S.M.A.R.T.® Vascular Stent Systems

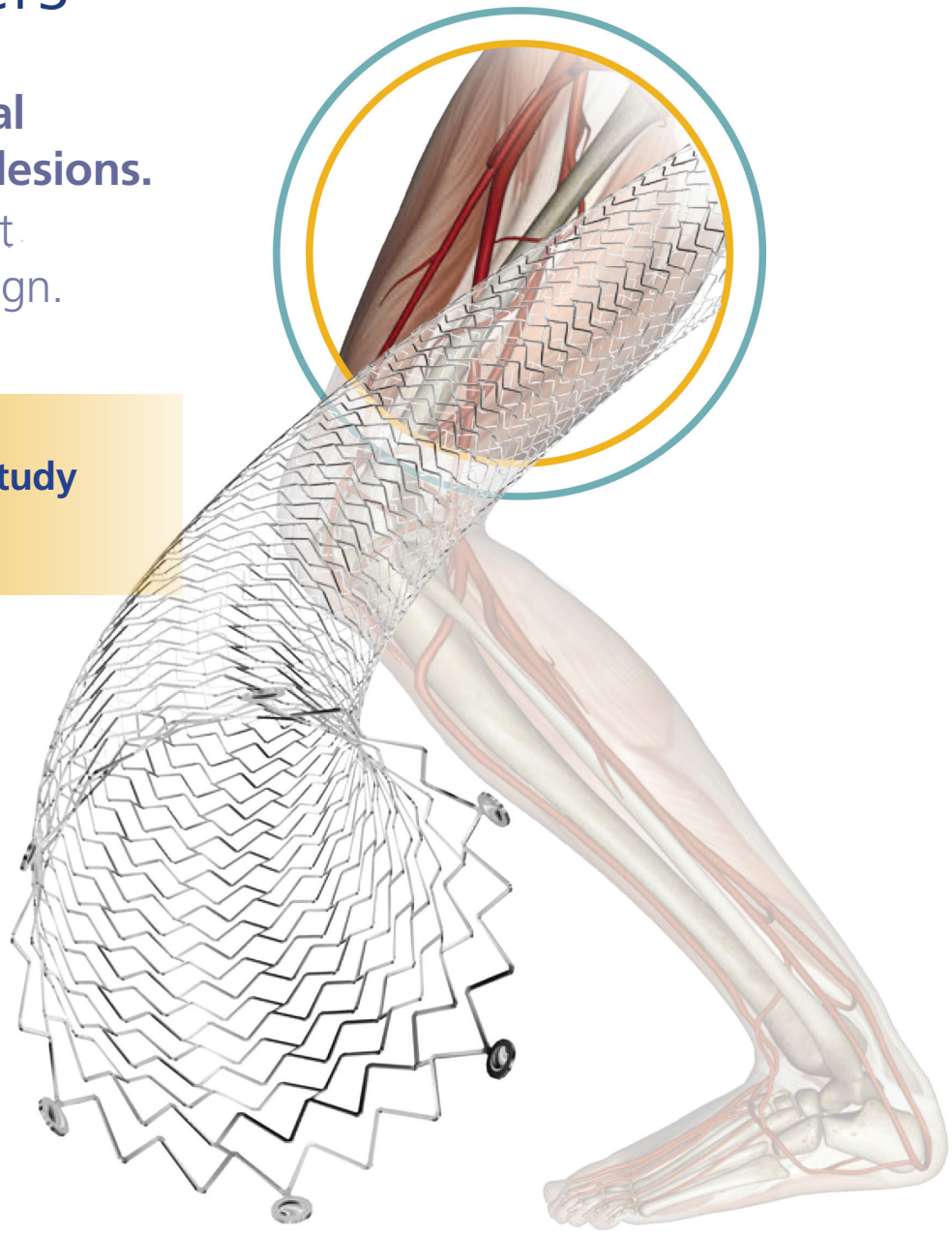
Lower Extremity Solutions

When Outcomes Matter, Design Matters

For superficial femoral artery (SFA) and iliac lesions.

Achieve optimal patient outcomes through design.

3-year STROLL Study results inside



Data on file at Cordis.

Cordis®

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OUTCOMES MATTER

Compelling outcomes in the STROLL* Study

"The STROLL outcomes both meet and exceed our expectations for patients with symptomatic disease of the superficial femoral artery."

—Dr William A. Gray,† Director of Endovascular Services
Cardiovascular Research Foundation, New York

Effective SFA revascularization through 3-years with the S.M.A.R.T.® Vascular Stent Systems[1]

STROLL Outcomes

Clinical Outcomes	1 year	2 years	3 years
Primary Patency†	81.7%	74.9%	72.7%
Freedom from TLR	87.6%	80.3%	78.5%
Stent fracture rate	2% (all Type I)	2% (all Type I)	3.6% (all Type I)
Patient Outcomes	**1 year**	**2 years**	**3 years**
Patients with minimal or no PAD symptoms§	76.6%	81.8%	77.8%
Patients with normal ABI (>0.8)	81.0%	80.7%	76.5%

Patient Reported Quality-of-Life Outcomes:

Health Related QoL benefit was very large and sustained out to 3-years

- **10-15** years of age on generic measures
- **~4x** the Minimum Clinically Importance Difference (MCID) on PAD-Specific scales

*The S.M.A.R.T.® Nitinol Self-expanding Stent in the Treatment of Obstructive Superficial Femoral Artery Disease (STROLL) study.
†A principal investigator of the STROLL study.
‡Defined as no significant reduction in flow detectable by duplex ultrasound and no further clinically driven target lesion revascularization.
§Defined as Rutherford-Becker classification 0 or 1.

Reference: 1. Data on file at Cordis.

DESIGN MATTERS

Designed for optimal performance

S.M.A.R.T.® Vascular Stent Systems—design is key

Scaffolding

Smaller cell size and uniform coverage can help prevent vessel prolapse.

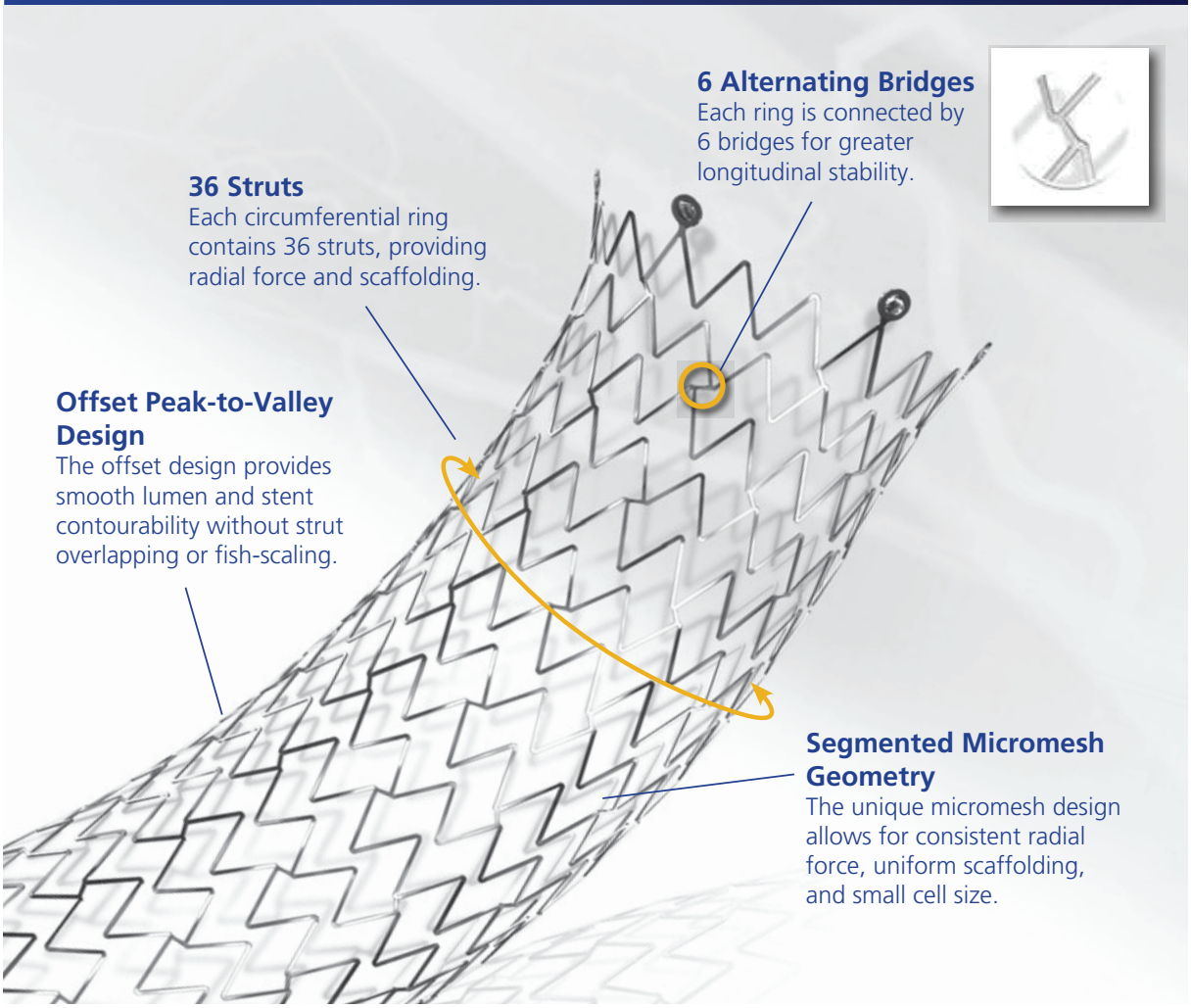
Longitudinal stability

Greater stability minimizes stretching at deployment, thereby increasing placement accuracy.

Radial force

The stent's ability to resist compression maintains luminal gain.

Unique 36 strut/6 bridge construction



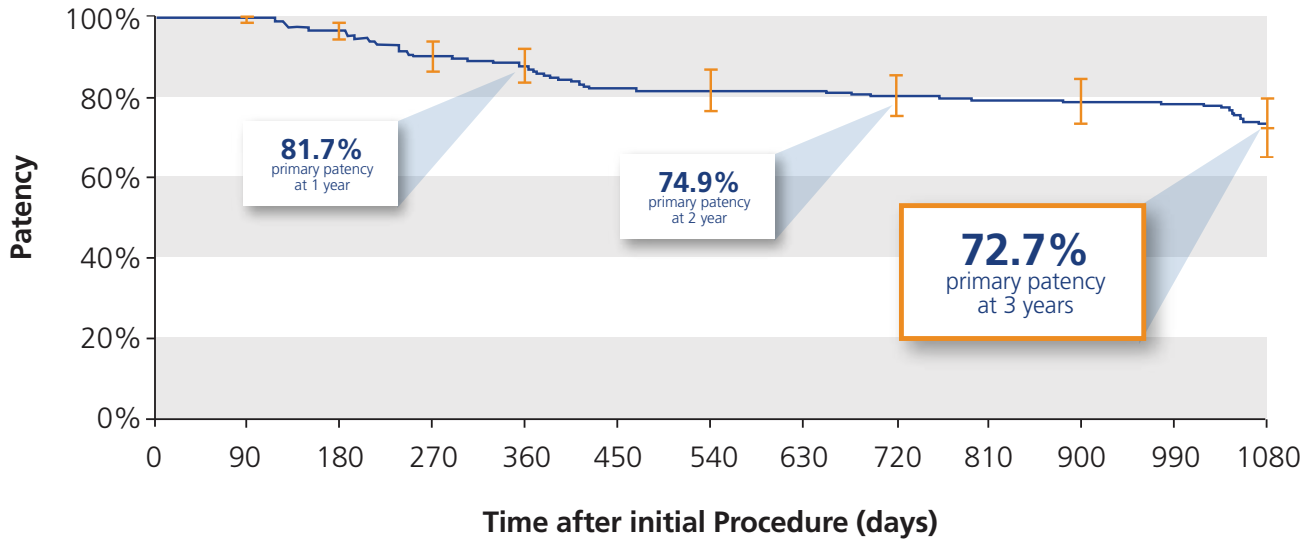
Data on file at Cordis.

OUTCOMES MATTER

Achieve desired clinical outcomes

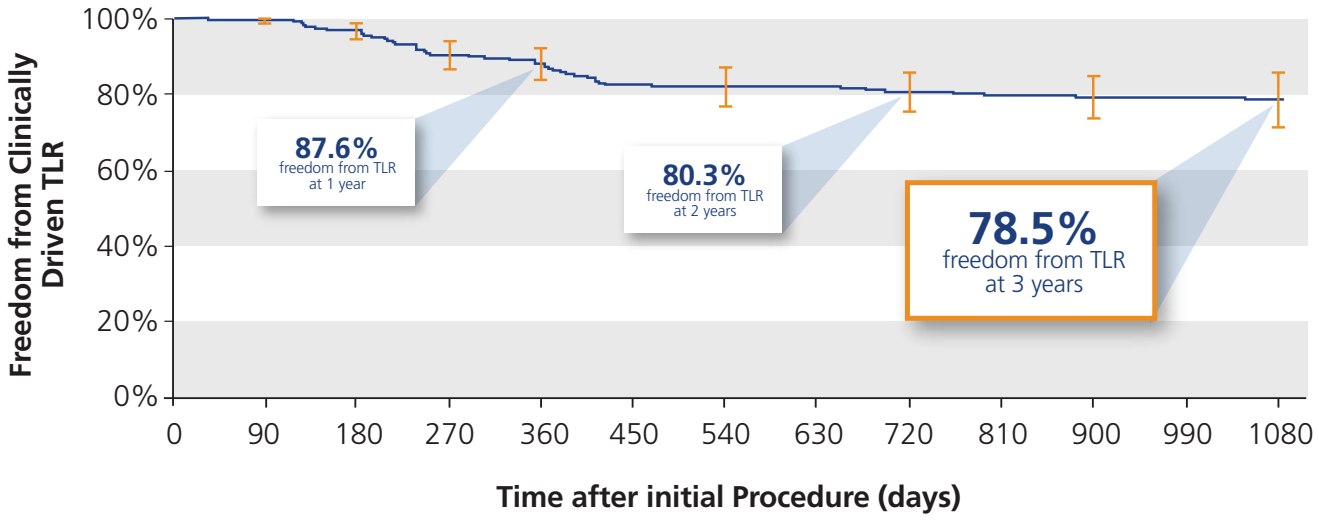
High primary patency rate maintained out to 3 years in the STROLL Study with the S.M.A.R.T.® Vascular Stent Systems[1]

Primary patency



Strong rate of freedom from TLR maintained out to 3 years in the STROLL study[1]

Freedom from TLR

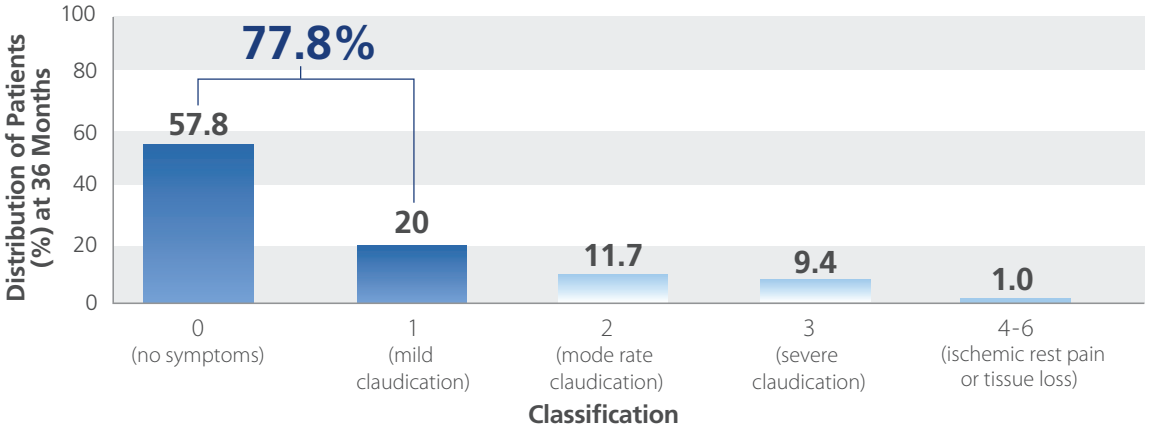


Reference: 1. Data on file at Cordis.

Provide critical patient outcomes

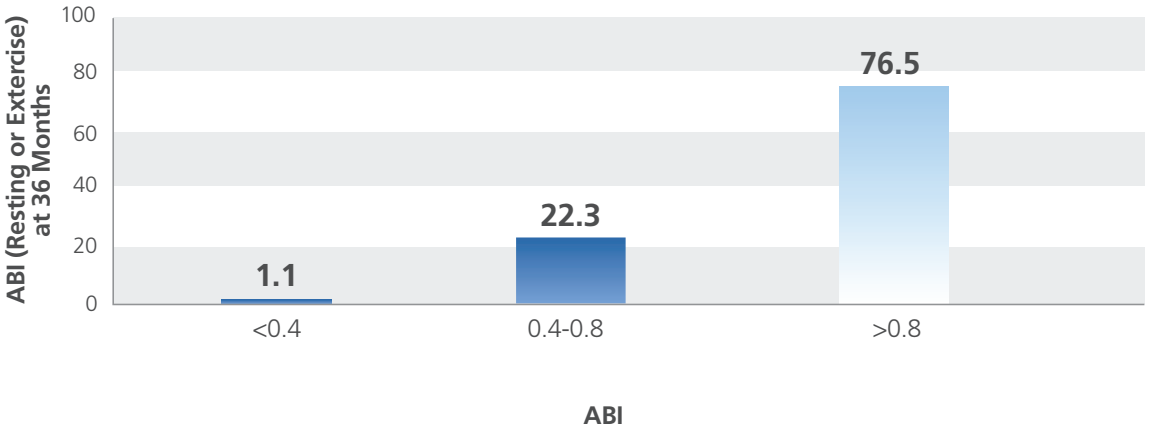
Minimal or no signs of PAD* in 3 of 4 patients maintained out to 3 years in the STROLL Study as measured **using Rutherford-Becker classification**[1]

Rutherford-Becker classification



Improvement in ABI was sustained out to 3 years

Ankle-Brachial Index



Normal ABI in over 3 out of 4 patients out to 3 years when treated with the S.M.A.R.T.® Vascular Stent

- 81%, 80.7% and 76.5% of patients had ABI >0.8 one, two and three years, respectively, after deployment of S.M.A.R.T.® Vascular Stent Systems

*Defined as Rutherford-Becker classification 0 or 1.

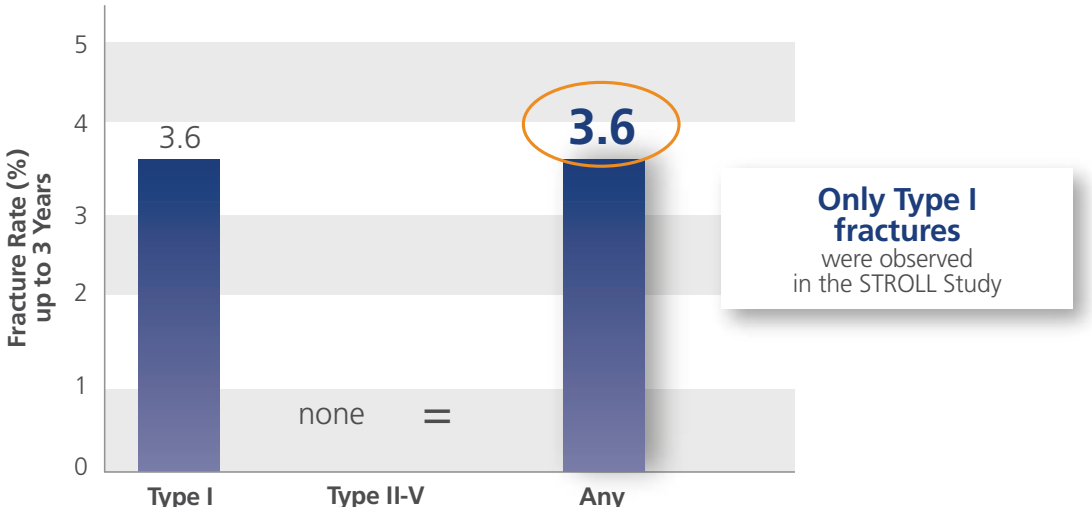
Reference: 1. Data on file at Cordis.

DURABILITY MATTERS

Experience sustained stent integrity

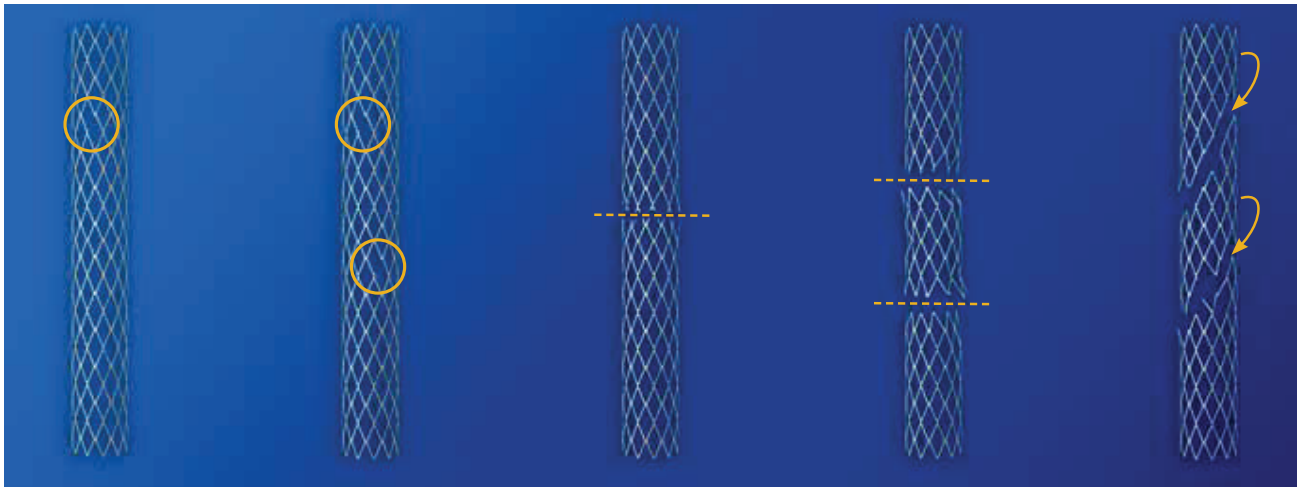
Low fracture rate maintained out to 3 years in the STROLL Study with the S.M.A.R.T.® Vascular Stent Systems[1]

Stent fracture rate



Assessing stent fractures, which may lead to adverse outcomes[2]

Stent fracture grading scale



Type I
One strut fracture

Type II
Multiple strut fractures

Type III
Complete transverse linear fracture

Type IV
Complete transverse linear fracture with displacement

Type V
Complete transaxial fracture

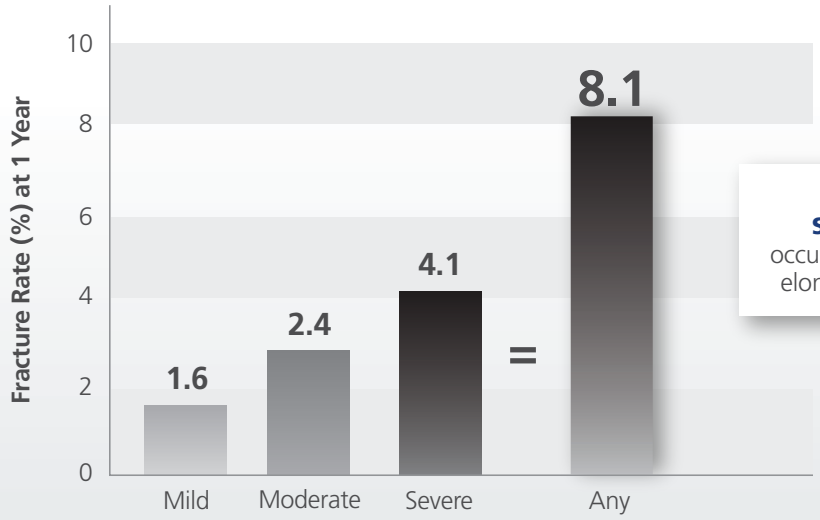
Adapted from Rocha-Singh et al.[2]

References: 1. Data on file at Cordis. **2**.Rocha-Singh KJ et al; on behalf of VIVA Physicians, Inc. *Catheter Cardiovasc Interv*. 2007;69:910-919.

Fracture rates with other stents

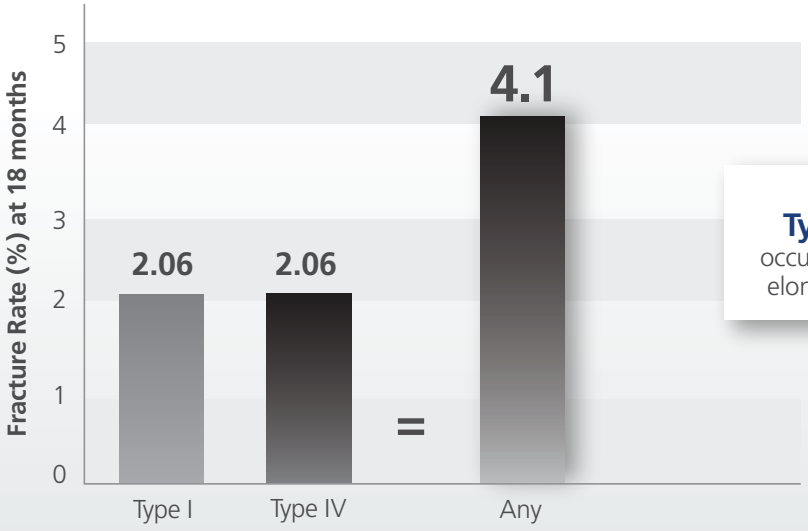
Severe fractures observed with **EV3 Protégé® EverFlex® Stent** and **Bard LifeStent® Stent**

EverFlex® (DURABILITY I Trial) at 1 year[1]



90% of all stent fractures
occurred in stents that were elongated at deployment[1]

LifeStent® (RESILIENT Trial—all phases and arms) at 18 months[2]



100% of Type IV fractures
occurred in stents that were elongated at deployment[2]

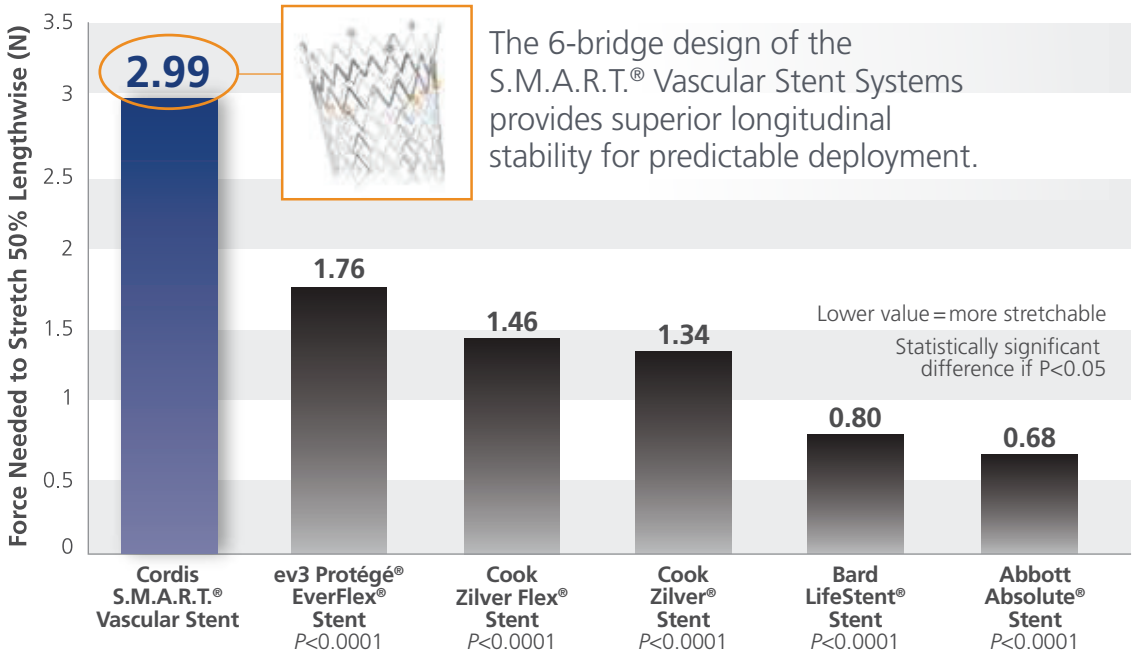
References: 1. Bosiers M et al. *J Endovasc Ther.* 2009;16:261-269. **2.** The RESILIENT Randomized Trial: Three-Year Results, Resiliant LINC Presentation 2013.

DESIGN MATTERS

Statistically superior stability

Up to 300% greater stability for accurate placement with the S.M.A.R.T.® Vascular Stent Systems[1]

Longitudinal stability[1]



Unique design provides **uniform scaffolding** and **small cell size**

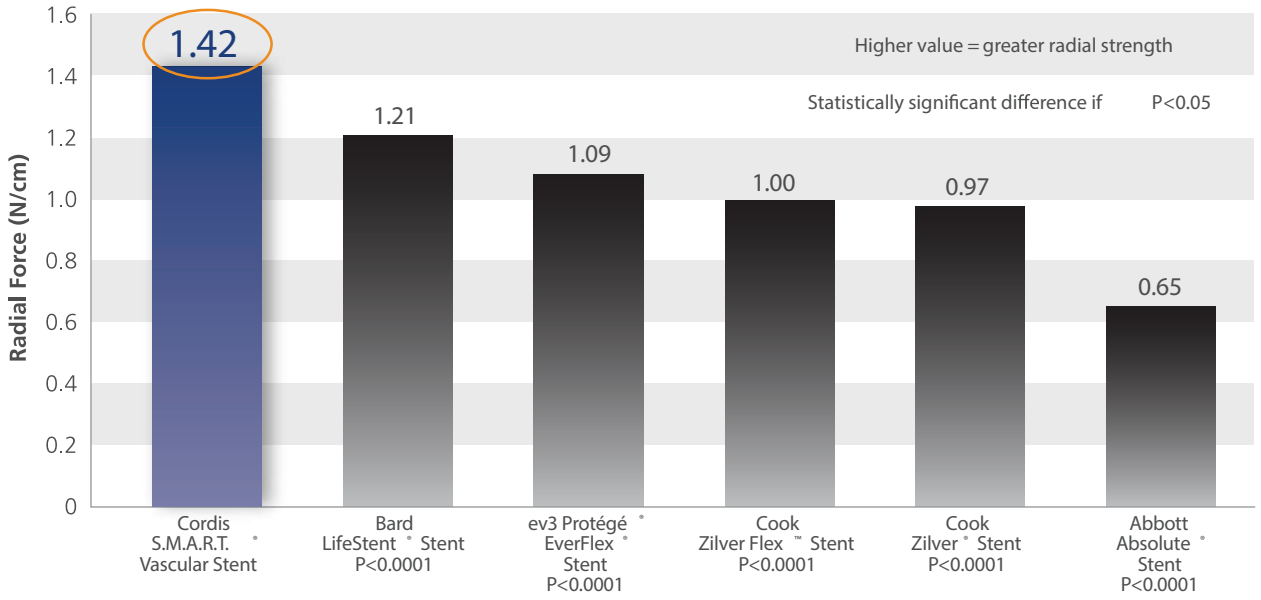
Cordis S.M.A.R.T.® Vascular Stent	ev3 Protégé® EverFlex® Stent	Abbott Absolute® Stent	Bard LifeStent® Stent	Cook Zilver® Stent
36 Struts/6 Bridges	32 Struts/4 Bridges	12 Struts/3 Bridges	36 Struts/4 Bridges	24 Struts/4 Bridges

Reference: 1. Data on file at Cordis.

Unmatched radial force

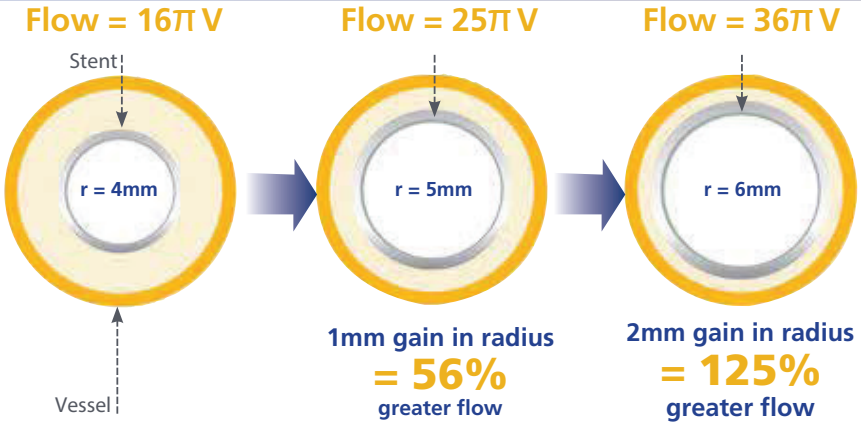
Up to 118% greater radial force than other nitinol stents with the S.M.A.R.T.® Vascular Stent Systems[1]

Radial force[1]



Increased radial force maximizes luminal gain

Greater radial force = Larger lumen = More flow



S.M.A.R.T.® Vascular Stent Systems are designed to maintain luminal gain

Reference: 1. Data on file at Cordis.

Cordis S.M.A.R.T.® CONTROL and S.M.A.R.T.® Vascular Stent Systems

Product Description

Type: MicroMesh Geometry, Segmented Design
Material: Nitinol, with MicroMarker™ Technology
Stent Diameters: 6-10mm (Stent diameter should be 1-2mm greater than vessel diameter)
Stent Delivery System Working Lengths: 80cm (S suffix) & 120cm (M suffix)
Stent Delivery Systems: Delivery Handle: 20-100mm Stent lengths.
Pin and Pull: 120 and 150mm Stent Lengths
Maximum Guidewire: .035"
Stent Lengths: 20 - 150mm
Sheath Compatibility: 6F (6-10mm)
Guide Catheter Compatibility: 8F (6-10mm)

Ordering information

20mm Stent Length

Catalog Number	Indication	Expanded Stent Diameter (mm)	SDS Length (cm)	Recommended Vessel Size (mm)
C06020SL	Iliac and SFA	6	80	4-5
C06020ML	Iliac and SFA	6	120	4-5
C07020SL	Iliac and SFA	7	80	5-6
C07020ML	Iliac and SFA	7	120	5-6
C08020SL	Iliac and SFA	8	80	6-7
C08020ML	Iliac and SFA	8	120	6-7
C09020SL	Iliac	9	80	7-8
C09020ML	Iliac	9	120	7-8
C10020SL	Iliac	10	80	8-9
C10020ML	Iliac	10	120	8-9

30mm Stent Length

Catalog Number	Indication	Expanded Stent Diameter (mm)	SDS Length (cm)	Recommended Vessel Size (mm)
C06030ML	Iliac and SFA	6	120	4-5
C06030SL	Iliac and SFA	6	80	4-5
C07030ML	Iliac and SFA	7	120	5-6
C07030SL	Iliac and SFA	7	80	5-6
C08030ML	Iliac and SFA	8	120	6-7
C08030SL	Iliac and SFA	8	80	6-7
C09030ML	Iliac	9	120	7-8
C09030SL	Iliac	9	80	7-8
C10030ML	Iliac	10	120	8-9
C10030SL	Iliac	10	80	8-9

Ordering Information: 40mm Stent Length

Catalog Number	Indication	Expanded Stent Diameter, mm	SDS Length, cm	Recommended Vessel Size, mm
C06040ML	Iliac and SFA	6	120	4-5
C06040SL	Iliac and SFA	6	80	4-5
C07040ML	Iliac and SFA	7	120	5-6
C07040SL	Iliac and SFA	7	80	5-6
C08040ML	Iliac and SFA	8	120	6-7
C08040SL	Iliac and SFA	8	80	6-7
C09040ML	Iliac	9	120	7-8
C09040SL	Iliac	9	80	7-8
C10040ML	Iliac	10	120	8-9
C10040SL	Iliac	10	80	8-9

Ordering Information: 60mm Stent Length

Catalog Number	Indication	Expanded Stent Diameter, mm	SDS Length, cm	Recommended Vessel Size, mm
C06060ML	Iliac and SFA	6	120	4-5
C06060SL	Iliac and SFA	6	80	4-5
C07060ML	Iliac and SFA	7	120	5-6
C07060SL	Iliac and SFA	7	80	5-6
C08060ML	Iliac and SFA	8	120	6-7
C08060SL	Iliac and SFA	8	80	6-7
C09060ML	Iliac	9	120	7-8
C09060SL	Iliac	9	80	7-8
C10060ML	Iliac	10	120	8-9
C10060SL	Iliac	10	80	8-9

Ordering Information: 80mm Stent Length

Catalog Number	Indication	Expanded Stent Diameter, mm	SDS Length, cm	Recommended Vessel Size, mm
C06080ML	Iliac and SFA	6	120	4-5
C06080SL	Iliac and SFA	6	80	4-5
C07080ML	Iliac and SFA	7	120	5-6
C07080SL	Iliac and SFA	7	80	5-6
C08080ML	Iliac and SFA	8	120	6-7
C08080SL	Iliac and SFA	8	80	6-7

Ordering Information: 100mm Stent Length

Catalog Number	Indication	Expanded Stent Diameter, mm	SDS Length, cm	Recommended Vessel Size, mm
C06100ML	Iliac and SFA	6	120	4-5
C06100SL	Iliac and SFA	6	80	4-5
C07100ML	Iliac and SFA	7	120	5-6
C07100SL	Iliac and SFA	7	80	5-6
C08100ML	Iliac and SFA	8	120	6-7
C08100SL	Iliac and SFA	8	80	6-7

Ordering Information: 120mm Stent Length

Catalog Number	Indication	Expanded Stent Diameter, mm	SDS Length, cm	Recommended Vessel Size, mm
C06120ML	SFA	6	120	4-5
C07120ML	SFA	7	120	5-6
C08120ML	SFA	8	120	6-7

Ordering Information: 150mm Stent Length

Catalog Number	Indication	Expanded Stent Diameter, mm	SDS Length, cm	Recommended Vessel Size, mm
C06150ML	SFA	6	120	4-5
C07150ML	SFA	7	120	5-6
C08150ML	SFA	8	120	6-7

S.M.A.R.T.® Flex Biliary Stent System

Product Description

Type: Fully connected yet flexible stent design
Material: Nitinol, with tantalum markers on stent ends
Maximum Guidewire: 0.035”
Stent Lengths: 30 - 150 mm
Sheath Compatibility: 6F
Stent Diameters: 5-10mm (Stent diameter should be 0.5-1.5 mm greater than vessel diameter)
Stent Delivery System Working Lengths: 80 cm (S suffix) and 120 cm (M suffix)

Ordering Information

Product Code		Stent			Delivery System	
80 cm Usable Length	120 cm Usable Length	Stent Diameter (mm)	Stent Length (mm)	Recommended Lumen Size (mm)	Recommended Sheath Introducer Size (F)	Guidewire Acceptance
	SF05030MB	5	30	3.5-4.5	6	.035"
	SF05040MB	5	40	3.5-4.5	6	.035"
	SF05060MB	5	60	3.5-4.5	6	.035"
	SF05080MB	5	80	3.5-4.5	6	.035"
	SF05100MB	5	100	3.5-4.5	6	.035"
	SF05120MB	5	120	3.5-4.5	6	.035"
	SF06030MB	6	30	4.5-5.5	6	.035"
	SF06040MB	6	40	4.5-5.5	6	.035"
	SF06060MB	6	60	4.5-5.5	6	.035"
	SF06080MB	6	80	4.5-5.5	6	.035"
	SF06100MB	6	100	4.5-5.5	6	.035"
	SF06120MB	6	120	4.5-5.5	6	.035"
	SF06150MB	6	150	4.5-5.5	6	.035"
	SF07030MB	7	30	5.5-6.5	6	.035"
	SF07040MB	7	40	5.5-6.5	6	.035"
	SF07060MB	7	60	5.5-6.5	6	.035"
	SF07080MB	7	80	5.5-6.5	6	.035"
	SF07100MB	7	100	5.5-6.5	6	.035"
	SF07120MB	7	120	5.5-6.5	6	.035"
	SF07150MB	7	150	5.5-6.5	6	.035"
SF08030SB	SF08030MB	8	30	6.5-7.5	6	.035"
SF08040SB	SF08040MB	8	40	6.5-7.5	6	.035"
SF08060SB	SF08060MB	8	60	6.5-7.5	6	.035"
SF08080SB	SF08080MB	8	80	6.5-7.5	6	.035"
SF08100SB	SF08100MB	8	100	6.5-7.5	6	.035"
	SF08120MB	8	120	6.5-7.5	6	.035"
	SF08150MB	8	150	6.5-7.5	6	.035"
SF09030SB	SF09030MB	9	30	7.5-8.5	6	.035"
SF09040SB	SF09040MB	9	40	7.5-8.5	6	.035"
SF09060SB	SF09060MB	9	60	7.5-8.5	6	.035"
SF09080SB	SF09080MB	9	80	7.5-8.5	6	.035"
SF09100SB	SF09100MB	9	100	7.5-8.5	6	.035"
SF10030SB	SF10030MB	10	30	8.5-9.5	6	.035"
SF10040SB	SF10040MB	10	40	8.5-9.5	6	.035"
SF10060SB	SF10060MB	10	60	8.5-9.5	6	.035"
SF10080SB	SF10080MB	10	80	8.5-9.5	6	.035"
SF10100SB	SF10100MB	10	100	8.5-9.5	6	.035"

Cordis S.M.A.R.T.® Flex Biliary Stent System: Essential Prescribing Information

Indication: The S.M.A.R.T.® Flex Biliary Stent System is indicated for use in the palliation of malignant strictures in the biliary tree.

Contraindications: Use of the S.M.A.R.T.® Flex Biliary Stent System
- Stent of a duct with total biliary occlusion which cannot be crossed by the delivery catheter
- Stenting of a perforated duct where leakage from the duct could be exacerbated by the prosthesis
- Patients with bleeding disorders
- Severe ascites.

General Warnings / Precautions:
- The safety and effectiveness of this device for use in the vascular system have not been established .
- Store at ambient room conditions out of direct sunlight.
- The device is provided STERILE and is intended for single use only. Do Not Resterilize the device and / or reuse the device. Do not autoclave.
- Do not use beyond the "Use By" date.
- Carefully inspect the sterile packaging and device prior to use. Do not use if it appears damaged.
- If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to the stent or lumen.
- If resistance occurs during movement through the sheath, carefully withdraw the stent system.
- Do not expose the delivery system to organic solvents.
- If resistance is encountered at any time during the insertion procedure, do not force passage. Resistance may cause damage to the stent or lumen.
- If resistance occurs during movement through the sheath, carefully withdraw the stent system.
- If resistance is felt when initially retracting the outer deployment sheath, do not force deployment. Carefully withdraw the stent system without deploying the stent.
- Persons allergic to nitinol (nickel titanium) may suffer an allergic reaction to this implant.
- This product should only be used by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for interventional procedures should be employed.
- Do not use power injection systems with the delivery system.
- Use in patients with a history of contrast sensitivity is not recommended unless the patient can be adequately pre-medicated.
- The system is not designed for stent repositioning or recapturing.
- Use caution when crossing a deployed stent with any adjunct device.

Potential Adverse Events:
Potential hazards and side effects include, but are not limited to:
- Infection secondary to contamination of the stent may lead to cholangitis, hemobilia, peritonitis, or abscess.
- Pancreatitis.
- Overstretching of the duct may result in rupture leading to infection or death.
- Persons with allergic reactions to nickel titanium (Nitinol) may suffer an allergic response to this implant.
- Drug reaction to contrast media.
- Tumor overgrowth at the stent ends.
- Intervention due to: stent migration, unintentional placement of stent, partial stent deployment, or stretched and/or damaged stents.

Please read the Instructions for Use (IFU) label provided at www.cordislabeling.com for indications, contraindications, potential complications, warnings/precautions, and information for use. You may also call 1-800-327-7714 to request a paper version of the IFU label.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. For information on indications, contraindications, warnings, precautions, and adverse events, see Full Instructions for Use.

Data on file at Cordis.

The Cordis® Commitment

Cordis Corporation is committed to unerring customer support and sponsoring extensive training programs for thousands of physicians each year across the globe.

The CORDIS® CARDIAC & VASCULAR INSTITUTE℠ comprises a global network of expertise dedicated to advancing cardiac and vascular care by providing essential educational programs, simulation workshops, technology forums, and scientific symposia.

Cordis® Lower Extremity Crossing Courses are specifically designed to further develop your specialized peripheral vascular procedural skills using our Lower Extremity Solutions to cross and treat the most difficult and diffuse vascular disease by providing:

- Live-case observation of complex Lower Extremity Interventions
- Didactic clinical overviews by host faculty on procedural techniques and clinical advantages
- Hands-on in-services

Connecting healthcare professionals to global expertise in cardiac and vascular technologies and treatment are some of the ways we further our global commitment to optimize outcomes on behalf of patients.

With a total of 11 locations, one of our facilities in the United States, South America, Europe, India, China, Japan, or Russia is convenient to you.

Cordis provides a comprehensive portfolio of Lower Extremity Solutions that helps simplify even your most difficult procedures. By sponsoring extensive educational programs and offering a broad range of access, crossing, and interventional products, we are living our commitment—partnering with you to improve clinical and patient outcomes.

For more information, please contact your local Cordis sales representative.

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