension	85%
Coronary Artery Disease	70%
Peripheral Vascular Surgery	10%
Other Peripheral Endovascular Interventions	35%
History of Claudication	90%

Diabetic Patients (n=20)

- 100% (14/14) 12-month primary patency
- 0% composite 12-month MAE rate

Safety	
12-Month MAE	0% (0/16)
All-Cause Death at 1 Month	0% (0/16)
Target Limb Major Amputation	0% (0/16)
Target Lesion Revascularization (TLR)	0% (0/16)

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Conclusions

- The MAJESTIC study of the Eluvia Drug-Eluting Stent in the femoropopliteal arteries showed a primary patency rate of 96.1% at 12 months
- Only 2 TLRs were reported through one year, yielding a TLR rate of 3.8%
- High patency and excellent safety profile achieved in the challenging subgroup of diabetic patients
- Zero stent fractures through 12 months
- Patients exhibited symptomatic and hemodynamic improvement through 12 months
- Eluvia's paclitaxel/polymer combination may provide a long-term benefit over the bare metal platform

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