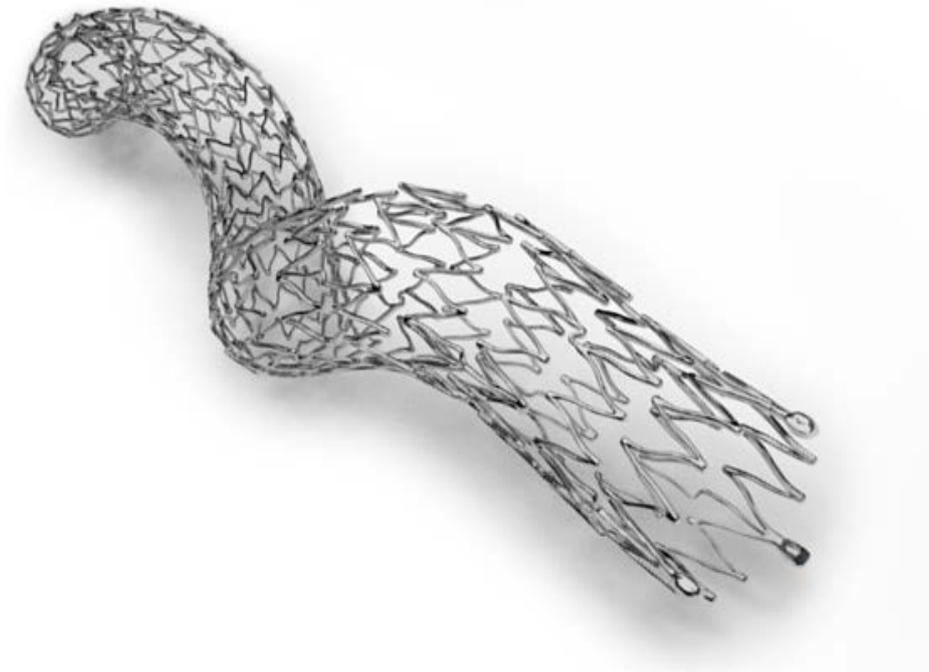




## **BioMimics 3D® Vascular Stent System**

A Treatment for Peripheral Arterial Disease in  
the Superficial Femoral and Proximal Popliteal  
Arteries

### **Patient Information**



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**Veryan Medical Ltd.**

Block 11

Galway Technology Park

Parkmore, Galway

Ireland

Tel: +353 91 750040

Email: [info@veryanmed.com](mailto:info@veryanmed.com)

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## Glossary

**Amputation:** Surgical removal of a body part.

**Angioplasty:** A procedure used to open narrow arteries using a small balloon-tipped catheter. It is a minimally-invasive treatment, where a tube (catheter), with a small balloon mounted on it is delivered to the diseased artery and inflated. The balloon compresses the plaque against the artery wall reducing the narrowing and increasing blood flow. The balloon is then deflated and removed.

**Artery (arteries):** A blood vessel that carries blood away from the heart to the rest of the body.

**Atherectomy** is a minimally-invasive procedure using a catheter to cut or abrade the atherosclerotic deposits, thus opening the channel for blood flow.

**Atherosclerosis:** A disease process involving the build-up of a fatty substance called plaque on the inside of the arteries.

**Blood vessel (vessel):** An artery or a vein.

**Bypass surgery:** See Open bypass.

**Bypass graft:** A fabric tube or blood vessel taken from another part of the patient's body used to restore blood flow in an open bypass.

**Catheter:** A thin, hollow tube that is inserted through a small opening in the body.

**Claudication:** Leg pain, cramping, or severe tiredness while exercising.

**CT scan:** A scan that uses X-rays to see inside the body.

**Delivery catheter:** A catheter used to implant a device, such as a stent.

**Endovascular:** Inside or within a blood vessel.

**Endovascular repair:** A procedure in which a small balloon attached to a catheter (angioplasty) or a small metallic mesh tube called a stent may be placed inside an artery without cutting open the leg.

**Femoral artery:** Artery that carries blood from the pelvis to the leg. Doctors can use this artery as a path to reach other arteries such as the iliac, superficial femoral and popliteal arteries.

**Hematoma:** A pocket of clotted blood that forms in tissue.

**Hypertension:** High blood pressure.

**Hypotension:** Low blood pressure.

**Imaging:** The use of X-rays, CT scans, MRI scans, ultrasound, or other techniques to get pictures of the inside of the body.

**Infection:** Attack of tissue due to the presence of tiny organisms, such as bacteria.

**Minimally invasive:** Involving a small cut of the skin without exposing the organs.

**Magnetic Resonance Imaging (MRI):** A technique that uses magnetic fields to get pictures of the inside of the body.

**Occlusion:** A complete blockage of an artery due to plaque.

**Open surgical repair / surgical bypass:** An open surgical repair in which a surgeon uses either a fabric tube (graft) or a blood vessel taken from another part of the patient's body to redirect blood around a narrowed

or blocked artery and restore blood flow. The bypass is performed by sewing the bypass graft to arteries above and below the diseased vessel.

**Percutaneous Transluminal Angioplasty (PTA):** See Angioplasty

**Peripheral Arterial Disease (PAD):** Atherosclerosis of the peripheral arteries, such as arteries of the pelvis and legs.

**Plaque:** Build-up of fat and cholesterol on the inner lining of arteries.

**Popliteal artery:** A continuation of the superficial femoral artery that crosses behind the knee to carry blood to the lower leg.

**Restenosis:** Re-narrowing of an artery at the site of angioplasty and/or stent placement.

**Spasm:** Contraction of an artery.

**Stenosis:** A narrowing on the inside of an artery due to plaque.

**Stent:** A small metallic mesh tube that is permanently placed in the vessel to support an artery that has been treated with angioplasty or atherectomy to restore blood flow.

**Stenting** is a minimally invasive procedure, in which a stent (metallic mesh tube) is permanently placed inside the artery. This acts as a support to the artery to keep the diseased artery open and maintain the increased blood flow resulting from the angioplasty or atherectomy procedure. The stent is delivered to the artery on a catheter that is removed once the stent is deployed. Over time, the artery will heal around the stent as it continues to support the artery.

**Stent fracture:** Breakage of the stent within the artery.

**Superficial Femoral Artery:** Artery that carries blood to the knee and lower leg. The superficial femoral artery transitions to the popliteal artery near the knee.

## 1 Introduction

This guide is intended to help you understand the treatment of Peripheral Arterial Disease (PAD) in the superficial femoral artery and proximal popliteal artery and to provide you with specific information about the BioMimics 3D Vascular Stent System.

If you are unsure of the meaning of any terms used in this guide, consult the glossary on page 3

### 1.1 What is Peripheral Arterial Disease?

Peripheral Arterial Disease (PAD) is a circulatory problem caused by the presence of atherosclerosis in peripheral arteries. The term peripheral arteries refer to all arteries except for the coronary arteries. Atherosclerosis occurs when the arterial walls become damaged by a build-up of fatty substances, fibrous tissue and calcium, which then reduces blood flow through the artery.

### 1.2 What Are the Superficial Femoral and Proximal Popliteal Arteries?

The superficial femoral artery starts at the groin and extends down to just above the knee. The superficial femoral artery connects with the popliteal artery, which runs behind the knees. The popliteal artery then branches into smaller arteries that supply oxygen-rich blood to the calves and feet (see Figure 1).

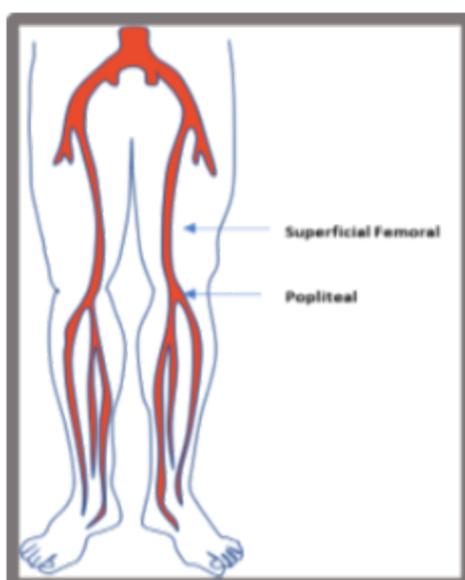


Figure 1: Arteries of the leg

### 1.3 What are the symptoms of Peripheral Arterial Disease?

There are a range of symptoms associated with PAD which include:

- Pain, discomfort or tiredness in the legs when walking;
- Pain in the foot, particularly at night, eased when lowering the foot out of bed (rest pain); and ultimately, as PAD progresses;
- Ulceration and gangrene of the toes and feet.

In the early stages of PAD, there may be no symptoms. In mild PAD, reduced blood flow may cause pain in the muscles when walking, which may be eased with rest (claudication). In severe cases, there may be pain, even at rest, with skin ulcers and infections of soft tissue causing gangrene as PAD worsens.

#### **1.4 What causes Peripheral Arterial Disease?**

PAD develops over time with the accumulation of atherosclerotic deposits in the vessel wall, which limits blood flow.

Factors associated with PAD are:

- smoking
- obesity
- diabetes
- high cholesterol
- high blood pressure
- heart disease
- renal failure
- inherited tendency

#### **1.5 What are the treatment options?**

There are a range of treatment options depending on the stage of PAD.

For mild symptoms, your physician may advise lifestyle changes such as stopping smoking, exercising regularly, reducing fat and cholesterol in your diet, and keeping your blood pressure under control.

Your physician may also prescribe medication to lower cholesterol and make cells in your blood less sticky (e.g. aspirin or clopidogrel).

For more severe symptoms or those that have not improved after lifestyle changes, your physician may advise a minimally-invasive procedure carried out through a catheter inserted into one of the arteries that enables access to the obstructed vessel. Using this route, the physician may use angioplasty or atherectomy to open the blockage, both of which are commonly accompanied by placing a stent, or scaffold, to keep the vessel open. This guide specifically looks at this treatment option. If the PAD is widespread, then the physician may advise an open surgical procedure such as bypass surgery to provide a new vessel so that blood can flow around the blockage and down to the arteries of the lower leg.

## **2 BioMimics 3D<sup>®</sup> Vascular Stent System**

The BioMimics 3D Vascular Stent System consists of a self-expanding stent that is loaded into a delivery catheter. The stent is made from a special alloy of nickel and titanium, called nitinol, that can store a specific shape within its memory, so that once the stent is released from the catheter it will provide just the right

amount of support to the vessel in which it is placed. Arteries naturally have a helical shape which leads to naturally-occurring swirling blood flow in vessels [1] which prevents the build-up of fatty substances, fibrous tissue and calcium. Stents are usually straight mesh tubes (Figure 3). The BioMimics 3D Stent has been developed with a unique three-dimensional helical shape (Figure 2) which mimics the natural curvature of the human vascular system. This helical shape enables the stent to shorten with the vessel as the knee/hip is bent.



Figure 2: BioMimics 3D helical stent

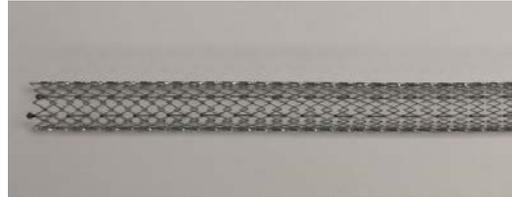


Figure 3: Straight stent

### 3 Stenting Procedure

After making the skin numb with local anesthetic, your physician will gain access to an artery through a small incision in your groin. A guidewire will be inserted and passed across the narrowed section in your artery.

Prior to inserting the stent, the physician may use an angioplasty balloon or atherectomy device to expand the narrowed region of the artery, which also allows room for placement of the stent to optimize blood flow in the treated vessel. The BioMimics 3D stent is supplied already loaded inside the delivery system and may be inserted over the same guidewire. The stent is deployed permanently in the treated artery to keep it open.

After the stent is implanted, the stent delivery system is removed, and the physician may choose to inflate a balloon within the stent to open it further. Once all procedures are complete, the guidewire is removed from the body. The puncture site in your groin is then closed.

#### 3.1 What are the risks associated with stenting?

Your physician may not consider you to be a good candidate for stenting if you have any of the following conditions:

- You have a history of intolerance or adverse reaction to antiplatelet and/or anticoagulation therapies, bleeding diathesis, severe hypertension or renal failure.
- You have a known hypersensitivity to nickel or titanium.

As with all procedures that introduce a catheter into an artery, complications may occur. These complications include, but are not limited to:

- **Stent system events:** Device embolization; device malfunction; serious injury or surgical intervention; stent strut fracture(s); stent migration; stent misplacement/jumping.
- **Vascular events:** aneurysm; arterial dissection; arterial perforation; arterial rupture; arterial spasm; arteriovenous fistula; embolism and/or arterial thrombosis; hematoma; hypotension; ischemia; vascular complications which may arise during placement of a bailout stent; pseudoaneurysm; restenosis of the treated segment; stenosis; total occlusion of the peripheral artery; abrupt occlusion of the peripheral artery; vascular complications which may require surgical repair (conversion to open surgery) or endovascular intervention; worsening of peripheral arterial disease leading to additional surgical intervention, endovascular intervention or amputation; vasospasm.
- **Bleeding events:** Access-site complications including bleeding or hemorrhage; gastrointestinal bleed; bleeding complications requiring transfusion.
- **Procedural events:** Allergic reaction to contrast media / medications; extravasation of contrast media; fracture of the guidewire or any component of the BioMimics Vascular Stent System that may or may not lead to device embolism; radiation exposure.
- Angina
- Bradycardia
- Cardiac arrest
- Cardiac arrhythmia
- Death
- Emergency or non-emergency arterial bypass surgery
- Infection or fever
- Leg pain/claudication
- Myocardial infarction or coronary ischemia
- Nausea/vomiting
- Neurological deficit
- Renal insufficiency or failure
- Respiratory distress or failure
- Serious injury requiring surgical intervention
- Stroke or transient ischemic attack

## **4 BioMimics 3D Clinical Data Summary**

### **4.1 MIMICS-2 Clinical Study:**

The safety and effectiveness of the unique helically-shaped BioMimics 3D Vascular Stent System was evaluated in the single-arm MIMICS-2 Clinical Study, which included 256 patients who completed their 12-month follow-up visit. Patients in the study will be followed until a maximum of 36-months. For the BioMimics 3D Vascular Stent System, the occurrence of major adverse events was 0.4% (1/269) at 30 days and 13.6% (35/258) at 12 months. These results show that patients who received the BioMimics 3D Vascular Stent System had a rate of major adverse events similar to that which has been reported for comparable patients in the published literature. A major adverse event is defined as death, repeat intervention in the lesion where the stent was placed, and/or major amputation.

The effectiveness endpoint of Primary Patency was defined as no significant reduction in luminal diameter (< 50% diameter stenosis) since the index procedure. Loss of patency was determined by an independent core laboratory when the peak systolic velocity ratio (PSVR) exceeds 2.0, or where angiography revealed > 50% diameter stenosis, or where the subject had a clinically driven target lesion revascularisation (CDTLR). Based on independent core laboratory determination, the observed 12-month primary stent patency rate was 73.0% (181/248).

In general, following angioplasty or stent implantation, there is a tendency for the artery to re-narrow in some patients. After 12 months of follow up, 32/256 subjects (12.5%) treated with the BioMimics 3D Stent in the MIMICS-2 Study required further intervention to the treated area of narrowing due to recurrence of symptoms. This is consistent with rates of re-intervention reported for comparable patients in recent clinical studies with current stent technologies.

### **4.2 Mimics Clinical Study:**

The safety and performance of the unique helically-shaped BioMimics 3D Stent were compared to a straight nitinol control stent in the Mimics Study. A total of 60 subjects treated with a total of 61 BioMimics 3D stents, were completely free of major adverse events through 30 days, including death, treated limb amputation or the need for further intervention to the area of vessel narrowing. This met the primary safety outcome measure of the Mimics Study. After 6 months of follow up, no subject treated with the BioMimics 3D stent in the Mimics Study required further intervention to the treated area of narrowing due to recurrence of symptoms.

## **5 Follow-Up Examinations**

Regular follow-up visits will be scheduled with your physician to check on you and your stent. These are important to attend, so that your physician can monitor your progress and see how the stent is working for you.

## **6 Implanted Device Identification Card**

After your procedure, your physician will give you an implanted device identification card. This card provides information about the stent you have received.

It is important to keep this card with you always and to present it in the event of an emergency as it identifies you as a patient who has a stent implanted.

## **7 Magnetic Resonance Imaging (MRI)**

It is safe to have MRI procedures after being implanted with a BioMimics 3D stent, under certain conditions. The BioMimics 3D Stent has been classified as MR Conditional, which means that an MRI can be done safely under specific testing conditions. Present your implant card to your physician so he/she can identify the MRI conditions that are appropriate for your BioMimics 3D stent.