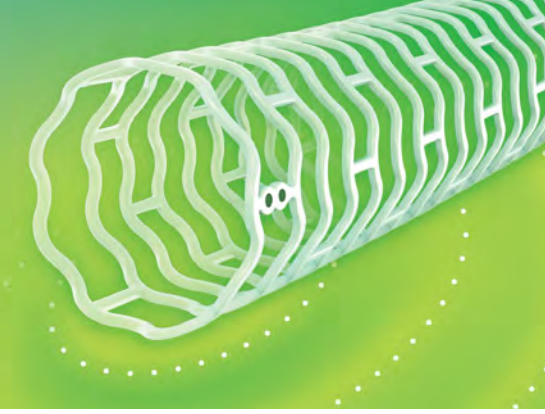
Esprit™ BTK
Everolimus Eluting Resorbable Scaffold System



CASE REPORT
Courtesy of J.D. Corl, MD, FACC, FSCAI

SUCCESSFUL TREATMENT OF ANTERIOR TIBIAL CTO WITH OVERLAPPING ESPRIT™ BTK SCAFFOLDS

This case study outlines the treatment and follow-up of a 78-year-old male with a complex medical history and a non-healing ulcer. The procedure involved the use of Jade‡ NC balloon and Esprit™ BTK scaffolds, resulting in successful revascularization and wound healing.

PATIENT PRESENTATION

A 78-year-old male with a medical history of PAD, CAD, HLD, DM-2, HTN, aortic stenosis, CKD, and carotid disease presented with a necrotic non-healing ulcer (4 cm) on the lateral aspect of his left foot for 8 months, categorized as Rutherford Becker Category 5 (**Figure 1**).

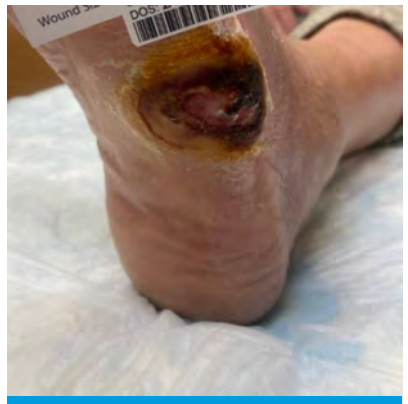


Figure 1
Necrotic non-healing ulcer

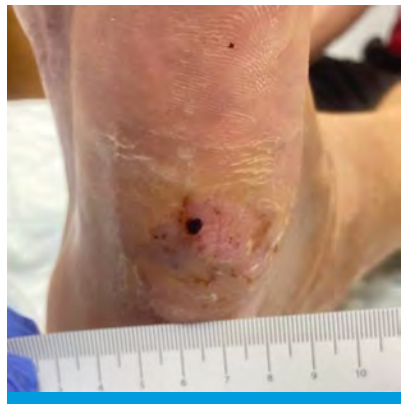


Figure 6
Healed wound 1 month post-procedure

Diagnostic Findings

Normal velocities in the left femoral and popliteal arteries, with duplex ultrasound demonstrating absent pulses in both the peroneal and anterior tibial arteries.

I/O Sustainable Inflow/Outflow

Pre-treatment flow was normal above the target tibial lesion, with a single vessel runoff in the left lower extremity and 100% total occlusion in the left anterior tibial (AT) and left peroneal arteries (**Figure 2**).

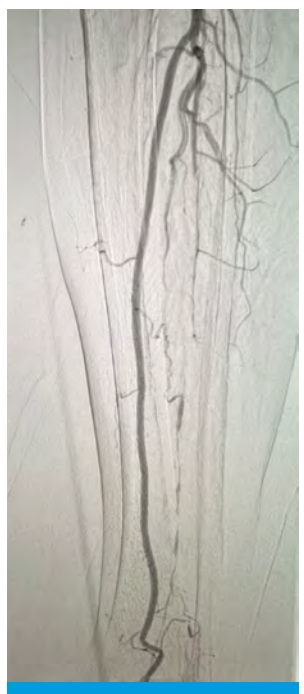


Figure 2
Diagnostic angiogram

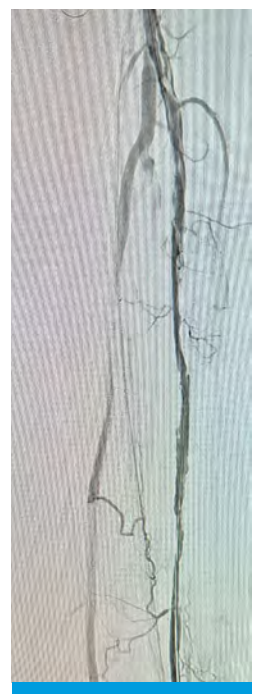


Figure 3
Post PTA areas of dissection

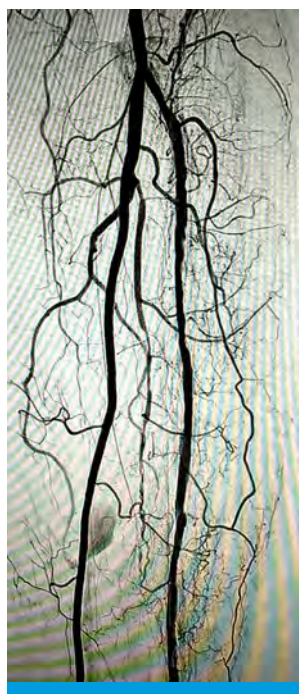


Figure 5
Post-procedure outcome

P Prepare the Lesion

Specialty balloons (3.5 x 210 mm and 4 x 210 mm tapered balloon dilatation catheter) were used to prep the lesion, resulting in a suboptimal outcome with residual 80% stenosis and areas of dissection (**Figure 3**).

INDICATIONS
The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is indicated for improving luminal diameter in infrapopliteal lesions in patients with chronic limb-threatening ischemia (CLTI) and total scaffolding length up to 170 mm with a reference vessel diameter of ≥ 2.5 mm and ≤ 4.00 mm.

See Important Safety Information referenced within.
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Abbott

S Size Appropriately

Using IVUS, proximal reference vessel diameter of target lesion was measured to be 3.99 mm in diameter (**Figure 4A**), tapering to 3.45 mm in mid AT (**Figure 4B**). Moderate calcification was noted throughout. Two overlapping Esprit™ BTK scaffolds were placed using an 0.014″ guidewire: a 3.75 x 38 mm scaffold in the proximal AT and a 3.5 x 38 mm scaffold in the mid AT.

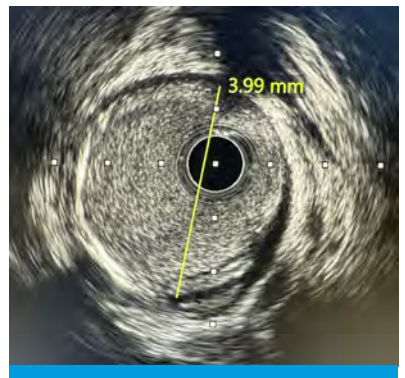

Figure 4A
3.99 mm proximal AT reference diameter

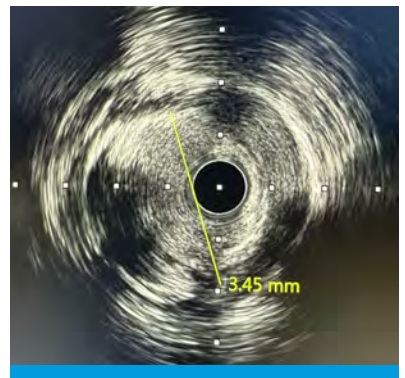

Figure 4B
3.45 mm mid AT reference diameter

P Post Dilate

Post-dilatation was performed with a 4 x 210 mm tapered balloon (proximal - mid AT) and a 3.5 x 60 mm Jade‡ balloon (mid AT) at 12 and 18 atms, respectively. Flow was brisk through AT following procedure. (**Figure 5**).

Post-Procedure Outcome

Follow-up showed the wound healed approximately 1 month post-procedure, and a duplex ultrasound 2 months later confirmed a widely patent Esprit™ BTK in the left anterior tibial artery (**Figure 6**). Duplex ultrasound demonstrated improved post-intervention vascularity with pulses of 86 cm/s in the peroneal and 120 cm/s anterior tibial artery.

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IMPORTANT SAFETY INFORMATION

℞ ONLY Esprit™ BTK Everolimus Eluting Resorbable Scaffold System

INDICATIONS

The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is indicated for improving luminal diameter in infrapopliteal lesions in patients with chronic limb-threatening ischemia (CLTI) and total scaffolding length up to 170 mm with a reference vessel diameter of ≥ 2.5 mm and ≤ 4.00 mm.

CONTRAINDICATIONS

The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is contraindicated for use in:

- Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or the post-procedural antiplatelet regimen.
- Patients with hypersensitivity or contraindication to everolimus or structurally related compounds or known hypersensitivity to scaffold components poly(L-lactide), poly(D, L-lactide), and platinum.

WARNINGS

- **This device is intended for single use only.** Do not reuse, reprocess, or re-sterilize. Note the product "Use-by" date on the package. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and / or delivery system and / or lead to device failure, which may result in patient injury, illness, or death. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and / or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device and / or delivery system may lead to injury, illness, or death of the patient.
- The Esprit™ BTK System is intended to perform as a system. The scaffold should not be removed for use with other dilatation catheters.
- The Esprit™ BTK System should not be used in conjunction with other non-everolimus drug eluting devices in the same vessel as the Esprit™ BTK Scaffold.
- It is not recommended to use this scaffold to treat lesions located at any joint or other hinge points, such as the knee or ankle. The recommended region for below-the-knee (BTK) treatment with the Esprit™ BTK Scaffold is the infrapopliteal arteries at a location ≥ 10 cm above the proximal margin of the ankle mortise. The Esprit™ BTK Scaffold has not been tested for use outside the recommended implant locations.
- This product should not be used in patients with aneurysms immediately adjacent to the scaffold implantation site.
- Insertion of the Esprit™ BTK System and implantation of the scaffold should be performed only under fluoroscopic observation with radiographic equipment providing high resolution images.
- **Quantitative imaging is strongly recommended to accurately measure and confirm appropriate vessel sizing (reference vessel diameter ≥ 2.5 mm).** If quantitative imaging determines a vessel size < 2.5 mm, do not implant the Esprit™ BTK Scaffold.
- Adequate lesion preparation prior to scaffold implantation is required to ensure safe delivery of the scaffold across the target lesion. It is not recommended to treat patients having a lesion that prevents complete inflation of an angioplasty balloon.
- **Successful pre-dilatation with residual diameter stenosis of < 30% by visual estimation is required for treatment of the target lesion; < 20% by visual estimation is preferred.**
- Ensure the scaffold is not post-dilated beyond the allowable expansion limits.
- Use of appropriate anticoagulant and / or antiplatelet therapy per standard of care is recommended for use of this scaffold system.
- This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.
- Judicious selection of patients is necessary, since the use of this device carries the associated risk of scaffold thrombosis, vascular complications, and / or bleeding events.

PRECAUTIONS

- Scaffold placement should not be performed in patients with known allergies to contrast agent that cannot be medically managed.
- It is not recommended to treat patients having a lesion with excessive tortuosity proximal to or within the lesion.
- When multiple scaffolds are required, only combinations of Esprit™ BTK Scaffolds must be used. Any potential interaction with other drug-eluting or coated devices has not been evaluated.
- The delivery system is intended for deployment of the scaffold only and should not be used to dilate other locations.
- Implantation of the scaffold should be performed **only** by physicians who have received appropriate training.
- As with all catheter-based procedures, scaffold placement should be performed at facilities where patient can be prepared for necessary intervention and / or surgical removal of the device and vessel repair as per facility protocol.
- Pre-dilatation should be performed with an angioplasty balloon. Cutting or scoring balloons can be used per physician discretion, if the lesion appears to be mildly calcified.
- Failure to pre-dilate the vessel may impair nominal / optimal scaffold delivery.
- Implanting a scaffold may lead to dissection of the vessel distal and / or proximal to the scaffold, requiring additional intervention. **Note:** In cases of bailouts, bailout treatment of the target lesion can be done using the Esprit™ BTK Scaffold of the appropriate length. If an appropriate length Esprit™ BTK Scaffold is not available, physicians should use standard of care.
- An unexpanded scaffold may be retracted into the introducer sheath **one time only.** An unexpanded scaffold should not be reintroduced into the artery once it has been pulled back into the introducer sheath.
- Post-dilatation is strongly recommended for optimal scaffold apposition. When performed, post-dilatation should be performed at high pressure (> 16 atm) with a non-compliant balloon up to 0.5 mm larger than the nominal scaffold diameter.
- Use an appropriately sized non-drug coated balloon to pre-dilate the lesion. When treating a long lesion, scaffold the distal portion of the lesion prior to scaffolding the proximal portion of the lesion.
- Ensure that the scaffolded area covers the entire lesion / dissection site and that no gaps exist between scaffolds.
- The extent of the patient's exposure to drug and polymer is directly related to the number of scaffolds implanted. The safety of everolimus, polymer, and polymer breakdown products was evaluated in pre-clinical studies and the biocompatibility assessment of the Esprit™ BTK Scaffold.
- The safety and effectiveness of the Esprit™ BTK Scaffold in patients with prior brachytherapy of the target lesion or the use of brachytherapy for treated-site restenosis in the Esprit™ BTK Scaffold have not been established. Both vascular brachytherapy and the Esprit™ BTK Scaffold alter arterial modeling. The potential combined effect on arterial remodeling by these two treatments is not known.
- The safety and effectiveness of the Esprit™ BTK System have not been established in clinical trials with the use of either mechanical atherectomy devices (directional atherectomy catheters, rotational atherectomy catheters) or laser atherectomy catheters.
- Formal drug interaction studies have not been performed with the Esprit™ BTK Scaffold because of limited exposure to everolimus eluted from the scaffold.
- Everolimus, the Esprit™ BTK Scaffold's active pharmaceutical ingredient, is an immunosuppressive agent. Therefore, consideration should be given to patients taking other immunosuppressive agents or who are at risk for immune suppression.
- Oral everolimus use in renal transplant and advanced renal cell carcinoma patients was associated with increased serum cholesterol and triglyceride levels, which in some cases required treatment.
- Non-clinical testing has demonstrated the Esprit™ BTK Scaffold is MR Conditional. A person with the Esprit™ BTK Scaffold may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.
  - Static magnetic field strength of 7 Tesla or less
- The Esprit™ BTK Scaffold should not migrate in this MRI environment. MRI at 7 Tesla or less may be performed immediately following the implantation of the Esprit™ BTK Scaffold.

POTENTIAL ADVERSE EVENTS

Potential adverse events include, but are not limited to:

Allergic reaction or hypersensitivity to contrast agent, anesthesia, scaffold materials (poly[L-lactide] [PLLA], poly[D, L-lactide] [PDLLA], platinum, or everolimus), and drug reactions to anticoagulation or antiplatelet drugs

- Vascular access complications which may require transfusion or vessel repair, including:
  - Catheter site reactions
  - Bleeding (ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage)
  - Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, and laceration
  - Embolism (air, tissue, plaque, thrombotic material, or device)
  - Peripheral ischemia
- Target artery complications which may require additional intervention, including:
  - Total occlusion or abrupt closure
  - Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture
  - Embolism (air, tissue, plaque, thrombotic material, or device)
  - Artery or scaffold thrombosis
  - Stenosis or restenosis
  - Vasospasm
  - Tissue prolapse / plaque shift
- Bleeding (non-access site)
- Additional surgery such as peripheral artery bypass graft surgery or amputation
- Peripheral nerve injury, neuropathy
- Compartment syndrome
- Tissue necrosis, gangrene, ulcer and acute limb ischemia
- Reperfusion injury
- New or worsening pain
- Intervention due to
  - Damaged scaffolds
  - Partial scaffold deployment
  - Scaffold migration / unintentional placement of scaffold
- Other general surgical risks, including:
  - Cardiac arrhythmias (including conduction disorders, atrial and ventricular arrhythmias, and blocks)
  - Stroke / cerebrovascular accident (CVA) and transient ischemic attack (TIA)
  - Venous thromboembolism (including pulmonary embolism)
  - Nausea and vomiting
  - Hypotension / hypertension
  - Infection – local and systemic (including post-procedural)
  - Fever
  - Blood cell disorders including heparin-induced thrombocytopenia (HIT) and other coagulopathy
  - Death
- System organ failures:
  - Cardiac Failure
  - Cardio-respiratory arrest (including pulmonary edema)
  - Respiratory failure
  - Renal failure
  - Shock

The risks described below include the anticipated adverse events referenced in the contraindications, warnings, and precautions sections of the everolimus labels / SmPCs and / or observed at incidences ≥ 10% in clinical trials with oral everolimus for different indications. Refer to the drug SmPCs and labels for more detailed information and less frequent adverse events.

- Abdominal pain

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IMPORTANT SAFETY INFORMATION (CON'T)

- Anemia
- Angioedema (increased risk with concomitant angiotensin-converting enzyme [ACE] inhibitor use)
- Arterial thrombotic events
- Bleeding and coagulopathy (including hemolytic uremic syndrome [HUS], thrombotic thrombocytopenic purpura [TTP], and thrombotic microangiopathy; increased risk with concomitant cyclosporine use)
- Constipation
- Cough
- Diabetes mellitus
- Diarrhea
- Dyspnea
- Embryo-fetal toxicity
- Erythema
- Erythroderma
- Headache
- Hepatic artery thrombosis (HAT)
- Hepatic disorders (including hepatitis and jaundice)
- Hypersensitivity to everolimus active substance, or to other rapamycin derivates
- Hypertension
- Infections (bacterial, viral, fungal, or protozoan infections, including infections with opportunistic pathogens). Polyoma virus-associated nephropathy (PVAN), JC virus-associated progressive multiple leukoencephalopathy (PML), fatal infections and sepsis have been reported in patients treated with oral everolimus.
- Kidney arterial and venous thrombosis
- Laboratory test alterations (elevations of serum creatinine, proteinuria, hypokalemia, hyperkalemia; hyperglycemia, dyslipidemia including hypercholesterolemia and hypertriglyceridemia; abnormal liver function tests; decreases in hemoglobin, lymphocytes, neutrophils, and platelets)
- Lymphoma and skin cancer
- Male infertility
- Menstrual irregularities
- Nausea
- Nephrotoxicity (in combination with cyclosporine)
- Non-infectious pneumonitis (including interstitial lung disease)
- Oral ulcerations
- Pain
- Pancreatitis
- Pericardial effusion
- Peripheral edema
- Pleural effusion
- Pneumonia
- Pyrexia
- Rash
- Renal failure
- Upper respiratory tract infection
- Urinary tract infection
- Venous thromboembolism
- Vomiting
- Wound healing complications (including wound infections and lymphocele)

There may be other potential adverse events that are unforeseen at this time.

Rx ONLY JADE‡ Rx, JADE‡ 014, JADE‡ 018, and JADE‡ 035 PTA Balloon Dilatation Catheters

INDICATIONS

The JADE‡ PTA Balloon Dilation Catheter is indicated for Percutaneous Transluminal Angioplasty in the peripheral vasculature, including iliac, femoral, iliofemoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for post-dilation of balloon expandable and self-expanding stents in the peripheral vasculature.

CONTRAINDICATIONS

The use of the JADE‡ PTA Balloon Dilatation Catheter is contraindicated:

- For use in the coronary or neuro vasculature.
- Where there is the inability to cross the target lesion with a guidewire.

WARNINGS

When using this type of device, the following warnings should be observed:

- This device is intended for single use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of cross-contamination.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding. **Applying excessive force to the catheter can result in separation of the tip or balloon.**
- To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- Balloon pressure should not exceed the rated burst pressure (RBP) indicated on the package. The rated burst pressure is based on the results of in vitro testing. At least 99.9 percent of the balloons, (with at least 95 percent confidence) will not burst at or below the rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- To reduce the potential for air embolus into the vessel, use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- For the rapid exchange catheters, do not re-straighten a kinked hypotube; straightening a kinked metal shaft may result in breakage of the shaft.

PRECAUTIONS

- The catheter system should be used only by physicians trained in percutaneous transluminal angioplasty.
- Use the catheter prior to the "Use By" date specified on the package.
- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Do not use oil-based contrast medium, organic solvents or alcohols; there is a possibility of catheter leak, damage or lubrication loss.
- The balloon deflation time has been established as 30 seconds (for 0.014″ Rx) and 60 seconds (for 0.014″, 0.018″, and 0.035″ OTW catheters) based on in vitro bench testing results.
- Use with caution for procedures involving calcified lesions or synthetic vascular grafts due to the abrasive nature of these lesions.
- Do not reinsert the PTA catheter into the coil dispenser after procedural use.
- Discard all disposable devices used during this procedure per local requirements for medical device waste disposal.

ADVERSE EFFECTS

Adverse effects due to the use of this product include, but are not limited to, the following:

- Acute or subacute thrombosis
- Acute vessel closure
- Allergic reaction to device, contrast medium, or medication
- Aneurysm
- Arrhythmias
- Arteriovenous fistula
- Death
- Dissection (perforation, rupture, or injury) of the vessel
- Hemorrhage or hematoma
- Hypertension
- Hypotension
- Infection
- Occlusion of the artery
- Restenosis of the dilated vessel
- Stroke, air embolism and embolization of fragmentation of thrombotic or atherosclerotic material

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *manuals.eifu.abbott* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

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