First-In-Human Experience With The Efemoral Bioresorbable Scaffold And New Sirolimus DCB (Scionix DCB From BD) In Femoro-Popliteal Disease

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Disclosures

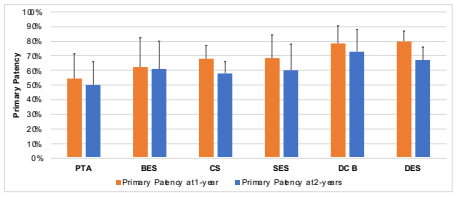
Andrew Holden, MBChB, FRANZCR:

Medical Advisory Board Member for Medtronic, Gore, Philips, Boston Scientific

Clinical Investigator for Bard-BD, Boston Scientific, Cagent Medical, Cook Medical, Efemoral, Endologix, Endospan, Gore Medical, Intact Vascular, Medtronic, Nectero, Philips, Reflow Medical, Shape Memory, Shockwave Medical, Terumo

No other disclosures

Primary Patency Following Femoropopliteal PPI



PTA = percutaneous transluminal angioplasty
BES = balloon expandable stents
CS = covered stents
SES = self-expanding stents
DCB = drug-coated balloons
DES = drug-eluting stents

El Khoury R, Jacobs CE, White JV, Conte MS, Schwartz LB. Primary patency of endovascular femoropopliteal intervention is superior in industry-sponsored clinical trials vs. physician-initiated investigations. Western Vascular Surgery Society, Jackson Hole, WY, October 15, 2021.

Bioresorbable Vascular Scaffolds (BVS) in the Femoropopliteal Arteries

Device	Study	Drug	n	Status
 Remedy	PERSEUS	None	45	50% restenosis @ 6-months
	GAIA		30	70% restenosis @ 12-months
	v. CFA endarterectomy		80	80% patency @ 12-months (inferior to endarterectomy)
	with DCB		20	58% restenosis @ 12-months
 Stanza	STANCE	None	60	Not yet reported
 Esprit	ESPRIT I	Everolimus	35	13% restenosis @ 12-months 14% TLR rate @ 3-years
 Pravo	DESAppear	Sirolimus	15	No MAE @ 6-months

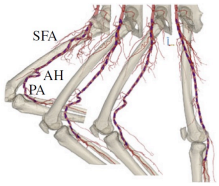
Werner M, Micari A, Cioppa A, Vadala G, Schmidt A, Sievert H, et al. Evaluation of the biodegradable peripheral Igaki-Tamai Stent in the treatment of de novo lesions in the superficial femoral artery: The GAIA Study. J Am Coll Cardiol Cardiovasc Interv. 2014;7:305-12.

Werner M, Schmidt A, Scheinert S, Banning-Eichenseer U, Ulrich M, Baumbach Y, et al. Evaluation of the biodegradable Igaki-Tamai scaffold after drug-eluting balloon treatment of de novo superficial femoral artery lesions: The GAIA-DEB Study. J Endovasc Ther. 2015;DOI: 10.1177/1526602815620818:1-6.

Lammer J, Bosiers M, Deloose K, Schmidt A, Zeller T, Wolf F, et al. Bioresorbable everolimus-eluting vascular scaffold for patients with peripheral artery disease (ESPRIT I): Two-year clinical and imaging results. J Am Coll Cardiol Intv. 2016;9:1179-87.

Why Don't We Have a BVS for the Femoropopliteal Arteries?

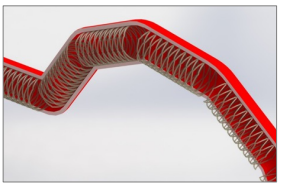
- Current technology of BVS is balloon-expandable only (challenging to make a self-expanding BVS)
- Long, balloon-expandable stents will be crushed within the deformable femoropopliteal arteries
- Long BVS are plagued by fracture during manufacture, delivery and expansion
- Short BVS (*e.g.*, ESPIRT) have been shown to be effective in the peripheral arteries but only minimally clinically useful and not commercially available



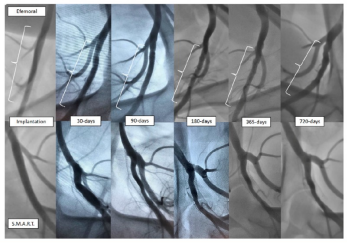
Desyatova A, Poulson W, Macaggart J, Maleckis K, Kamenskiy A. Cross-sectional pinching in human femoropopliteal arteries due to limb flexion, and stent design optimization for maximum cross-sectional opening and minimum intramural stresses. J. R. Soc. Interface 15:20180475.

Efemoral Vascular Scaffold System (EVSS)

- Multiple short drug-eluting balloon-expandable resorbable elements
- Mounted on a single delivery system
- Deployed via balloon inflation
- Provides high radial strength typical of balloon-expandable metal stents
- Spacing allows for unencumbered motion of the treated peripheral artery
- Proprietary Sirolimus coating



Chronic Implantation in an Animal (Porcine) Model of Arterial Deformation



Efemoral Vascular Scaffold System

Nitinol Self-Expanding Stent

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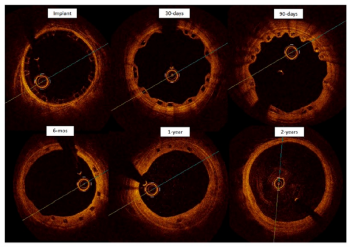


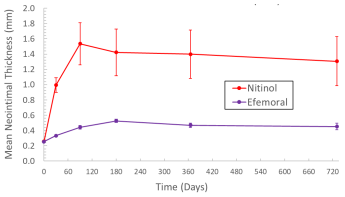
Complete strut coverage @ 6-months

Minimal neointimal hyperplasia

Histologically absorbed @ 2 years

Chronic Implantation in an Animal (Porcine) Model of Arterial Deformation

Mean Neointimal Thickness (as measured by OCT)

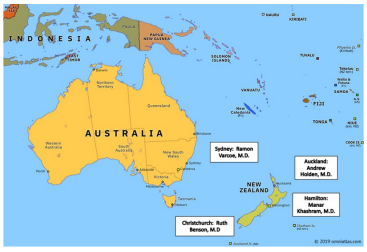


EFEMORAL I Clinical Study

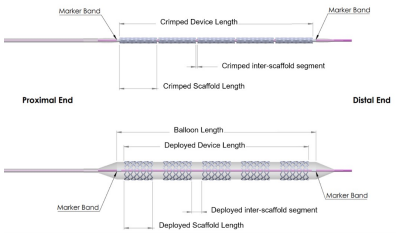
One hundred (n=100) patients with symptomatic peripheral arterial disease (Rutherford-Becker Category 2-4) due to a single *de novo* stenotic or occlusive atherosclerotic lesion in the femoropopliteal artery

- Prospective, single arm, multi-center trial
- Reference Vessel Diameter (RVD) ≥ 5.5 and ≤ 6.5 mm; lesion length ≤90 mm
- Single target lesion treated with a single Efemoral BVS
- Clinical endpoints include RB category and clinically-driven target lesion revascularization
- Quantitative imaging endpoints include duplex-derived peak-systolic velocity ratio and angiographically-derived in-scaffold/in-segment late lumen loss and % diameter stenosis

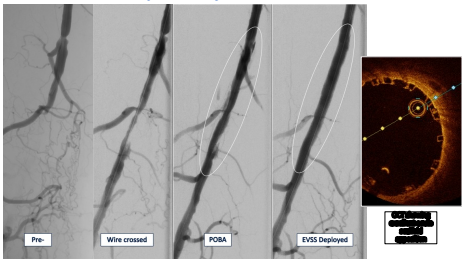
EFEMORAL I Investigative Sites



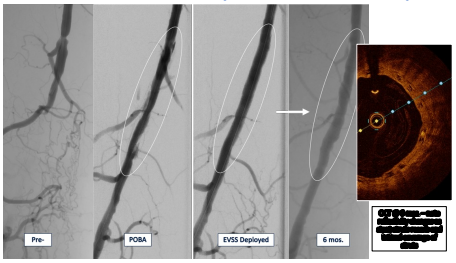
EFEMORAL Vascular Scaffold System (EVSS)



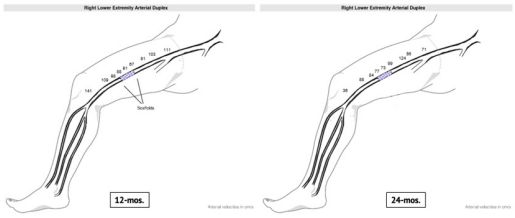
EFEMORAL I Case Example – 69-year male, short distance claudicant



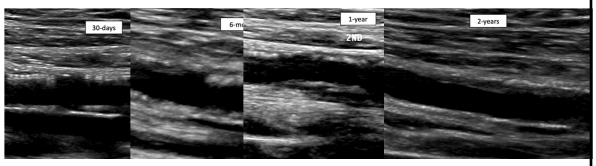
EFEMORAL I Case Example – 6 Month Follow-Up



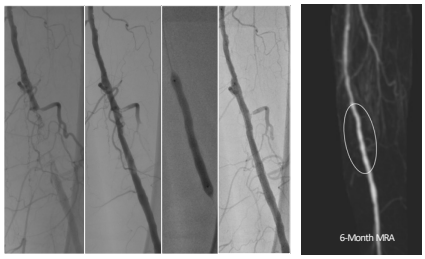
EFEMORAL I Case Example – Longer Term Follow-Up



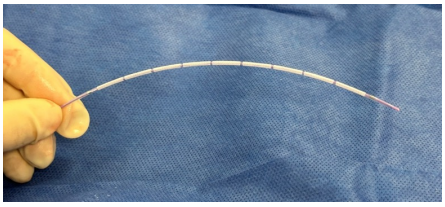
EFEMORAL I Case Example – Scaffold



EFEMORAL I Case Example – Lack of MRI Artefact



EFEMORAL Tibial Device



- 3.0 x 100 mm (9 scaffolds)
- 0.018" wire and 6Fr (.087" ID) guiding sheath compatible

U.S. FOOD & DRUG ADMINISTRATION

Breakthrough Devices Program

The designation criteria, as defined in section 515B(b) of the FD&C Act (21 U.S.C. 360e-3(b)), provide for a Program for devices:

"(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

(2)(A) that represent breakthrough technologies;

(B) for which no approved or cleared alternatives exist;

(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

(D) the availability of which is in the best interest of patients."

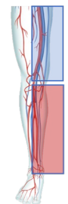
The Efemoral Vascular Scaffold System (EVSS) was granted Breakthrough Device Designation by the FDA for the treatment of infrapopliteal arteries in patients with CLTI.

VEITH SYMPOSIUM Connecting The Vascular Community

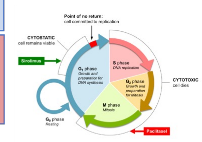
Limus-based DCBs: A new opportunity to cover unmet needs?

What are the **current DCB challenges**?

- Restenosis
- Late lumen loss
- Inflammation
- Thrombosis
- Suboptimal outcomes



How do Limus and Paclitaxel address the phases of cell replication? **Battle or opportunity?**



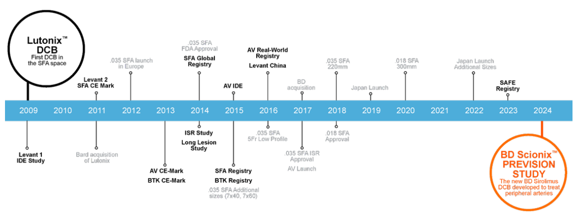
Which **effects are we seeking to maximize** in a new generation of DCBs?

- ✓ Anti-inflammatory
- ✓ Anti-restenotic
- ✓ Cytostatic
- ✓ Wider therapeutic range
- ✓ **Durable effects**

Image source: Michael et al 2024
Joner_Michael_20230516_1345_Room_241.pdf (PROTEGIDO) (pcronline.com)

VEITH SYMPOSIUM Connecting The Vascular Community

The only company to have an in-house Sirolimus DCB development program in addition to a full Paclitaxel DCB program



VEITH SYMPOSIUM Connecting The Vascular Community

BD sirolimus-based Scionix™ DCB Catheter with phased drug release

With decades of experience in the DCB world, the internal BD engineering team has created a dynamic product designed to address four important needs.

THERAPEUTIC DRUG DOSE	PHASED DRUG RELEASE	UNIFORM DRUG APPLICATION	DURABLE DRUG THERAPY

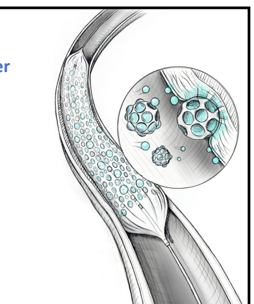


Image Source: courtesy of BD

VEITH SYMPOSIUM Connecting The Vascular Community

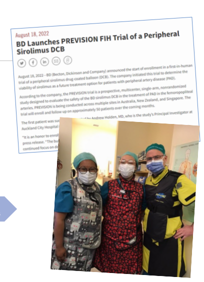
BD PREVISION FIH Trial
Study Design: Overview

This is a prospective, multi-center, non-randomized, single-arm early feasibility study designed to assess the safety and performance of the **BD Scionix™ Sirolimus DCB Catheter** for the treatment of stenosis in the femoropopliteal arteries.

Follow-up for all treated subjects will be performed at:

Post-Procedure → 30 Days → 6 Months → 12 Months → 18 Months → 24 Months

10 participating sites (New Zealand, Australia and Singapore)



VEITH SYMPOSIUM Connecting The Vascular Community

BD PREVISION FIH Trial
Study Design: Endpoints

PRIMARY ENDPOINT	FOLLOW UP
Late lumen loss (QVA)	6 Months

SECONDARY ENDPOINT	FOLLOW UP
All Cause Death	Post-procedure 1 Months 6 Months 12 Months 24 Months
Major Adverse Cardiovascular Events (Mace)	
Safety Composite	
Revascularization rate (CD-TLR)	
Technical & Procedural Success	
Freedom of Embolization	
ABI Improvement	
Rutherford Improvement	
Patient Reported Outcome Improvement	

VEITH SYMPOSIUM Connecting The Vascular Community

BD PREVISION FIH Trial
Study Design: Inclusion/Exclusion Criteria

1. One Lesion of ≥ 3 cm and ≤ 17 cm in length
2. Lesion ≥70% stenosis by visual estimate
3. Lesion location starts ≥1 cm below the common femoral bifurcation and terminates distally ≥2 cm above the tibial plateau.
4. De novo or non-stented restenotic lesion(s) in native femoropopliteal arteries >90 days from prior interventional procedure
5. Lesion is located at least 3 cm from any stent
6. Target reference vessel diameter of 5-6 mm and able to be treated with available device size
7. Successful, uncomplicated antegrade wire crossing of lesion
8. Successful vessel preparation of the target lesion
9. A patent inflow artery free from significant lesion stenosis (≥50% stenosis) as confirmed by standard of care imaging and the discretion of the investigator.
10. At least one patent native outflow artery to the ankle, free from significant (≥50%) stenosis as confirmed by angiography, that has not previously been revascularized

1. Severe Calcification as defined as PARC scoring system (> 180 degrees of the target lesion.
2. Intended use of adjunctive primary treatment modalities (e.g., atherectomy, laser, cutting balloons, radiation therapy, stents, other drug coated devices.)
3. Use of reentry devices during the index procedure for antegrade recanalization, which include but are not limited to percutaneous intentional extraluminal recanalization (PIER) and subintimal arterial flossing with antegrade retrograde intervention (SAFARI) techniques.

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BD PREVISION FIH Trial
Study Update: Enrollment Complete!

- ✓ **Study follow up is ongoing and statistical analysis will follow**
- ✓ **First results and preclinical-data will be disclosed in 2024**

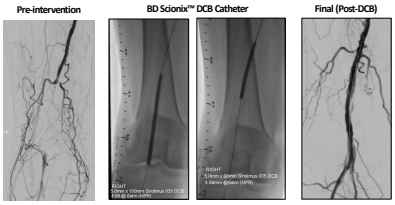
... and MORE NEWS SOON!

Post-Procedure → 30 Days → 6 Months → 12 Months → 18 Months → 24 Months

FIRST CLINICAL RESULTS WILL BE PRESENTED IN 2025!

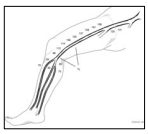
BD PREVISION FIH Trial
Clinical Case 1

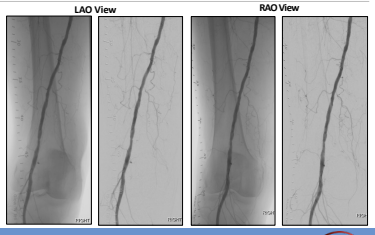
- Pre-dilatation:
  - 5x120 mm PTA Balloon
  - Residual stenosis after pre-dil (%) = 0%
- Investigational Device:
  - 5x100 mm and 5x60 mm Sirolimus DCBs



BD PREVISION FIH Trial
Clinical Case1 : 6 Month Follow Up

Duplex US





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