# Summary of Safety and Clinical Performance
# for
# AZUR™ Peripheral Coil System
# SSCP23-0001

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# DOCUMENT CHANGE HISTORY

| SSCP Revision | Change Description | NB approved/verified |
|---|---|---|
| A | Initial release | ☒Yes; Validation language: English<br>☐ No* |
| B | AZUR HydroPack 18 Coil System is added as a line extension to AZUR Peripheral Coil System. | ☐ Yes; Validation language:<br>☒ No* |
| C | External standard references were revised per section 1.8 | ☐ Yes; Validation language:<br>☒ No* |
| D | Annual update to the existing revision in new template with updates to the section 1.2, safety and performance data in section 1.5. Added edition information in section 1.8. Removed the ® symbol from the logo in first page and the headers. | ☐ Yes; Validation language:<br>☒ No* |
| E | External standard references were revised per section 1.8 and added validation language for Initial release version. | ☐ Yes; Validation language:<br>☒ No* |
| F | RA updated CF 184 Rev U to Rev V that directly impacts external standard references mentioned in this document | ☐ Yes; Validation language:<br>☒ No* |
| G | Updated Sections 1.4.1, 1.4.4, 1.5.1, 1.5.3, 1.5.4, 1.5.5, and 1.9.1–1.9.2 to align with CER22-0008E (2025), including revised clinical data, updated complication rates, PMCF conclusions, CAPA/FCA safety context, and literature summaries. | ☐ Yes; Validation language:<br>☒ No* |

*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

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 SSCP is not intended to replace the Instructions For Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

## 1.1 Device Identification and General Information

**Table 1.1 Device Identification and General Information**

| **Device Names** | |
|---|---|
| Device Trade Name | AZUR Peripheral Coil System |
| EMDN Code | C010402020301 |
| Medical Device Nomenclature (EMDN) | C010402020301 - EMBOLIZATION COILS<br>C010402020380 - EMBOLISATION DEVICES – ACCESSORIES |
| Device Class | IIb, Implantable |
| Basic UDI-DI | 08402732AZURCOILZN |
| Year when first certificate (CE) was issued for the device | 2008 |
| **Legal Manufacturer** | |
| Name & Address | MicroVention, Inc.<br>35 Enterprise<br>Aliso Viejo, CA, 92656 USA |
| Manufacturer SRN | US-MF-000016658 |
| **Authorized Representative** | |
| Name & Address | MicroVention Europe SARL<br>30 bis, rue du Vieil Abreuvoir<br>78100 Saint-Germain-en-Laye, France |
| Authorized Representative SRN | FR-AR-000004448 |
| **Notified Body** | |
| Name & Address | DQS Holding GmbH<br>60433 Frankfurt am Main,<br>Germany |
| Notified Body Identification Number | 0297 |

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## 1.2 Intended Purpose of the Device

**Table 1.2 Intended Use**

| **Intended Purpose** | |
|---|---|
| Intended Purpose | The devices are designed for use by physicians specially trained in endovascular techniques and are deployed through standard commercially available catheters and micro-catheters to the target site. The primary purpose of coil embolization with the AZUR system is to exclude the vascular lesion from the peripheral vascular circulation while preserving blood flow in the normal vasculature. Following placement, the embolization coils form a mechanical obstruction that affects total vascular occlusion. This keeps blood from flowing into the target lesion, thereby protecting the vascular lesions from rupture and hemorrhage. Embolic coils can also be placed within parent vessels to “shut down” the artery and block blood flow. |
| Indications for Use | The Indications for Use for the AZUR Peripheral Coil system are:<br>The AZUR Peripheral Coil 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. |
| Target Population | The AZUR Peripheral Coil System is primarily intended for placement of the AZUR implantable coil into a peripheral vascular structure in patients with a need to permanently occlude blood flow in a blood vessel, arteriovenous malformations or arteriovenous fistulae, an aneurysm, or other peripheral vascular lesions. |
| Contraindications and/or Limitations | The contraindications for the AZUR Peripheral Coil system are:<br>Use of the AZUR system is contraindicated in any of the following circumstances:<br>• When super selective coil placement is not possible.<br>• When end arteries lead directly to nerves.<br>• When the arteries supplying the lesion to be treated are not large enough to accept emboli.<br>• When the A-V shunt is larger than the coil.<br>• In the presence of severe atheromatous disease.<br>• In the presence of vasospasm (or likely onset of vasospasm). |

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## 1.3 Device Description

**Table 1.3 Device Description**

| **Device Description** | |
|---|---|
| Description of the Device | The AZUR Peripheral Coil System is divided into two categories based on the delivery method:<br>• Pushable Delivery System<br>• Controlled Detachable Delivery System<br><br>The AZUR Peripheral Coil System is available with a detachable delivery system and a pushable delivery system. The AZUR Peripheral Coil System with a detachable delivery system consists of an implantable coil that is attached to a delivery pusher using a polyolefin elastomer filament. The proximal end of the delivery pusher is inserted into a hand-held battery-powered AZUR Detachment Controller. When the Detachment Controller is activated, the flow of electrical current heats the polyolefin elastomer filament, resulting in detachment of the implant segment. The AZUR Detachment Controller is packaged and sold separately. The AZUR Peripheral Coils System, 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 coil is delivered to the treatment site through the delivery catheter using a standard guidewire. |
| Design Characteristics of the Device | The AZUR Peripheral Coil System, manufactured by MicroVention, that are CE-Mark approved and commercialized in the EU are:<br>• AZUR™ 18 Pushable - Helical Coil<br>• AZUR™ 35 Pushable - Helical Coil<br>• AZUR™ 18 Detachable - Helical HydroCoil<br>• AZUR™ 35 Detachable - Helical HydroCoil<br>• AZUR™ 18 Detachable - Framing Coil<br>• AZUR™ 35 Detachable - Framing Coil<br>• AZUR™ CX18 Detachable - CX Coil<br>• AZUR™ CX35 Detachable - CX Coil<br>• AZUR™ HydroPack 18 Detachable - Coil<br><br>**The AZUR Peripheral Coil System with a pushable coil delivery system**<br><br>This method consists of an implantable coil, an introducer sheath, and a stainless-steel stylet. The Pushable 18 and 35 main coils are made of platinum alloy and have an outer hydrophilic layer on the coil. The Pushable 18 family has a platinum alloy over coil, while the Pushable 35 family doesn’t have an over coil. A stainless-steel stylet is used to deploy (push) the coil from the introducer into the catheter. The coil is delivered to the treatment site via a microcatheter using a standard guidewire. Neither the microcatheter and guidewire is included in the system.<br><br>**The AZUR Peripheral Coil System with a controlled detachable delivery system**<br><br>This method consists of an implantable coil, a delivery pusher, and a Detachment Controller (sold separately). The implantable coils are made of platinum alloy with a hydrogel inner core. The coil is attached to the delivery pusher via a polyolefin elastomer |

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| Device Description | |
|---|---|
| | material. The coil implant is delivered to the target treatment site through a microcatheter with a compatible inner dimension. The proximal end of the delivery pusher is inserted into the hand-held battery-powered Detachment Controller. When the Detachment Controller is activated, the flow of electrical current heats the polyolefin elastomer filament, resulting in detachment of the implant segment.<br><br>The delivery pusher is comprised of a stainless steel/Pt mandrel with a tapered profile. Two gold electrical leads run along the outside of the mandrel from the proximal to the distal end. Platinum and stainless wires are wound around the distal end of the mandrel to form the electrical heater and provide kink-resistance. Outer layers of PET and polyimide insulation cover the entire assembly. A gold-plated stainless-steel connector at the proximal end of the delivery pusher is used to connect the pusher to the Detachment Controller. The proximal end of the pusher is inserted into the hand-held, battery-operated AZUR Detachment Controller. When the Detachment Controller is activated, the flow of electrical current melts the polyolefin elastomer filament, resulting in detachment of the implant segment.<br><br>The AZUR Detachment Controller is a self-contained, disposable, hand-held, battery-powered unit that provides the controlled electrical energy for the detachment of the coil from the Delivery Pusher. The detachment controller is packaged and sold separately as a sterile device for a single patient only. |
| Previous Generations or Variants, if applicable | The first generation of AZUR Peripheral Coil System (AZUR HydroCoil Detachable Embolization Coils 18 and AZUR HydroCoil Pushable Embolization Coils 18 and 35) was CE certified in the year 2008 and has been in the market for 16 years.<br><br>All generations of the AZUR Peripheral Coil System devices have the same Intended Purpose/Indications for Use and are Class IIb, implantable devices.<br><br>The AZUR Peripheral Coil System contains the following device configurations/variants that are CE-Marked:<br><br>AZUR Pushable Peripheral Coil System:<br>• AZUR 18 Pushable - Helical Coil<br>• AZUR 35 Pushable - Helical Coil<br><br>AZUR Detachable Peripheral Coil System:<br>• AZUR 18 Detachable - Helical HydroCoil<br>• AZUR 35 Detachable - Helical HydroCoil<br>• AZUR 18 Detachable - Framing Coil<br>• AZUR 35 Detachable - Framing Coil<br>• AZUR CX18 Detachable - CX Coil<br>• AZUR CX35 Detachable - CX Coil<br>• AZUR HydroPack 18 Detachable Coil |
| Single use – sterilization method | Single use. Sterilized using e-beam irradiation. |

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| **Device Description** | |
|---|---|
| Description of Accessories | During a clinical procedure, the coil implant component of the AZUR Peripheral Embolization Coil System is delivered to the target treatment site, and the proximal end of the delivery pusher is inserted into the hand-held battery-powered AZUR Detachment Controller. When the Detachment Controller is activated, the flow of electrical current heats the polyolefin elastomer filament, resulting in detachment of the implant segment.<br>The AZUR Detachment Controller is a self-contained, disposable, hand-held, battery-powered unit that provides the controlled electrical energy for the detachment of the coil from the Delivery Pusher. The detachment controller is packaged and sold separately as a sterile device for a single patient only |
| Description of other Devices or Products intended to be used in combination | None |

## 1.4 Risks and Warnings

### 1.4.1 Residual Risks and Undesirable Effects

Adverse events found in the subject device's scientific literature analysis in the Clinical Evaluation Report (CER) are included in the table below. Where the CER did not report a rate or follow-up duration for a specific harm, the value is indicated as “NR”. Post-Market Surveillance (PMS), vigilance, and MAUDE data, including deaths, were assessed in the CER and PSUR but are not included in this table.

Harms associated with the residual risks identified in the AZUR Peripheral Coil System IFU as Potential Complications were quantified in the table below. The analysis includes all the associated data reported in the scientific literature that are of sufficient scientific validity and relevance to the intended use to assess the safety and performance. All the harms are minimized through the use of risk mitigation/control measures and have been evaluated and mitigated.

The CER and systematic literature review report complication rates ranging from 0.0% to 5.1%, consistent with the state of the art for peripheral embolization procedures. Although the CER notes that some PMS-integrated assessments suggest minor complications may occur at rates up to approximately 5.5%, this higher estimate reflects incomplete denominator reporting in certain publications rather than an increased device risk. Importantly, no new risks were identified during the evaluation period, and all residual risks remain acceptable and adequately mitigated through design controls, verification/validation testing, and labeling. One death was reported in the literature, but was assessed as unrelated to the device. When combined with PMS and risk-management data, the evidence shows no indication of increased or unmitigated patient risk.

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* Coil migration: CER subject-device literature includes one case (1/1 = 100%).

### 1.4.2 Warnings and Precautions

The warnings/precautions for the AZUR Peripheral Coil system are:

**AZUR Pushable Coils:**

This device should only be used by physicians who have received appropriate training in peripheral vascular embolization procedures.

- The AZUR system is sterile and non-pyrogenic unless the unit package is opened or damaged.
- The AZUR system is intended for single use only. Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and/or lead to device failure, which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
- Angiography is required for pre-embolization evaluation, operative control, and post-embolization follow-up. Fluoroscopic road mapping is recommended to achieve optimal device placement.
- Always inspect the AZUR system prior to both preparation and insertion to ensure that the coil has not shifted within the introducer or migrated into the introducer caps. If the coil is not secure within the introducer prior to both the preparation and introduction processes, damage may result.
- Hydration of the AZUR system prior to use is mandatory. A 3-minute hydration period is required to soften the coil. Failure to hydrate may result in the coil not taking its secondary shape, which can result in deployment away from the intended location, migration, or protrusion outside the delivery location.
- The coil must be delivered through a compatibly sized catheter or microcatheter with a PTFE inner surface coating using a compatibly sized guidewire. Failure to correctly size

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the delivery system may result in damage to the device and necessitate removal of both the device and delivery catheter from the patient.

- Always select a wire-reinforced delivery catheter/microcatheter when delivering the coil through highly tortuous vasculature. Non-reinforced catheters may ovalize under such circumstances, potentially resulting in coil damage and necessitating removal of both the device and delivery catheter from the patient.
- Do not use a syringe to deliver the coil. The coil is intended to be delivered using a compatible guidewire only. Delivery via syringe injection may result in the coil not taking its secondary shape, which can result in deployment away from the intended location, migration, or protrusion outside the delivery location.
- Do not advance the coil with excessive force. If unusual resistance is noted during advancement, determine its cause before proceeding by verifying that the appropriate delivery catheter and guidewire are being used, and that both are free from damage and kinking. If necessary, replace the delivery catheter, coil, and/or guidewire before proceeding.
- The coil is not retractable or repositionable. If a coil must be retrieved from the vasculature after deployment, 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, microcatheter, and any retrieval device from the vasculature simultaneously.
- If the coil and/or pushing guidewire get stuck within the delivery catheter lumen, do not continue advancing. Remove the catheter, and replace the catheter, coil, and/or guidewire when necessary.
- Delivery of multiple coils is generally required to achieve the desired occlusion of some vessels, aneurysms, and vascular lesions. The desired procedural endpoint is angiographic occlusion. The filling properties of the coil facilitate angiographic occlusion and reduce the need to tightly pack. Multiple embolization procedures may be required to achieve the desired occlusion of some vessels/vascular lesions.
- Tortuosity or complex vessel anatomy may affect the accurate placement of the coil.
- The long-term effect of this product on extravascular tissues has not been established. Care should be taken to retain the device in the intravascular space.
- Always advance an appropriately sized 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.

**AZUR Detachable Coils (Helical, Framing & HydroPack):**

- This device should only be used by physicians who have received appropriate training in peripheral vascular embolization procedures.
- The AZUR System is supplied sterile and non-pyrogenic unless the package is opened or damaged.

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- This device is intended for single use only. Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
- Angiography is required for pre-embolization evaluation, operative control, and post-embolization follow-up
- Do not advance the delivery pusher with excessive force. Determine the cause of any unusual resistance, remove the AZUR System, and check for damage.
- Advance and retract the AZUR System slowly and smoothly. Remove the entire AZUR-System if excessive friction is noted. If excessive friction is noted with a second AZUR-System, check the microcatheter for damage or kinking.
- Due to the delicate nature of the coils, the tortuous vascular pathways that lead to certain lesions, and the varying morphologies of the vasculature, a coil may occasionally stretch while being maneuvered. Stretching is a precursor to potential coil breakage and migration.
- If repositioning is necessary, take special care to retract the coil under 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 repositioning is difficult, the coil may have become stretched and could possibly break. Gently remove and discard the entire device.
- If a coil must be retrieved from the vasculature after detachment, 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, microcatheter, and any retrieval device from the vasculature simultaneously.
- Delivery of multiple coils is usually required to achieve the desired occlusion of some vasculatures or lesions. The desired procedural endpoint is usually angiographic occlusion. The filling properties of the coils facilitate angiographic occlusion and reduce the need to tightly pack with numerous coils.
- Tortuosity or complex vessel anatomy may affect the accurate placement of the coil.
- The long-term effect of this product on extravascular tissues has not been established so care should be taken to retain this device in the intravascular space.
- Always ensure that at least two AZUR Detachment Controllers are available before starting an AZUR System procedure.
- The coil cannot be detached 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 in conjunction with radio frequency (RF) devices.

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**Only applicable to Helical & HydroPack Detachable Coils**

- The coil must be properly positioned in the vessel or aneurysm within three minutes from the time the device is first introduced into the microcatheter. If the coil cannot be positioned and detached within this time, simultaneously remove the device and the microcatheter. Positioning the device in a low-flow environment may increase the reposition time.

**Only applicable to Framing Detachable Coils**

Always advance an appropriately sized guidewire through the microcatheter after detaching the coil and removing the pusher to ensure that no part of the coil remains within the microcatheter.

### 1.4.3 Potential Complications / Adverse Effects

Potential complications include, but are not limited to:

- Hematoma at the site of entry
- Vessel/Aneurysm perforation
- Unintended parent artery occlusion
- Incomplete filling
- Vascular thrombosis
- Hemorrhage
- Ischemia
- Vasospasm
- Edema
- Coil migration or misplacement
- Premature or difficult coil detachment
- Clot formation
- Revascularization
- Post-embolization syndrome
- Neurological deficits, including Stroke
- Possibly Death.

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The physician should be aware of these complications and instruct patients when indicated. Appropriate patient management should be considered. No new/unmitigated riskswere identified during the current CER period.

### 1.4.4 Other Aspects of Safety

During the time period covered by the PSUR (01 October 2021 to 30 September 2025) there were nine (9) CAPAs opened or in process that pertained to the Azur Peripheral Coil System (Table 1.4). Six (6) of these CAPAs have been closed, and three (3) are in the Verification of Effectiveness phase.

**Table 1.4: CAPAs for Subject Device Azur Peripheral Coil System**

| Record # | Device | Description | Stage (Ex: Closed, Eff Check) | Date Initiated |
|---|---|---|---|---|
| Corrective QAR20-0024 | AZUR™ Pushable 18 and 35 System Hydrocoil | Complaint investigation concluded that on the returned Pushable Coil device, the coil loop diameter dimension indicated on the device packaging label was 10mmx20cm; however, the loop diameter marked on the device's introducer hub was 16mmx20cm. | Closed | 11/20/2021 |
| Corrective QAR22-0005 | AZUR™ and VTRAK pusher | During MVCR 2021, an internal audit was conducted at AZUR™ production line at ultrasonic cleaning process. Employees were not able to provide the maximum number of units to be washed and the documented evidence of the change of washing solutions (every two hours). | Closed | 5/22/2024 |
| Corrective CAPAC23-018 | AZUR™ Detachable 35 Part # MV-AZ50305HD | The Complaint Investigation for P23-6394 (AZUR™ Detachable 35) found a mandrel (tool used in manufacturing) within the implant. | Closed | 4/7/2025 |
| Corrective CAPAC24-009 | AZUR™ 35 Hydrocoil Part #45-450820 | Per Complaint, a reject label was detected on the pouch of a trunk-stock AZUR™ 35 Detachable Hydrocoil. | Implementation | 5/3/2024 |
| CAPAC24-019 | AZUR production line | AZUR production line | Effectiveness Check | 9/12/2024 |
| Corrective CAPAC24-020 | coils (AZUR™ - MCS-HYDRO) | During the revision of the last 3 months for the coils (AZUR™ -MCS-HYDRO) area, the manufacturing reject rate was above the threshold for the FY2024 | Closed | 1/16/2025 |

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| Record # | Device | Description | Stage (Ex: Closed, Eff Check) | Date Initiated |
|---|---|---|---|---|
| Corrective CAPAC24-032 | 0000455283 AZUR™ CX 18D | Per Complain, excess epoxy was detected on the proximal connector at the proximal tip in one unit of lot 0000455283 AZUR™ CX 18D – Longer | Effectivenes s Check | 10/7/2024 |

During the same time period covered by the PSUR (01 October 2021 to 30 September 2025) there was one (1) Field Action involving the Azur Peripheral Coil System.

| Record # | Device | Description | Stage (Ex: Closed, Eff Check) | Date Initiated |
|---|---|---|---|---|
| FCA2023-04<br>CAPAC23-018 | AZUR™ TM CX 35 Peripheral Coil System Detachable 13mm x 24 CM | **CAPAC23-018**- One complaint (P23-1981) related to an incomplete seal for one unit of AZUR CX 35 Peripheral Coil System Detachable 13mm x 24 CM (Part number 45-751324, batch number 0000190693) was received and confirmed. This issue was detected prior to use.<br>Examination of the returned packaging showed that the seal was not fully intact. A visible seal machine imprint was observed, which is consistent with the condition observed in the customer-provided images. When the reported package seal was visually compared to a normal package seal and to a previously opened package, it was confirmed that the returned packaging seal was not fully intact. | Open-Implementat ion Phase | 11/3/2023 |

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During the PSUR reporting period, several CAPAs and one Field Corrective Action (FCA) were initiated and managed; all were related to isolated manufacturing or packaging issues identified through routine quality system processes. These events were fully assessed in the Clinical Evaluation and were not associated with any patient injury. No newrisks were identified, and it did not alter the established safety or performance of the AZUR Peripheral Coil System. The completion status and effectiveness checks confirm that these actions are appropriately implemented and do not impact the overall benefit–risk profile.

## 1.5 Summary of the Clinical Evaluation and PMCF

Based on the most recent Clinical Evaluation (CER22-0008E, 2025 update), all available clinical data covering 01 January 2009 through 31 December 2025 were systematically collected and appraised. The totality of evidence from post-market clinical experience, PMS inputs, and the device Risk Management File, demonstrates that the AZUR Peripheral Coil System continues to meet its intended safety and performance in accordance with EU MDR 2017/745 requirements.

Reported complications remain low (approximately 5.5%) and are generally minor; one death was reported during the evaluation period, but was determined to be unrelated to the device. No new or unmitigated risks were identified. Despite incomplete reporting in some publications, the available data are sufficient to confirm that the device achieves the intended clinical benefit of effective embolization with an acceptable safety profile.

When compared with the current state of the art in peripheral embolization, the AZUR Peripheral Coil System demonstrates a favorable and clinically acceptable benefit–risk profile.

**Table 1.5: Summary of Subject Device Evaluation**

| Clinical Data Source(s) | Device Specific Clinical Literature |
|---|---|
| **Key Outcome measures used to assess Benefit/Risk** | **Performance:**<br>• Technical Success<br>• Complete Obliteration rate<br>**Safety:**<br>• Adverse Events |
| **Expected Clinical Benefit (When used according to instructions for use and recommended Technique)** | The AZUR Peripheral Coil System is placed in the peripheral vasculature to coil embolize arteriovenous malformations, arteriovenous fistulae, aneurysms, and other lesions, to exclude the vascular lesion from peripheral vascular circulation while preserving blood flow in the normal vasculature. AZUR system coils can also be placed within vessels to “shut down” the artery and block blood flow. Following the coil placement, the embolization coils form a mechanical obstruction that affects total vascular occlusion. This keeps blood from flowing into the target lesion, thereby protecting the vascular lesions from rupture and/or hemorrhage. AZUR coil embolization may thus improve the treated organ function. Furthermore, coil embolization, including using the AZUR system, may also reduce peri-procedural complications compared to surgical treatment. |
| **Clinical claims (beyond those identified in the intended use and expected clinical benefit).** | None |

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### 1.5.1 Equivalent Device Clinical Data

Not Applicable- Safety and Performance of all the AZUR family of devices is not based on equivalency. AZUR Peripheral Coil System has robust clinical data of its own to support the safety and performance.

### 1.5.2 Pre-CE-Mark Clinical Data

The AZUR Peripheral Coil System is a legacy device originally CE-marked in 2008 under the Medical Devices Directive (MDD). As such, no premarket clinical studies were required at the time of its initial approval. Under the EUMDR framework, the device continues to be supported by a substantial body of post-market clinical evidence, including published literature and

real-world clinical experience, which together provide sufficient data to demonstrate its safety and performance for the intended use.

### 1.5.3 Clinical Data

#### 1.5.3.1 Systematic Literature Review

**Table 1.6: Scientific Literature Review**

| **Overall Literature search** | 01 August 2024 to 31 December 2025 |
|---|---|
| **Total Included Publications supporting Safety and Performance Conformity** | 40 publications (337 patients). See section 1.9.2 for included literature details |
| **Overall follow-up time** | 1-2 years |
| **Patient Population Demographics** | All the patients included in the studies were adult patients, and the use of the AZUR device in the pediatric population was not reported. |
| **Key Performance Outcomes** | • **Performance:**<br>Technical Success: 76% - 100%<br>Complete Obliteration of Fistula: Up to 100%<br>• **Safety:**<br>Adverse Events Rate: 0.0% to 5.5%. |
| Serious Adverse Events | • 1 reported death unrelated to the device |
| **Activity Limitations** | Incomplete denominators in some studies; no impact on benefit–risk profile. |

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### 1.5.4 Clinical Performance and Safety

**Clinical Safety**

The clinical safety data presented in this document, collected from published literature, post-market clinical studies, and post-market surveillance, demonstrate the overall safety and effectiveness of the AZUR Peripheral Coil System. The literature review demonstrated acceptable clinical safety outcomes with no new  risks found. One death was noted in the literature, but confirmed to be unrelated to the device. The post-market surveillance data demonstrate low rates of reportable complaints, showing the safety of the device. The data collected is considered sufficient to determine that the AZUR Peripheral Coil Systems do not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons.

**Clinical Performance**

The clinical performance data presented in this document, collected from published literature, post-market clinical studies, and post-market surveillance, demonstrate the overall performance of the AZUR Peripheral Coil System. The literature review demonstrated acceptable clinical performance outcomes, shown in high technical success rates and lower recurrence/recanalization rates associated with the use of the subject device. The post-market surveillance data demonstrate

acceptable overall clinical performance through the high AZUR Peripheral Coil System device technical success and coil embolization durability in the vast majority of the patients receiving the AZUR coil devices, as evidenced by the extremely low rates of vigilance reportable complaints and adverse events that are attributable to the subject devices. The data collected is considered sufficient to determine that the AZUR Coil System devices achieve the performance intended and are suitable for the intended purpose.

### 1.5.5 Post-Market Clinical Follow-up

No active or prospective PMCF studies are planned. Based on established clinical use, sufficient literature evidence, and PMS inputs, passive PMCF is considered adequate. Ongoing PMCF includes systematic literature surveillance, continuous monitoring of complaints and adverse events, vigilance trend analysis, and review of emerging clinical information. This approach is sufficient to maintain verification of the device's benefit–risk profile.

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## 1.6 Possible Diagnostic or Therapeutic Alternatives

### 1.6.1 Treatment Options and Interventions

**Table 1.7: Treatment options**

| Treatment Option | Pro/Benefit | Con/Risks | Notes |
|---|---|---|---|
| **Surgical Treatment** | | | |
| Supra Orbital Keyhole (SOK) surgery (Abdulateef et al., 2023) | SOK was introduced as an alternative approach for clipping Internal Carotid Artery (ICA) aneurysms. SOK surgery provides adequate aneurysmal access while minimizing trauma to the surrounding structures, including the skin, bone, dura, and, most importantly, the brain. | The residual neck is the most documented complication of SOK, due to a lack of visualization of the clip condition and it usually occurs in posterity-located or directed aneurysms so it will require more careful checking for aneurysmal dome direction and origin before selection of the approach, high rates of visual impairment generally after aneurysm clipping had been reported, as found that 39% experienced postoperative visual complications. | None Available |
| **Type of Endovascular Repair (EVSR)** | | | |
| Flow-Diverter stents (FDs) | FD is designed to provide sufficient metal coverage across the neck of the aneurysm to physiologically exclude the lesion from the circulation. More importantly, flow diverters induce thrombosis into the aneurysmal sac while preserving physiological flow in the parent vessel and adjacent branches. This excellent function is based on the special structure of a braided mesh cylinder composed of individual platinum and cobalt chromium microfilaments (Wang et al., 2021) | A major limitation of flow diversion is ischemic stroke associated with stent thrombogenicity, necessitating dual-antiplatelet therapy and its associated risk (Li et al., 2021) | Endovascular repair has become an established treatment for aneurysms, with a demonstrated perioperative and early survival advantage over open surgical repair.<br><br>Recent randomized clinical trials reporting long-term outcome data have shown that EVAR carries an increased risk of secondary intervention, aneurysm-related mortality, and aneurysm rupture compared with open surgery. Patients receiving EVAR require lifelong imaging surveillance, which aims to predict, detect, and rectify aneurysm-related complications (Antoniou, 2020) |
| Stent-assisted coiling (Heo and Ko et al., 2024) | Stent-assisted coiling is a widely accepted method for treating intracranial wide-necked aneurysms, especially in unruptured cases. Its use is becoming increasingly common, particularly in | Application of stent assisted coiling in ruptured cases remains a topic of debate due to potential complications such as thromboembolic events (Abdulateef et al., 2023) and | |

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| Treatment Option | Pro/Benefit | Con/Risks | Notes |
|---|---|---|---|
| | cases where coils alone are not suitable or present challenges. | hemorrhagic complications related to antiplatelet therapy. | |
| Balloon Assisted Coiling (BAC) (Lee et al., 2022) | Balloon remodeling during endovascular coiling involves the temporary inflation of a balloon catheter across the aneurysm neck during the placement of coils. | BAC is associated with an increased risk of long-term coil compaction and recanalization due to limited filling of the volume. | Several special types of balloons, such as hypercompliant, round-shaped, and double-lumen balloons are used depending on the situation |

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### 1.6.2 Available Technologies

Devices similar to the AZUR Peripheral Coil System are listed in Table 1.8.

**Table 1.8: Similar Devices**

| Device | Manufacturer | Intended Purpose |
|---|---|---|
| Interlock Detachable Embolization Coil | Boston Scientific | The Interlock IDC Occlusion System is a modified interlocking detachable coil. The Interlock IDC Occlusion Systems are indicated for obstructing or reducing blood flow in the peripheral vasculature during embolization procedures. These devices are not intended for neurovascular use. |
| Nester Pushable Embolization Coil | Cook Medical | Nester Embolization Coils are intended for arterial and venous embolization in the peripheral vasculature. |

## 1.7 Suggested Profile and Training for Users

These devices are not to be used by unqualified personnel. This device should only be used by physicians who have received appropriate training in peripheral vascular embolization procedures.

## 1.8 Reference to any Harmonized Standards and CS

AZUR Peripheral Coil System:

| Standard Number | Edition | Standard Title (equivalent edition) |
|---|---|---|
| EN ISO 13485 | 2016/A11:2021 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) |
| EN ISO 14971 | 2019/A11:2021 | Medical devices - Application of risk management to medical devices (ISO 14971:2019) |
| EN IEC 60812 | 2018 | Failure modes and effects analysis (FMEA and FMECA) (IEC 60812:2018) |
| EN 62366-1 | 2015/A1:2020 | Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020) |
| EN ISO 14155 | 2020 | Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020) |
| ISO/TR 20416 | 2020 | Medical devices - Post-market surveillance for manufacturers |
| EN ISO 15223-1 | 2021 | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) |
| EN ISO 20417 | 2021 | Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12) |

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|---|---|---|
| EN ISO 11607-1 | 2020/A1:2023 | Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019/Amd 1:2023) |
| EN ISO 11607-2 | 2020/A1:2023 | Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019/Amd 1:2023) |
| ISTA 3A | 2018 | Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lbs) or Less |
| ASTM F88 | 2023 | Standard Test Method for Seal Strength of Flexible Barrier Materials |
| ASTM F1886 | 2016 | Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection |
| ASTM F1929 | 2023 | Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration |
| ASTM F2096 | 2011R2019 | Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) |
| ASTM F1980 | 2016 | Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices |
| EN ISO 10993-1 | 2020 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10) |
| EN ISO 10993-3 | 2014 | Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014) |
| EN ISO 10993-4 | 2017 | Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017) |
| EN ISO 10993-5 | 2009 | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009) |
| EN ISO 10993-6 | 2016 | Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016) |
| EN ISO 10993-10 | 2023 | Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021) |
| EN ISO 10993-11 | 2018 | Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017) |

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|---|---|---|
| EN ISO 10993-12 | 2021 | Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021) |
| EN ISO 10993-23 | 2021 | Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021) |
| EN ISO 14644-1 | 2015 | Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015) |
| EN ISO 14644-2 | 2015 | Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015) |
| ANSI/AAMI ST72 | 2019 | Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing |
| EN 556-1 | 2001/AC:2006 | Sterilization of medical devices – Requirements for medical devices to be designated ‘STERILE’ – Part 1: Requirements for terminally sterilized medical devices |
| EN ISO 11737-1 | 2018/A1:2021 | Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018/Amd 1:2021) |
| EN ISO 11737-2 | 2020 | Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019) |
| ISO 11737-3 | 2023 | Sterilization of health care products - Microbiological methods - Part 3: Bacterial Endotoxin testing |
| EN ISO 11137-1 | 2015/A2:2019 | Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006/Amd 2:2018) |
| EN ISO 11137-2 | 2015/A1:2023 | Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013/Amd 1:2022) |
| EN ISO 14630 | 2012 | Non-active surgical implants - General requirements (ISO 14630:2012) |
| ASTM F2052 | 2021 | Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment |
| ASTM F2119 | 2024 | Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants |

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|---|---|---|
| ASTM F2182 | 2019e2 | Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging |
| ASTM F2213 | 2017 | Standard test method for measurement of magnetically induced torque on passive implants in the magnetic resonance |
| ASTM F2503 | 2023e1 | Standard practice for marketing medical devices and other items for safety in the magnetic resonance environment |
| ANSI T564 | 2021 | Transparent Chart for the Estimation of Defect Size |

Detachment Controller:

| Standard Number | Edition | Standard Title (equivalent edition) |
|---|---|---|
| EN ISO 13485 | 2016/A11:2021 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) |
| EN ISO 14971 | 2019/A11:2021 | Medical devices - Application of risk management to medical devices (ISO 14971:2019) |
| EN IEC 60812 | 2018 | Failure modes and effects analysis (FMEA and FMECA) (IEC 60812:2018) |
| EN 62366-1 | 2015/A1:2020 | Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020) |
| EN ISO 14155 | 2020 | Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020) |
| ISO/TR 20416 | 2020 | Medical devices - Post-market surveillance for manufacturers |
| EN ISO 15223-1 | 2021 | Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021) |
| EN ISO 20417 | 2021 | Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12) |
| EN ISO 11607-1 | 2020/A1:2023 | Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019/Amd 1:2023) |
| EN ISO 11607-2 | 2020/A1:2023 | Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019/Amd 1:2023) |

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| ISTA 3A | 2018 | Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lbs) or Less |
|---|---|---|
| ASTM D4169 | 2023e1 | Standard Practice for Performance Testing of Shipping Containers and Systems |
| ASTM F88 | 2023 | Standard Test Method for Seal Strength of Flexible Barrier Materials |
| ASTM F1886 | 2016 | Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection |
| ASTM F1929 | 2023 | Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration |
| ASTM F2096 | 2011R2019 | Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) |
| ASTM F1980 | 2016 | Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices |
| EN ISO 10993-1 | 2020 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10) |
| EN ISO 14644-1 | 2015 | Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015) |
| EN ISO 14644-2 | 2015 | Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015) |
| ANSI/AAMI ST72 | 2019 | Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing |
| EN 556-1 | 2001/AC:2006 | Sterilization of medical devices – Requirements for medical devices to be designated 'STERILE' – Part 1: Requirements for terminally sterilized medical devices |
| EN ISO 11737-1 | 2018/A1:2021 | Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018/Amd 1:2021) |
| EN ISO 11737-2 | 2020 | Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, |

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| | | |
|---|---|---|
| | | validation and maintenance of a sterilization process (ISO 11737-2:2019) |
| ISO 11737-3 | 2023 | Sterilization of health care products - Microbiological methods - Part 3: Bacterial Endotoxin testing |
| EN ISO 11138-1 | 2017 | Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017) |
| EN ISO 11135 | 2014/A1:2019 | Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014/Amd 1:2018) |
| EN ISO 10993-7 | 2008/A1:2022 | Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008/Amd 1:2019) |
| EN 62304 | 2006/A1:2015 | Medical device software — Software life-cycle processes (IEC 62304:2006/A1:2015) |
| EN 60601-1 | 2006/A2:2021 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A2:2020) |
| EN 60601-1-2 | 2015/A1:2021 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014/A1:2020) |
| ANSI T564 | 2021 | Transparent Chart for the Estimation of Defect Size |

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