SELUTION SLR™: Sustained Limus Release DEB for long term patient benefit

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DISCLOSURE STATEMENT OF FINANCIAL INTEREST

Thomas Zeller, MD

For the 12 months preceding this presentation, I disclose the following types of financial relationships:

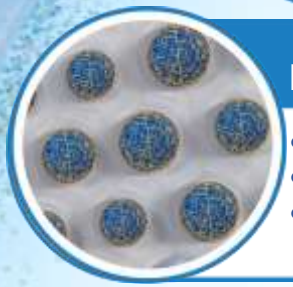
- **Honoraria received from:** Abbott Vascular, B. Braun, Biotronik, Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Philips-Spectranetics, TriReme, Veryan, Shockwave
- **Consulted for:** Boston Scientific Corp., Cook Medical, Gore & Associates, Medtronic, Spectranetics, Veryan, Intact Vascular, MedAlliance, Vesper Medical
- **Common stock:** QT Medical

Sirolimus-Eluting Balloon with Sustained Release

Selution™SLR
SUSTAINED LIMUS RELEASE

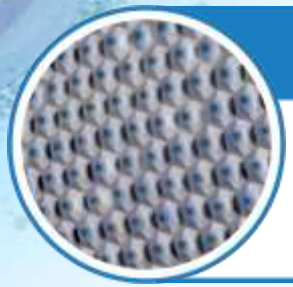
Proprietary MicroReservoir Technology

- MicroReservoirs combining sirolimus & biodegradable polymer
- Sirolimus - a proven safe & effective cytostatic drug
- Offering a wider therapeutic range



MicroReservoirs: Miniature Drug-Delivery Systems

- Optimal size micro-reservoirs achieve elution kinetics similar to best in class DES
- Controlled and sustained release of sirolimus
- Providing therapeutic effect for over 60 days



Cell Adherent Technology (CAT™)

Proprietary amphipatic lipid technology binds MicroReservoirs to balloon surface

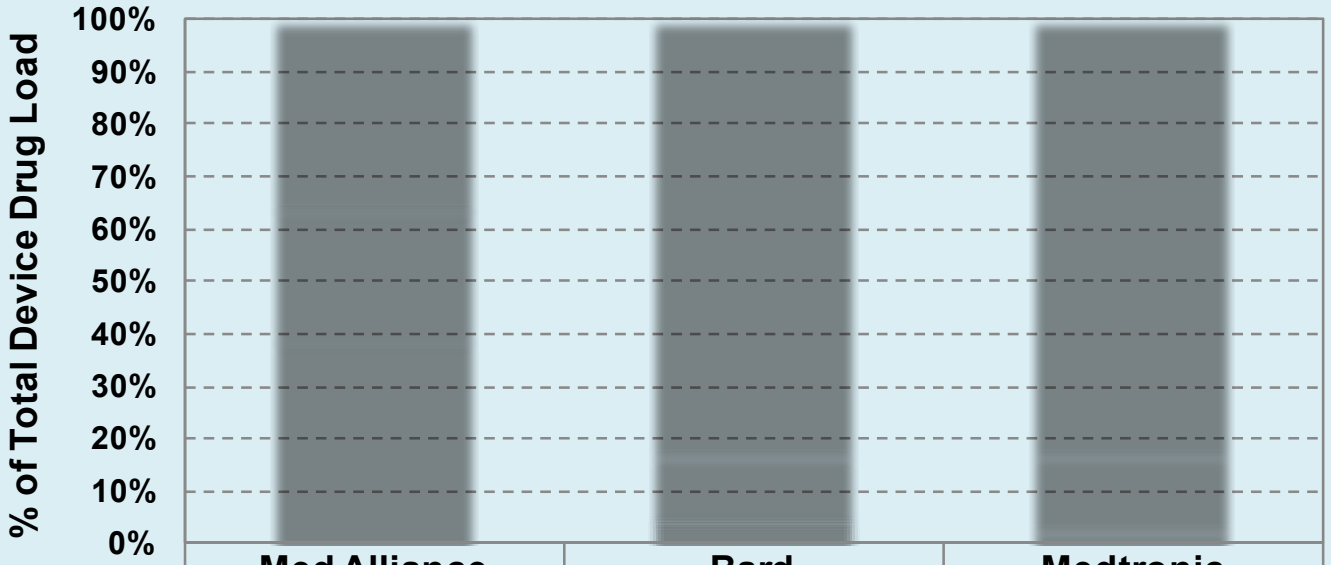
- Contains and protects micro-reservoirs during insertion and inflation
- Facilitates higher drug transfer efficiency allowing for low drug dose on balloon surface
- Maximises drug bioavailability

MedAlliance

*Device not approved and available for sale in the US

SELUTION SLR™ vs. Competition

Drug Transfer



	Med Alliance SELUTION	Bard LUTONIX	Medtronic IN.PACT
Lost during procedure	36%	83%	83%
Retained on balloon	25%	12%	14%
Transferred to vessel (1 hr)	39%	5%	3%

Source: Med Alliance – Bench Test Data on File
Bard-LUTONIX & Medtronic-IN.PACT – Presentation Granada at CRT 2014.

SELUTION SFA FIM TRIAL

ClinicalTrials.gov ID: NCT02941224

OBJECTIVES	To assess the safety and efficacy of the SELUTION SLR DEB in treatment of de-novo occluded/stenotic or re-occluded/restenotic lesions of SFA and/or PA, assessed at multiple time points clinical, angiographic and/or ultrasound assessment
DESIGN	▶ Prospective, controlled, multi-center, open, single-arm clinical investigation ▶ 50 patients
PRIMARY ENDPOINTS	▶ **Angiographic Late Lumen Loss (LLL) by QVA – 6M**
SECONDARY ENDPOINTS	▶ **Major adverse Events** (Death, Thrombosis, Amputation, CD-TLR) **6M** ▶ **Primary Patency –** Freedom from CD-TLR and absence of Restenosis by DUS - **6, 12 and 24M** ▶ **Angiographic Binary Restenosis** (ABR) by QVA – **6M** ▶ **Composite of Freedom from Amputation and Freedom from CD-TVR** – **12 and 24M** ▶ **Change of ABI, WIQ and Qol** - **6, 12 and 24M**

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SELUTION SFA Trial Baseline Characteristics

CLINICAL CHARACTERISTICS	N=50
Age, Y ± SD	69.6 ± 10.4
Male, % (n)	58% (29)
Previous Intervention, % (n)	30% (13)
Myocardial Infarction, % (n)	6% (3)
Renal Insufficiency, % (n)	22% (11)
Hypertension, % (n)	80% (40)
Hyperlipidemia, % (n)	90% (45)
Diabetes (Type 2), % (n)	28% (14)
Smoking History, % (n)	58% (29)
Anticoagulation Therapy	22% (11)
Angina Pectoris	14% (7)

LESION CHARACTERISTICS	N=50
De Novo	96% (48)
Lesion Length, mm ± SD	64.30 ± 42.8
RVD, mm ± SD	5.1 ± 0.8
% Diameter Stenosis, % ± SD	90 ± 8.0
Occlusion	30% (15)
Calcification	
None	12% (6)
Mild	44% (22)
Moderate	10% (5)
Moderately severe	26% (13)
Severe	8% (4)
Target Lesion Location, % (n)	
SFA prox	12% (6)
SFA mid	34% (17)
SFA dist	54% (27)
POP 1	24% (12)
POP 2/POP 3/TPT	16% (8)

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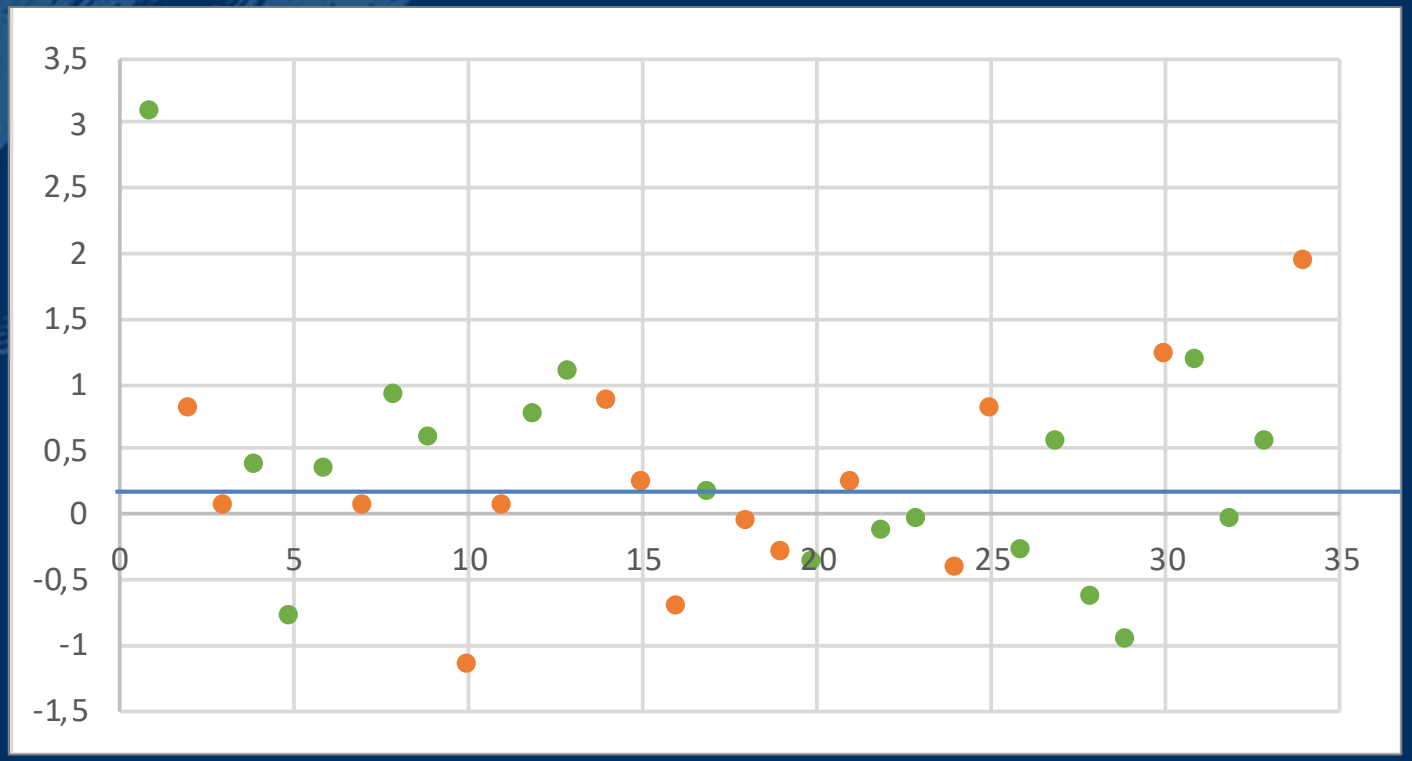
SELUTION SFA Primary Endpoint

LLL at 6M (N=34)



0.19 mm*

- Calcified Target Lesion (CoreLab assessed by 360 score)

*Late Lumen Loss presented as median value

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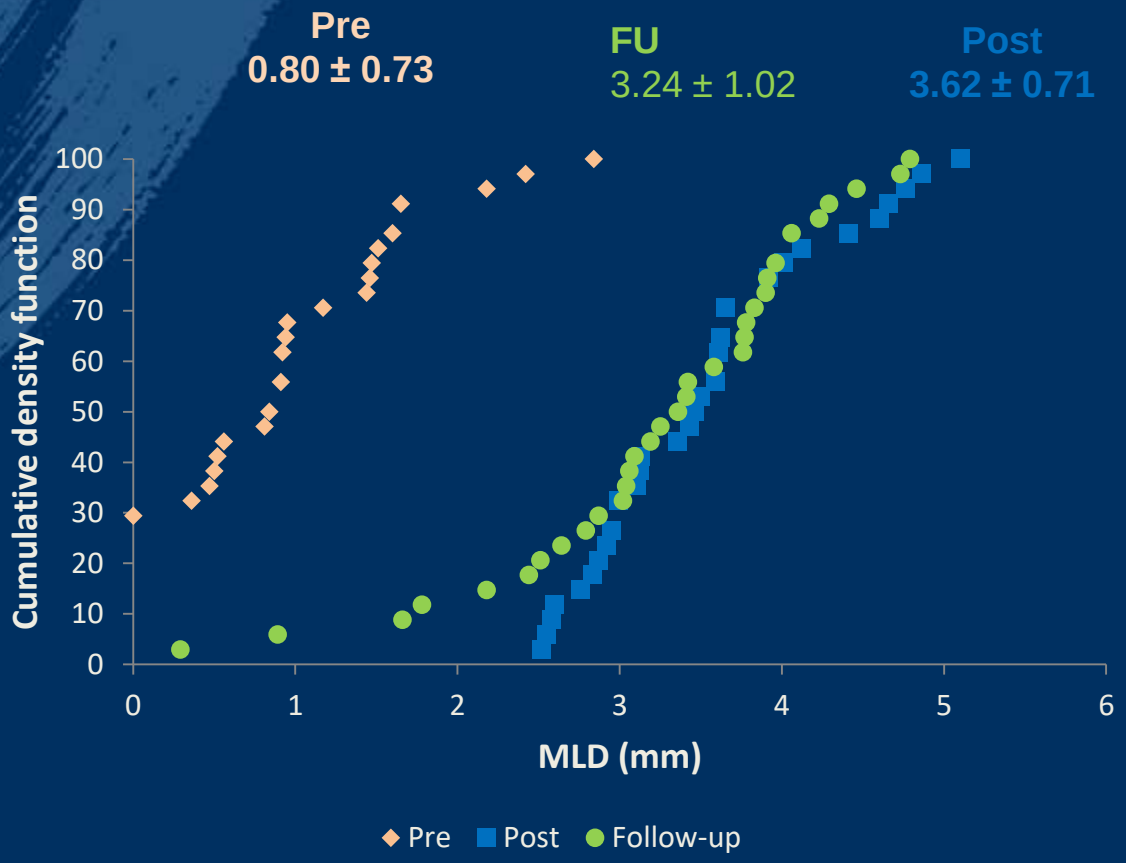
SELUTION SFA Minimal Lumen Diameter



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SELUTION SFA TRIAL ANALYSIS

Clinical Results at 6M, 12M and 24M

	6M	12M	24M
Cumulative Clinical Events			
Death	0 (0%)	0 (0%)	0 (0%)
Minor and Major Amputation	0 (0%)	0 (0%)	0 (0%)
Primary Patency (ITT)	88.4%	75.7%	81.6%
Primary Patency (PP)	95.2%	88.9%	94.4%
Freedom from Index Limb Amputation and CD TVR	97.7%	87.6%	85.4%
TLR (ITT)	1 (2.3%)	6 (12.5%)	6 (12.5%)
TLR (PP Lesion Prep)[1]	1 (2.3%)	2 (4.3%)	2 (4.3%)
TLR (Ca^{++})[2]	0 (0%)	1 (6.6%)	1 (7.7%)

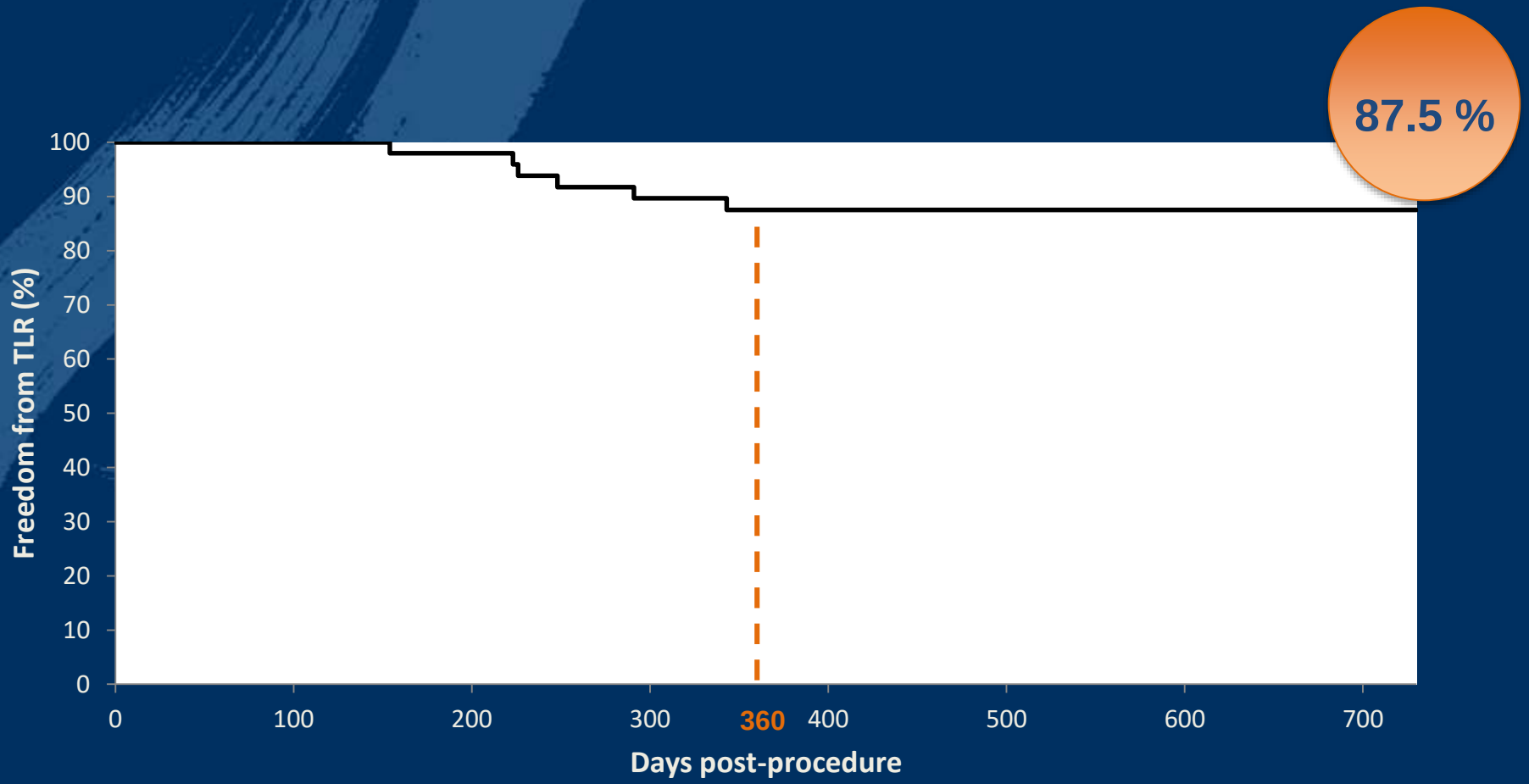
1. Inadequate Lesion Prep: Residual Stenosis >35% by CoreLab Assessment
2. Moderately Severe/ Severe Calcification = Calcification score 3 or 4 by 360Score = outside of Protocol

ITT: all patients enrolled in the trial, whether or not they were treated the Investigational Device

PP: all patients enrolled and treated with the Investigational Device and had no bailout . Includes only patients who had a post-procedure angio residual stenosis ≤ 30%

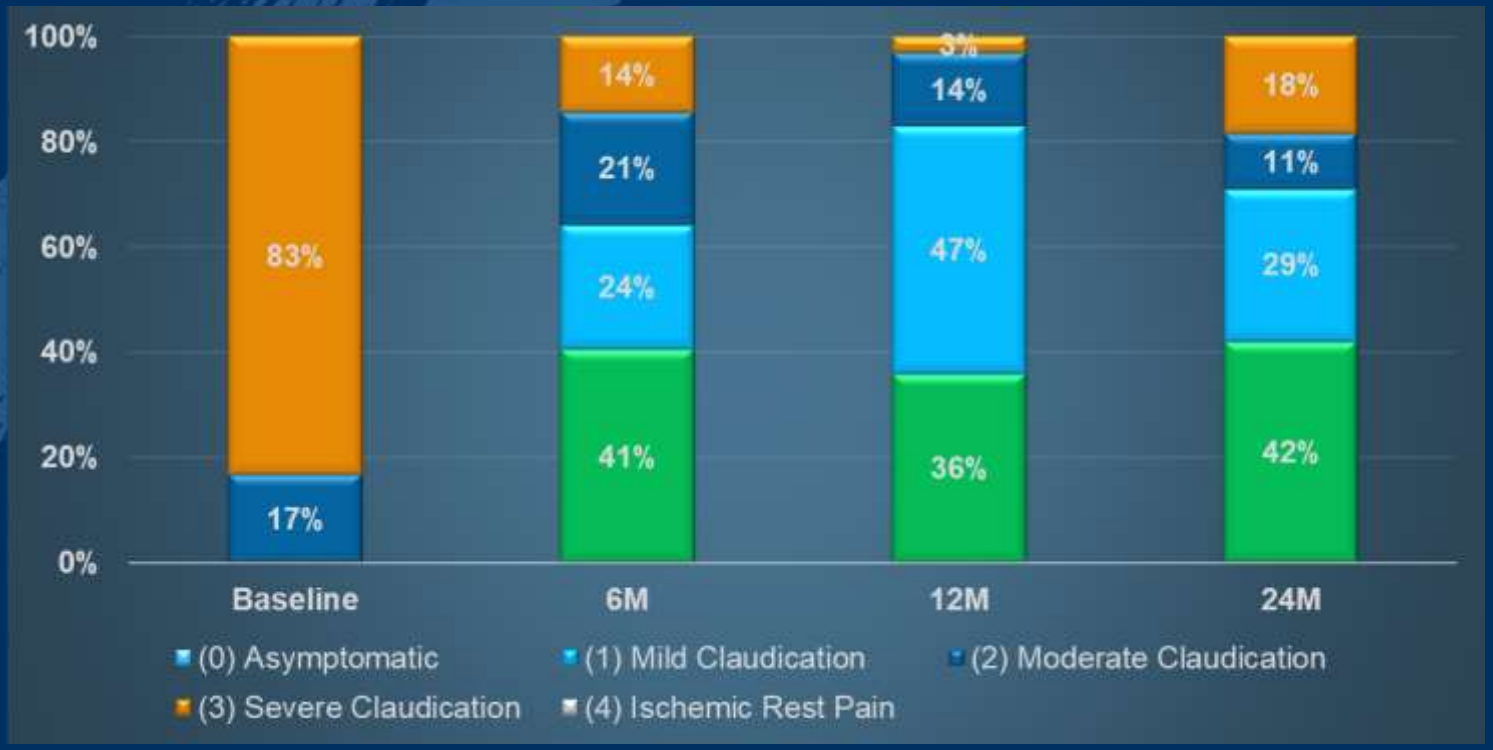
SELUTION SFA Freedom from TLR

Kaplan Meier Estimates



SELUTION SFA Trial Rutherford

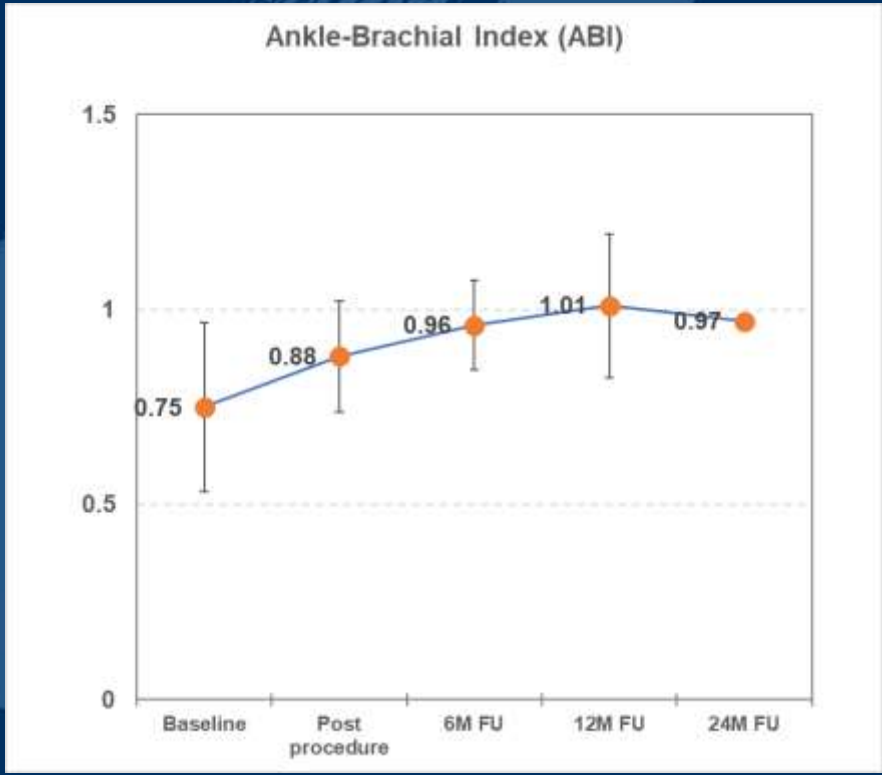
Baseline, 6M, 12 M and 24M

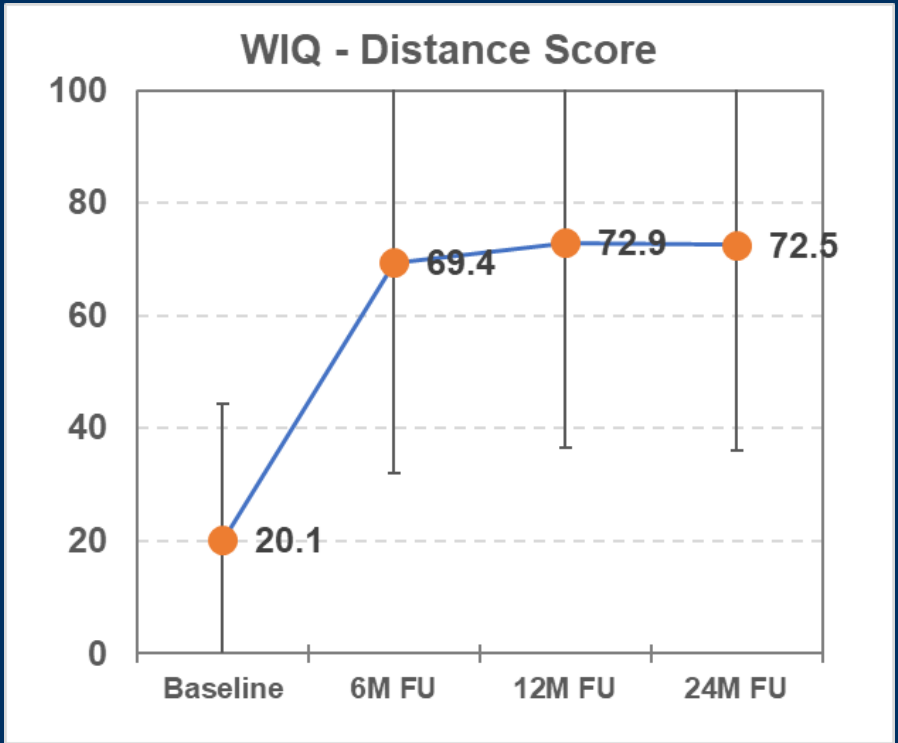


Improvement from Baseline to 24M
> 2 categories in 67% of patients
>1 category in 84% of patients

SELUTION SFA Trial ABI & WIQ

Baseline, 6M, 12 M and 24M





Change from Baseline to 24M: p 0.0242
Change from Baseline to 12M: p < 0.0001
Change from 6M to 12M: p = 0.0125

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SELUTION SFA Trial Conclusions

- First demonstration of Sirolimus safety and efficacy in peripheral intervention
- Met the primary endpoint (Median LLL 0.19mm at 6M)
- Low 6 M CD TLR maintained through 24 M
- No primary TLR event after Month 11
- Clinical improvements in Rutherford classification, ABI and Walking Impairment @ 6M and was further improved to 12M and maintained to 24M
- **SELUTION Sirolimus DEB is safe and effective**
- Based on these data, TLR with SELUTION SLR™ DEB is not impacted by Ca++
- CD TLR were associated with high residual stenosis post procedure
- Further studies are required to confirm these findings in larger patient populations
- These results support CE Mark submission of the SELUTION SLR™ 018 PTA

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