

# MEETING THE NEEDS OF PATIENTS ENROLLED IN CLINICAL TRIALS



These tools and resources are designed to make it easier for you to participate in a clinical trial

CHALLENGES	SOLUTIONS
Can't afford to come to visit.	Ask your care team about options for covering your travel expenses.
It's too hard to get to the doctor's office – public transportation, traffic, parking, etc.	<b>Lyft</b> car service can drive you to and from your visits at no cost to you. Leave the planning to us. All you have to do is wait for your car at the door.
I don't want to come back to the doctor's office for my follow-up visits.	<ul style="list-style-type: none"><li>• With your doctor's approval a trained professional can complete certain study visits in the comfort of your home.</li><li>• Located across the United States, these medical professionals have all had background checks and are highly trained and certified to perform the study visits.</li><li>• Your study doctor receives a full report of the visit and will review all the information.</li></ul>
I live too far for a day trip study visit.	Ask your care team about making travel arrangements at no cost to you. A travel agent will book airfare and hotel reservations for you. Take advantage of the concierge service!
I don't speak English well and want the visits in my own language.	<ul style="list-style-type: none"><li>• Your care team has access to interpreters who speak over 48 languages.</li><li>• Your doctor can call anytime 24/7 and speak to an interpreter.</li></ul>

CAUTION: Esprit™ BTK System is an investigational device limited by Federal (US) law for investigational use only.  
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LIFE-BTK Patient Brochure CL1015489



## LIFE-BTK CLINICAL TRIAL PATIENT INFORMATION

**See Important Safety Information referenced within.**  
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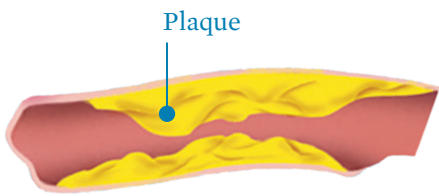


# CLI DISEASE

## AND CURRENTLY AVAILABLE TREATMENTS

### WHAT IS CRITICAL LIMB ISCHEMIA (CLI)?

In patients with CLI, blood vessels in the legs are blocked, drastically reducing blood flow to the feet

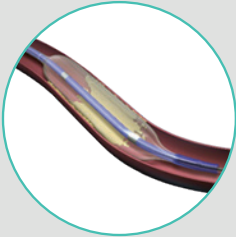
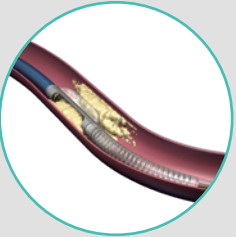


### HOW DOES CLI AFFECT YOU?

- Pain or numbness in the feet
- Absent or reduced pulse in the legs or feet
- Wound(s) in the leg or feet that will not heal



### WHAT DOES TREATMENT PROCESS LOOK LIKE?

DIAGNOSIS OF CLI	MOST COMMON TREATMENT	OTHER POTENTIAL TREATMENTS
<b>ANGIOGRAM (X-RAY)</b> Looks for blocked vessels in the leg	 <b>PTA</b> <ul style="list-style-type: none"><li>• Percutaneous transluminal angioplasty (PTA)</li><li>• A small balloon is inserted into the vessel and inflated to open the blockage, and re-establish blood flow to the lower leg and feet</li><li>• The balloon is then removed from the vessel</li></ul>	 <b>ATHERECTOMY</b> <ul style="list-style-type: none"><li>• Method used to remove significant blockages and/or calcium buildup that could prevent the vessel from opening</li><li>• PTA is then performed to completely open the vessel</li></ul> <b>SURGERY</b> Operation performed on your artery to clean out or bypass the narrowed part of your artery

### LIFE-BTK STUDY

- If you have been diagnosed with CLI, you may qualify for the LIFE-BTK study
- This is a study to test an investigational new device, called Esprit™ BTK, for treatment of CLI
- The device is made of a material that goes away (i.e. dissolves) over time and will be gone from your body in about 3 years
- Study participants will have in-person visits with a dedicated team of specialists focused on their care

*You can still see your personal physician for regular checkups and care.*

### WHAT IS INVOLVED IF I CHOOSE TO PARTICIPATE?

Before you are enrolled, you will be screened to make sure you are a good candidate for the study. You will also have to sign a consent form to participate in the study.

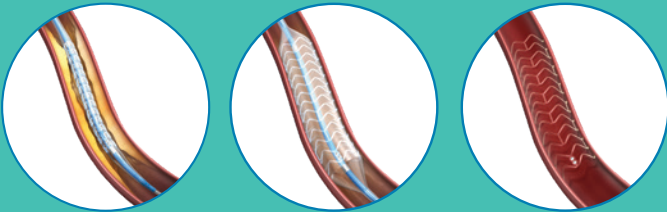
#### The screening may include:

- Review of your medical history with a study representative
- Laboratory tests
- Assessment of wound(s) on the leg or feet (if applicable)
- Angiogram (type of X-ray) to diagnose where the blockage is in your vessel

### WHAT HAPPENS IF I PASS THE SCREENING PROCESS?

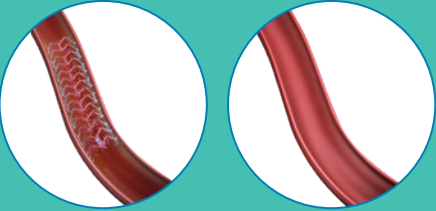
- 1 You will be assessed in-person at the treatment center and then registered in the study
- 2 You will be randomly assigned to a treatment group
- 3 You will have the procedure to treat your blocked vessel
- 4 You will have 10 study visits over a 5-year period, at the following time points:
  - 14 days
  - 30 days
  - 42 days
  - 90 days
  - 180 days
  - 1 year
  - 2 years
  - 3 years
  - 4 years
  - 5 years

### WHAT DOES TREATMENT WITH ESPRIT™ BTK LOOK LIKE?



1 Device inserted into blocked vessel to open up the blockage.

2 Device holds your vessel open, and releases a small amount of drug to help your vessel heal.

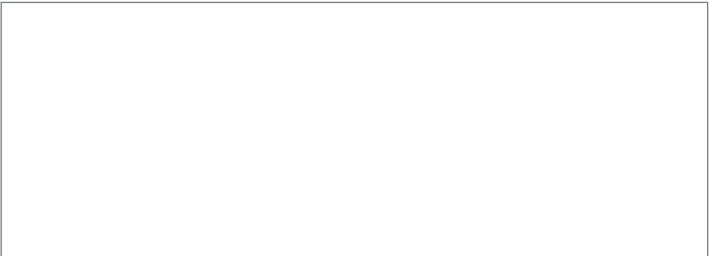


3 Device slowly goes away over time, so that nothing is left behind in your vessel, after about 3 years.

### WHERE CAN I LEARN MORE ABOUT THE LIFE-BTK STUDY?

- Visit [www.LIFE-BTK.com](http://www.LIFE-BTK.com) for all the information related to the trial. The website includes:
  - Videos about the disease and the LIFE-BTK trial
  - Information on the Esprit BTK device
  - FAQs

For any questions, please contact the study team at the below information:



For more information please refer to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT04227899)

**See Important Safety Information referenced within.**