Summary of Safety and Clinical Performance

for

AZUR™ Peripheral Coil System

SSCP23-0001

MicroVention, Inc.
35 Enterprise
Aliso Viejo, California 92656, USA

DOCUMENT CHANGE HISTORY

SSCP Revision	Change Description	NB approved/verified
A	Initial release	☒Yes; Validation language: English ☐ No*
B	AZUR HydroPack 18 Coil System is added as a line extension to AZUR Peripheral Coil System.	☐ Yes; Validation language: ☒ No*
C	External standard references were revised per section 1.8	☐ Yes; Validation language: ☒ 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: ☒ No*
E	External standard references were revised per section 1.8 and added validation language for Initial release version.	☐ Yes; Validation language: ☒ 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)	EMBOLIZATION COILS
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. 35 Enterprise Aliso Viejo, California, 92656 USA
Manufacturer SRN	US-MF-000016658
Authorized Representative	
Name & Address	MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye, France
Authorized Representative SRN	FR-AR-000004448
Notified Body	
Name & Address	DQS Holding GmbH 60433 Frankfurt am Main, Germany
Notified Body Identification Number	0297

1.2 Intended Purpose of the Device

Table 1.2 Intended Use

Intended Purpose	
Intended Purpose	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.
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.
Target Population	The AZUR Peripheral Coil System is primarily intended for placement of 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: Use of the AZUR system is contraindicated in any of the following circumstances: • 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 vasospasm (or likely onset of vasospasm).

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: • Pushable Delivery System • Controlled Detachable Delivery System 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 which 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	There are eight (8) types, or families, of the AZUR Peripheral Coil System manufactured by MicroVention that are CE-Mark approved and commercialized in the EU: AZUR Peripheral Coil System: • AZUR™ 18 Pushable - Helical Coil • AZUR™ 35 Pushable - Helical Coil • AZUR™ 18 Detachable - Helical HydroCoil • AZUR™ 35 Detachable - Helical HydroCoil • AZUR™ 18 Detachable - Framing Coil • AZUR™ 35 Detachable - Framing Coil • AZUR™ CX18 Detachable - CX Coil • AZUR™ CX35 Detachable - CX Coil • AZUR™ HydroPack 18 Detachable - Coil **The AZUR Peripheral Coil System with a pushable coil delivery system** 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. Both the microcatheter and guidewire are not included in the system.

Device Description	
	The AZUR Peripheral Coil System with a controlled detachable delivery system 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 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. 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. The AZUR Detachment Controller is self-contained, disposable, hand-held, battery-powered unit which 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 single patient only.
Previous Generations or Variants, if applicable	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. All generations of the AZUR Peripheral Coil System devices have the same Intended Purpose/Indications for Use and are Class IIb, implantable devices. The AZUR Peripheral Coil System contains the following device configurations/variants that are CE-Marked: AZUR Pushable Peripheral Coil System: • AZUR 18 Pushable - Helical Coil • AZUR 35 Pushable - Helical Coil AZUR Detachable Peripheral Coil System: • AZUR 18 Detachable - Helical HydroCoil • AZUR 35 Detachable - Helical HydroCoil • AZUR 18 Detachable - Framing Coil • AZUR 35 Detachable - Framing Coil

Device Description	
	• AZUR CX18 Detachable - CX Coil • AZUR CX35 Detachable - CX Coil • AZUR HydroPack 18 Detachable Coil
Single use – sterilization method	Single use. Sterilized using e-beam irradiation.
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. The AZUR Detachment Controller is self-contained, disposable, hand-held, battery-powered unit which 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 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

Hazards 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 suitable access the safety and performance. All the harms are minimized through the use of risk mitigation/control measures and. have been evaluated and mitigated.

Risks associated with the subject device:

IFU Residual Risk/Harm Category	Scientific Literature	
	Rate (%)	Follow-up (Days)
Vessel/Aneurysm Perforation	0.0%	1-12 Months
Hematoma at the site of entry	NR	NR
Unintended parent artery occlusion	NR	NR
Incomplete filling	NR	NR
Vascular thrombosis	NR	NR
Hemorrhage	NR	NR
Ischemia	NR	NR
Vasospasm	NR	NR
Edema	NR	NR
Coil migration or misplacement,	NR	NR

IFU Residual Risk/Harm Category	Scientific Literature	
	Rate (%)	Follow-up (Days)
Premature or difficult coil detachment	NR	NR
Clot formation	NR	NR
Revascularization	NR	NR
Post-embolization syndrome	NR	NR
Neurological deficits such as stroke	NR	NR
Death	100%*	8 days

* 1 patient (His hospital course was complicated by hypoxemic respiratory failure, acute respiratory distress syndrome, atrial fibrillation with rapid ventricular response, as well as a right parietal ischemic stroke. The patient died 8 days after the embolization procedure from cardiac arrest)

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 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 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 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 package is opened or damaged.
- 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 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.

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.

The physician should be aware of these complications and instruct patients when indicated. Appropriate patient management should be considered.

1.4.4 Other Aspects of Safety

During the time period (01 October 2019 to 30 September 2023) covered by the PSUR there were two (2) Field Action involving AZUR Peripheral Coil System. (Table 1.4).

A brief summary of each Field Action is provided below. For further details pertaining to each Field Action, refer to the applicable Field Action file.

Table 1.4: Azur Field Actions

Record #	Device	Description	Stage (Ex: Closed, Eff Check)	Date Initiated
FCA2019-03	AZUR CX Detachable 35 coils and AZUR Detachable 18	As of November 18, 2019, a total of 15 complaints were received for embolization coil devices where the coil was missing. Of these 15 complaints, 6 were from the United States, 4 were from Japan, 3 were from Spain and 2 were from Belgium. There were no reported injuries with any of these complaints.	Closed	11/26/2019
FCA2023-04	AZUR CX 35 Peripheral Coil System Detachable 13mm x 24 CM	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	8/18/2023

1.5 Summary of the Clinical Evaluation and PMCF

The clinical data used to access safety and performance of the AZUR Peripheral Coil System is summarized below. The data presented include information on the key device related clinical outcome parameters (i.e., the parameters deemed most relevant to establishing the performance and safety of the device). These were selected based on the State of The Art (SOTA) review and input by internal clinicians and other clinical stakeholders. While other outcomes are reported in the clinical data sources, including the known potential device or procedural residual risks and undesirable effects identified in the IFU, they may not have been selected as key outcomes based upon the device-relatedness, prevalence, patient impact, required medical intervention, or frequency of reporting in clinical data source. These data were used to assess the expected clinical benefits of the device.

Table 1.5: Summery of Subject Device Evaluation

Clinical Data Source(s)	Device Specific Clinical Literature
Key Outcome measures used to assess Benefit/Risk	**Performance:** • Technical Success • Complete Obliteration rate **Safety:** • 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

Clinical Data Source(s)	Device Specific Clinical Literature
	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

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 family has robust clinical data of its own to support the safety and performance.

1.5.2 Pre-CE-Mark Clinical Data

There is no Clinical Development Plan for the AZUR coils because they were approved for CE Mark under the MDD, and no premarket clinical studies were required for market approval. Under EUMDR , there is sufficient clinical data on the Azur Coils to support safety and performance for its intended use.

1.5.3 Summary of Clinical Data

1.5.3.1 Systematic Literature Review

Table 1.6: Sceintific Literature Review

Overall Literature search	01 September 2008 to 31 July 2024
Total Included Publications supporting Safety and Performance Conformity	19 publications (135 patients)
Overall follow-up time	1-2 years
Patient Population Demographics	All the patients included in the studies were adult patients and the use of AZUR device in pediatric population was not reported.
Key Performace Outcomes	• **Performance:** Technical Success: 94.7% - 100% Complete Obliteration of Fistula: 100% • **Safety:** Adverse Events Rate: 0.0% to 5.1%.

Activity Limitations	None

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, demonstrates the overall safety and effectiveness of the AZUR Peripheral Coil System. The literature review demonstrated acceptable clinical safety outcomes with no new hazards found. The post-market surveillance data demonstrates 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, demonstrates 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 demonstrates 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

There are no planned/ongoing studies for AZUR Peripheral Coil System.

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
Surgical Clipping (Shao et al., 2019)	Surgical clipping is widely applied treatment method for patients with IA. Angiographic occlusion rate is higher for surgical clipping and is associated with lower mortality. surgical clipping might exert a beneficial effect on rebleeding in patients with specific characteristics.	Studies found that unruptured IA that received surgical clipping was associated with a high incidence of cognitive impairment, neurologic morbidity, and mortality. In this condition, an additional effective strategy should be used to avoid potential adverse events.	The decreased rate of retreatment provided by open clipping is still a determinant factor in selecting microsurgical treatment as the best therapeutic option for many aneurysms, especially in young patients with relatively easily accessed aneurysms such as in the middle cerebral artery distribution (Martinez-Perez et al., 2021)
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	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 of aneurysm, with a demonstrated perioperative and early survival advantage over open surgical repair.

Treatment Option	Pro/Benefit	Con/Risks	Notes
	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)		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 (SAC)	SAC is a well-established technique for endovascular treatment of intracranial aneurysms, in particular for wide-necked aneurysms that are otherwise difficult to treat by non-assisted coiling alone (Goertz et al., 2019).	The principal limitation SAC is the high IA recurrence rate.	
Balloon Assisted Coiling (BAC) (Lee et al., 2022b)	Balloon remodeling during endovascular coiling involves the temporary inflation of a balloon catheter across the aneurysm neck during the placement of coils. Balloon-assisted coiling (BAC) or balloon remodeling is a method originally described in the cardiac literature and subsequently adapted for use in the cerebrovascular field for the treatment of IAs with a wide neck	BAC is associated with an increased risk of long-term coil compaction and recanalization due to limited filling of the IA volume.	During placement of the coil, a compliant balloon is inflated in the parent vessel lumen to create a temporary IA neck allowing the coil to frame inside the IA and preventing it from herniating out into the parent vessel. This technique is particularly useful when treating ruptured IAs with unfavorable anatomy for standalone coiling. Several special types of balloons such as hypercompliant, round-shaped, and double lumen balloons are used depending on the situation
Simple Coiling (Lee et al., 2022b)	In 1990, a detachable bare platinum coil device (Guglielmi) was introduced into clinical practice. Since then, endovascular treatment with coils has gained worldwide acceptance as an effective treatment for IAs. The goal in coiling is to achieve dense packing through the delivery of detachable platinum wires, resulting in an unorganized thrombus and granulation	Coiling is increasingly popular but does come with several shortcomings. Not all IAs are completely cured at first treatment necessitating post-treatment surveillance imaging and, in a minority, may require retreatment. Another drawback of coiling is the need for retreatment due to coil	There are several major complications associated with coil embolization: thromboembolism, perforation of the IA, early rebleeding, parent artery obstruction, collapsed coils, coil malposition, even coil migration

Treatment Option	Pro/Benefit	Con/Risks	Notes
	tissue formation, to limit blood circulation to the IA lumen.	compaction or IA recurrence, hence also further necessitating follow-up.	
Intrasaccular flow disruptor (Lee et al., 2022a)	80% occlusion rates • 10% recurrence rate • 10% retreatment rate There is little risk posed to surrounding perforators, and antiplatelet medication is not required after the procedure	Unfavorable factors include Aneurysm-specific factors: • Tortuous anatomy, e.g., ACommA aneurysms, as difficult to navigate with the large microcatheters	Aneurysm-specific factors: • Not amenable to simple coiling or BAC/SAC • Primarily for wide-necked IAs, bifurcation IAs, and sidewall IAs

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. It is essential that the surgeon and operating room staff are fully conversant with the appropriate surgical technique and associated accessories.

1.8 Reference to any Harmonized Standards and CS

AZUR Peripheral Coil System:

Category	Standard Number	Edition	Standard Title (equivalent edition)
Quality System	EN ISO 13485	2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
Risk Management	EN ISO 14971	2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
Risk Management	EN IEC 60812	2018	Failure modes and effects analysis (FMEA and FMECA) (IEC 60812:2018)
Usability	EN ISO 62366-1	2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020)

Clinical	EN ISO 14155	2020	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)
Post Market Surveillance	ISO/TR 20416	2020	Medical devices - Post-market surveillance for manufacturers
Labeling	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)
Labeling	EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
Packaging	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)
Packaging	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)
Packaging	ISTA 3A	2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lbs) or Less
Packaging	ASTM F88	2023	Standard Test Method for Seal Strength of Flexible Barrier Materials
Packaging	ASTM F1886	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Packaging	ASTM F1929	2023	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
Packaging	ASTM F2096	2011R2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
Shelf Life & Stability	ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
Biocompatibility	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)
Biocompatibility	EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
Biocompatibility	EN ISO 10993-4	2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
Biocompatibility	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
Biocompatibility	EN ISO 10993-6	2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016)
Biocompatibility	EN ISO 10993-10	2023	Biological evaluation of medical devices - Part 10:

			Tests for skin sensitization (ISO 10993-10:2021)
Biocompatibility	EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
Biocompatibility	EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
Biocompatibility	EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
Manufacturing (Environmental Controls)	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
Manufacturing (Environmental Controls)	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)
Manufacturing (Environmental Controls)	ANSI/AAMI ST72	2019	Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
Sterilization	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

Sterilization	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)
Sterilization	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)
Sterilization (Bacterial Endotoxin Testing)	ISO 11737-3	2023	Sterilization of health care products - Microbiological methods - Part 3: Bacterial Endotoxin testing
Sterilization (Gamma or E-Beam Radiation)	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)
Sterilization (Gamma or E-Beam Radiation)	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)
Device Specific (Implants)	EN ISO 14630	2012	Non-active surgical implants - General requirements (ISO 14630:2012)
Device Specific (MRI)	ASTM F2052	2021	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

Device Specific (MRI)	ASTM F2119	2007R2013	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
Device Specific (MRI)	ASTM F2182	2019e2	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging
Device Specific (MRI)	ASTM F2213	2017	Standard test method for measurement of magnetically induced torque on passive implants in the magnetic resonance
Device Specific (MRI)	ASTM F2503	2023e1	Standard practice for marketing medical devices and other items for safety in the magnetic resonance environment
Device Specific (Medical Electrical Equipment)	EN 60601-1	2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A2:2020)

Detachment Controller:

Category	**Standard Number**	**Edition**	**Standard Title (equivalent edition)**
Quality System	EN ISO 13485	2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
Risk Management	EN ISO 14971	2019/A11:2021	Medical devices - Application of risk management to medical devices (ISO 14971:2019)
Risk Management	EN IEC 60812	2018	Failure modes and effects analysis (FMEA and FMECA) (IEC 60812:2018)

Usability	EN ISO 62366-1	2015/A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015/A1:2020)
Post Market Surveillance	ISO/TR 20416	2020	Medical devices - Post-market surveillance for manufacturers
Labeling	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)
Labeling	EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
Packaging	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)
Packaging	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)
Packaging	ISTA 3A	2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lbs) or Less
Packaging	ASTM D4169	2023e1	Standard Practice for Performance Testing of Shipping Containers and Systems
Packaging	ASTM F88	2023	Standard Test Method for Seal Strength of Flexible Barrier Materials

Packaging	ASTM F1886	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
Packaging	ASTM F1929	2023	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
Packaging	ASTM F2096	2011R2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
Shelf Life & Stability	ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
Biocompatibility	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)
Biocompatibility	EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
Biocompatibility	EN ISO 10993-4	2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)
Biocompatibility	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
Biocompatibility	EN ISO 10993-10	2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)

Biocompatibility	EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
Biocompatibility	EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
Biocompatibility	EN ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
Manufacturing (Environmental Controls)	EN ISO 14644-1	2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)
Manufacturing (Environmental Controls)	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)
Manufacturing (Environmental Controls)	ANSI/AAMI ST72	2019	Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing
Sterilization	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
Sterilization	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)

Sterilization	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)
Sterilization (Bacterial Endotoxin Testing)	ISO 11737-3	2023	Sterilization of health care products - Microbiological methods - Part 3: Bacterial Endotoxin testing
Sterilization (Biological Indicators)	EN ISO 11138-1	2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
Sterilization (Ethylene Oxide)	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)
Sterilization (Ethylene Oxide)	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)
Device Specific (Software)	EN 62304	2006/A1:2015	Medical device software — Software life-cycle processes (IEC 62304:2006/A1:2015)
Device Specific (Medical Electrical Equipment)	EN 60601-1	2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A2:2020)

Device Specific (Medical Electrical Equipment)	EN 60601-1-2	2020	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)

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