

Drug-Eluting Resorbable Scaffold System

Abbott Esprit™ BTK

ICD-10 Coordination and Maintenance Committee Meeting

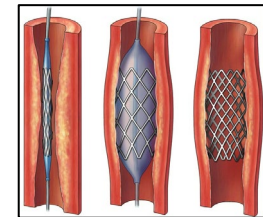
March 19, 2024

Endovascular Therapy

Chronic limb-threatening ischemia (CLTI) is associated with a high risk for cardiovascular events and mortality and accounts for approximately 90% of major amputations performed worldwide^{1,2}.

To avoid amputations, patients with blockage from below the knee (BTK) disease from CLTI may be treated with:

- Autologous vein grafts/ peripheral bypass to reroute blood flow around blockage
- Catheter based endovascular techniques to optimize lumen and restore blood flow
 - Vessel pre-treatment
 - Balloon angioplasty to stretch vessel
 - Atherectomy to remove plaque
 - Intravascular lithotripsy (IVL) to break up plaque
 - Stenting/ device placement (*none currently FDA approved*)
 - Permanent (Bare metal, drug-eluting)
 - Temporary (Drug-eluting resorbable scaffold or DRS)



To date, drug coated balloons (DCB's) have not shown to be effective for BTK.

1 - Uccioli L, Meloni M, Izzo V, et al. Critical limb ischemia: current challenges and future prospects. Vasc Health Risk Manag 2018;14:63–74.

2 - Karnabatidis D, Spiliopoulos S, Katsanos K, Siablis D. Below-the-knee drug-eluting stents and drug-coated balloons. Expert Rev Med Devices 2012;9:85–94.

Esprit™ BTK is a drug-eluting resorbable scaffold (DRS)

D
DRUG-ELUTING

R
RESORBABLE

S
SCAFFOLD

EVEROLIMUS

Drug elution
to reduce neointimal hyperplasia

Elution rate matches to
restenosis cascade

Cytostatic; broad therapeutic
range

Poly-L-Lactic Acid (PLLA) RESORBABLE SCAFFOLD

Resorbs over
time leaving
nothing behind

Resists recoil

Provides a platform for
sustained drug delivery

Provides temporary wall support
and uniformity for healing

Resorbs in a benign, controlled
manner (~36 months)

Allows for more options of future
interventions if needed

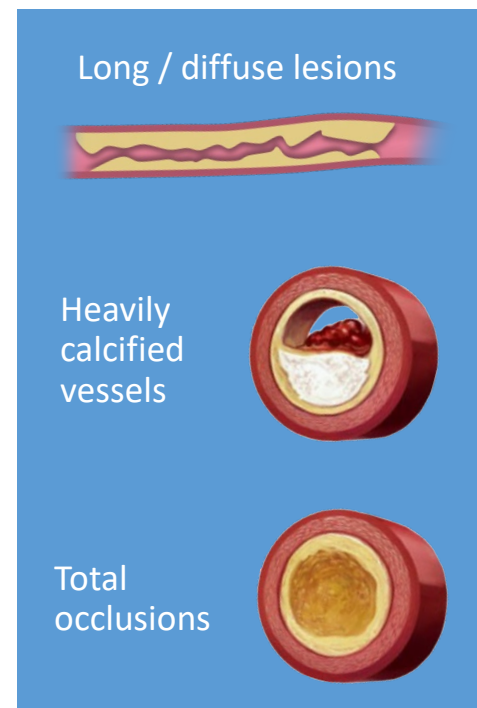
- Adverse events and complications are comparable to other drug eluting stenting procedures.
- Esprit™ BTK is contraindicated for use in patients with known intolerance for procedure regime or scaffold components:
 - Allergic reaction or hypersensitivity to latex, contrast agent, anesthesia, device material (poly p[L-lactide] [PLLA], polymer poly [D, L-lactide] [PDLLA], platinum), and drug reactions to anticoagulation, or antiplatelet drugs

Complexities of treating lower extremity vasculature limit treatment options

The Esprit™ BTK Everolimus Eluting Resorbable Scaffold is a temporary scaffold that will resorb over time and is indicated for improving luminal diameter in BTK lesions in patients with CLTI.

TO EFFECTIVELY TREAT BTK LESIONS					
	ANGIOPLASTY	ATHERECTOMY	BMS	DES	DCB
DRUG (<i>inhibit NIH</i>)	✗	✗	✗	✓	✓
SCAFFOLD (<i>minimize recoil</i>)	✗	✗	✓	✓	✗
LEAVE NOTHING BEHIND	✓	✓	✗	✗	✓
					IDEAL TREATMENT

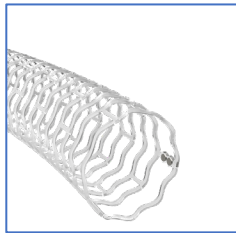
BMS = bare metal stent
 DES = drug-eluting stent (*metallic*)
 DCB = drug-coated balloon
 NIH = neointimal hyperplasia



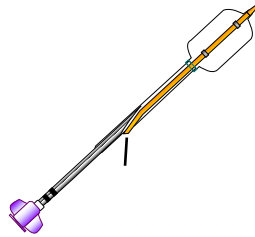
Esprit™ BTK Procedure

System Overview:

- **Delivery catheter**
- **Resorbable scaffold**
- **Resorbable polymer drug-eluting coating (everolimus)**
 - Everolimus elutes from the scaffold over time to help treat the lesion and prevent restenosis



Device



Delivery System

Procedural Highlights:

- **Vessel selection**
- **BTK Vessel pre-treatment/ pre-dilation**
- **Implant scaffold**
- **Post-dilate device to ensure complete apposition to vessel wall**



Multiple occluded vessel segments may require more than 1 scaffold based on lesion length

Esprit™ BTK Approval

- FDA approval for is anticipated by May 1, 2024
- Esprit™ BTK is a breakthrough designated device system
 - Abbott intends to apply for FY 2026 NTAP following the alternative pathway for devices with breakthrough designation

Medical record of procedure/ technology

- Documentation of the Esprit™ BTK System implant procedure will be included in the operative report

Terms for procedure/ technology

- Esprit™ BTK
- Esprit™ stent
- Esprit™ BTK Everolimus Eluting Resorbable Scaffold System
- Everolimus Eluting Resorbable Scaffold System
- Drug-eluting resorbable scaffold intraluminal device

Open Discussion

Thank you for your time.