

# AZUR

Peripheral Coil System

# AZUR™

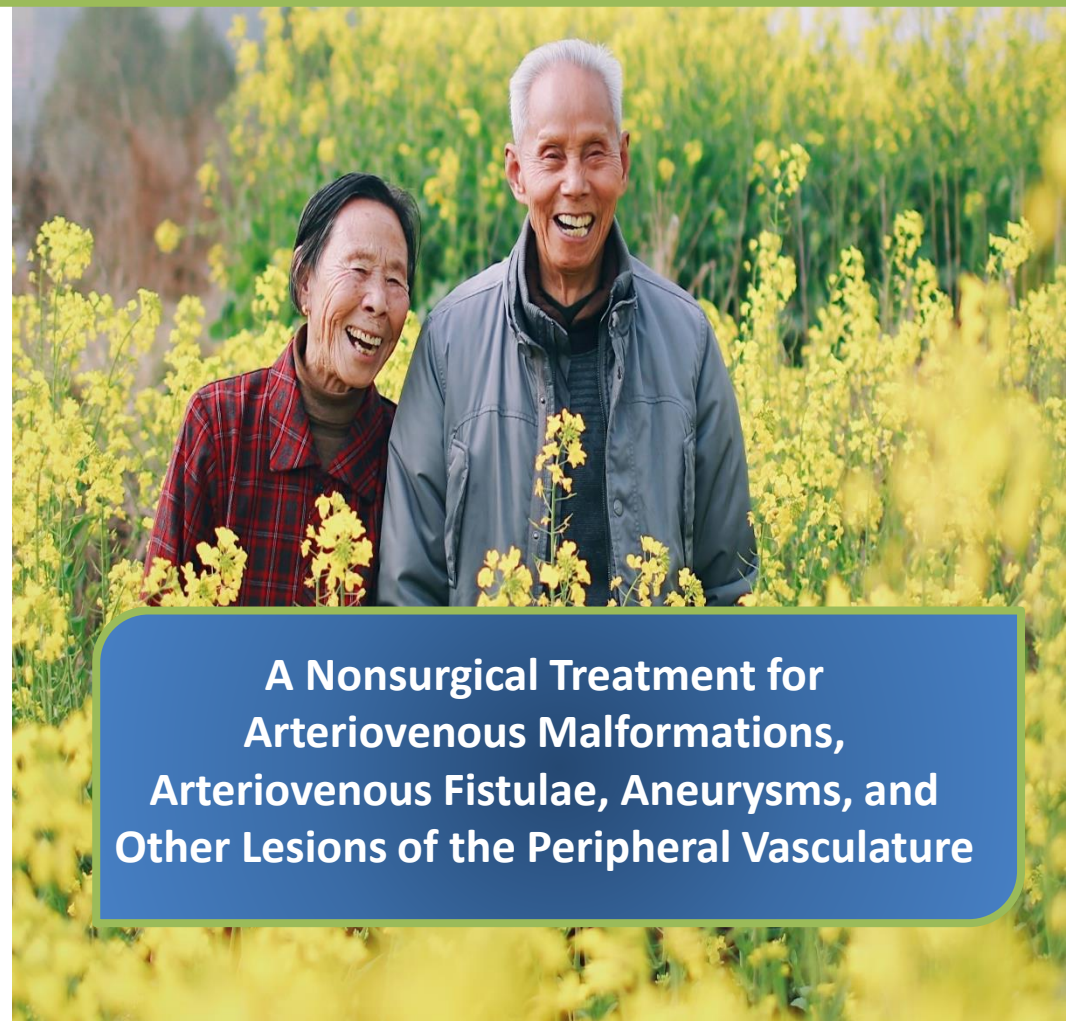
Peripheral Coil System

## Indications for Use:

The AZUR system is intended to reduce or block the rate of blood flow in vessels of the peripheral vasculature. It is intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

## References:

1. Ferral H. Hydrogel-coated coils: product description and clinical applications. *Semin Intervent Radiol.* 2015;32(4):343-8.
2. Hongo N, et al. Vessel occlusion using hydrogel-coated versus nonhydrogel embolization coils in peripheral arterial applications: a prospective, multicenter, randomized trial. *J Vasc Interv Radiol.* 2021;32.4:602-9.
3. Shimohira et al. Usefulness of hydrogel-coated coils in embolization of pulmonary arteriovenous malformations. *Cardiovasc Intervent Radiol.* 2018;41, 848–855.
4. Aswathy SH, et al. Commercial hydrogels for biomedical applications. *Heliyon.* 2020; 6(4):e03719.



**A Nonsurgical Treatment for  
Arteriovenous Malformations,  
Arteriovenous Fistulae, Aneurysms, and  
Other Lesions of the Peripheral Vasculature**

**Manufacturer:**  
MicroVention, Inc.  
1311 Valencia Avenue  
Tustin, CA 92780 USA

**Distributed by:**  
Terumo Australia Pty Ltd  
Macquarie Park, NSW, 2113, Australia T: 1800 837 866  
Mount Albert, Auckland, 1025, New Zealand T: 0800 66 77 57

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# Understanding when the AZUR Peripheral Coil System is used

## What are the Indications?

The indications include: arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.

## What is an Aneurysm?

An aneurysm is a bulge filled with blood in the wall of an artery.

- Aneurysms may rupture, which can be fatal.
- May form in the arteries of the heart, kidneys, or gut.
- There are usually no symptoms.



Ruptured aneurysm

## What is a Hemorrhage?

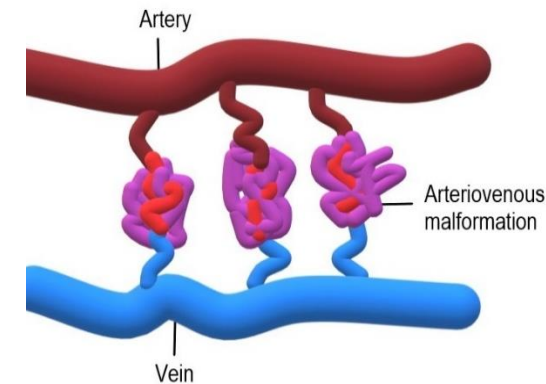
A hemorrhage is bleeding from damaged blood vessels. It usually involves a lot of bleeding in a short time.

- May happen in the gut, lungs, urinary tract, limbs, or reproductive organs.
- May happen after trauma or can be caused by other medical conditions.

## What is an Arteriovenous Malformation (AVM)?

An arteriovenous malformation (AVM) is an abnormal tangle of blood vessels connecting arteries and veins.

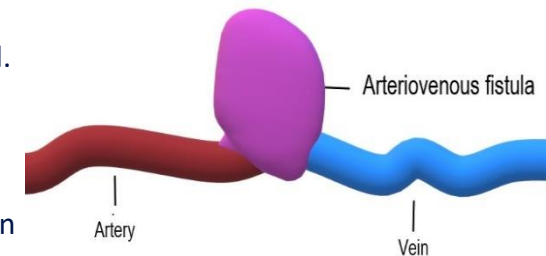
- AVMs disrupt normal blood flow.
- May occur during development before birth or shortly after.
- May form in the arms, legs, lungs, or liver but can form anywhere in the body.



## What is an Arteriovenous Fistula (AVF)?

An arteriovenous fistula (AVF) is a bad connection between an artery and a vein.

- AVFs can bypass some tissues, and these tissues don't receive enough blood.
- May happen after an accident or trauma.
- May form in the legs but can develop anywhere in the body.



# Treatment Options



## Treatment Goal

The goal of treatment for arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature is to reduce or block the rate of blood flow.

## Surgery

Different types of surgery may be used for your treatment.

### Open surgery

- The surgeon makes a large and deep cut into the skin to access the lesion.

### Laparoscopic surgery

- The surgeon makes a small cut into the abdomen to access the lesion.

### Surgical resection

- The surgeon cuts out the lesion.

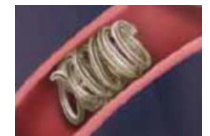


## Endovascular Therapy

Nonsurgical and minimally invasive procedures that are done inside blood vessels.

### Coil embolization

- Coils are placed inside the vessel or aneurysm to reduce or block the rate of blood flow.



**Coil Embolization**

## Which Treatment is Right for Me?

The treatment option that is best for you may be based on:

- Location, size, and shape of your vessel.
- Impact of the lesion on your quality of life.
- Your risk of complications for each treatment option.

**Discuss the treatment options  
with your physician.**

# AZUR Peripheral Coil System

The AZUR Peripheral Coil System is a device used during an endovascular therapy procedure. It reduces or blocks the rate of blood flow in the peripheral vasculature.

May be used to treat arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions of the peripheral vasculature.<sup>1-3</sup>

A broad range of coil models and sizes are available:



**AZUR Framing Coil**



**AZUR HydroCoil Detachable**



**AZUR CX Detachable**

- The device consists of a coil implant attached to a delivery system.
- Except for AZUR Framing coils, the platinum coils are coated with hydrogel.<sup>1</sup>
- Hydrogel is a material that expands when exposed to blood, which increases the filling volume of the coils.<sup>1,2,4</sup>
- Hydrogel creates mechanical occlusion (blockage of a blood vessel), which may reduce the need for reintervention.<sup>1-3</sup>
- The device does not contain latex or PVC.
- Hydrogel-coated platinum coils can be used safely for coil embolization in the peripheral vasculature.<sup>2,3</sup>



**A magnified view of the hydrogel-coated coil.**

## What Might Happen if the Device Malfunctions?

There is a chance that the device might malfunction during the procedure. Potential malfunctions may include:

- Coils may break or migrate.
- The catheter could perforate the aneurysm or vessel.
- Unintended blockage of a parent artery could happen.
- Incomplete filling of the lesion by the coils could lead to recurrence of the lesion.

Malfunctions of the device may result in injury, illness, or death.

**Any serious incident that occurs in relation to the AZUR Peripheral Coil System should be reported to MicroVention, Inc. and Therapeutic Goods Administration ([www.tga.gov.au](http://www.tga.gov.au)).**

## What Care Does the Device Need?

The device does not require any patient care.

There is no ongoing monitoring or maintenance of the device. There are no expected limitations to the lifetime of the device. Check with your physician prior to MRI scan.

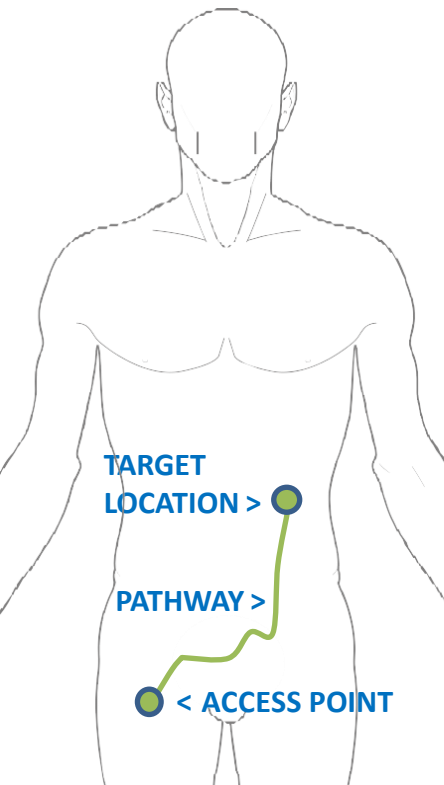
# Embolization Procedure

The procedure used for the AZUR Peripheral Coil System is nonsurgical and minimally invasive.

## Before the Procedure

You will undergo an angiography (examination by X-ray). The puncture site (e.g. groin) will be prepared for the procedure.

## During the Procedure



**1)** A small puncture is made to access the vasculature.

**2)** Using fluoroscopy (continuous X-ray imaging), the physician will advance a catheter into the target location.

**3)** The coil is delivered through the catheter and permanently placed in the vessel at the target location. Angiography determines proper placement.

**4)** The implanted AZUR coil forms a mechanical obstruction to reduce or block blood from flowing into the target location.

**5)** Delivery of multiple coils is usually required to achieve the desired results.

## After the Procedure

You may experience mild discomfort or bruising at the puncture site. No major side effects are expected.<sup>2,3</sup>

### Symptoms to Watch for:

- Combined pain, nausea, vomiting, and fever (post-embolization syndrome)
- Difficulties talking, moving, or seeing
- Swelling
- Bleeding
- Stroke or other neurological impairment

**If you experience any of these symptoms or any unexpected symptoms, contact your physician immediately.**

### Other Complications:

- Blood clots
- Vascular thrombosis (when a blood clot blocks a vein)
- Ischemia (not enough blood flow to an area of the body)
- Vasospasm (narrowing of arteries that reduces blood flow)
- Revascularization (the restoration of blood flow)
- Possibly death

