

# **Esprit™ BTK Everolimus Eluting Resorbable Scaffold System (Esprit™ BTK System)**

## **Category:**

Best Medical Technology

## **Company Name:**

Abbott

## **Product/Solution Name:**

Esprit™ BTK Everolimus Eluting Resorbable Scaffold System (Esprit™ BTK System)

## **Compound/Tech Name:**

Esprit™ BTK Everolimus Eluting Resorbable Scaffold System (Esprit™ BTK System)

## **Trade Name:**

ABT

## **Corporate Name:**

Abbott

## **Date of Approval:**

2025-04-25

## **Indications:**

Peripheral Artery Disease (PAD) below-the-knee (BTK) is a highly prevalent painful disease that occurs when arteries become clogged with fatty plaque, preventing blood oxygen from reaching the legs and foot. These blocked vessels often lead to severe pain, non-healing wounds, and, in some cases, limb amputation. Associated with high amputation and mortality rates, PAD BTK affects over 200 million people globally, yet only 10% of those people have been diagnosed.

Abbott's Esprit™ BTK Everolimus Eluting Resorbable Scaffold System (Esprit™ BTK System) is a first-of-its-kind dissolving stent for people living with PAD BTK. It is designed to keep arteries open and deliver a medication to support vessel healing before dissolving, leaving an open vessel. The device is indicated for re-opening arteries BTK in patients with PAD by treating lesions (artery blockages or narrowings) in

vessels between 2.5 and 4.0 mm in diameter and a total treatment length of up to 170 mm.

## **Therapeutic Areas:**

Esprit™ BTK System directly supports the vascular space as it encompasses the treatment of arteries in people with severe cases of PAD. Compared to existing options, this device contributes to the advancements of PAD BTK treatments by supporting the reduction of disease progression and offering the possibility of improved lifestyles for the millions of people living with PAD.

## **General Information File Document upload:**

N/A

## **Background information and need for drug / device:**

There is a significant need for new treatment options for people with PAD BTK. More than 200 million people across the globe are affected by this condition, which can cause blocked vessels, severe pain, and limb amputation, significantly impairing the ability to walk and quality of life. The most severe form of PAD BTK, called Chronic Limb-Threatening Ischemia (CLTI), results in 150,000 amputations each year in the U.S., emphasizing the severity of the condition and the need for improved treatment options.

Previously, the availability of BTK therapies was relatively limited and the standard of care since the 1970s had been balloon angioplasty, which relies on a small balloon inserted through the groin and inflated to open the vessel and restore blood flow. The balloon is then removed from the vessel. However, blockages treated only with balloon angioplasty have poor short- and long-term results and, in many instances, the vessels become blocked again, requiring additional treatment which can be costly for the healthcare system and arduous for people with PAD.

Metallic stents are another available treatment for people living with PAD BTK; however, as these stents are made of a metal mesh, they can put a strain on arteries because they are unable to bend and flex as the body moves. They also leave a permanent implant behind, which can cause inflammation in the artery, resulting in poor outcomes and make it challenging for doctors to treat the vessel again if the person returns with recurring symptoms.

Esprit BTK System sets a new standard of care for people with PAD BTK. Engineered with poly-L-lactic acid (PLLA), a flexible material that gradually dissolves over time, Esprit BTK System provides support to the vessel until it can stay open on its own, after

which the scaffold slowly disappears, leaving no permanent implant behind. The drug on the scaffold also prevents the artery from re-narrowing or creating another blockage, which is a common phenomenon in other treatment options.

## **Background File Document upload:**

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[EspritBTK 4.png](#)

## **History of the development of the solution/product:**

The Esprit BTK System is designed with qualities that offer improved outcomes for people with the most severe form of PAD in their lower leg. Designing a drug-eluting resorbable scaffold for BTK arteries is an engineering challenge, as prior scaffolds have been designed on metallic systems with inherent strength. Manufacturing a dissolving scaffold with equivalent strength and durability to a permanent metallic stent was a significant undertaking. Creating a device that can dissolve over time while delivering a medication posed an additional challenge.

Abbott combined key elements to create a first-of-its-kind resorbable stent with groundbreaking effectiveness. Esprit BTK System is engineered with a poly-L-lactic acid (PLLA) resorbable scaffold to help keep the treated artery open and stable after a procedure, which is crucial to prevent the vessel from narrowing or tearing. The Esprit BTK System slowly releases a medication to prevent the re-narrowing of a blood vessel which can lead to restricted flow. Finally, the scaffold is slowly and naturally resorbed, leaving nothing but four small platinum marker beads behind. This offers flexibility for future treatments and the opportunity for the gradual restoration of healthy vascular function.

In November 2024 at the Vascular InterVentional Advances (VIVA) Conference in Las Vegas, Abbott released late-breaking clinical data on the LIFE-BTK trial two-year results. The trial evaluated the Esprit BTK System and demonstrated that it reduces disease progression and helps improve medical outcomes compared to balloon angioplasty.

The two-year outcomes presented at VIVA showed that Esprit BTK System offered greater long-term benefits compared to balloon angioplasty, and strong two-year results.

Results after two years from the LIFE-BTK clinical trial showed:

- 30.8% superior outcomes vs balloon angioplasty at one year, with sustained effectiveness at two years, demonstrating that Esprit BTK System's long-term durability is effective in reducing reclosures and promoting the vessel to stay open.
- 90.3% of patients in the Esprit BTK System arm did not require a reintervention at the original treatment site at two-year, a 48% reduction vs those who received balloon

angioplasty.

## **Development File Document upload:**

[EspritBTK 3.png](#)

[EspritBTK 1.png](#)

[Esprit BTK How it Works Animation .mp4](#)

## **Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:**

The Esprit BTK System offers advantages for people living with PAD by effectively addressing the challenges of existing treatments. Current available therapies struggle to address the complex challenges BTK, where PAD blocks arteries and prevents blood flow, which can lead to amputation in extreme cases.

Comprised of materials similar to dissolving sutures, Esprit BTK System offers advantages over other stents used to treat blocked arteries. Unlike these metal stents, Esprit BTK System is not a permanent implant, as blocked vessels only need support for a few months after the blockage is cleared. At that point, the vessel can stay open on its own, which is why Esprit BTK System is designed to serve a temporary, yet crucial role.

With other treatment options, it is common for arteries to shrink or experience another blockage, but Esprit BTK System's PLLA is designed to prevent these outcomes. The scaffold also provides a vehicle for sustained local delivery of the medication, which helps to prevent re-narrowing of the vessel, and gradually allowing for the return of the normal vessel's ability to dilate and constrict with blood flow fluctuations.

Across its clinical landscape, the Esprit BTK System is the first-and-only device to demonstrate superiority over the standard of care for PAD, balloon angioplasty, in a gold standard randomized controlled trial. The Esprit BTK System demonstrated a groundbreaking 30.8% improvement in the landmark LIFE-BTK paper published in The New England Journal of Medicine.

Esprit BTK System received approval from the Food and Drug Administration (FDA) in April 2024. Since then, the Esprit BTK System has been implanted across the United States, helping people living with PAD. An implanting physician from Doylestown Health Vascular Surgery in Philadelphia, PA stated, \"This new treatment option supports healing, while reducing the risk of long-term complications. We're excited to be able to offer our patients the latest technological advancements to treat chronic limb-threatening ischemia below-the-knee such as Abbott's new dissolvable stent.\"

Patrick Curran, a person with diabetes who received the Esprit BTK System in May 2024, shared that the device was a \"big breakthrough.\"

**Innovation File Document upload:**

N/A

**Please provide appropriate references (PubMed, Abstract, Website):**

CDC Website: <https://www.cdc.gov/heart-disease/about/peripheral-arterial-disease.html>

Esprit BTK System Homepage:

<https://www.cardiovascular.abbott/us/en/hcp/products/peripheral-intervention/esprit-btk-resorbable-scaffold-system.html>

Case Studies:

<https://www.cardiovascular.abbott/us/en/hcp/products/peripheral-intervention/esprit-btk-resorbable-scaffold-system/case-studies.html>

Esprit BTK System FDA Approval Press Release:

<https://abbott.mediaroom.com/2024-04-29-Abbotts-Breakthrough-Dissolving-Stent-Receives-FDA-Approval-for-Arteries-Below-the-Knee>

LIFE-BTK Late-Breaker Results:

<https://abbott.mediaroom.com/press-releases?item=124676>

**References File Document upload:**

N/A