Summary of Safety and Clinical Performance

for

Chaperon™ Guiding Catheter System

SSCP1100127

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DOCUMENT CHANGE HISTORY

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

*Annual entries must be included. If a revision is not required, an entry stating such must be added.

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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. Following this information there is a summary intended for patients.

1.1 Device Identification and General Information

Table 1: Device Identification and General Information

Device Names	
Device Trade Name	Chaperon Guiding Catheter System
EMDN Code	C0104020204 – Peripheral Angiography Guide Catheters
Medical Device Nomenclature (EMDN or GMDN Description)	Vascular Guide Catheter, single use
Device Class	Class III
Basic UDI-DI	08402732CHAPERONJ3
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-MF-000004448
Notified Body	
Name & Address	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany
Notified Body Identification Number	0297

1.2 Intended Purpose of the Device

Table 2: Intended Use

Intended Purpose	
Intended Purpose / Indications for Use	The Chaperon Guiding Catheter System and Chaperon Guiding Catheter are intended for general intravascular use, including the neuro and peripheral vasculature. The Chaperon Guiding Catheter System and Chaperon Guiding Catheter can be used to facilitate introduction of diagnostic or therapeutic devices. The Chaperon Guiding Catheter System and Chaperon Guiding Catheter are not intended for use in coronary arteries.
Target Population	Patients requiring guiding catheter to facilitate placement of diagnostic or interventional devices in neuro or peripheral vasculature during endovascular procedures.
Contraindications and/or Limitations	There are no known contraindications for the Chaperon Guiding Catheter System. It should be noted that the Indications for Use do state that the "Chaperon Guiding Catheter System and Chaperon Guiding Catheter are not intended for use in coronary arteries."

1.3 Device Description

Table 3: Device Description

Device Description	
Description of the Device	The Chaperon Guiding Catheter System consists of a Guiding Catheter and Inner Catheter. The Guiding Catheter, also available individually, can be used with a guidewire or combined with the Inner Catheter to access the neuro and peripheral vasculature. The Guiding Catheter is designed to facilitate passage of intravascular devices through the vasculature. The Guiding Catheter is a non-tapered, braid-reinforced, variable stiffness catheter with a pre-shaped distal segment and incorporates a radiopaque marker located approximately 2 mm proximal to the distal tip. The Inner Catheter, if supplied, is designed to facilitate advancement of the Guiding Catheter through the vasculature. The Inner Catheter is a braid-reinforced, variable stiffness catheter with a pre-shaped distal segment. The distal end of the catheter is coated with a hydrophilic polymer and the proximal end contains a Luer lock adapter for connection to the Guiding Catheter hub. Both Guiding Catheter and Inner Catheter are fabricated with various pre-shaped tips. An example is illustrated below.
Design Characteristics of the Device	Guiding Catheter - The guiding catheter is a single lumen catheter that is reinforced by a stainless-steel braiding coated with a polytetrafluoroethylene (PTFE) and is constructed with a strain relief and a catheter hub. The guiding catheter is fabricated with a pre-shaped distal segment to facilitate catheter advancement. The catheter incorporates a radiopaque marker located approximately 5 mm proximal to the distal tip. Inner Catheter - The inner catheter is also a single lumen catheter designed to advance interventional and diagnostic devices through human vasculature. The Inner Catheter is reinforced by a stainless-steel braiding that is coated with hydrophilic polymer at the 15 cm distal. The catheter is fabricated with a lock adapter at the proximal end. The catheter is constructed with a radiopaque marker at the distal segment.

Device Description	
	Both the guiding and inner catheters are fabricated with a pre-shape distal segment designed to advance interventional and diagnostic devices through human vasculature and are available in varying tip-shapes specific to patient anatomy and physician preference. The guiding catheter is available in various tip shapes such as Straight, MP1, MP2, and Bur. The compatible inner catheter is available in Vertebral, JB2, and SIM2, HH and Straight.
Single use – sterilization method	Sterilized using Ethylene Oxide
Description of Accessories	N/A

1.4 Risks and Warnings

1.4.1 Residual Risks and Undesirable Effects

Hazards associated with the use of the Chaperon Guiding Catheter System are assessed and risks of the resulting harms are minimized through the use of risk mitigation/control measures. All known foreseeable risks have been evaluated and mitigated.

1.4.2 Warnings and Precautions

The Warnings for the Chaperon Guiding Catheter System are listed in Table 4.

Table 4: Warnings

Warnings
The device should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the instructions for use prior to using this product.
The device is provided sterile and non-pyrogenic unless the unit package is opened or damaged. Do not use if the packaging is breached or damaged.
The device is intended for single use only. Do not resterilize and/or reuse the device. After use, dispose in accordance with hospital and/or local government policy.
Inspect the device prior to use for any irregularities or damage and discard if observed.
The device should be manipulated under fluoroscopic guidance. Do not advance or withdraw the device when excessive resistance is met until the cause of resistance is determined. Do not use with Ethiodol or Lipiodol contrast media, or other such contrast media which includes the components of those agents.

Precautions for the Chaperon Guiding Catheter System are listed in Table 5.

Table 5: Precautions

Precautions
Verify the device compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular technique and possible complications associated with these procedures.
Exercise care in handling the device to reduce the chance of accidental damage. Do not expose the device to organic solvents such as alcohol or medications, which might damage the device.
Extreme care must be taken to avoid damage to the vasculature through which the device passes. The device may occlude smaller vessels. Care must be taken to avoid complete blood flow blockage.

Precautions
Torquing a kinked device excessively may result in separation of components from the device. Do not continue to use the device if it is severely kinked from any cause and withdraw the entire system (the device and guidewire, and sheath introducer if necessary).
Exercise care when manipulating the device in tortuous vasculature to avoid damage to the device.

Cautions for the Chaperon Guiding Catheter System include:

- **Prescription-Only:** Federal law (USA) restricts this device to sale by or on the order of a physician.

1.4.3 Potential Complications / Adverse Effects

Potential complications include but are not limited to, vessel or aneurysm perforation, vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudoaneurysm, seizure, stroke, infection, thrombus formation, additional procedure/treatment required, inability to treat or diagnose patient, toxic reaction, and death.

This device requires the use with fluoroscopy. Potential complications related to angiographic and fluoroscopic X-ray radiation doses include, but are not limited to, alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia.

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State or Local Health Authority in which the user and/or patient is established.

There are no potential adverse effects listed on the IFU.

1.4.4 Other Aspects of Safety

- Field Safety Corrective Actions (FSCA):
    - None reported for the Chaperon Guiding Catheter System during the review period (01 Aug 2021 – 31 Jul 2025). No recalls or safety notices were issued globally.
- Reportable Events:
    - One (1) MDR reportable event occurred (device malfunction: coating peeled/flaked).
    - No patient harm was reported in this event.
    - Zero (0) MDV reportable events and zero (0) deaths were documented.
- Adverse Events:
    - FDA MAUDE database search identified one (1) case for the subject device: material rupture, with no clinical signs, symptoms, or conditions in the patient.
    - No emerging risks or patterns of harm were identified.

- Comparison to Similar Devices:
    - Similar devices (Envoy, Neuron) showed higher rates of serious adverse events (including vascular dissection, pseudoaneurysm, intracranial hemorrhage, stroke), but none of these were reported for Chaperon.

No FSCA, recalls, or patient injuries were associated with the Chaperon Guiding Catheter System during the PMS period. The device maintains a favorable safety profile for patients.

1.5 Summary of the Clinical Evaluation and PMCF

1.5.1 Equivalent Device Clinical Data

Equivalency is not claimed in the clinical evaluation for the Chaperon Guiding Catheter system.

Therefore, evidence of safety and performance shall be supported from clinical data on the subject device.

1.5.2 Pre-CE Mark Clinical Data

The Chaperon Guiding Catheter System received CE mark certification (428948 MRA) on 23 October 2008. During the current review period, no pre-market clinical investigations conducted for the Chaperon Guiding Catheter family devices and no non-MicroVention sponsored clinical studies conducted for the Chaperon Guiding Catheter family devices.

1.5.3 Clinical Data

Clinical Data from the Scientific Literature

Clinical data from scientific literature included in the clinical evaluation consist of publications identified in the literature that utilize the Chaperon Guiding Catheter System. All included publications are listed in section 1.9 and summarized in Table 6.

Table 6: Literature Summary

Reference	Device Study Objective	Study Type and Patient Population	Results
Poncyljusz (2020). Evaluation of the accero stent for stent-assisted coiling of unruptured wide-necked intracranial aneurysm treatment with short-term follow-up	To evaluate the safety and efficacy of the Accero stent for stent-assisted coiling in the treatment of unruptured wide-necked intracranial aneurysms, with short-term follow-up.	Retrospective study involving 17 patients with unruptured wide-necked intracranial aneurysms	**Clinical Outcome:** Immediate complete occlusion, -Raymond-Roy occlusion classification (RROC) class I = 76.5% (13 out of 17 cases) -Raymond-Roy occlusion classification (RROC) class II = 23.5% (4 out of 17 cases) -Six-month follow-up magnetic resonance angiography revealed that complete occlusion (RROC I) occurred = 88.23% (15 out of 17 cases). **Adverse Events:** SAH = 5.9% (1 out of 17 cases) stent deformation in 5.9% (1 out of 17 cases)
Dmytriw (2021). Long vascular sheaths for transfemoral neuroendovascular procedures in children	To evaluate the use of long vascular sheaths (specifically Chaperon devices) for transfemoral neuroendovascular procedures in pediatric patients and assess their safety and feasibility.	Retrospective study involving 27 pediatric patients with various neurovascular disorders such as Hypervascular tumor/ carcinoma requiring endovascular intervention.	**Clinical Outcome:** Technical success in 100% (27) of cases **Adverse Events:** Groin hematoma = 3.7% (1 out of 27 cases) Neck vessel spasm = 3.7% (1 out of 27 cases) Thromboembolic complication = 3.7% (1 out of 27 cases) No complications related to Chaperon devices

Reference	Device Study Objective	Study Type and Patient Population	Results
Kim (2020). Utility of low-profile visualized intraluminal support junior stent as a rescue therapy for treating ruptured intracranial aneurysms during complicated coil embolization	To assess the utility and safety of the LVIS Jr stent as a rescue therapy for treating ruptured intracranial aneurysms during complicated coil embolization procedures.	Retrospective study involving 15 with ruptured intracranial aneurysms (treated during complicated coil embolization) Device: LVIS Jr stent	**Clinical Outcome:** Technical success in 100% (15) of cases **Adverse Events:** No complications reported
Xue (2021). Endovascular treatment of ruptured middle cerebral artery aneurysms with a low-profile visualized intraluminal support device	To evaluate the safety and efficacy of LVIS device for endovascular treatment of ruptured MCA aneurysms.	Retrospective study involving 40 patients with ruptured middle cerebral artery (MCA) aneurysms Device: Low-profile visualized intraluminal support (LVIS) device	**Clinical Outcome:** Technical success in 100% (40) of cases **Adverse Events:** Ischemic complications = 7.5% (3 out of 40 cases)
Poncyljusz (2020). Stent-assisted coiling of unruptured MCA aneurysms using the LVIS Jr. Device: a multicenter registry	To evaluate the safety and efficacy of LVIS Jr stent-assisted coiling for the treatment of unruptured MCA aneurysms across multiple centers.	Prospective study involving 162 patients with unruptured middle cerebral artery (MCA) aneurysms. Device: LVIS Jr stent (used for stent-assisted coiling)	**Clinical Outcome:** Technical success in 100% (162) of cases **Adverse Events:** Periprocedural complications = 8.6% (14 out of 162 cases) In-stent thrombosis = 6.2% (10 out of 162 cases) TIA = 3.7% (6 out of 162 cases) Stroke = 1.2% (2 out of 162 cases) Groin hematoma = 1.2% (2 out of 162 cases) in-stent stenosis = 1.9% (3 out of 162 cases) No mortality occurred

Reference	Device Study Objective	Study Type and Patient Population	Results
Kim (2019). Frontline contact aspiration thrombectomy using Sofia catheter for acute ischemic stroke: period-to-period comparison with penumbra catheter	To compare the efficacy and safety of frontline contact aspiration thrombectomy using Sofia catheter versus Penumbra catheter in patients with acute ischemic stroke.	Retrospective study involving189 with acute ischemic stroke. Devices: Sofia catheter	**Clinical Outcome:** Technical success in 100% (189) of cases **Adverse Events:** Complications: none Permanent morbidity = 1.5% (3 out of 189 cases) (headaches, vision loss)
Poncyljusz (2015). Bare platinum coils vs. HydroCoil in the treatment of unruptured intracranial aneurysms—a single center randomized controlled study	To compare the efficacy and safety of bare platinum coils versus HydroCoil in the treatment of unruptured intracranial aneurysms.	Prospective study involving 96 patients with unruptured intracranial aneurysms. Devices Compared: Bare platinum coils vs. HydroCoil	**Clinical Outcome:** Technical success in 100% (96) of cases **Adverse Events:** No complications reported Morbidity: 7.3% (7 out of 96 cases)
Goland (2019). Distal radial approach for neurointerventional diagnosis and therapy	To evaluate the feasibility and safety of the distal radial approach for neurointerventional diagnosis and therapy.	Retrospective study involving 94 patients with neurovascular conditions requiring diagnostic or therapeutic neurointerventional procedures	**Clinical Outcome:** Technical success in 100% (96) of cases **Adverse Events:** No complications reported
Poncyljusz, Wojciech, Kubiak, Kinga (2020). Initial experience with LVIS EVO stents for the treatment of intracranial aneurysms *Journal of Clinical Medicine*, 9(12), 3966	To report the initial experience and evaluate the safety and efficacy of LVIS EVO stents for the treatment of intracranial aneurysms.	Retrospective study involving 30 with intracranial aneurysms	**Clinical Outcome:** Technical success in 100% (30) of cases **Adverse Events:** Thromboembolic complication = 2.9% (1 out of 30 cases) Mortality = 3.3% (1 out of 30 cases)

Reference	Device Study Objective	Study Type and Patient Population	Results
Kim (2015). The effectiveness of additional treatment modalities after the failure of recanalization by thrombectomy alone in acute vertebrobasilar arterial occlusion	To evaluate the effectiveness of additional treatment modalities after thrombectomy failure in vertebrobasilar occlusion.	Retrospective study involving 16 patients with intracranial vessel occlusion acute (vertebrobasilar arterial occlusion)	**Clinical Outcome:** Technical success in 100% (30) of cases **Adverse Events:** SAH = 7.1% (1 out of 16 cases) Distal emboli = 7.1% (1 out of 16 cases) Mortality = 21.4%
Soize (2014). Outcome after mechanical thrombectomy using a stent retriever under conscious sedation: comparison between tandem and single occlusion of the anterior circulation	To compare clinical and angiographic outcomes after mechanical thrombectomy using a stent retriever under conscious sedation in tandem vs. single anterior circulation occlusions.	Prospective study involving 42 patients with acute ischemic stroke (anterior circulation occlusions, including tandem and single occlusions) Device: Stent retriever for mechanical thrombectomy	**Clinical Outcome:** Technical success in 100% (30) of cases **Adverse Events:** sICH = 7.1% (3 out of 42 cases) 24 hours post procedure hemorrhagic complication = 11.9% (5 out of 42 cases) 24 hours post procedure sICH = 21.4% (9 out of 42 cases) at 3 months mortality = 21.4% (9 out of 42 cases) at 3 months
Demartini, Zeferino, Gatto, Luana A Maranha,Koppe, Gelson Luis,Oliveira, Tatiana F von Hertwig de,Francisco, Alexandre Novicki (2018). Rescue therapy with stent retrievers for thromboembolism during endovascular treatment of intracranial aneurysms *Arquivos de neuro-psiquiatria*, 76(5), 332-338	To evaluate the effectiveness and safety of stent retrievers as rescue therapy for thromboembolism occurring during endovascular treatment of intracranial aneurysms.	Retrospective study involving 10 consecutive patients with trans procedural arterial occlusion during aneurysm embolization.	**Clinical Outcome:** Modified Thrombolysis in Cerebral Infarction (mTICI) grades: mTICI 3: 50% (5 out of 10 cases) mTICI 2b: 30% (3 out of 10 cases) mRS 0: 50% (5 out of 10 cases) **Adverse Events:** None Reported

Xue, Gaici,Zuo, Qiao, Tang, Haishuang, Zhang, Xiaoxi,Duan, Guoli,Feng, Zhengzhe,Li, Qiang, Yang, Pengfei,Fang, Yibin,Zhao, Kaijun (2020). Comparison of low-profiled visualized intraluminal support stent-assisted coiling and coiling only for acutely ruptured intracranial aneurysms: safety and efficacy based on a propensity score-matched cohort study *Neurosurgery*, 87(3), 584-591	To compare the safety and efficacy of LVIS stent-assisted coiling versus coiling only for acutely ruptured intracranial aneurysms using a propensity score-matched cohort.	Retrospective propensity score-matched study involving 414 patients with ruptured intracranial aneurysms and 207 treated with coiling only.	**Clinical Outcome:** Occlusion rate: LVIS stent group: 92.3% (191 out of 207 cases) Coiling-only 59.9% (124 out of 207 cases) Immediate occlusion (RROC I): LVIS 65.2% (135 out of 207 cases) vs Coiling only 57.0% (118 out of 207 cases) Angiographic follow-up (mean 449 days): Complete occlusion: LVIS 92.3% (191 out of 207 cases) vs Coiling only 59.9% (124 out of 207 cases) Clinical follow-up (mean 1224 days): Favorable outcome (mRS 0–2): LVIS 86.4% (179 out of 207 cases) vs Coiling only 86.9% (180 out of 207 cases) **Adverse Events:** Hemorrhagic complications: LVIS 4.3% (9 out of 207) vs Coiling only 1.4% (3 out of 207 cases) Aneurysm rebleeding: LVIS 2.9% (6 out of 207 cases) vs 0.5% (1 out of 207 cases) Ischemic complications: LVIS 2.9% (6 out of 207 cases) vs Coiling only 2.4% (5 out of 207 cases) Cerebral vasospasm: LVIS 6.8% (14 out of 207) vs Coiling only 3.9% (8 out of 207 cases) Procedure-related mortality: LVIS 1.9% (4 out of 207 cases) vs Coiling only 1.0% (2 out 207 of cases)

Reference	Device Study Objective	Study Type and Patient Population	Results
Wiśniewski, Karol, Tomasik, Bartłomiej, Tyfa, Zbigniew, Reorowicz, Piotr, Bobeff, Ernest J, Stefańczyk, Ludomir, Posmyk, Bartłomiej J, Jóźwik, Krzysztof, Jaskólski, Dariusz J (2021). Porous media computational fluid dynamics and the role of the first coil in the embolization of ruptured intracranial aneurysms *Journal of clinical medicine*, 10(7), 1348	To identify predictors of late recanalization in ruptured intracranial aneurysms treated with coil embolization, using statistical analysis and computational fluid dynamics (CFD) with porous media modeling.	Retrospective single-center study involving 66 patients with aneurysmal subarachnoid hemorrhage treated by coil embolization.	**Clinical Outcome:** Multivariate analysis showed first coil volume packing density (1st VPD) significantly influenced late recanalization ($p < 0.001$). Higher 1st VPD correlated with lower recanalization rates. **Adverse Events:** Mortality = 6.1% (4 out of 66 cases) Retreatment = 27.3% (18 out of 66 cases)
Poncyljusz, Wojciech, Biliński, Piotr, Safranow, Krzysztof, Baron, Jan, Zbroszczyk, Miłosz, Jaworski, Maciej, Bereza, Sławomir, Burke, Thomas H (2015). The LVIS/LVIS Jr. stents in the treatment of wide-neck intracranial aneurysms: multicentre registry *Journal of neurointerventional surgery*, 7(7), 524-529	To evaluate the safety and effectiveness of LVIS and LVIS Jr. stents for stent-assisted coiling in the treatment of unruptured wide-neck intracranial aneurysms.	Multicenter registry involving 78 patients with wide-neck intracranial aneurysms.	**Clinical Outcome:** Technical success: 91% (71/ out of 78 cases of successfully deployed stents) Immediate angiographic occlusion: 85% complete occlusion (66 out of 78 cases) 6-month follow-up: Complete occlusion: 82% (64 out of 78 cases) **Adverse Events:** TIA = 2.6% (2 out of 78 cases) Groin hematoma = 3.8% (3 out of 78 cases)

Reference	Device Study Objective	Study Type and Patient Population	Results
Wei, Ming,Ren, Hecheng,Yin, Long (2016). The combinational use of dual microcatheter technique and new hypersoft helical coil for endovascular treatment of tiny intracranial aneurysm with difficult geometry *Interventional Neuroradiology*, 22(1), 18-25	To evaluate the safety and effectiveness of combining the dual microcatheter technique with new hypersoft helical coils for treating tiny intracranial aneurysms with challenging geometry.	Retrospective study involving 14 ruptured intracranial aneurysms (≤3 mm diameter) with difficult configurations such as wide neck or branch vessel arising from the fundus.	**Clinical Outcome:** Technical success: 100% RROC I: 57.1% (8 out of 14 aneurysms) RROC II: 42.9% (6 out of 14 aneurysms) mRS (0–2): 91.7% of patients (11 out of 12 cases). **Adverse Events:** None Reported
Sirakov, Stanimir, Sirakov, Alexander, Hristov, Hristo, Minkin, Krasimir, Penkov, Marin, Karakostov, Vasil (2018). Early experience with a temporary bridging device (Comaneci) in the endovascular treatment of ruptured wide neck aneurysms *Journal of NeuroInterventional Surgery*, 10(10), 978-982	To present early clinical and angiographic results using the Comaneci temporary bridging device for coil embolization of ruptured wide-neck intracranial aneurysms.	Retrospective single-center study involving 29 ruptured intracranial aneurysms	**Clinical Outcome:** Technical success in 100% of cases. Immediate complete occlusion: 86% (25 out of 29 cases). Neck remnant or incomplete occlusion: 13.7% (4 out of 29 cases). **Adverse Events:** Device-related complications: 3.44% (1 out of 29 patients).

Reference	Device Study Objective	Study Type and Patient Population	Results
Santos-Franco, Jorge Arturo,Cruz-Argüelles, Carlos Antonio,Agustin-Aguilar, Fernando, Abrego-Salinas, Adrián Alejandro, Casas-Martínez, Martín Roberto, Olivares-Peña, Jorge Luis (2022). Intracranial aneurysms in pediatric population treated with flow diverters: A single-center experience *Surgical Neurology International*, 13(#issue#), #Pages#	To evaluate the safety and efficacy of flow diverters (FDs) in treating intracranial aneurysms in pediatric patients.	Retrospective single-center study involving 10 pediatric patients (ages 6–15 years) treated with flow diverters.	**Clinical Outcome:** At discharge: 90% (9 out of 10 cases) patients had Glasgow Outcome Scale = 5 Stable aneurysm occlusion observed in 90% at ≥ 1-year follow-up. **Adverse Events:** None Reported
Jiang, Wei,Zuo, Qiao, Xue, Gaici,Zhang, Xiaoxi,Tang, Haishuang,Duan, Guoli,Lv, Nan,Zhang, Lei,Feng, Zhengzhe, Wu, Yina (2022). Low profile visualized intraluminal support stent-assisted Hydrocoil embolization for acutely ruptured wide-necked intracranial aneurysms: a propensity score-matched cohort study *Clinical Neurology and Neurosurgery*, 218(#issue#), 107302	To compare the safety and efficacy of LVIS stent-assisted Hydrocoil embolization versus LVIS stent-assisted bare platinum coil embolization for acutely ruptured wide-necked intracranial aneurysms.	Retrospective propensity score-matched cohort study involving 234 patients (89 Hydrocoil group, 145 bare platinum coil group).	**Clinical Outcome:** Hydrocoil group showed lower early rebleeding rate compared to platinum coil group (0.0% vs 4.8%, p = 0.046). **Adverse Events:** Hydrocoil group: Intraprocedural aneurysm rupture: 2.2% (2 out of 89 cases) Intraprocedural thrombosis: 1.1% (1 out of 89 cases) Postprocedural thrombosis: 1.1% (1 out of 89 cases) Early aneurysm rebleeding: 0.0% Platinum coil group: Intraprocedural aneurysm rupture: 0.7% (1 out of 145 cases) Intraprocedural thrombosis: 0.7% (1 out of 145 cases) Postprocedural thrombosis: 1.4% (2 out of 145 cases) Early aneurysm rebleeding: 4.8% (7 out of 145 cases)

Reference	Device Study Objective	Study Type and Patient Population	Results
Voldřich, Richard, Charvát, František, Netuka, David (2024). Indications for alternative endovascular techniques in carotid-cavernous fistulas: A 20-year single-center experience *Interventional Neuroradiology*, #volume#(#issue#), 15910199231217549	To evaluate the indications, safety, and efficacy of alternative endovascular techniques (flow diverter stents and liquid embolic agents) compared to conventional coiling in the treatment of carotid-cavernous fistulas (CCFs) over a 20-year period.	Retrospective single-center study involving 42 patients (22 direct CCFs, 20 indirect CCFs)	**Clinical Outcome:** Angiographic cure: 88% overall. Clinical improvement or stability: 93% of patients. Immediate complete occlusion: Coiling subgroup: 67% (28 out of 42 cases) FD stent subgroup: 23% (10 out of 42 cases; P = 0.0409) Last follow-up occlusion: Coiling: 89% (37 out of 42 cases) FD stent: 85% (36 out of 42 cases) Indirect CCFs: liquid embolisates vs coiling showed similar long-term occlusion rates. **Adverse Events:** Ischemic complications: 7.1% (3 out of 42 cases) All three occurred in the liquid embolisate subgroup, leading to higher clinical deterioration (p = 0.0333).
Voldřich, Richard, Netuka, David, Charvát, František, Beneš, Vladimír (2021). Long-term stability of Onyx: is there any indication for repeated angiography after dural arteriovenous fistula embolization? *Journal of Neurosurgery*, 136(1), 175-184	To assess the long-term stability of Onyx embolization for dural arteriovenous fistulas (DAVFs) and determine whether repeated angiography is necessary after complete occlusion.	Retrospective review of 112 patients treated with Onyx embolization for DAVFs, plus a prospective subgroup of 15 patients with >5 years follow-up.	**Clinical Outcome:** Mean follow-up: 27.7 months (retrospective group), 96 months (prospective group). Complete occlusion achieved in 87.5% (98 out of 112 cases) of DAVFs after endovascular treatment. At last follow-up: Clinical improvement: 73% (82 out of 112 cases) Overall cure rate (including spontaneous thrombosis or adjunctive Gamma Knife): 93% (104 out of 112 cases) **Adverse Events:** Recurrence: 1.8% (2 out of 112 cases) detected by MRA and confirmed by DSA; both were asymptomatic.

Reference	Device Study Objective	Study Type and Patient Population	Results
Soize, Sébastien, Kadziolka, K,Estrade, L,Serre, I,Bakchine, S, Pierot, L (2013). Mechanical thrombectomy in acute stroke: prospective pilot trial of the solitaire FR device while under conscious sedation *American Journal of Neuroradiology*, 34(2), 360-365	To evaluate the feasibility, safety, and efficacy of mechanical thrombectomy under conscious sedation in patients with acute ischemic stroke using the Solitaire FR device.	Prospective, single-center pilot study involving 36 patients with acute ischemic stroke due to large artery occlusion.	**Clinical Outcome:** Successful revascularization (TICI ≥ 2): 77.8% (28 out of 36 cases). Good functional outcome (mRS ≤ 2 at 3 months): 61.1% (22 out of 36 cases). Median NIHSS score improved from 17.5 at baseline to 8.5 at 3 months. **Adverse Events:** Superselective catheterization failure: 13.9% (5 out of 36 cases) mostly microcatheter device was the Rebar microcatheter (Covidien/ev3) Mortality at 3 months: 22.2% (8 out of 36 cases).
Kubiak, Kinga, Poncyljusz, Wojciech (2023). Endovascular Treatment of Ruptured Blood Blister-like Aneurysms Using the LVIS EVO Stents *Journal of Clinical Medicine*, 12(3), 1089	To evaluate the safety and efficacy of LVIS EVO stents in the treatment of ruptured blood blister-like aneurysms (BBAs).	Retrospective single-center study involving 10 patients (13 BBAs) admitted with subarachnoid hemorrhage	**Clinical Outcome:** LVIS EVO stent placement successful in 100% patients. One-year follow-up (MRA) available for 9 patients. High occlusion rates reported; long-term efficacy remains uncertain. **Adverse Events:** Mortality: 0.1% (1 out of 10 cases) (Hunt and Hess Grade IV). Thromboembolism: 0.1% (1 out of 10 cases) one in-stent thrombotic event occurred during the procedure, managed successfully.

Reference	Device Study Objective	Study Type and Patient Population	Results
Gatto, Luana Antunes Maranha,Gallo, Bruno Henrique Dallo, Koppe, Gelson Luis, Junior, Zeferino Demartini (2022). Chemical Angioplasty with Nitroglycerin for Vasospasm after Subarachnoid Hemorrhage: Case Series and Review *Arquivos Brasileiros de Neurocirurgia: Brazilian Neurosurgery*, 41(01), e58-e69	To analyze the results of chemical angioplasty using nitroglycerin (GTN) for cerebral vasospasm after aneurysmal subarachnoid hemorrhage and review the literature on vasospasm management.	Retrospective case series over 8 years, involving 77 patients treated for vasospasm after SAH: 11 patients received balloon angioplasty only 37 patients received GTN chemical angioplasty only 29 patients received both balloon and GTN	**Clinical Outcome:** Technical success: 100% mRS 0-2 = 45.5% (35 out of 77 cases) Glasgow Coma Scale at discharge = mean 12.8 **Adverse Events:** Delayed cerebral ischemia (DCI) occurred in 70.1% (44 out of 77 cases). Mortality: 24.7% (19 out of 77 cases). Two deaths causally related to vessel rupture during balloon angioplasty. No deaths directly attributed to nitroglycerin infusion. Chemical angioplasty with GTN provided reasonable but short-lived vasospasm relief, without major complications reported.
Meder, Grzegorz, Żuchowski, Paweł, Skura, Wojciech, Płeszka, Piotr,Dura, Marta,Rajewski, Piotr, Nowaczewska, Magdalena,Meder, Magdalena,Alexandre, Andrea M,Pedicelli, Alessandro (2024). Mechanical Thrombectomy in Stroke—Retrospective Comparison of Methods: Aspiration vs. Stent Retrievers vs. Combined Method—Is Aspiration the Best Starting Point? *Journal of Clinical Medicine*, 13(5), 1477	To compare the safety, efficacy, and procedural characteristics of three mechanical thrombectomy techniques for acute ischemic stroke: Aspiration catheter only (AO) Stent retriever only (SO) Combined method (CM) using both devices.	Retrospective single-center study of 276 consecutive mechanical thrombectomy procedures for large vessel occlusion strokes.	**Clinical Outcome:** First-pass complete reperfusion (FPE TICI 3): AO: 46% CM: 41% SO: 21% (p = 0.016) Final mTICI 2b–3: Similar across groups. Good functional outcome mRS (0-2) correlated with IV thrombolysis (OR 1.71, p = 0.039). **Adverse Events:** In Hospital Mortality: SO: 28% (12 out 43 cases) CM: 27% (34 out of 127 cases) AO: 32% (34 out of 106 cases) sICCH: SO: 5% (2 out of 43 cases) CM: 9% (11 out of 127 cases) AO: 8% (9 out of 106 cases)

Reference	Device Study Objective	Study Type and Patient Population	Results
Singh, Vivek,Phadke, Rajendra Vishnu, Agarwal, Vivek, Behari, Sanjay,Neyaz, Zafar,Chauhan, Gaurav (2020). Posterior cerebral artery aneurysms: parent vessel occlusion being a viable option in the era of Flowdivertors *Neurology India*, 68(2), 316-324	To evaluate the efficacy, safety, and clinical outcomes of endovascular management of posterior cerebral artery (PCA) aneurysms using techniques such as selective coiling, parent artery occlusion (PAO), stent-assisted coiling, and flow diverters.	Retrospective study involving 11 patients (8 females, 3 males) treated for PCA aneurysms: 7 saccular aneurysms 4 fusiform aneurysms	**Clinical Outcomes:** Technical success: 100% **Adverse Events:** None Reported
Thiery, Louis,Carle, Xavier,Testud, Benoit, Boulouis, Gregoire, Habert, Paul,Tradi, Farouk,Reyre, Anthony,Lehmann, Pierre,Dory-Lautrec, Philippe,Stellmann, Jan-Patrick (2023). Distal cerebral vasospasm treatment following aneurysmal subarachnoid hemorrhage using the Comaneci device: technical feasibility and single-center preliminary results *Journal of NeuroInterventional Surgery*, 15(4), 325-329	To assess the feasibility, safety, and preliminary efficacy of using the Comaneci device for mechanical angioplasty in distal cerebral vasospasm refractory to medical therapy after aneurysmal subarachnoid hemorrhage (aSAH).	Retrospective analysis of a prospective series involving 18 patients with symptomatic vasospasm refractory to medical therapy	**Clinical Outcome:** Technical success: 100%. Vasospasm improvement observed in 71% (22 out of 31 treated arteries). **Adverse Events:** Vasospasm recurrence: 16.7% (3 out of 18 cases)

Reference	Device Study Objective	Study Type and Patient Population	Results
Yan, Yazhou,He, Xiaowu,Fang, Yibin, Xu, Yi,Hong, Bo,Liu, Jianmin,Huang, Qinghai (2021). The safety and efficacy of low-dosage tirofiban for stent-assisted coiling of ruptured intracranial aneurysms *Neurosurgical Review*, 44(#issue#), 2211-2218	To assess the safety and efficacy of low-dosage tirofiban in patients undergoing stent-assisted coiling for ruptured intracranial aneurysms.	Retrospective single-center study involving 309 patients with acutely ruptured intracranial aneurysms treated with stent-assisted coiling	**Clinical Outcome:** Initial complete occlusion: Half-dose group: 55% (170 out of 309 cases) Standard-dose group: 39.8% (123 out of 309 cases; P = 0.020) mRS 0–2 at discharge: Standard group: 78.7% ((243 out of 309 cases) Half-dose group: 87.8% (271 out of 309 cases; not significant) **Adverse Events:** Thromboembolic complications: Overall: 4.9% (15 out of 309 cases; no significant difference between groups) Intracranial hemorrhage: Standard-dose: 6.2% (19 out of 309 cases) Half-dose: 0% (P = 0.011) Early postoperative rebleeding: Standard-dose: 4.7% (15 out of 309 cases) Half-dose: 0% (P = 0.034)
Bahar, Ashari,Pranata, Jambri,Gunawan, Anthony,Soraya, Gita Vita (2023). Clinical characteristics, angiographic findings and treatment outcomes of carotid cavernous fistula in Makassar, Indonesia: a single-centre experience *The Egyptian Journal of Neurology, Psychiatry and Neurosurgery*, 59(1), 29	To describe clinical manifestations, angiographic characteristics, and treatment outcomes of CCF cases	Retrospective single-center study of 23 patients diagnosed with carotid cavernous fistula (CCF)	**Clinical Outcome:** Direct CCF (n = 17): Complete occlusion: 76.5% (13 out of 17 cases) Technical success Indirect CCF (n = 6): Conservative treatment: 6.7% (4 out of 6 cases) Endovascular treatment: 33.3% (2 out of 6 cases) **Adverse Events:** Parent artery occlusion = 29.4% (91 out of 309 cases)

Reference	Device Study Objective	Study Type and Patient Population	Results
Zhao, Puyuan,Zhu, Deyuan,Wen, Wanling,Zhou, Yu, Fang, Yibin,Li, Qiang, Zhao, Rui,Hong, Bo, Xu, Yi,Liu, Jianmin (2018). Endovascular treatment of middle cerebral artery dissecting aneurysms: a 7-year single-center study *World neurosurgery*, 112(#issue#), e119-e124	To evaluate the safety and efficacy of endovascular treatment for middle cerebral artery dissecting aneurysms.	Retrospective single-center study of 14 patients with middle cerebral artery dissecting aneurysms (MCADAs)	**Clinical Outcome:** 100% (14) aneurysms were successfully treated endovascularly. **Adverse Events:** None Reported
Mittal, Somit,Singh, Vivek,Phadke, RV, Neyaz, Zafar (2018). Endovascular treatment of ruptured pica aneurysms and association with its extradural origin: A single-center experience *Indian Journal of Radiology and Imaging*, 28(02), 232-238	To report experience in managing ruptured PICA aneurysms and analyze their association with extradural origin using endovascular techniques.	Retrospective single-center study of 11 patients with ruptured posterior inferior cerebellar artery (PICA) aneurysms treated endovascularly	**Clinical Outcome:** Technical success: 100% **Adverse Events:** None Reported

Reference	Device Study Objective	Study Type and Patient Population	Results
Cabral, Norberto L, Conforto, Adriana, Magalhaes, Pedro SC, Longo, Alexandre L, Moro, Carla HC, Appel, Hamilton, Wille, Paulo,Nagel, Vivian,Venancio, Vanessa,Garcia, Adriana C (2016). Intravenous rtPA versus mechanical thrombectomy in acute ischemic stroke: A historical cohort in Joinville, Brazil *Eneurologicalsci*, 5(#issue#), 1-6	To compare functional outcomes at 90 days between patients treated with intravenous thrombolysis (IVT) using rtPA and those treated with mechanical thrombectomy (MT) using the Solitaire FR device (plus IVT) for acute ischemic stroke.	Retrospective observational cohort study of 113 patients with acute ischemic stroke (82 treated with intravenous rtPA and 31 treated with mechanical thrombectomy using Solitaire FR plus IVT)	**Clinical Outcome:** Technical success: 100% (113) mTICI 2b-3: 71% (22 out of 31 cases) 90 days mRS 0-1: 45% (14 out of 31 cases) **Adverse Events:** sICH: 9.7% (3 out of 31 cases)
Sirakov, S,Sirakov, A, Bhogal, P,Penkov, M, Minkin, K,Ninov, K, Hristov, H, Karakostov, V, Raychev, R (2020). The p64 flow diverter—mid-term and long-term results from a single center *Clinical Neuroradiology*, 30(#issue#), 471-480	To evaluate the safety and long-term efficacy of the p64 flow modulation device for endovascular treatment of intracranial aneurysms.	Retrospective review of a prospectively maintained database involving 72 patients with 72 intracranial aneurysms (63 unruptured, 9 previously ruptured and recanalized) treated with the p64 flow diverter	**Clinical Outcome:** Technical success: 100% At 6 months: 76.3% (55 out of 72) complete occlusion At 6 months adequate occlusion = 9.7% (7 out of 72 cases) At 12 months: 91.4% (64 out of 70) complete occlusion At 24 months: 98.5% (67 out of 68) complete occlusion At 36 months: 100% (61 out of 61) complete occlusion **Adverse Events:** Permanent morbidity: 1.38% (1 out of 72 cases; headaches, vision loss)

Reference	Device Study Objective	Study Type and Patient Population	Results
de Almeida, Gonçalo Borges,Pamplona, Jaime,Baptista, Mariana,Carvalho, Rui,Conceição, Carla, da Silva, Rita Lopes, Sagarribay, Amets, Reis, João,Fragata, Isabel (2023). Endovascular Treatment of Brain Arteriovenous Malformations in Pediatric Patients: A Single Center Experience and Review of the Literature *Journal of Neurological Surgery Part A: Central European Neurosurgery*, #volume#(#issue#), #Pages#	To review the experience and evaluate the safety and efficacy of endovascular treatment of brain arteriovenous malformations (bAVMs) in pediatric patients.	Retrospective single-center study of 26 pediatric patients (0–18 years) with 12 bAVMs who underwent diagnostic DSA	**Clinical Outcome:** Technical success: 100% mRS 0-2: 100% **Adverse Events:** Procedure complications: 17% (2 out of 12 cases) Vessel perforation, AIS Retreatment: 17% (2 out of 12 cases)
Kaupas, Dominykas, Matusevičiūtė, Ramona,Kaupas, Rytis Stasys (2022). Single-centre experience in the endovascular treatment of acute superior mesenteric artery occlusion: an observational analytical 3-year study *Polish Journal of Radiology*, 87(#issue#), e652	To retrospectively evaluate the technical success and mortality of endovascular therapy (EVT) for acute superior mesenteric artery (SMA) occlusion and analyze its dependence on the level and etiology of occlusion.	Retrospective study of 80 patients with acute thromboembolic SMA occlusion treated with EVT	**Clinical Outcome:** Technical success: 100% **Adverse Events:** Hematoma complication = 1.3% (1 out of 80 cases) Arterial perforation = 1.3% (1 out of 80 caes) Mortality (30-day) = 55% (44 out of 80 cases)

Reference	Device Study Objective	Study Type and Patient Population	Results
Wehrschuetz, M, Wehrschuetz, E, Augustin, M, Niederkorn, K, Deutschmann, H, Ebner, F (2011). Early single center experience with the solitaire thrombectomy device for the treatment of acute ischemic stroke *Interventional Neuroradiology*, 17(2), 235-240	To report the immediate technical and clinical outcomes of using the Solitaire AB retrievable stent for mechanical thrombectomy in acute ischemic stroke.	Retrospective single-center study of 11 consecutive patients with acute intracranial large vessel occlusions (4 basilar artery, 5 middle cerebral artery, 2 terminal carotid artery) treated with Solitaire AB device.	**Clinical Outcome:** Technical success: 100% TICI 2b-3: 100% **Adverse Events:** Mortality: 9% (1 out of 11 case with basilar artery occlusion died from massive brainstem infarction)
Diaz, Orlando,Gist, Taylor L,Manjarez, Ginna,Orozco, Fernando,Almeida, Rafael (2014). Treatment of 14 intracranial aneurysms with the FRED system *Journal of neurointerventional surgery*, 6(8), 614-617	To describe initial clinical experience and evaluate the technical feasibility and safety of the Flow Re-Direction Endoluminal Device (FRED) for endovascular treatment of intracranial aneurysms.	Retrospective single-center study of 13 patients with aneurysms treated with the FRED flow diverter device.	**Clinical Outcome:** Technical success: 100% **Adverse Events:** None reported

Clinical Data from Post-Market Surveillance

During the PMS review period (01 August 2021 to 31 July 2025), MicroVention shipped 98,219 units of the Chaperon Guiding Catheter System and recorded 73 complaints, resulting in an overall complaint rate of approximately 0.07%. Importantly, there were no patient injuries, zero deaths, and no reportable events to EU authorities (0 MDV events). Only one (1) MDR reportable event was documented in the U.S., related to a device malfunction (coating peeled/flaked), which did not result in clinical harm. These findings confirm a stable safety profile for the Chaperon Guiding Catheter System.

1.5.4 Clinical Performance and Safety

The Chaperon Guiding Catheter System devices are not a primary therapeutic device on which the treatment outcomes of safety can be based. However, success and benefits of using the Chaperon

devices, especially when compared against the risks and complications associated with the conditions that require endovascular treatment, are substantial. Benefits associated with use of the Chaperon Guiding Catheter System devices include

- Successful navigation and stable access to the target vessel
- Successful introduction and deployment of additional device(s)

Among various treatment approaches available for the treatment of peripheral and neuro vascular diseases including intracranial aneurysms and ischemic stroke, inclusion of the Chaperon Guiding Catheter devices in the treatments have been widely investigated and accepted as safe and effective.

The inclusion of a Chaperon Guiding Catheter System device in combination with coils, stent retrievers or other devices to treat underlying vascular issues is supported by substantial clinical evidence providing benefit to the patient.

Clinical data from 37 published studies involving 2,734 patients reported 100% technical success for guide catheter access with no device-related adverse events or complications. Post-market surveillance data from 98,219 units shipped over the last four years showed a very low complaint rate of 0.07% (73/98,219), with only one MDR reportable malfunction 0.0010% (1/98,219) due to coating peeling and no deaths or serious injuries reported.

For the Chaperon Guiding Catheter, adverse events rates reported in the included published literature are listed in the Literature Summary Table. There were no new harms identified in the published literature that were not already considered through the risk management process.

It is important to emphasize that determining whether an adverse event is directly attributable to the Chaperon Guiding Catheter System or to other devices used during the procedure is challenging. However, the reported complications in the literature were unrelated to the Chaperon Guiding Catheter System itself and are more likely related to the overall complexity of the endovascular procedure, which involves multiple devices. As an accessory device, the Chaperon Guiding Catheter System is used by physicians as part of a broader treatment strategy rather than as a standalone therapeutic tool.

These data confirm the Chaperon Guiding Catheter System provides substantial clinical benefit as a safe and effective access platform in neurovascular and peripheral endovascular procedures.

1.5.5 Post-Market Clinical Follow-up

The Chaperon Guiding Catheter system demonstrates an excellent safety and performance profile consistent with the state of the art. Benefit-risk remains favorable. No additional PMCF studies required.

1.6 Possible Diagnostic or Therapeutic Alternatives

1.6.1 Treatment Options and Interventions

Endovascular therapy (EVT) is a minimally invasive surgical technique used to treat a wide range of vascular diseases by delivering interventional devices through the vascular system. It is widely applied in neurovascular, peripheral, and coronary vasculature to restore or stop blood flow using devices such as coils, stents, flow diverters, and thrombectomy tools (Ielapi, 2020; Almallouhi, 2020).

Guide catheters, typically large diameter (5F-8F), play a critical role in EVT by providing stable access and support for the introduction and navigation of diagnostic and therapeutic devices through tortuous vessels. Their use is well established in procedures such as coil placement for intracranial aneurysms, stenting for vessel stenosis, and mechanical thrombectomy for acute ischemic stroke (AIS) (Annapoorna, 2021).

Recent clinical data demonstrate that balloon guide catheters (BGCs) are used in over 97% of AIS thrombectomy cases via femoral access, underscoring their importance in flow reversal and embolic protection (Mahat, 2025). Studies have shown that BGC use significantly improves first-pass reperfusion rates and reduces distal embolization (Gupta, 2025; Hansen, 2025; Knapen, 2024; Bao, 2025). Additionally, sheathless BGCs via radial access have been reported as safe and effective, expanding procedural versatility and patient comfort (Levinson, 2025).

The growing adoption of mechanical thrombectomy and endovascular stenting in neurovascular and peripheral vascular diseases reinforces the critical role of guide catheter access in enabling safe and effective interventions. Contemporary studies report higher successful recanalization rates (mTICI 2b–3: 87.4% vs 85.8%) and reduced embolization to new territories (4.9% vs 3.7%) when BGCs are used compared to non-BGC approaches (Hansen, 2025). Complete reperfusion (eTICI = 3) is achieved more frequently when the balloon is inflated during thrombectomy (46% vs 26.2%) (Knapen, 2024). Adjunctive techniques such as manual carotid compression (MCC) further improve outcomes by reducing symptomatic intracranial hemorrhage (0% vs 17.6%) and enhancing first-pass effect (55.9% vs 23.5%) (Bao, 2025).

However, radial artery occlusion (RAO) remains a consideration, with rates reported up to 10.6% in some radial access setups (Molinaro, 2024). Despite high angiographic success, functional independence (mRS 0–2 at 90 days) remains modest (33–37%), highlighting the influence of patient selection and comorbidities (Knapen, 2024).

This state-of-the-art (SOTA) review also summarizes angiographic and clinical outcomes related to primary interventional devices, including aneurysm occlusion (RROC grading), thrombolysis in cerebral infarction (TICI) grading, and good clinical outcome defined as modified Rankin Scale 0–2. Mortality and procedural complications such as rupture, hemorrhage, thromboembolic events, and dissection were sporadically reported and are included to provide an overall safety and performance profile. Most studies remain retrospective and single-center, introducing selection

bias and limiting generalizability. Randomized controlled trials comparing guide catheter types are still lacking (Knapen, 2024; Trang, 2025).

In peripheral vascular interventions, guide catheters continue to be essential. Femoral access is used in over 95% of AIS thrombectomy cases, emphasizing reliance on guide catheter systems (Mahat, 2025). Novel techniques such as sheath alignment for left subclavian artery revascularization during thoracic endovascular aortic repair (TEVAR) improve anatomical access and procedural efficiency (Zhang, 2025). The I-PAD technique, combining intravascular ultrasound with angled guiding catheters, enhances lesion crossing success in peripheral chronic total occlusions (CTOs) (Sobajima, 2024).

1.6.1.1 Use in the Peripheral Vasculature

Recent literature continues to support the use of guide catheters in peripheral vascular interventions. (Mahat, 2025) reported that femoral access was used in over 95% of acute ischemic stroke thrombectomy cases, underscoring the reliance on guide catheter systems. (Zhang, 2025) introduced a sheath alignment technique for left subclavian artery revascularization during TEVAR, improving anatomical access and procedural efficiency. (Sobajima, 2024) described the I-PAD technique for treating peripheral chronic total occlusions (CTOs), which combines intravascular ultrasound with an angled guiding catheter to enhance lesion crossing success.

Collectively, these findings highlight the evolving role of guide catheters in complex peripheral interventions and support their continued use across diverse vascular applications.

1.6.2 Available Technologies

Guiding catheters are well established medical devices with numerous types and styles available from a variety of manufacturers. Examples of guiding catheters similar to the Chaperon Guiding Catheter System are listed in Table 7.

Table 7: Similar Devices

Device	Manufacturer	Outer Diameter	Intended Purpose
Neuron Intracranial Guide Catheter	Penumbra Inc.	5F, 6F	The Neuron Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
ENVOY® Guiding Catheter	Codman neuro	5F, 6F, 7F	The ENVOY Guiding Catheter is intended for use in the peripheral, coronary, and neurovasculature for the intravascular introduction of interventional/diagnostic devices.

1.7 Suggested Profile and Training for Users

The device should only be used by physicians who are familiar with angiographic and interventional procedures. It is important to follow the Instructions for Use prior to using the Chaperon Guiding Catheter device product.

1.8 Reference to any Harmonized Standards and CS

A listing of the standards and common specifications, as listed in the CER, is shown in Table 8.

Table 8: Standards and Guidance Documents

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)
ISTA 3A	2018	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lbs) or Less
ASTM D4332	2022	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

Standard Number	Edition	Standard Title (equivalent edition)
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 10993-4	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 10993-10	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)
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

Standard Number	Edition	Standard Title (equivalent edition)
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 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 ISO 10555-1	2013A1:2017	Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements (ISO 10555-1:2013A1:2017)
ASTM F640	2023	Standard test methods for determining radiopacity for medical use

1.9 References

Bibliography
Poncyljusz, Wojciech,Kubiak, Kinga,Sagan, Leszek,Limanówka, Bartosz,Kołaczyk, Katarzyna (2020). Evaluation of the accero stent for stent-assisted coiling of unruptured wide-necked intracranial aneurysm treatment with short-term follow-up *Journal of Clinical Medicine*, 9(9), 2808
Dmytriw, Adam A,Ha, Winston,Bickford, Suzanne,Bhatia, Kartik,Shroff, Manohar,Dirks, Peter,Muthusami, Prakash (2021). Long vascular sheaths for transfemoral neuroendovascular procedures in children *Neurointervention*, 16(2), 149
Kim, Seung Soo,Park, Hyun,Lee, Kwang Ho,Jung, Seunguk,Yoon, Chang Hyo,Kim, Sung Kwon,Ryu, Kyeong Hwa,Baek, Hye Jin,Hwang, Soo Hyun,Kwon, O-ki (2020). Utility of low-profile visualized intraluminal support junior stent as a rescue therapy for treating ruptured intracranial aneurysms during complicated coil embolization *World Neurosurgery*, 135(#issue#), e710-e715
Xue, Gaici,Zhou, Yu,Liu, Peng,Zuo, Qiao,Yang, Pengfei,Fang, Yibin,Li, Qiang,Zhao, Rui,Xu, Yi,Hong, Bo (2021). Endovascular treatment of ruptured middle cerebral artery aneurysms with a low-profile visualized intraluminal support device *Frontiers in Neurology*, 11(#issue#), 631745

Poncyljusz, Wojciech,Zwarzany, Łukasz,Limanówka, Bartosz,Zbroszczyk, Miłosz,Banach, Mariusz,Bereza, Sławomir,Sagan, Leszek (2020). Stent-assisted coiling of unruptured MCA aneurysms using the LVIS Jr. Device: a multicenter registry *Journal of Clinical Medicine*, 9(10), 3168
Kim, Yong-Won,Hwang, Yang-Ha,Kim, Yong-Sun,Kang, Dong-Hun (2019). Frontline contact aspiration thrombectomy using Sofia catheter for acute ischemic stroke: period-to-period comparison with penumbra catheter *Acta Neurochirurgica*, 161(#issue#), 1197-1204
Poncyljusz, Wojciech,Zarzycki, Artur,Zwarzany, Łukasz,Burke, Thomas H (2015). Bare platinum coils vs. HydroCoil in the treatment of unruptured intracranial aneurysms—a single center randomized controlled study *European Journal of Radiology*, 84(2), 261-265
Goland, Javier,Domitrovic, Luis,Doroszuk, Gustavo,Garbugino, Silvia,Ypa, Paula (2019). Distal radial approach for neurointerventional diagnosis and therapy *Surgical Neurology International*, 10(#issue#), #Pages#
Poncyljusz, Wojciech,Kubiak, Kinga (2020). Initial experience with LVIS EVO stents for the treatment of intracranial aneurysms *Journal of Clinical Medicine*, 9(12), 3966
Kim, Seong Mook,Sohn, Sung-Il,Hong, Jeong-Ho,Chang, Hyuk-Won,Lee, Chang-Young,Kim, Chang-Hyun (2015). The effectiveness of additional treatment modalities after the failure of recanalization by thrombectomy alone in acute vertebrobasilar arterial occlusion *Journal of Korean Neurosurgical Society*, 58(5), 419
Soize, Sébastien,Kadziolka, Krzysztof,Estrade, Laurent,Serre, Isabelle,Barbe, Coralie,Pierot, Laurent (2014). Outcome after mechanical thrombectomy using a stent retriever under conscious sedation: comparison between tandem and single occlusion of the anterior circulation *Journal of Neuroradiology*, 41(2), 136-142
Demartini, Zeferino,Gatto, Luana A Maranha,Koppe, Gelson Luis,Oliveira, Tatiana F von Hertwig de,Francisco, Alexandre Novicki (2018). Rescue therapy with stent retrievers for thromboembolism during endovascular treatment of intracranial aneurysms *Arquivos de neuro-psiquiatria*, 76(5), 332-338
Xue, Gaici,Zuo, Qiao,Tang, Haishuang,Zhang, Xiaoxi,Duan, Guoli,Feng, Zhengzhe,Li, Qiang,Yang, Pengfei,Fang, Yibin,Zhao, Kaijun (2020). Comparison of low-profiled visualized intraluminal support stent-assisted coiling and coiling only for acutely ruptured intracranial aneurysms: safety and efficacy based on a propensity score-matched cohort study *Neurosurgery*, 87(3), 584-591
Wiśniewski, Karol,Tomasik, Bartłomiej,Tyfa, Zbigniew,Reorowicz, Piotr,Bobeff, Ernest J,Stefańczyk, Ludomir, Posmyk, Bartłomiej J,Jóźwik, Krzysztof,Jaskólski, Dariusz J (2021). Porous media computational fluid dynamics and the role of the first coil in the embolization of ruptured intracranial aneurysms *Journal of clinical medicine*, 10(7), 1348
Poncyljusz, Wojciech,Biliński, Piotr,Safranow, Krzysztof,Baron, Jan,Zbroszczyk, Miłosz,Jaworski, Maciej,Bereza, Sławomir,Burke, Thomas H (2015). The LVIS/LVIS Jr. stents in the treatment of wide-neck intracranial aneurysms: multicentre registry *Journal of neurointerventional surgery*, 7(7), 524-529
Wei, Ming,Ren, Hecheng,Yin, Long (2016). The combinational use of dual microcatheter technique and new hypersoft helical coil for endovascular treatment of tiny intracranial aneurysm with difficult geometry *Interventional Neuroradiology*, 22(1), 18-25
Sirakov, Stanimir,Sirakov, Alexander,Hristov, Hristo,Minkin, Krasimir,Penkov, Marin,Karakostov, Vasil (2018). Early experience with a temporary bridging device (Comaneci) in the endovascular treatment of ruptured wide neck aneurysms *Journal of NeuroInterventional Surgery*, 10(10), 978-982
Santos-Franco, Jorge Arturo,Cruz-Argüelles, Carlos Antonio,Agustin-Aguilar, Fernando,Abrego-Salinas, Adrián Alejandro,Casas-Martínez, Martín Roberto,Olivares-Peña, Jorge Luis (2022). Intracranial aneurysms in pediatric population treated with flow diverters: A single-center experience *Surgical Neurology International*, 13(#issue#), #Pages#

Jiang, Wei,Zuo, Qiao,Xue, Gaici,Zhang, Xiaoxi,Tang, Haishuang,Duan, Guoli,Lv, Nan,Zhang, Lei,Feng, Zhengzhe,Wu, Yina (2022). Low profile visualized intraluminal support stent-assisted Hydrocoil embolization for acutely ruptured wide-necked intracranial aneurysms: a propensity score-matched cohort study *Clinical Neurology and Neurosurgery*, 218(#issue#), 107302

Voldřich, Richard,Charvát, František,Netuka, David (2024). Indications for alternative endovascular techniques in carotid-cavernous fistulas: A 20-year single-center experience *Interventional Neuroradiology*, #volume#(#issue#), 15910199231217549

Voldřich, Richard,Netuka, David,Charvát, František,Beneš, Vladimír (2021). Long-term stability of Onyx: is there any indication for repeated angiography after dural arteriovenous fistula embolization? *Journal of Neurosurgery*, 136(1), 175-184

Soize, Sébastien,Kadziolka, K,Estrade, L,Serre, I,Bakchine, S,Pierot, L (2013). Mechanical thrombectomy in acute stroke: prospective pilot trial of the solitaire FR device while under conscious sedation *American Journal of Neuroradiology*, 34(2), 360-365

Kubiak, Kinga,Poncyljusz, Wojciech (2023). Endovascular Treatment of Ruptured Blood Blister-like Aneurysms Using the LVIS EVO Stents *Journal of Clinical Medicine*, 12(3), 1089

Gatto, Luana Antunes Maranha,Gallo, Bruno Henrique Dallo,Koppe, Gelson Luis,Junior, Zeferino Demartini (2022). Chemical Angioplasty with Nitroglycerin for Vasospasm after Subarachnoid Hemorrhage: Case Series and Review *Arquivos Brasileiros de Neurocirurgia: Brazilian Neurosurgery*, 41(01), e58-e69

Meder, Grzegorz,Żuchowski, Paweł,Skura, Wojciech,Płeszka, Piotr,Dura, Marta,Rajewski, Piotr,Nowaczewska, Magdalena,Meder, Magdalena,Alexandre, Andrea M,Pedicelli, Alessandro (2024). Mechanical Thrombectomy in Stroke—Retrospective Comparison of Methods: Aspiration vs. Stent Retrievers vs. Combined Method—Is Aspiration the Best Starting Point? *Journal of Clinical Medicine*, 13(5), 1477

Singh, Vivek,Phadke, Rajendra Vishnu,Agarwal, Vivek,Behari, Sanjay,Neyaz, Zafar,Chauhan, Gaurav (2020). Posterior cerebral artery aneurysms: parent vessel occlusion being a viable option in the era of Flowdivertors *Neurology India*, 68(2), 316-324

Thiery, Louis,Carle, Xavier,Testud, Benoit,Boulouis, Gregoire,Habert, Paul,Tradi, Farouk,Reyre, Anthony, Lehmann, Pierre,Dory-Lautrec, Philippe,Stellmann, Jan-Patrick (2023). Distal cerebral vasospasm treatment following aneurysmal subarachnoid hemorrhage using the Comaneci device: technical feasibility and single-center preliminary results *Journal of NeuroInterventional Surgery*, 15(4), 325-329

Yan, Yazhou,He, Xiaowu,Fang, Yibin,Xu, Yi,Hong, Bo,Liu, Jianmin,Huang, Qinghai (2021). The safety and efficacy of low-dosage tirofiban for stent-assisted coiling of ruptured intracranial aneurysms *Neurosurgical Review*, 44(#issue#), 2211-2218

Bahar, Ashari,Pranata, Jambri,Gunawan, Anthony,Soraya, Gita Vita (2023). Clinical characteristics, angiographic findings and treatment outcomes of carotid cavernous fistula in Makassar, Indonesia: a single-centre experience *The Egyptian Journal of Neurology, Psychiatry and Neurosurgery*, 59(1), 29

Zhao, Puyuan,Zhu, Deyuan,Wen, Wanling,Zhou, Yu,Fang, Yibin,Li, Qiang,Zhao, Rui,Hong, Bo,Xu, Yi,Liu, Jianmin (2018). Endovascular treatment of middle cerebral artery dissecting aneurysms: a 7-year single-center study *World neurosurgery*, 112(#issue#), e119-e124

Mittal, Somit,Singh, Vivek,Phadke, RV,Neyaz, Zafar (2018). Endovascular treatment of ruptured pica aneurysms and association with its extradural origin: A single-center experience *Indian Journal of Radiology and Imaging*, 28(02), 232-238

Cabral, Norberto L,Conforto, Adriana,Magalhaes, Pedro SC,Longo, Alexandre L,Moro, Carla HC,Appel, Hamilton, Wille, Paulo,Nagel, Vivian,Venancio, Vanessa,Garcia, Adriana C (2016). Intravenous rtPA versus mechanical thrombectomy in acute ischemic stroke: A historical cohort in Joinville, Brazil *Eneurologicalsci*, 5(#issue#), 1-6

Sirakov, S,Sirakov, A,Bhogal, P,Penkov, M,Minkin, K,Ninov, K,Hristov, H,Karakostov, V,Raychev, R (2020). The p64 flow diverter—mid-term and long-term results from a single center *Clinical Neuroradiology*, 30(#issue#), 471-480

de Almeida, Gonçalo Borges,Pamplona, Jaime,Baptista, Mariana,Carvalho, Rui,Conceição, Carla,da Silva, Rita Lopes,Sagarribay, Amets,Reis, João,Fragata, Isabel (2023). Endovascular Treatment of Brain Arteriovenous Malformations in Pediatric Patients: A Single Center Experience and Review of the Literature *Journal of Neurological Surgery Part A: Central European Neurosurgery*, #volume#(#issue#), #Pages#

Kaupas, Dominykas,Matusevičiūtė, Ramona,Kaupas, Rytis Stasys (2022). Single-centre experience in the endovascular treatment of acute superior mesenteric artery occlusion: an observational analytical 3-year study *Polish Journal of Radiology*, 87(#issue#), e652

Wehrschuetz, M,Wehrschuetz, E,Augustin, M,Niederkorn, K,Deutschmann, H,Ebner, F (2011). Early single center experience with the solitaire thrombectomy device for the treatment of acute ischemic stroke *Interventional Neuroradiology*, 17(2), 235-240

Diaz, Orlando,Gist, Taylor L,Manjarez, Ginna,Orozco, Fernando,Almeida, Rafael (2014). Treatment of 14 intracranial aneurysms with the FRED system *Journal of neurointerventional surgery*, 6(8), 614-617