

# MAJESTIC Clinical Trial

## 9-Month Data Presented at Charing Cross 2015

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

### OBJECTIVE:

To determine whether the Eluvia Drug-Eluting Vascular Stent System shows acceptable performance when treating superficial femoral (SFA) and/or proximal popliteal artery (PPA) lesions up to 110 mm in length as compared to a literature-derived performance goal, with a primary endpoint of primary patency at 9 months.

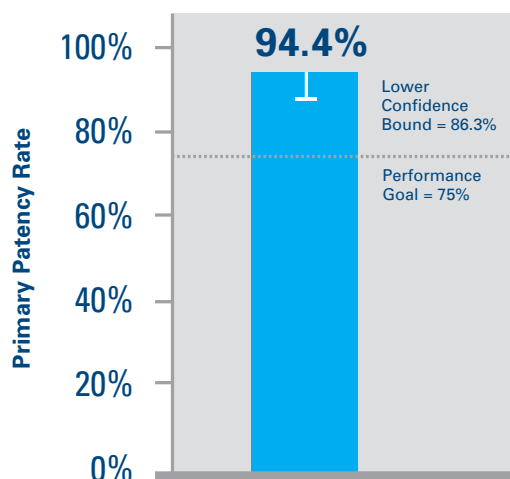
### TRIAL DESIGN:

- 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  $\geq 70\%$  (visual angiographic assessment)
- Vessel diameter  $\geq 4$  and  $\leq 6$ mm
- Total lesion length  $\geq 30$  mm and  $\leq 110$  mm

### BASELINE CHARACTERISTICS:

| Patient Demographics    | n = 57 subjects | Lesion Characteristics (Core Lab) | n = 57 lesions    |
|-------------------------|-----------------|-----------------------------------|-------------------|
| Age (Years)             | 69.3 $\pm$ 9.3  | Reference Vessel Diameter         | 5.2 $\pm$ 0.8     |
| Male Gender             | 82.5%           | Target Lesion Length              | 70.8 $\pm$ 28.1   |
| Diabetes Mellitus       | 35.1%           | Severely Calcified                | 64.9%             |
| History of Smoking      | 87.7%           | Percent Diameter Stenosis         | 86.3% $\pm$ 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%              |

### 9-Month Primary Patency



### PRIMARY ENDPOINT:

#### DEFINITION

- Primary patency at 9 months post-procedure assessed by duplex ultrasound as adjudicated by an independent core laboratory<sup>1</sup>

#### OUTCOME

- 94.4% primary patency at 9 months
  - The one-sided lower 95% confidence bound (86.3%) exceeded the performance goal of 75%
- 3.6% target lesion revascularization (TLR) rate at 9 months (2/55)

<sup>1</sup>Primary patency defined as duplex ultrasound PSVR  $\leq 2.5$  and absence of TLR or bypass. Data on file at Boston Scientific.

# MAJESTIC Clinical Trial

## 9-Month Data Presented at Charing Cross 2015

### SAFETY ENDPOINT:

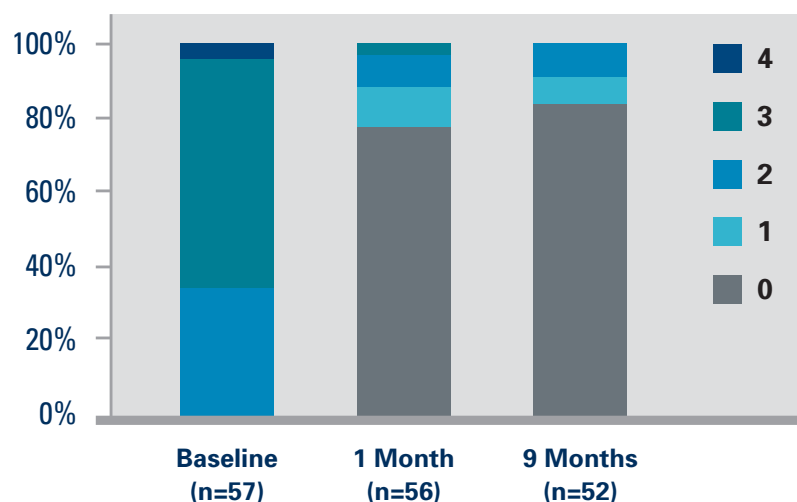
- 3.6% composite major adverse event rate at 9 months
- No deaths or amputations; 2 TLRs (2/55)

|                                       | Overall | 95% CI        |
|---------------------------------------|---------|---------------|
| <b>9-Month MAE</b>                    | 3.6%    | [0.4%, 12.5%] |
| All-Cause Death at 1 Month            | 0.0%    | [0.0%, 6.5%]  |
| Target Limb Major Amputation          | 0.0%    | [0.0%, 6.5%]  |
| Target Lesion Revascularization (TLR) | 3.6%    | [0.4%, 12.5%] |

### PATIENT OUTCOMES:

- 92.3% of patients presented with no or minimal claudication (Rutherford 0-1) at 9 months
- Mean ABI improved from  $0.73 \pm 0.22$  at baseline to  $1.01 \pm 0.18$  at 9 months

**Rutherford Category**



### CONCLUSIONS:

- The MAJESTIC clinical trial met its primary efficacy endpoint with a 9-month primary patency of 94.4%. The Eluvia stent's patency was accompanied by a TLR rate of 3.6%.
- The Eluvia stent demonstrated a 9-month composite major adverse event rate of 3.6%, driven by two TLRs, with no deaths or amputations.
- In the MAJESTIC trial, 92.3% of patients treated with the Eluvia stent had no or minimal claudication at 9 months.