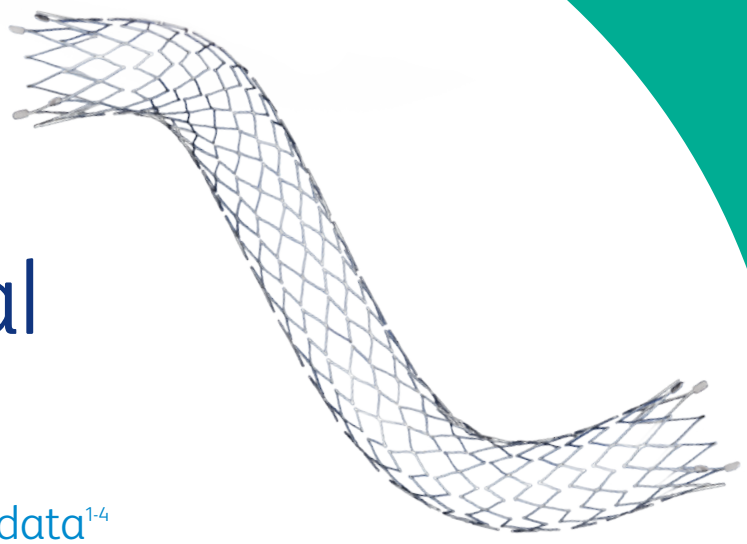
E·Luminexx™
Vascular Stent



Clinical trial outcomes

A review of clinical trial data[1-4]

The displayed clinical data are taken from a number of different studies, not a head-to-head study. Each study may have varying patient profiles and protocol structures that may affect the outcome rates set forth below, and therefore is not intended to demonstrate superiority of any one product.

The Luminexx™ Iliac Stent Clinical Study met the success criteria for the primary endpoint: posterior probability of at least 96% that the 9-month MACE rate was < 25%. MACE included peri-procedural death, TLR and stent segment restenosis, and non-study stent. (Non-study stent was added post hoc to the protocol definition of MACE.)

E·Luminexx™ Vascular Stent
(P080007)

94.03%
Primary patiency rate

98.72%
Anatomic success
(Site reposted)

0.75%
Mortality Rate
Devise or Procedure

The Luminexx™ Iliac Stent Clinical Study demonstrated competitive results when considering Primary Patency Rate, Anatomic Success and Mortality Rate.

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Ordering information

BF Catheter System: 0.035" Guidewire

Order Code	Stent Diameter (mm)	Catheter Length (cm)	Stent Length (atm)
ZVM06020	6	80	20
ZVM06030			30
ZVM06040			40
ZVM06050			50
ZVM06060			60
ZVM06080			80
ZVM06100			100
ZVM06120			120
ZVL06020		135	20
ZVL06030			30
ZVL06040			40
ZVL06050			50
ZVL06060			60
ZVL06080			80
ZVL06100			100
ZVL06120			120
ZVM07020	7	80	20
ZVM07030			30
ZVM07040			40
ZVM07050			50
ZVM07060			60
ZVM07080			80
ZVM07100			100
ZVM07120			120
ZVL07020		135	20
ZVL07030			30
ZVL07040			40
ZVL07050			50
ZVL07060			60
ZVL07080			80
ZVL07100			100
ZVL07120			120
ZVM08020	8	80	20
ZVM08030			30
ZVM08040			40
ZVM08050			50
ZVM08060			60
ZVM08080			80
ZVM08100			100
ZVM08120			120
ZVL08020		135	20
ZVL08030			30
ZVL08040			40
ZVL08050			50
ZVL08060			60
ZVL08080			80
ZVL08100			100
ZVL08120			120
ZVM09020	9	80	20
ZVM09030			30
ZVM09040			40
ZVM09050			50
ZVM09060			60
ZVM09080			80
ZVM09100			100
ZVM09120			120

BF Catheter System: 0.035" Guidewire

Order Code	Stent Diameter (mm)	Catheter Length (cm)	Stent Length (atm)
ZVL09020	9	135	20
ZVL09030			30
ZVL09040			40
ZVL09050			50
ZVL09060			60
ZVL09080			80
ZVL09100			100
ZVL09120			120
ZVM10020	10	80	20
ZVM10030			30
ZVM10040			40
ZVM10050			50
ZVM10060			60
ZVM10080			80
ZVM10100			100
ZVM10120			120
ZVL10020		135	20
ZVL10030			30
ZVL10040			40
ZVL10050			50
ZVL10060			60
ZVL10080			80
ZVL10100			100
ZVL10120			120
ZVM12020	12	80	20
ZVM12030			30
ZVM12040			40
ZVM12050			50
ZVM12060			60
ZVM12080			80
ZVM12100			100
ZVM12120			120
ZVL12020		135	20
ZVL12030			30
ZVL12040			40
ZVL12050			50
ZVL12060			60
ZVL12080			80
ZVL12100			100
ZVL12120			120
ZVM14020	14	80	20
ZVM14030			30
ZVM14040			40
ZVM14050			50
ZVM14060			60
ZVM14080			80
ZVM14100			100
ZVM14120			120
ZVL14020		135	20
ZVL14030			30
ZVL14040			40
ZVL14050			50
ZVL14060			60
ZVL14080			80
ZVL14100			100
ZVL14120			120

References

1. S.M.A.R.T.® Control™ Nitinol Stent System. Premarket Approval Application Number P020036. Summary of Safety and Effectiveness Data, 2003. **2.** Zilver® 635™ Vascular Stent. Premarket Approval Application Number P050017. Summary of Safety and Effectiveness Data, 2006. **3.** Wallstent-Uni™ Iliac Endoprosthesis. Premarket Approval Application Number P940019. Summary of Safety and Effectiveness Data, 1996. **4.** Ponec D, Jaff MR, Swischuk J, Feiring A, Laird J, Mehra M, Popma JJ, Donohoe D, Firth B, Heim E, Snead D. The nitinol SMART stent vs. Wallstent for suboptimal iliac artery angioplasty: CRISP-US trial results. J Vase Interv Radiol. 2004;15:911-918.

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions, and information for use

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