Summary of Safety and Clinical Performance

for

AZUR Peripheral Coil System

SSCPPT23-0001

MicroVention, Inc.
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DOCUMENT CHANGE HISTORY

SSCP Revision	Change Description	NB approved/verified
A	Initial release	☐Yes ☒ No* Validation language:

*Annual entries must be included. An entry stating such must be added if a revision is not required.

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TABLE OF CONTENTS

LIST OF TABLES

1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE [PATIENT VERSION]

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This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

1.1 Device Identification and General Information

Table 1.1 Device Identification and General Information

Device Names	
Device Trade Name	AZUR Peripheral Coil System
Device Class	IIb, Implantable
Basic UDI-DI	08402732AZURCOILZN
Year when first certificate (CE) was issued	2008
Legal Manufacturer	
Name & Address	MicroVention, Inc. 35 Enterprise Aliso Viejo, California, 92656 USA
Authorized Representative	
Name & Address	MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye, France
Notified Body	
Name & Address	DQS Medizinprodukte GmbH August-Schanz-Straße 21 D-60433 Frankfurt am Main Germany

1.2 Intended Use of the Device

Table 1.2 Intended Use

Intended Use	
Intended Purpose	These devices are used to reduce or block the flow in blood vessels that take blood to arms, legs, hand and feet. It is meant for use in the procedures done inside the blood vessels. These are also used in situations where there will be abnormal connection between blood vessels which carry good and bad blood.
Indications for Use	These devices are used to reduce or block the flow in blood vessels that take blood to arms, legs, hand and feet. It is meant for use in the procedures done inside the blood vessels. These are also used in situations where there will be abnormal connection between blood vessels which carry good and bad blood.
Intended Patient Group(s)	These implants are used in patients with a need to permanently occlude blood flow in a blood vessels that take blood to arms, legs, hand and feet.
Contraindications and/or Limitations	• When super selective coil placement is not possible. • When end arteries lead directly to nerves. • When arteries supplying the lesion to be treated are not large enough to accept emboli. • When the A-V shunt is larger than the coil. • In the presence of severe atheromatous disease. • In the presence of narrowing blood vessels (or likely at the beginning stage of narrowing).

1.3 Device Description

Table 1.3 Device Description

Device Description	
Description of the Device	The Device has two parts, based on the way it is placed in the body: • Pushable Delivery System • Controlled Detachable Delivery System The implant is available with a removable delivery system and a delivery system that helps to push the loop in to problem area. The removable delivery system has spring like loop which is attached to the device that pushes it in to the problem site, the pushing device uses a synthetic filament called polyolefin elastomer. The front end of the device is inserted into a hand-held battery powered device called as Detachment Controller. When it is activated, the current flow heats the filament, causing detachment of the part of the device. The device with a pushable delivery system consists of an implantable coil packaged in an introducer. A stainless-steel stylet is used to deploy the coil from the introducer into a delivery catheter. The loops are delivered to the problem site through the flexible tubes using a wire.
Materials or substances in	Implant: Platinum/Tungsten alloy/ Platinum/Iridium alloy/Hydrogel

Device Description	
contact with the patient's tissues	
Information about medicinal substances in the device	The device does not contain any medicinal substances.
Description of how device achieves its intended mode of action	These devices, when placed inside the blood vessels that supply the arms, hands, legs and feet helps to remove the damaged area and at the same time these devices will help the blood flow normally into areas that have no damage.
Description of Accessories	The device is introduced into the patient body using commercially available controllers.
Description of other Devices or Products intended to be used in combination	None.

1.4 Risks and Warnings

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

- **How potential risks have been controlled or managed**
  The company uses a standard process to predict device risk. The process gives a thorough estimate of what might happen when the device is used. A list of possible harms and what might cause them is compiled. The Instructions of Use also describes any warning or precautions. These may be associated with remaining risk. Reports of any harms are tracked in a complaint database. Reports can come from users or other health care professionals or from publications. The database is assessed on a regular basis. Harms are investigated if rates are increasing or at a certain level. Actions such as changes in labelling or recall can be taken if needed.
- **Remaining risks and undesirable effects**
  There is always a risk of undesirable side effects when you have any type of surgery. It can be difficult to know the exact source of some side effects.

  The device Instructions of Use identified the following known potential side effects:
  - Blood vessel rupture or Blood vessel bulge rupture
  - Narrowing of the blood vessels
  - Bad Bruise at the entry site of the device
  - Seizure

- Stroke
- Tear on the inside of the blood vessel- perforation
- Reduced blood flow through a vessel caused by clot
- Possible death
- Misplacement of the device
- Swelling of the body or particular area

- **Warnings and precautions**

There are some warnings and precautions related to the use of AZUR Peripheral Coil System listed as follows:

AZUR Detachable Coils (Helical, Framing and HydroPack)

- This device should only be used by physicians who have received proper training in these procedures
- The AZUR system is supplied clean (sterile) and will not cause fever or inflammation (non-pyrogenic) unless package is opened or damaged
- This device is used for one time (single use) only. Do not reuse, fix or reclean. Reuse, fixing or recleaning may damage the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, fixing or recleaning may also create a risk of making the device dirty (contaminate) and/or cause patient infection. This may also lead to injury, illness or death of the patient.
- Imaging of the blood vessels (Angiography) is required before the procedure (pre-embolization evaluation), during the procedure (operative control), and after the procedure (post-embolization follow up).
- Do not push the delivery pusher too hard. Determine the cause of any unusual resistance, remove the AZUR system, and check for damage
- Push and pull back the AZUR system slowly and smoothly. Remove the entire AZUR system if there is too much heat (excessive friction). If too much heat (excessive friction) is noted with a second AZUR system, check the tiny tube (microcatheter) for damage or kinking
- If changing the position is necessary, take special care to pull back the coil using blood vessel pictures (fluoroscopy) in a one-to-one motion with the delivery pusher. If the coil does not move in a one-to-one motion with the delivery pusher, or if changing the position is difficult, the coil may have become stretched and could possibly break. Gently remove and throw out the entire device
- Due to the fragile nature of the coils, the windy blood vessel pathways that lead to some abnormal bulges/sores/growth which are all different in shape and sizes, a coil

may occasionally stretch while being put in place. Stretching tends to happen before the coil breaks and moves to the wrong place (migrates)

- If a coil must be pulled back from the blood vessel after separation, do not attempt to pull back the coil with a removal device, such as a snare, into the delivery catheter. This could damage the coil and result in device separation. Remove the coil, tiny tube (microcatheter), and any removal device from the blood vessels at the same time
- Delivery of more than one coil is usually needed to fill the blood vessel bulge to fully block the blood flow into the bulge. Success of the procedure is when the blood flow is blocked from going into the bulge and seen in Xray pictures
- Curvy or complex blood vessel pathways may affect correct placement of the coil.
- The long-term effect of this product on tissues outside the blood vessels (extravascular) has not been assessed, so care should be taken to keep this device in the blood vessel space
- Always make sure that at least two AZUR Detachment Controllers are available before starting an AZUR system procedure
- The coil cannot be separated with any power source other than an AZUR Detachment Controller
- Do NOT place the delivery pusher on a metal surface
- Always handle the delivery pusher with surgical gloves
- Do NOT use in together with radio frequency (RF) devices

Only applicable to AZUR Detachable Coils - Helical & HydroPack

- The coil must be properly placed in the blood vessel or bulge in the blood vessel wall (aneurysm) within the specified time from the time the device is first introduced into the tiny tube (microcatheter). If the coil cannot be positioned and detached within this time, remove the device and the tiny tube (microcatheter). Putting the device in a low-flow spot may allow more time to correct the position.

Only applicable to AZUR Detachable Coils - Framing

- Always push with a correct sized wire through the tiny tube (microcatheter) after separating the coil and removing the pusher to make sure no part of the coil remains inside the tiny catheter (microcatheter)

AZUR Pushable Coils

- This device should only be used by physicians who have received proper training in these procedures
- The AZUR system is supplied clean (sterile) and will not cause fever or inflammation (non-pyrogenic) unless package is opened or damaged
- This device is used for one time (single use) only. Do not reuse, fix or reclean. Reuse, fixing or recleaning may damage the device and/or lead to device failure which,

in turn, may result in patient injury, illness, or death. Reuse, fixing or recleaning may also create a risk of making the device dirty (contaminate) and/or cause patient infection. This may also lead to injury, illness or death of the patient

- Imaging of the blood vessels (Angiography) is required before the procedure (pre-embolization evaluation), during the procedure (operative control), and after the procedure (post-embolization follow up)
- Always inspect the AZUR system before preparation and pushing into the body (insertion) to make sure the coil has not moved within the introducer or moved into the introducer caps. If the coil is not secure within the introducer prior to both the preparation and introduction processes, damage may result
- Adding moisture (Hydration) of the AZUR system prior to use is required. A 3-minute moisturizing period is required to soften the coil. Failure to moisten may result in the coil not taking its secondary shape, which can result in the coil moving away from or poke through the correct location
- The coil must be delivered through a correct-sized tube (catheter) or tiny tube (microcatheter) with a correct size coating guiding wire (guidewire). Failure to correctly size the delivery system may result in damage to the device and the need to remove both the device and delivery catheter from the patient
- Always select a wire-reinforced delivery tube/tiny tube (catheter/microcatheter) when delivering the coil through windy blood vessels. Using a tube that is not reinforces may cause coil damage and may need to remove both the device and the delivery tube from the patient
- Do not use a syringe to deliver the coil. The coil is to be delivered using a suitable guiding wire (guidewire only). Delivery via syringe injection may result in the coil not taking its secondary shape, which can result the coil not making it to the correct location, to poke out of the correct location
- Do not push the coil with too much force. If strange resistance is noted during pushing, determine its cause before proceeding make sure the correct delivery tube (catheter) and guiding wire (guidewire) are being used, and that both are free from damage and kinking. If necessary, replace the delivery tube (catheter), coil, and/or guiding wire (guidewire) before continuing
- If a coil must be pulled back from the blood vessel(vasculature) after insertion, do not attempt to withdraw the coil with a retrieval device, such as a snare, into the delivery catheter. This could damage the coil and result in device separation. Remove the coil, tiny tube (microcatheter), and any retrieval device from the blood vessel at the same time
- If the coil and/or pushing wire guide (guidewire) gets stuck within the delivery tube (catheter) do not continue advancing. Remove the tube (catheter), and replace the tube (catheter), coil, and/or wire guide (guidewire) when necessary

- Delivery of more than one coil is usually needed to fill the blood vessel bulge to fully block the blood flow into the bulge. Success of the procedure is when the blood flow is blocked from going into the bulge and seen in Xray pictures
- Curvy or complex blood vessel pathways may affect correct placement of the coil.
- The long-term effect of this product on tissues outside the blood vessels (extravascular) has not been assessed so care should be taken to keep this device in the blood vessel space
- Always push a correct sized wire guide (guidewire) through the delivery catheter after deployment to ensure that no part of the coil remains within the catheter prior to delivering the next coil or removing the catheter from the patient.

- **Summary of any field safety corrective action, (FSCA including FSN) if applicable**
  There were 2 problems identified in 2019 and 2023. One was about damaged cover that protects the product, and the other was about some parts that were missing.

1.5 Summary of Clinical Evaluation and Post-Market Clinical Follow-up

- **Clinical background of the device**
  These devices were first placed in the market in 2008.

- **The clinical evidence for the CE-marking**
  A thorough search of journals was done to find studies where the AZUR Peripheral Coil System was used. The date range for the search was 01 January 2009 to 31 July 2024. The search found 19 studies using the device in 135 patients. Several results were studied to evaluate how well the device work. Results tell how well the device cleared the clump of hardened blood and bring back the blood flow to arms, hands, legs and feet.

- **Safety**
  When compared, AZUR Peripheral Coil System was safe and successful as other similar devices. Rates of undesirable side effects were low and similar. No new or unknown risks were found, benefits will be more than the risks when used as they should be.

1.6 Possible Diagnostic or Therapeutic Alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

- **General description of therapeutic alternatives**

Treatment other than surgical procedures may be best for some patients. You and your doctor will decide what is right for you. When symptoms are more severe and non-surgical procedures does not work, then your doctor will use surgical procedures to help get the blood supply to normal. There are befits and risks to each treatment option.

1.7 Suggested Training for Users

This device is not used directly by the patient. No training is required for the patient.