ABOUT THE SAVAL PIVOTAL STUDY:

The SAVAL PIVOTAL Study is comparing the safety and effectiveness of the Drug-Eluting Stent (DES) Below the Knee (BTK) Vascular Stent System to percutaneous transluminal angioplasty (PTA) for people suffering from narrowing or blockages in one, or more, of the blood vessels in the lower leg, also known as peripheral artery disease (PAD).

WHAT WILL PARTICIPATION PROVIDE?

The purpose of this study is to compare the safety and effectiveness of the DES BTK Vascular Stent System to percutaneous transluminal angioplasty (PTA). This is a surgical procedure using a thin tube with a tiny inflatable balloon for the treatment of your blocked or narrowed blood vessels in your lower leg.

YOUR PARTICIPATION IN THIS CLINICAL STUDY WILL PROVIDE ACCESS TO:

- Effective treatment of the narrowed or blocked areas in your lower leg vessels with improvement in the symptoms
- Specialists who are dedicated to improving treatment of peripheral artery disease (PAD)
- Close care and monitoring during your study participation

THANK YOU

We appreciate your time and your consideration of the **SAVAL PIVOTAL STUDY.**

Please feel free to ask any questions you may have.

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1. Kinlay S. Management of critical limb ischemia. Circulation: Cardiovascular Interventions. 2016;9:2 Article Number: e001946.

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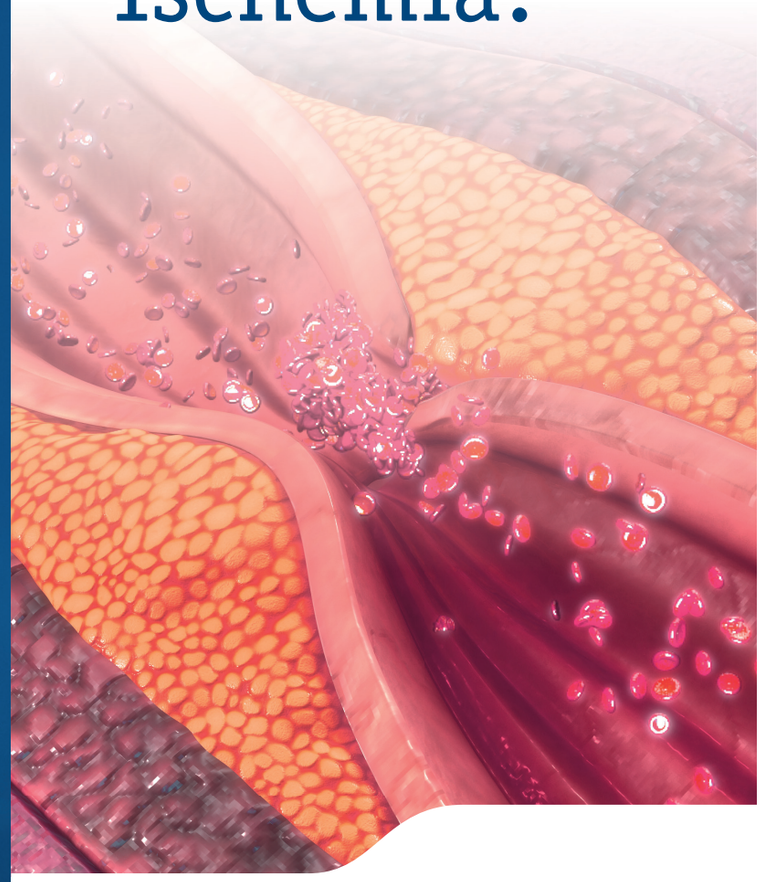
DO YOU SUFFER FROM Critical Limb Ischemia?



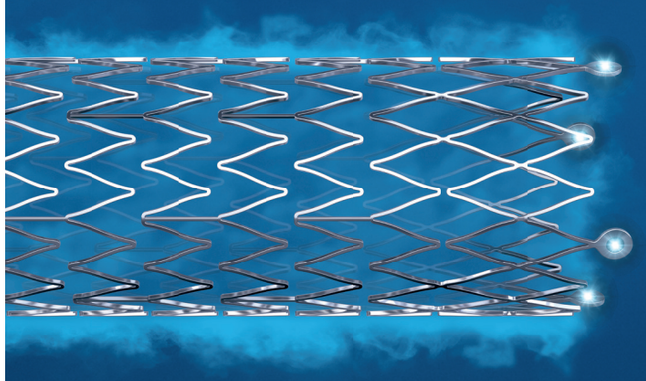
CRITICAL LIMB ISCHEMIA: WHAT IS IT?

Critical Limb Ischemia (CLI) is a progression of peripheral artery disease (PAD), characterized by severe obstruction of arteries (especially in lower limbs) which reduces blood flow to the legs.

Patients with Critical Limb Ischemia (CLI) experience debilitating clinical outcomes, including severe pain in the impacted limb, even at rest, the risk of open ulceration, gangrene and, if not treated properly, limb amputation.[1]

WHAT ARE DRUG-ELUTING STENTS (DES)?

The DES BTK Vascular Stent System is made of two parts: the metal stent and the long flexible tube delivery system used to place the stent in the blood vessel of the leg. The stent is made of a nickel and titanium mixture (Nitinol). It is designed to open up after it is placed in the blood vessel. The stent also contains a drug coating, called Paclitaxel. Paclitaxel is the active ingredient in Taxol®, a drug originally developed to treat cancer. The addition of the paclitaxel coating to the stent could improve the performance of the stent by decreasing the possibility of re-narrowing of the treated blood vessels. This re-narrowing is called restenosis and is the result of an inflammatory response at the treated site of the blood vessel.



TREATMENT OPTIONS

WHAT IS THE COMPARATOR TREATMENT VS. DRUG-ELUTING STENTS (DES)?

Percutaneous transluminal angioplasty (PTA) is a general medical procedure that is not investigational, and is available for treatment of narrowed or blocked blood vessels in the lower leg. A balloon that is located in a thin tube is passed through the skin and into the blood vessel. The balloon is placed across the area of the blood vessel that is narrow and then inflated. The tube is then removed.

WHAT ARE THE RISKS?

Patients who take part in this study are subject to similar risks shared by all patients who receive a similar type of device but are not in this study. Your physician will discuss the risks with you prior to your decision of participating in the clinical study.

WHAT WILL HAPPEN IF YOU TAKE PART IN THIS STUDY?

If you choose to participate in this study, you will be asked to see your study doctor at regular intervals and undergo medical tests including physical exams and tests to evaluate the blood circulation in your lower leg(s). The visits are at 1 month, 3 months, 6 months, 12 months, 24 months, and 36 months after the procedure. There will also be telephone contact at 18 months and 30 months after the procedure.

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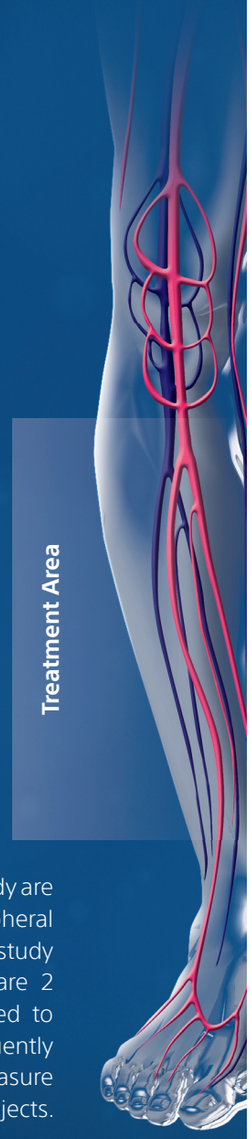
POTENTAL BENEFITS FROM YOUR PARTICIPATION

Potential anticipated benefits of receiving either the DES BTK vascular stent or percutaneous transluminal angioplasty include the effective treatment of the narrowed or blocked areas in your lower leg vessels with improvement in the symptoms. However, the DES BTK vascular stent is an investigational device and these potential benefits may or may not actually be present. You may not receive any benefit from participating in this study.



The medical tests used in this study are often used in people with peripheral artery disease. The tests in this study are not investigational. There are 2 questionnaires you will be asked to complete and they are frequently used in research studies to measure the overall wellbeing of study subjects.