Summary of Safety and Clinical Performance

for

AZUR™ Vascular Plug

SSCPPT23-0011

Rev. A

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DOCUMENT CHANGE HISTORY

SSCP Revision	Change Description	NB approved/verified
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*Annual entries must be included. An entry stating such must be added if a revision is not required.

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1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE [PATIENT VERSION]

Document Revision:
Date Issued: 09 May 2025

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 Vascular Plug
Device Class	Class IIb
Basic UDI-DI	08402732AZURPLUG4X
Year when first certificate (CE) was issued	2019
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 60433 Frankfurt am Main Germany

1.2 Intended Use of the Device

Table 1.2 Intended Use

Intended Use	
Intended Purpose	The AZUR Vascular Plug is used to lower or stop blood flow into the blood vessels that do not include the brain, spine or the heart. (peripheral vasculature).
Intended User	This device should only be used by doctors who have been properly trained in the use of the AZUR system for the surgical procedures as prescribed by the Manufacturer.
Intended Patient Group(s)	The AZUR Vascular Plug is used in patients who require blood flow to be lowered or stopped from flowing into blood vessels that do not include the brain, spine or heart. (peripheral vasculature).
Contraindications and/or Limitations	Use of the AZUR Vascular Plug is not to be used in any of the following circumstances: • When patient has known allergy (hypersensitivity) to nickel-titanium. • When the end of the blood vessel goes directly to a nerve. • When blood vessels supplying a growth (lesion) are too small to accept the treatment (emboli). • When there is severe buildup of plaque in the blood vessel (atheromatous disease). • When the blood vessel walls contract and narrow reducing blood flow (vasospasm)

1.3 Device Description

Table 1.3 Device Description

Device Description	
Description of the Device	The AZUR Vascular Plug is a permanent implant that slows or blocks blood flow in a vessel and consists of a self-expanding wire frame surrounding a flexible covering (Figure 2.1). The AZUR Vascular Plug is placed in the blood vessel by a surgeon using a delivery device that pushes the implant through a small tube (microcatheter) and then separates from the implant at the desired location. **Figure 2.1** AZUR Vascular Plug Diagram

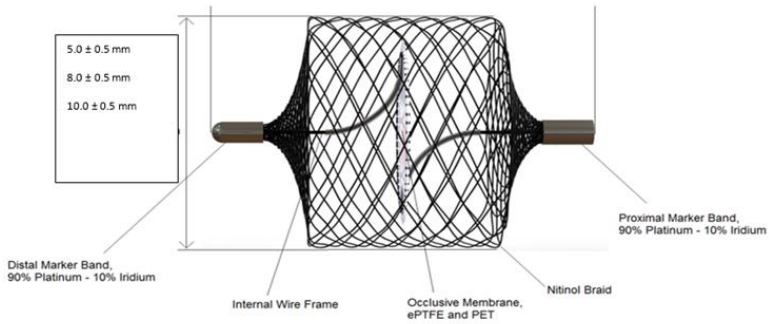
<table>
<tr><td></td><td> 
</td></tr>
<tr><td>Materials or substances in contact with the patient’s tissues</td><td>Implant materials are provided in Table 1.4. The AZUR Vascular Plug does not contain drugs, animal tissues, or blood products.

Table 1.4 Implant Materials
<table>
<tr><th>Component</th><th colspan="2">Material</th></tr>
<tr><td>Braid Wire</td><td colspan="2">Nitinol</td></tr>
<tr><td rowspan="3">Internal Member</td><td>Internal Wire Frame</td><td>Nitinol</td></tr>
<tr><td>Heat Shrink</td><td>PET</td></tr>
<tr><td>Membrane</td><td>ePTFE, PET</td></tr>
<tr><td>Proximal Marker Band</td><td colspan="2">90% Platinum/
10% Iridium</td></tr>
<tr><td>Distal Marker Band</td><td colspan="2">90% Platinum
10% Iridium</td></tr>
<tr><td>Adhesive</td><td colspan="2">Dymax 1128</td></tr>
<tr><td>Monofilament</td><td colspan="2">Engage 8540 Polyolefin</td></tr>
</table></td></tr>
<tr><td>Information about medicinal substances in the device</td><td>AZUR Vascular Plug does not include any drugs, animal tissues, or blood products.</td></tr>
<tr><td>Description of how device achieves its intended mode of action</td><td>AZUR Vascular Plug is placed through a small tube (microcatheter) by the delivery device to the target blood vessel by a surgeon. Once through the small tube, AZUR Vascular Plug expands to lower or block the blood flow. The surgeon can then disconnect AZUR Vascular Plug from the delivery device, and it becomes permanently implanted in the blood vessel.</td></tr>
<tr><td>Description of Accessories</td><td>None</td></tr>
<tr><td>Description of other Devices or Products intended to be used in combination</td><td>A small tube (microcatheter) is used to help deliver AZUR Vascular Plug implant to the target blood vessel. The AZUR Detachment Controller is used to separate the delivery device from the implant.
The small tube (microcatheter) and AZUR Detachment Controller are provided separately.</td></tr>
</table>

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
  Hazards associated with the use of AZUR Vascular Plug are lowered using control measures that reduce these risks. All known foreseeable risks have been evaluated and prevented.

- Remaining risks and undesirable effects
  - Vessel/tissue damage
  - Swelling
  - Bruising
  - Stroke
  - Implant movement to another vessel location
  - Blockage other than target vessel
  - Death
  - Allergic reaction
  - Toxic reaction
  - Blood clots

- Warnings and precautions
  - Refer to instructions supplied with all treatment devices to be used with AZUR Vascular Plug for their intended uses, when the device should not be used (contraindication), and potential complications.
    - This device is to be used only one time. Do not reuse, fix, or reclean. Reuse, fixing, or recleaning may 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 spreading harmful bacteria and/or cause patient infection or cross-infection. A device with harmful bacteria may lead to injury, illness, or death of the patient.
    - An X-ray used to check blood vessels (Angiography) is required before the surgical procedure, during the surgery, and after the surgery.
    - Do not push the delivery pusher with too much force. 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 too much resistance is noted. If too much resistance is noted with a second AZUR system, check the small tube (catheter) for damage or kinking.
    - The implant must be properly positioned within a maximum of 3 positioning attempts. If the implant cannot be properly positioned after 3 attempts, remove the device and the small tube (catheter) at the same time.
    - If repositioning is necessary, take special care to retract the implant using X-ray video (fluoroscopy) in a one-to-one motion with the delivery pusher. If the implant does not move in a one-to-one motion with the delivery pusher, or if repositioning is difficult, gently remove and dispose of the entire device.

- Curvy or complex blood vessels may affect accurate placement of the implant.
- The long-term effect of this product on tissues outside the blood vessels has not been established so care should be taken to retain this device in the blood vessels.
- Always ensure that at least two AZUR Detachment Controllers are available before starting an AZUR system procedure.
- The implant cannot be separated with any power source other than an AZUR Detachment Controller.
- Do NOT place the delivery pusher on a bare metallic surface.
- Always handle the delivery pusher with surgical gloves.
- Do NOT use with radio frequency (RF) devices.

- Summary of any field safety corrective action, (FSCA including FSN) if applicable

  None.

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

- Clinical background of the device
-

  The AZUR Vascular Plug has been available for use in patients since 2019 with a low overall complaint rate (0.8%) with no complaints resulting in patient injury or death.

- The clinical evidence for the CE-marking

  Clinical evidence for the safety and performance of AZUR Vascular Plug comes from the published scientific studies on the equivalent device, the AZUR Peripheral Embolization Coil System (AZUR PECS). The recent studies describe the successful use of AZUR PECS in 19 articles including 923 patients treated for a range of peripheral vascular diseases, irregularities, or injuries.

- Safety

  The manufacturer continuously collects information concerning the safety and performance of the device, and studies that information for any new risks or hazards. Steps are taken to remove any possible risks and to make sure the device still provides benefits to the patient. The manufacturer continuously studies data for the device and makes sure the benefits of the use of the device are better for the patient than any possible risk.

1.6 Possible Diagnostic or Therapeutic Alternatives

- General description of therapeutic alternatives

- Conservative management: Non-surgical management (e.g., compression garments, pain medication)
- Open or endoscopic surgery: Surgical approach from the exterior of the vessels, generally considered more invasive. (e.g., metal clips, tying vessels with sutures, or surgical removal of vessels)
- Endovascular treatments: Surgical approach from within the vessels, generally considered least invasive.
  - Embolic liquids/gels: Injection of liquid or gel that becomes solid to block blood flow within a vessel.
  - Particulates: Injection of small spheres designed to swell and block blood flow within a vessel.
  - Coils: Small metal coils can be placed in the blood vessel to block blood flow.

1.7 Suggested Training for Users

AZUR Vascular Plug is not intended to be used by patients. It should be used by trained surgeons only.