Summary of Safety and Clinical Performance

for

Scepter™ Occlusion Balloon Catheters

SSCP1105554

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

MicroVention Europe SARL
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye, France

DOCUMENT CHANGE HISTORY

SSCP Revision	Change Description	NB approved/verified
A	Initial release	☒Yes ☐ No* Validation language:
B	Annual update in the new template with updates to section 1.4.4, 1.5.3 and 1.5.4. Changed the title of the document to match with Technical documentation. Removed trademark symbol next to the device name after the first mention of the device name as suggested by Legal. Removed trademark symbol next to microvention logo in the first page and headers as suggested by legal based on new guidelines.	☐ Yes ☒ No* Validation language:

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

TABLE OF CONTENTS

LIST OF TABLES

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 Scepter C™, Scepter XC™ and Scepter Mini™ Occlusion Balloon Catheters (hereafter referred to as Scepter devices).

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	Scepter C / Scepter XC/ Scepter Mini Occlusion Balloon Catheter
EMDN Code	C0104020202
Medical Device Nomenclature (EMDN)	Peripheral embolisation catheters and microcatheters
Device Class	Class III
Basic UDI-DI	08402732SCEPTERKS
Year when first certificate (CE) was issued for the device	Scepter C - 07 June 2011 Scepter XC- March 2012 Scepter Mini - 20 April 2019
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-Straβe 21 D-60433 Frankfurt am Main
Notified Body Identification Number	0297

1.2 Intended Purpose of the Device

Table 1.2 Intended Use

Intended Purpose	
Intended Purpose	The Scepter devices are intended: • For use in the peripheral and neuro vasculature where temporary occlusion is desired. The balloon catheters provide temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheters also offer balloon assisted embolization of intracranial aneurysms. • For use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents such as embolization materials. For neurovascular use for the infusion of diagnostic agents such as contrast media, and therapeutic agents, such as embolization materials, that have been approved or cleared for use in the neurovasculature and are compatible with the inner diameter of the Scepter C/XC balloon catheter or inner lumen of Scepter Mini balloon catheter.
Indications for Use	The Scepter devices are intended: • For use in the peripheral and neuro vasculature where temporary occlusion is desired. The balloon catheters provide temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The balloon catheters also offer balloon assisted embolization of intracranial aneurysms. • For use in the peripheral vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents such as embolization materials. • For neurovascular use for the infusion of diagnostic agents such as contrast media, and therapeutic agents, such as embolization materials, that have been approved or cleared for use in the neurovasculature and are compatible with the inner diameter of the Scepter C/XC or inner lumen of Scepter Mini.
Target Population	The intended patient population to be treated includes those patients presenting medical conditions requiring temporary occlusion, the delivery of diagnostic agents such as contrast media, and therapeutic agents such as embolization materials, in the peripheral or neurovasculature.
Contraindications and/or Limitations	The contradictions for the Scepter devices are: • Not intended for embolectomy or angioplasty procedures • Not intended for use in coronary vessels • Not intended for pediatric or neonatal use

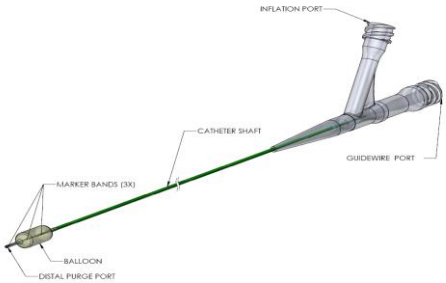
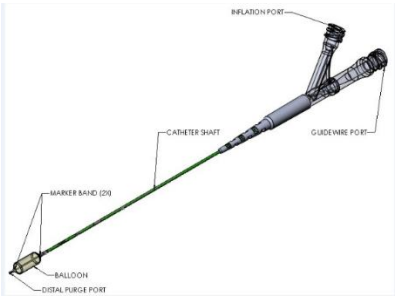
1.3 Device Description

Table 1.3 Device Description

<table>
<tr><th colspan="2">Device Description</th></tr>
<tr><td>Description of the Device</td><td>The Scepter devices are dual coaxial lumen catheters with a polyurethane elastomeric balloon at the distal tip which can be inflated/deflated by the user. The Scepter devices include a lubricous inner liner made from polytetrafluoroethylene (PTFE) which forms the inner (guidewire) lumen to introduce the guidewire. A coaxial outer lumen is used to inflate and deflate the balloon with a syringe filled with contrast media through the inflation port. The outer surface of the catheter shaft is made up of segments of decreasing durometers to form the flexible distal section, facilitating vascular access.
The Scepter devices are hydrophilically coated to provide a lubricious outer interface. A dual port hub is attached to the proximal end to provide access to the guidewire and inflation lumens. The entire catheter is reinforced with a coil. Radiopaque marker bands indicate the position of the balloon and the distal tip under fluoroscopy.
The Scepter Mini balloon catheter incorporates several minor design differences in comparison to the Scepter C and XC. The table below provides a detailed side-by-side comparison of the Scepter Mini balloon catheter versus the Scepter C/XC balloon catheter. The differences are minor, and do not affect the operation or intended use of the device.
<table>
<tr><th>Feature</th><th>Scepter C/XC</th><th>Scepter Mini</th></tr>
<tr><td>Catheter Length</td><td>150 cm</td><td>165 cm</td></tr>
<tr><td>Catheter distal tip</td><td>Extends 5 mm beyond distal edge of balloon.

Shapeable.</td><td>Extends 2.5 mm beyond distal edge of balloon.

Not shapeable.</td></tr>
<tr><td>Catheter Outside Diameter</td><td>Proximal = 2.8Fr
Distal = 2.6 Fr</td><td>Proximal = 2.8Fr
Distal = 1.6 Fr</td></tr>
<tr><td>Catheter Inside Diameter</td><td>0.0165"</td><td>Proximal=0.0100"
Distal=0.0155"</td></tr>
<tr><td>Balloon Length</td><td>C = 10,15, 20 mm
XC = 11 mm</td><td>9.0 mm</td></tr>
<tr><td>Distal Purge Hole</td><td>Uncovered</td><td>Covered by PTFE membrane (Aeos ePTFE).</td></tr>
<tr><td>PTFE Liner - Supplier Change</td><td>Supplied by Zeus</td><td>Supplied by Junkosha</td></tr>
<tr><td>Cobalt 4:1 Shrink Iridium</td><td>None</td><td>A 4:1 Shrink Iridium Tubing (Cobalt p/n U4-040-CLR) is added to the distal 31 cm.</td></tr>
<tr><td>Number of Marker Bands</td><td>3</td><td>2</td></tr>
<tr><td>Balloon Coating Process</td><td>Utilizes oxygen</td><td>Utilizes argon</td></tr>
<tr><td>Accessories</td><td>Packaged with shaping mandrel</td><td>Does not include shaping mandrel</td></tr>
</table>
</td></tr>
</table>

Device Description	
	The differences described in this section are considered minor, and do not affect the operation or intended use of the device. Schematic illustrations of Scepter devices are provided below. **Figure 1-1: Scepter C, XC Catheter**  **Figure 1-2: Scepter Mini Catheter** 
Design Characteristics of the Device	The Scepter devices achieve their intended use through the following principle of operation. In most cases, a guide sheath is placed in the femoral artery to gain access. Then a guiding catheter and guidewire are placed through the sheath and are used to navigate into the neurovasculature. This guidewire is removed since it is typically an 0.035" or larger outer diameter (OD) select type of wire. The balloon catheter is then advanced over a micro guidewire to the target location for treatment. The balloon can be inflated for occlusion and deflated for removal or repositioning. The balloon's soft, compliant properties allow it to automatically occlude a vessel by expanding to take the shape of the vessel. Diagnostic agents such as contrast media or therapeutic agents such as embolic materials can be delivered through the guidewire lumen. The other lumen is used for balloon inflation/deflation only. Once the treatment is complete, the balloon is deflated and removed from the patient through the guiding catheter. The materials for Scepter devices are listed in the table below.

Component	Scepter C/XC	Scepter Mini
Catheter	Polyether block amide Polyolefin Stainless steel Polytetrafluoroethylene (Zeus) Nylon	Polyether block amide Polyolefin Stainless steel Polytetrafluoroethylene (Junkosha) Aeos ePTFE (purge hole membrane)

Device Description	
	<table><tr><td></td><td>Polyimide</td><td>Polyurethane Nylon Polyimide</td></tr><tr><td>Balloon</td><td>Compliant, Polyurethane elastomeric</td><td>Compliant, Polyurethane elastomeric</td></tr><tr><td>Marker Band</td><td>Platinum-Iridium alloy</td><td>Platinum-Iridium alloy</td></tr><tr><td>Coating</td><td>Hydak B23K, 1000 mL Hydak A-15, 975 mL Dowanol PMA, 2000 mL Desmodur N-75, 100mL Crosslinker CX-100, 10 mL 2,2,4-Trimethylpentane, 500 mL</td><td>Hydak B23K, 1000 mL Hydak A-15, 975 mL Dowanol PMA, 2000 mL Desmodur N-75, 100mL Crosslinker CX-100, 10 mL 2,2,4-Trimethylpentane, 500 mL</td></tr><tr><td>Hub</td><td>Nylon</td><td>Nylon</td></tr><tr><td>Strain Relief</td><td>Polyether block amide (Pebax)</td><td>Polyether block amide (Pebax)</td></tr></table>
Previous Generations or Variants, if applicable	This is the first generation of these products
Single use – sterilization method	The device is single use only. The device is sterilized using 100% ethylene oxide (EtO)
Description of Accessories	- The Scepter Occlusion Balloon Catheters are packaged with one introducer sheath and one catheter stylet. The introducer sheath is a simple split-away tube that allows for the Scepter balloon catheter to be more easily inserted into a larger guide catheter. The catheter stylet serves to prevent the catheter from being damaged during shipping. It is removed from the catheter before use. The Scepter C and XC are also packaged with a shaping mandrel. The Scepter Mini does not come with a shapeable tip, so a shaping mandrel is not included.
Description of other Devices or Products intended to be used in combination	- Scepter C and XC balloon catheters are compatible with .014” (0.36mm) or smaller guidewires. Scepter Mini balloon catheter is compatible with .008” (0.20mm) or smaller guidewire. Guidewires are not required for inflation of balloon. - Scepter C, XC, and Mini balloon catheters are compatible with guiding catheters with a minimum inner diameter larger than or equal to 0.053” (1.35mm). The maximum outer diameter of the Scepter Mini balloon catheter is 0.037” (0.94mm). The maximum outer diameter of the Scepter C and Scepter XC balloon catheters is 0.038” (0.97mm). • Scepter C, XC, and Mini balloon catheters are compatible for use with dimethyl sulfoxide (DMSO). Scepter C and Scepter XC balloon catheters have been verified to be compatible for use with diagnostic agents (such as contrast media) and liquid embolic agents (i.e. Onyx Liquid Embolic System). For all other liquid embolics, refer to their Instructions for Use.

1.4 Risks and Warnings

1.4.1 Residual Risks and Undesirable Effects

Hazards associated with the use of the Scepter devices 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.

Risks associated with the Scepter devices include the following:

- Additional procedure/treatment required
- Aneurysm rupture
- Cerebral Edema
- Peripheral Edema
- Hematoma/Bleeding inside the brain
- Hemorrhage/Bleeding inside the brain
- Hypertension
- Inability to treat or diagnose patient
- Increased procedure time (> 15 minutes)
- Increased procedure time (< 15 minutes)
- Infection and/or fever
- Inflammatory complication
- Ischemic stroke/Embolic Stroke
- Limb Ischemia
- Limiting patient's future therapy or diagnosis
- Toxic reaction
- Undesirable clot formulation (emboli)
- Vessel/tissue damage
- Blood loss from luer (include RHV, other accessories, etc.)
- Hydrocephalus, aseptic meningitis, peri-aneurysmal edema
- Delayed or acute visual deterioration
- Chronic visual deterioration
- Non-abrupt headache
- Product migration
- Anaphylaxis
- Seizure
- Post-operative ICA (Internal Carotid Artery) occlusion
- Cardiac arrest/Heart attack
- Vasospasm
- Blockage other than target vessel
- In-complete embolization
- Death
- Pulmonary embolism/Pulmonary infarction
- Myocardial embolism/ Myocardial infarction
- Tissue necrosis
- No Clinical Effect (Customer dis-satisfaction)

1.4.2 Warnings and Precautions

The warnings / precautions for the Scepter devices are listed as follows:

WARNING

- Verify the size of the vessel under fluoroscopy. Ensure that the balloon catheter isappropriate for the size of the vessel.
- Do not exceed the maximum recommended inflation volume as balloon rupture may occur.
- The balloon catheter has been tested for compatibility or use with Onyx™ Liquid Embolic System and DMSO. For all other liquid embolic, refer to their Instructions For Use.
- The balloon catheter is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.
- Viscosity and concentration of contrast will affect balloon inflation and deflation times.
- During preparation, do not deflate the balloon unless the distal tip is submerged in saline or contrast to prevent air from entering balloon.
- Do not attach any high-pressure devices to the balloon inflation port as this may rupture the balloon. Do not inflate the balloon with air or any other gas while in the body.
- Do not use click activated flow control switch, such as FloSwitch™ with the balloon catheter.
- Do not inflate the balloon with air or any other gas while in the body.
- Improper preparation may introduce air into the system. The presence of air may inhibit proper fluoroscopic visualization.
- Excessive pressure higher than 700 PSI (4826kPa, 47.6atm) may cause leakage or rupture of the balloon catheter guidewire lumen.
- When air-purging the balloon catheter, inject fluid slowly otherwise balloon rupture may occur.
- If back-loading the balloon catheter over a guidewire, ensure distal tip of the balloon catheter is not damaged.
- Do not over-tighten the RHV around the balloon catheter. Over-tightening damage the catheter shaft and delay balloon inflation and deflation.
- Do not advance the balloon catheter or guidewire against resistance. If resistance is felt, assess the source of resistance using fluoroscopic means.
- Always inflate and deflate the balloon while visualizing under fluoroscopy to

ensure patient safety.

- The shaping mandrel is not intended for use inside the body. Ensure shaping mandrel is removed from balloon catheter prior to introduction into the RHV or other accessories.
- NBCA and solutions containing ethyl esters of iodized fatty acids of poppy seed oil are not compatible with the balloon.

PRECAUTIONS

- Immediately prior to use visually inspect all the sterile barrier systems, that are labeled as sterile. Do not use if breaches in sterile barrier system integrity are evident such as a damaged pouch.
- After balloon preparation for use and prior to use, re-inflate to nominal volume and inspect for any irregularities or damage. Do not use if any inconsistencies areobserved.
- Verify balloon catheter compatibility when using other ancillary devices commonly used in intravascular procedures. Physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.
- The balloon catheter has a lubricious surface and should be hydrated for at least 30 seconds prior to use.Once the balloon catheter is hydrated, do not allow it to dry.
- Protect the balloon when tip steam shaping or purge hole sealing of the balloon catheter as it may affect the integrity of the balloon material.
- Exercise care in handling the balloon catheter to reduce the chance of accidentaldamage. With the exception of dimethyl sulfoxide (DMSO), use of other organicsolvents may damage the balloon catheter and/or coating on the surface.
- DMSO-based embolization materials should only be used in accordance with their neurovascular approved intended use.

Verify that the diameter of any guidewire or accessory used is compatible with the inner diameter of the balloon catheter prior to use.

- Take precaution when manipulating the balloon catheter in tortuous vasculature to avoid damage. Avoid advancement or withdrawal against resistance until the cause of resistance is determined.
- Presence of calcifications, irregularities or existing devices may damage the balloon catheter and potentially affect its insertion or removal.
- Always verify proper balloon vessel occlusion prior to and during embolic material delivery. Sealing the purge hole prior to embolic material delivery may provide assistance during use.

- Excessive torque applied to the syringe might result in damage to the Scepter hub assembly.
- Exercise necessary precautions to limit X-radiation doses to patients and operators by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors where possible.
- Continuing negative aspiration after the balloon is fully deflated will result in blood entering the balloon and will reduce fluoroscopic visibility.

1.4.3 Potential Complications / Adverse Effects

Scepter C/XC balloon catheter

The potential complications / adverse effects for the Scepter C/XC balloon catheter are

vessel or aneurysm perforation, vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudoaneurysm, seizure, stroke, infection, vessel dissection, thrombus formation, and death.

Scepter Mini balloon catheter

The potential complications / adverse effects for the Scepter Mini balloon catheter are:

vessel or aneurysm perforation, vasospasm, hematoma at the site of entry, embolism, ischemia, intracerebral/intracranial hemorrhage, pseudoaneurysm, seizure, stroke, infection, vessel dissection, thrombus formation, and death.

Exposure to angiographic and fluoroscopic X-radiation presents potential risks of alopecia, burns ranging in severity from skin reddening to ulcers, cataracts, and delayed neoplasia that increase in probability as procedure time and number of procedures increase.

1.4.4 Other Aspects of Safety

Data relevant to the clinical safety and performance of the Scepter devices was collected and evaluated from routine data sources from PMS such as complaints, Corrective and Preventative Action (CAPA), as well as post-market clinical follow-up (PMCF). The data has demonstrated the clinical safety of the subject devices.

- From 01 Sep 2020 through 31 Aug 2024, MVI received 1,666 product complaints concerning the Scepter devices, and 139,536 units of the Scepter devices been sold worldwide, resulting in a complaint rate of 1.19% (1,666/139,536). The complaint rate is defined as the number of complaints per sale for the given period. Of these complaints, 112 were considered reportable to EU authorities for a reportable complaint rate of 0.08% (112/139,536).
- There were seven (7) Corrective and Preventive Actions (CAPAs) and no field actions or recalls initiated.

The clinical evidence generated through this PMS will be used in the clinical evaluation of the Scepter devices with the aim of confirming the safety and performance throughout the expected lifetime of the device, of ensuring the continued acceptability of identified risks and of detecting emerging risks.

1.5 Summary of the Clinical Evaluation and PMCF

A Clinical Evaluation of the Scepter devices is continuously updated in conducted in accordance with the requirements in MEDDEV.2.7.1 Revision 4– Guidelines on Medical Devices – Evaluation of Clinical Data: A Guide for Manufacturers and Notified Bodies. It includes the following:

- Literature Based Safety Appraisal
- A search of published relevant and available scientific literature was performed to assess the risks and benefits associated with other similar competitive devices
- Summary of Clinical Studies
- Performance and Safety - Design Verification and Validation Data Analysis
- Product Literature and Instructions for Use
- The CER includes the methodology, literature references and conclusions and are reviewed and signed by an appropriately qualified physician.

The Clinical Evaluation Report, documents available clinical data relevant to the Scepter devices. The available clinical data was collected, appraised, and analyzed, and it was determined that there is sufficient clinical evidence on the safety and performance in accordance with the intended purpose.

The Clinical Evaluation Report documents the benefit-risk profile, including side-effects, in the intended target patient populations and medical indications by assessing the clinical evidence against the hazards and patient harms as informed by the Risk Management and Post-Market Surveillance (PMS) documentation. The report also demonstrates the acceptability of the benefit-risk profile based on the current knowledge and state of the art in the concerned medical fields. Therefore, the clinical evaluation has established that the available clinical data are sufficient to establish conformity with all relevant Safety and Performance Requirements (Annex I) of EU MDR 2017/745 and confirm the safety and performance of the Scepter devices.

In addition, Post-Market Surveillance (PMS) is a continuous process at MicroVention to gather, record, and analyze relevant data on the quality, performance, and safety of a device throughout its entire lifetime actively and systematically. The planning and execution of PMS are conducted in accordance with the European Medical Device Regulation (MDR (EU) 2017/745), Chapter VII, Section 1 Post-Market Surveillance and MicroVention Post Market Procedures.

Given the evidence and data presented in the clinical evaluation and post market surveillance, and when the Scepter devices is used according to the manufacturer's Instructions for Use, the risk to benefit profile is deemed acceptable.

1.5.1 Equivalent Device Clinical Data

Equivalency is not claimed in the clinical evaluation for the Scepter devices.

1.5.2 Pre-CE-Mark Clinical Data

There was no pre-market clinical investigation conducted for the Scepter devices.

1.5.3 Clinical Data

Clinical data sources to evaluate the safety and performance of the Scepter devices was collected from the following reputable data sources*:*

Post-Market Clinical Studies
There were no post-market clinical studies conducted for the Scepter devices.

Published Peer-reviewed Clinical Literature

The literature review presented has shown the clinical use of the Scepter devices for peripheral and neuro vasculature where temporary occlusion is desired in 1,495 patients. 28 Retrospective Studies, one (1) Prospective Study, three (3) Journals and six (6) Case Reports/Case Series. As such, the overall quality of the data from the published clinical studies was high. The analysis of the published literature demonstrates clinical performance outcomes Technical or procedural Success of 80 % to 100% and clinical safety outcomes of Thrombosis, Hemorrhage and Ischemic Lesions ranged from 3.6% to 10.7%.

PMCF Report
Relevant data collected from PMCF activities in the PMCF Report described as routine data sources were integrated into the above data sections. These data sources include,

- Scientific Literature
- Sponsor-initiated post-market clinical studies
- There were no additional PMCF activities initiated to address specific findings of the previous clinical evaluation.

1.5.4 Clinical Performance and 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 Scepter devices. 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 Scepter devices do not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons.

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 Scepter devices. The literature review demonstrated acceptable clinical performance outcomes, shown in high technical success rates and lower complication rates associate with the use of the subject device. The post-market surveillance data demonstrates acceptable overall clinical performance through the high Scepter devices technical success in the vast majority of the patients that the Scepter devices were used for treatment, 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 Scepter devices achieve the performance intended and is suitable for the intended purpose.

Complications directly associated with use of the Scepter Occlusion Balloon Catheters include Thrombosis (3.6%-7.4%) , Bleeding (3.3%) and Ischemic Lesions (3.3%). The thrombosis rate of the similar devices (HyperForm/HyperGlide and Transform) in the state of the art analysis is Thrombosis at 11.6% , Bleeding at 4.6% and Ischemic Lesion at 2.7%. The rate of adverse events identified for Scepter devices are comparatively within acceptable range from the state of the art.

1.5.5 Post-Market Clinical Follow-up

From the evidence provided in this clinical evaluation, no PMCF studies are required for the Scepter devices. The level of clinical evidence presented in this report is sufficient to support conformity to the relevant Essential Requirements, including a favorable benefit/risk ratio. No potential residual risks and/or unclarity on long term clinical performance that may impact the benefit/risk ratio were identified. No concerns were identified regarding the benefit-risk determination, the consistency of that evidence with the intended purpose, including the medical indication(s). This clinical evaluation has demonstrated that the Scepter devices maintain an acceptable safety and performance profile and did not identify any questions relating to clinical safety or performance (i.e., residual risks) when used in accordance with its approved labelling.
Based on the data above, both safety and effectiveness data had no untoward trends or events uncovered through the clinical evaluation, additional (or non-routine) PMCF activities are not required.

1.6 Possible Diagnostic or Therapeutic Alternatives

1.6.1 Treatment Options and Interventions

Intracranial Aneurysms

In unruptured aneurysms, the decision as to whether to treat or observe the malformation is made on a case-by-case basis. The International Study of Unruptured Intracranial Aneurysms (ISUIA) suggested that aneurysm size and location were independent predictors for aneurysm rupture. The primary goal of treating unruptured intracranial aneurysm is to exclude the aneurysm sac from the active intracranial circulation while preserving the parent artery.(Grasso et al., 2017) Given the high mortality rate and poor prognosis associated with ruptured aneurysms, the primary goal of therapy is to prevent aneurysm rupture or re-rupture. Current approaches to treating intracranial aneurysm include observation (no treatment), surgical treatment (including temporary clipping), and endovascular treatment (coiling, stent-assisted coiling and the use of intrasaccular flow disruptors or endoluminal flow diverters).

Surgical Treatment

Surgical treatments for intracranial aneurysm include surgical clipping, bypass, and bipolar coagulation. Simple surgical clipping refers to the practice of the exposure of the aneurysmal neck via craniotomy and the exclusion of the entire abnormal vascular wall from the circulation using single or multiple clips. The key to clipping surgeries lies in good neck exposure, and in cases where visual exposure and clip insertion is limited by the operating field, endoscope-assisted clipping can be used. (Chen et al., 2019)

Bypass techniques occlude the inflow artery and resume regional circulation through a bypass from an extracranial artery (termed extracranial-to-intracranial bypass) or intracranial artery (termed intracranial-to-intracranial bypass). For intracranial complex aneurysms, superficial temporal artery bypass remains a major option that can serve as a flow replacement bypass during aneurysmal trapping or insurance bypass during temporary parent artery occlusion.(Chen et al., 2019)

Bipolar coagulation is a surgical treatment option for microaneurysms, in which aggressive surgery is not required, and clipping is not suitable.(Chen et al., 2019)

Endovascular Coiling

Endovascular coiling is a less invasive, endovascular treatment approach which is an alternative to surgical clipping for the treatment of most intracranial aneurysms. The goal of endovascular coiling is to isolate aneurysms from the active circulation by achieving dense packing of coils and inducing blood clot formation within the aneurysmal sac. Endovascular coiling includes simple coiling, balloon-assisted coiling (BAC), and stent-assisted coiling (SAC). Simple coiling is suitable for all intracranial aneurysms with desirable dome-to-neck ratios (>2.0), excluding blood blister-like aneurysms, as their fragile wall poses high risks of perforation.(Chen et al., 2019) BAC and SAC are often used in wide-necked, giant, fusiform and other complex intracranial aneurysms. Use of permanent SAC and temporary BAC techniques has been developed to prevent coils from prolapsing out of the aneurysm sac during the procedure.(Phan et al., 2016, Shapiro et al., 2012) During SACs, a stent is deployed to cover the aneurysmal neck before coil placement. Different SAC techniques have been developed to assist coil

packing.(Chen et al., 2019) During BAC, one or multiple balloons are temporarily inflated to block the aneurysmal neck before coil packing. Balloon-assisted coiling embolization is an endovascular remodeling technique that employs the use of flexible, compliant balloons to facilitate coil deployment during aneurysm embolization.(Moret et al., 1997) Use of BAC allows wide-neck aneurysms to be coiled by helping to prevent coils from protruding into the parent vessel;(Pierot and Biondi, 2016) outcomes following BAC coiling result in high aneurysms occlusion rates 64%-78% at follow-ups,(Consoli et al., 2016, Invergo and Gordhan, 2012) and lower recurrence rates ranging from 6% to 11%,(Consoli et al., 2016, Invergo and Gordhan, 2012) compared to conventional coiling ranging from 20% to 34%.(Campi et al., 2007, Molyneux et al., 2002, Piotin et al., 2010, Thompson et al., 2015)

Intrasaccular Flow Disruption

Intrasaccular flow disruption involves the placement of a self-expanding, roughly spherically shaped, cage-like devices within the aneurysmal sac to cover the aneurysm neck and promote aneurysm thrombosis and parent artery neoendothelialization. In distinction to the intracranial stents, intrasaccular flow disruption device, such as the WEB™ Device, does not require dual-antiplatelet therapy.(Pierot et al., 2019) For this reason, the WEB™ Device can be used in both ruptured and unruptured aneurysms. Furthermore, only one device is needed to occlude the aneurysmal sac, compared to multiple coils. As such, use of intrasaccular flow disruption devices may shorten the procedure duration and reduce radiation exposure.(Pierot et al., 2019). More recently, the mechanical and technical development of the WEB resulted in expanding the indications for the treatment of intracranial aneurysms (Lee et al., 2022).

Flow Diversion

Flow diverters are placed in the parent artery at the level of the aneurysm neck to disrupt blood flow away from the aneurysmal sac, inducing intra-aneurysmal stasis with subsequent thrombosis while maintaining perfusion to side branches. Instead of acting on the aneurysmal sac, flow diverters act on the parent artery, supporting vessel reconstruction. By disrupting the hemodynamic exchange across the aneurysm neck and into the aneurysmal sac, flow diverters allow re-endothelialization of the parent artery, effectively excluding the aneurysm from the vessel wall.(Maragkos et al., 2020) Flow diverters are suitable for wide-necked, fusiform IAs, ruptured, dissecting, distal, bifurcation, small, previously coiled/clipped and blood blister-like aneurysms. Clinical trials (such as PITA, PUFS, ASPIRe, IntrePED, PFLEX, PREMIER, SAFE, SCENT, PARAT) have demonstrated long-term safety and efficacy outcomes of flow diverters in the treatment of cerebral aneurysms.(Chancellor et al., 2020) A meta-analysis by Giorgianni et al. on 389 aneurysms reported the pooled proportion of aneurysms who had complete aneurysm occlusion as 78% (95% confidential interval (CI), 73%-83%), while the pooled proportion of aneurysm rebleeding and intrastent stenosis was 12% and 15% respectively, for a total of 27% rate (Giorgianni et al., 2022). Li et al. compared the flow diversion with conventional endovascular treatment with 1001 and 1133 patients respectively, concluding that the placement

of a flow diverter may lead to more procedure-related complications, but there is no difference in safety, and it is more effective in the long term (Li et al., 2022).

Arteriovenous Malformations and Arteriovenous Fistulas

Treatment strategies for AVMs and AVFs include surgical resection, endovascular embolization, and microsurgery and radiosurgery.(Ogilvy et al., 2001, Pradilla et al., 2012, Lee et al., 2015) Microsurgery is an invasive procedure that involves a craniotomy to resect the lesion.(Pradilla et al., 2012) This approach is common for patients with AVMs (Pradilla et al., 2012), and specifically remains the cornerstone of Sylvian fissure arteriovenous malformation treatment (Tarokhian et al., 2021). Microsurgery for the treatment of AVFs is often reserved for cases in which other treatment options are not possible or have failed. For example AVFs that have numerous, tortuous arterial feeders that are not amenable to embolization, AVFs with arterial feeders with prominent branches into normal structures near or at the fistulous connection, and AVFs with a long, tortuous feeder that may be difficult to navigate may be candidates for microsurgery.(Pabaney et al., 2016, Pradilla et al., 2012) Stereo static radiosurgery uses radiation to obliterate vascular abnormalities, though complete obliteration may require 1-3 years of treatment and a cure may not be achieved in all cases.(Steinmetz et al., 2004) This treatment approach may be an effective option for patients who are not eligible for embolization or microsurgery.(Niranjan and Lunsford, 2013) Multimodal treatment approaches for AVFs and AVMs are sometimes used, particularly in patients with large lesions that are not amenable to microsurgery alone.(Pradilla et al., 2012, Yang et al., 2013) Obliteration rates, morbidity, and mortality rates for microsurgery and stereotactic radiosurgery vary. A systematic meta-analysis of 137 studies including a total of 13,698 patients found that complete obliteration was achieved in 96% of patients after microsurgery and in 38% of patients after stereotactic radiotherapy.(Steinmetz et al., 2004) Complications leading to permanent neurological deficits or death occurred in 0%-40% of patients after microsurgery and in 0%-21% of patients after stereotactic radiosurgery.(Niranjan and Lunsford, 2013, Steinmetz et al., 2004, Yang et al., 2013) Another systematic review of stereotactic radiosurgery for the treatment of AVFs including 19 studies and 729 patients with 743 AVFs found a mean obliteration rate of 63%.(Chen et al., 2015) Intracranial hemorrhagic complication rate was 1%, neurological deficit was 1%, and mortality was 0.3%.(Chen et al., 2015)

Alternatively, endovascular treatment options for AVMs and AVFs may involve the use of a variety of devices or occlusive agents, including permanent balloons, sclerosing drugs, thrombosing coils, polyvinyl alcohol particles, Onyx™, and rapidly acting glues, such as n-butyl cyanoacrylate (n-BCA).(Meyers et al., 2010, Ogilvy et al., 2001) Embolic agents are used to occlude abnormal vasculature, allowing resection of the lesion and allowing blood to flow through normal vasculature. In a study including over 1,200 patients with morbidity and mortality associated with embolization of intracranial AVMs, low rates of temporary and permanent morbidity were observed after embolization (10% and 8%, respectively), and 1% of patients died after the embolization procedures.(Frizzel and Fisher, 1995) Other studies report that a risk of

permanent morbidity after embolization of 2%-3%.(Meyers et al., 2010) Additionally, subsequent treatments may be performed after embolization; for example, embolization may significantly reduce the size of the lesion, permitting surgical or radio surgical resection of the embolized lesion. A meta-analysis on the results of medical management on uterine malformations in 121 premenopausal women by Rosen et al. reported a success rate of 88% (Rosen et al., 2021).

1.6.2 Available Technologies

Balloon Guide Catheters are well established medical devices with numerous types and styles available from a variety of manufacturers. Examples of Balloon Occlusion Catheters similar to Scepter devices are listed in Table 1.4.

Table 1.4 Similar Devices

Device	Manufacturer	Intended Purpose
HyperForm/ HyperGlide™Occlusion Balloon Catheter	Medtronic	The HyperForm andHyperGlide occlusion balloon catheters are indicated for use in blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired. These cathetersoffer a vessel selective technique of temporary vascular occlusion, which is useful in selectively stopping or controlling blood flow; the occlusion balloon catheters mayalso be used in balloon-assisted embolization of intracranial aneurysms.
Transform Occlusion Balloon Catheter	Stryker	The Stryker NeurovascularTransForm Occlusion Balloon Catheters are indicated for use in theneuro and peripheral vasculature to temporarily stop or control blood flow and for balloon assisted embolization of intracranial aneurysms.

1.7 Suggested Profile and Training for Users

This device should be used only by physicians with neuro or peripheral interventional training and a thorough knowledge of the vascular pathology to be treated, vascular architecture, angiographic techniques, and super-selective embolization techniques.

1.8 Reference to any Harmonized Standards and CS

The Scepter devices was designed, developed, and tested following the standards and guidance documents listed in the tables below.

Standards	Edition	Standard Title
Quality System		
EN ISO 13485	2016 / A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)

Standards	Edition	Standard Title
Risk Management		
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)
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)
EN ISO 20417	2021	Medical devices - Information supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)
Packaging		
EN ISO 11607-1	2020/A11:2022	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	2020/A11:2022	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
ISTA 3A	2018	Packaged-Products for Parcel Delivery System Shipment 150 lbs. (70 kg) or Less
ASTM D4169	2023e1	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F88	2023	Standard Test Method for Seal strength of Flexible Barrier Material
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)
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)
EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)

Standards	Edition	Standard Title
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)
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)
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
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
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)
Biological Indicators		
-EN ISO 11138-1	2017	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)
Ethylene Oxide		
EN ISO 11135	2014 / A1:2019	Sterilization of health care products — Ethylene oxide — Requirements for 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)
Device Specific		
Catheters		
EN ISO 10555-1	2013/A1: 2017	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements (ISO 10555-1:2013A1:2017)
EN ISO 10555-4	2013	Intravenous catheters – Sterile and single use catheters – Part 4: Balloon dilation catheters (ISO 10555-4:2013)
EN ISO 11070	2014/A1:2018	Sterile single-use intravascular introducers, dilators and guidewires (ISO 11070:2014/Amd 1:2018)

Standards	Edition	Standard Title
EN ISO 80369-7	2021	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)
EN ISO 80369-20	2015	Small-bore connectors for liquids and gases in healthcare applications -- Part 20: Common test methods (ISO 80369-20:2015)

1.9 References Cited

CAMPI, A., RAMZI, N., MOLYNEUX, A. J., SUMMERS, P. E., KERR, R. S., SNEADE, M., YARNOLD, J. A., RISCHMILLER, J. & BYRNE, J. V. 2007. Retreatment of ruptured cerebral aneurysms in patients randomized by coiling or clipping in the International Subarachnoid Aneurysm Trial (ISAT). *Stroke,* 38**,** 1538-44.

CHANCELLOR, B., RAZ, E., SHAPIRO, M., TANWEER, O., NOSSEK, E., RIINA, H. A. & NELSON, P. K. 2020. Flow Diversion for Intracranial Aneurysm Treatment: Trials Involving Flow Diverters and Long-Term Outcomes. *Neurosurgery,* 86**,** S36-S45.

CHEN, C. C., CHEN, C. T., HSIEH, P. C., YEAP, M. C. & WU, Y. M. 2021. Rescue embolization with direct coil delivery from dual-lumen balloon microcatheter. *Interv Neuroradiol***,** 15910199211060987.

CHEN, C. J., LEE, C. C., DING, D., STARKE, R. M., CHIVUKULA, S., YEN, C. P., MOOSA, S., XU, Z., PAN, D. H. & SHEEHAN, J. P. 2015. Stereotactic radiosurgery for intracranial dural arteriovenous fistulas: a systematic review. *J Neurosurg,* 122**,** 353-62.

CHEN, C. T., CHEN, C. C., WANG, A. Y., WU, Y. M., CHIN, S. C., HSIEH, P. C., YEAP, M. C., HSU, S. Y. & LIN, Y. J. 2020. Early strategy of scepter XC balloon angioplasty and simultaneous Nimodipine infusion for vasospasm following ruptured aneurysm. *BMC Neurol,* 20**,** 271.

CHEN, S. H., SNELLING, B. M., SHAH, S. S., SUR, S., BRUNET, M. C., STARKE, R. M., YAVAGAL, D. R., OSBUN, J. W. & PETERSON, E. C. 2019. Transradial approach for flow diversion treatment of cerebral aneurysms: a multicenter study. *J Neurointerv Surg,* 11**,** 796-800.

CONSOLI, A., VIGNOLI, C., RENIERI, L., ROSI, A., CHIAROTTI, I., NAPPINI, S., LIMBUCCI, N. & MANGIAFICO, S. 2016. Assisted coiling of saccular wide-necked unruptured intracranial aneurysms: stent versus balloon. *J Neurointerv Surg,* 8**,** 52-7.

FRIZZEL, R. T. & FISHER, W. S., 3RD 1995. Cure, morbidity, and mortality associated with embolization of brain arteriovenous malformations: a review of 1246 patients in 32 series over a 35-year period. *Neurosurgery,* 37**,** 1031-9; discussion 1039-40.

GIORGIANNI, A., AGOSTI, E., MOLINARO, S., TERRANA, A. V., VIZZARI, F. A., NATIVO, L., GARG, K., CRAPARO, G., CONTI, V., LOCATELLI, D., BARUZZI, F., VALVASSORI, L. & LANZINO, G. 2022. Flow Diversion for Acutely Ruptured

Intracranial Aneurysms Treatment: A Retrospective Study and Literature Review. *J Stroke Cerebrovasc Dis,* 31**,** 106284.

GRASSO, G., ALAFACI, C. & MACDONALD, R. L. 2017. Management of aneurysmal subarachnoid hemorrhage: State of the art and future perspectives. *Surg Neurol Int,* 8**,** 11.

GROSS, B. A., TONETTI, D. A., WEINER, G. M., PANCZYKOWSKI, D. M., ARES, W. J., KENMUIR, C. L., JADHAV, A. P., JOVIN, T. G. & JANKOWITZ, B. T. 2017. Septoplasty: Scepter Balloon Angioplasty for Vasospasm after Aneurysmal Subarachnoid Hemorrhage. *Interv Neurol,* 6**,** 229-235.

HAFAZALLA, K., BALDASSARI, M. P., SWEID, A., STARKE, R., SAJJA, K., LEBOVITZ, J., STOREY, C., HERIAL, N., TJOUMAKARIS, S., GOOCH, M. R., ZARZOUR, H., ROSENWASSER, R. & JABBOUR, P. 2020. A comparison of dual-lumen balloon and simple microcatheters in the embolization of DAVFs and AVMs using onyx. *J Clin Neurosci,* 81**,** 295-301.

INVERGO, D. & GORDHAN, A. 2012. Endovascular treatment of cerebral aneurysms at a low-volume community hospital practice: management strategies, complications, and outcomes. *J Neuroimaging,* 22**,** 233-42.

JAGADEESAN, B. D., GRANDE, A. W. & TUMMALA, R. P. 2018. Safety and Feasibility of Balloon-Assisted Embolization with Onyx of Brain Arteriovenous Malformations Revisited: Personal Experience with the Scepter XC Balloon Microcatheter. *Interv Neurol,* 7**,** 439-444.

JANG, C. K., KIM, B. M., PARK, K. Y., LEE, J. W., KIM, D. J., CHUNG, J. & KIM, J. H. 2021. Scepter dual-lumen balloon catheter for Onyx embolization for dural arteriovenous fistula. *BMC Neurol,* 21**,** 31.

JEREMIC, P. A., DO NASCIMENTO, V. C., RICE, H. & VILLIERS, L. 2022. Single Centre Initial Experience with the Scepter Mini Balloon Microcatheter. *Interv Neuroradiol***,** 15910199221128442.

LEE, K. B., SUH, C. H., SONG, Y., KWON, B., KIM, M. H., YOON, J. T. & LEE, D. H. 2022. Trends of Expanding Indications of Woven EndoBridge Devices for the Treatment of Intracranial Aneurysms: A Systematic Review and Meta-analysis. *Clin Neuroradiol*.

LEE, S. K., HETTS, S. W., HALBACH, V., TERBRUGGE, K., ANSARI, S. A., ALBANI, B., ABRUZZO, T., ARTHUR, A., ALEXANDER, M. J., ALBUQUERQUE, F. C., BAXTER, B., BULSARA, K. R., CHEN, M., DELGADO ALMANDOZ, J. E., FRASER, J. F., FREI, D., GANDHI, C. D., HECK, D., HUSSAIN, M. S., KELLY, M., KLUCZNIK, R., LESLIE-MAZWI, T., MCTAGGART, R. A., MEYERS, P. M., PATSALIDES, A., PRESTIGIACOMO, C., PRIDE, G. L., STARKE, R., SUNENSHINE, P., RASMUSSEN, P., JAYARAMAN, M. V., STANDARD & GUIDELINES COMMITTEE FOR THE SOCIETY OF NEUROINTERVENTIONAL, S. 2015. Standard and Guidelines: Intracranial Dural Arteriovenous Shunts. *J Neurointerv Surg*.

LI, S., ZENG, C., TAO, W., HUANG, Z., YAN, L., TIAN, X. & CHEN, F. 2022. The Safety and Efficacy of Flow Diversion versus Conventional Endovascular Treatment for Intracranial Aneurysms: A Meta-analysis of Real-world Cohort Studies from the Past 10 Years. *AJNR Am J Neuroradiol,* 43**,** 1004-1011.

MARAGKOS, G. A., DMYTRIW, A. A., SALEM, M. M., TUTINO, V. M., MENG, H., COGNARD, C., MACHI, P., KRINGS, T. & MENDES PEREIRA, V. 2020. Overview of Different Flow Diverters and Flow Dynamics. *Neurosurgery,* 86**,** S21-S34.

MARTINEZ-GALDAMEZ, M., ORLOV, K., KADZIOLKA, K., PUTHURAN, M., KALOUSEK, V., PABON, B., ESCARTIN, J., RODRIGUEZ, C., CHANDRAN, A., KISLITSIN, D., BERESTOV, V., VEGA, P., DIAZ, C. & DABUS, G. 2019. Safety and efficacy of intracranial aneurysm embolization using the "combined remodeling technique": low-profile stents delivered through double lumen balloons: a multicenter experience. *Neuroradiology,* 61**,** 1067-1072.

MEYERS, P. M., SCHUMACHER, H. C., HIGASHIDA, R. T., BARNWELL, S. L., CREAGER, M. A., GUPTA, R., MCDOUGALL, C. G., PANDEY, D. K., SACKS, D. & WECHSLER, L. R. 2010. Indications for the performance of intracranial endovascular neurointerventional procedures. A scientific statement from the American Heart Association Council on Cardiovascular Radiology and Intervention, Stroke Council, Council on Cardiovascular Surgery and Anesthesia, Interdisciplinary Council on Peripheral Vascular Disease, and Interdisciplinary Council on Quality of Care and Outcomes Research. *J Neurointerv Surg,* 2**,** 177-88.

MOLYNEUX, A., KERR, R., STRATTON, I., SANDERCOCK, P., CLARKE, M., SHRIMPTON, J., HOLMAN, R. & INTERNATIONAL SUBARACHNOID ANEURYSM TRIAL COLLABORATIVE, G. 2002. International Subarachnoid Aneurysm Trial (ISAT) of neurosurgical clipping versus endovascular coiling in 2143 patients with ruptured intracranial aneurysms: a randomised trial. *Lancet,* 360**,** 1267-74.

MORET, J., COGNARD, C., WEILL, A., CASTAINGS, L. & REY, A. 1997. The "Remodelling Technique" in the Treatment of Wide Neck Intracranial Aneurysms. Angiographic Results and Clinical Follow-up in 56 Cases. *Interv Neuroradiol,* 3**,** 21-35.

NIRANJAN, A. & LUNSFORD, L. D. 2013. Stereotactic radiosurgery guidelines for the management of patients with intracranial dural arteriovenous fistulas. *Prog Neurol Surg,* 27**,** 218-26.

OGILVY, C. S., STIEG, P. E., AWAD, I., BROWN, R. D., JR., KONDZIOLKA, D., ROSENWASSER, R., YOUNG, W. L., HADEMENOS, G. & STROKE COUNCIL, A. S. A. 2001. Recommendations for the management of intracranial arteriovenous malformations: a statement for healthcare professionals from a special writing group of the Stroke Council, American Stroke Association. *Circulation,* 103**,** 2644-57.

PABANEY, A. H., ROBIN, A. M., BASHEER, A. & MALIK, G. 2016. Surgical Management of Dural Arteriovenous Fistula After Craniotomy: Case Report and Review of Literature. *World Neurosurg,* 89**,** 731.e7-731.e11.

PHAN, K., HUO, Y. R., JIA, F., PHAN, S., RAO, P. J., MOBBS, R. J. & MORTIMER, A. M. 2016. Meta-analysis of stent-assisted coiling versus coiling-only for the treatment of intracranial aneurysms. *J Clin Neurosci,* 31**,** 15-22.

PIEROT, L., ARTHUR, A. S., FIORELLA, D. & SPELLE, L. 2019. Intrasaccular Flow Disruption with WEB Device: Current Place and Results in Management of Intracranial Aneurysms. *World Neurosurg,* 122**,** 313-316.

PIEROT, L. & BIONDI, A. 2016. Endovascular techniques for the management of wide-neck intracranial bifurcation aneurysms: A critical review of the literature. *J Neuroradiol,* 43**,** 167-75.

PIOTIN, M., BLANC, R., SPELLE, L., MOUNAYER, C., PIANTINO, R., SCHMIDT, P. J. & MORET, J. 2010. Stent-assisted coiling of intracranial aneurysms: clinical and angiographic results in 216 consecutive aneurysms. *Stroke,* 41**,** 110-5.

PRADILLA, G., COON, A. L., HUANG, J. & TAMARGO, R. J. 2012. Surgical treatment of cranial arteriovenous malformations and dural arteriovenous fistulas. *Neurosurg Clin N Am,* 23**,** 105-22.

RHO, M. H., KIM, B. M., SUH, S. H., KIM, D. J. & KIM, D. I. 2013. Initial experience with the new double-lumen scepter balloon catheter for treatment of wide-necked aneurysms. *Korean J Radiol,* 14**,** 832-40.

ROSEN, A., CHAN, W. V., MATELSKI, J., WALSH, C. & MURJI, A. 2021. Medical treatment of uterine arteriovenous malformation: a systematic review and meta-analysis. *Fertil Steril,* 116**,** 1107-1116.

SHAPIRO, M., BECSKE, T., SAHLEIN, D., BABB, J. & NELSON, P. K. 2012. Stent-supported aneurysm coiling: a literature survey of treatment and follow-up. *AJNR Am J Neuroradiol,* 33**,** 159-63.

SIRAKOV, A., BHOGAL, P., BOGOVSKI, S., MATANOV, S., MINKIN, K., HRISTOV, H., NINOV, K., KARAKOSTOV, V., PENKOV, M. & SIRAKOV, S. 2022. Comaneci plus Balloon-assisted Embolization of Ruptured Wide-necked Cerebral Aneurysms. *Clin Neuroradiol,* 32**,** 773-782.

SPIOTTA, A. M., MIRANPURI, A., HAWK, H., CHAUDRY, M. I., TURK, A. S. & TURNER, R. D. 2013. Balloon remodeling for aneurysm coil embolization with the coaxial lumen Scepter C balloon catheter: initial experience at a high volume center. *J Neurointerv Surg,* 5**,** 582-5.

STEINMETZ, M. P., CHOW, M. M., KRISHNANEY, A. A., ANDREWS-HINDERS, D., BENZEL, E. C., MASARYK, T. J., MAYBERG, M. R. & RASMUSSEN, P. A. 2004. Outcome after the treatment of spinal dural arteriovenous fistulae: a contemporary single-institution series and meta-analysis. *Neurosurgery,* 55**,** 77-87; discussion 87-8.

TAKAHIRA, K., KATAOKA, T., OGINO, T., ENDO, H. & NAKAMURA, H. 2017. Efficacy of a coaxial system with a compliant balloon catheter for navigation of the Penumbra reperfusion catheter in tortuous arteries: technique and case experience. *J Neurosurg,* 126**,** 1334-1338.

TAROKHIAN, A., SABAHI, M., DMYTRIW, A. A. & ARJIPOUR, M. 2021. Sylvian fissure arteriovenous malformations: case series and systematic review of the literature. *Neuroradiol J,* 34**,** 656-666.

THOMPSON, B. G., BROWN, R. D., JR., AMIN-HANJANI, S., BRODERICK, J. P., COCKROFT, K. M., CONNOLLY, E. S., JR., DUCKWILER, G. R., HARRIS, C. C., HOWARD, V. J., JOHNSTON, S. C., MEYERS, P. M., MOLYNEUX, A., OGILVY, C. S., RINGER, A. J., TORNER, J., AMERICAN HEART ASSOCIATION STROKE COUNCIL, C. O. C., STROKE, N., COUNCIL ON, E., PREVENTION, AMERICAN

HEART, A. & AMERICAN STROKE, A. 2015. Guidelines for the Management of Patients With Unruptured Intracranial Aneurysms: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke,* 46**,** 2368-400.

TSOGKAS, I., MALINOVA, V., SCHREGEL, K., MIELKE, D., BEHME, D., ROHDE, V., KNAUTH, M. & PSYCHOGIOS, M. N. 2020. Angioplasty with the scepter C dual lumen balloon catheter and postprocedural result evaluation in patients with subarachnoid hemorrhage related vasospasms. *BMC Neurol,* 20**,** 260.

VOLLHERBST, D. F., CHAPOT, R., WALLOCHA, M., SAATCI, I., CEKIRGE, S., ROUCHAUD, A., MOUNAYER, C., KOCER, N., KIZILKILIC, O., SOUROUR, N. A., SHOTAR, E., PSYCHOGIOS, M. N., BREHM, A., BENDSZUS, M. & MOHLENBRUCH, M. A. 2021. First clinical multicenter experience with the new Scepter Mini microballoon catheter. *J Neurointerv Surg,* 13**,** 261-266.

WALLACE, A. N., KAYAN, Y., DELGADO ALMANDOZ, J. E., FEASE, J. L., MILNER, A. A. & SCHOLZ, J. M. 2019a. Endovascular Treatment of Wide-Necked Intracranial Aneurysms with the Scepter XC Balloon Catheter, with Low-Profile Visualized Intraluminal Support (LVIS) Jr. Deployment as a "Bailout" Technique. *World Neurosurg,* 121**,** e798-e807.

WALLACE, A. N., SAMANIEGO, E., KAYAN, Y., DERDEYN, C. P., DELGADO ALMANDOZ, J. E., DANDAPAT, S., FEASE, J. L., THOMAS, M., MILNER, A. M., SCHOLZ, J. M. & ORTEGA-GUTIERREZ, S. 2019b. Balloon-assisted coiling of cerebral aneurysms with the dual-lumen Scepter XC balloon catheter: Experience at two high-volume centers. *Interv Neuroradiol,* 25**,** 414-418.

WHITE, T. G., SHAH, K. A., TURPIN, J., DEHDASHTI, A. R., LINK, T., KATZ, J. M. & WOO, H. H. 2021. Single institution early clinical experience with the Scepter Mini balloon catheter. *Neuroradiol J,* 34**,** 562-567.

YANG, H., KANO, H., KONDZIOLKA, D., NIRANJAN, A., FLICKINGER, J. C., HOROWITZ, M. B. & LUNSFORD, L. D. 2013. Stereotactic radiosurgery with or without embolization for intracranial dural arteriovenous fistulas. *Prog Neurol Surg,* 27**,** 195-204.

Bibliography
Jeremic, P. A., do Nascimento, V. C., Rice, H., Villiers, L.. Single Centre Initial Experience with the Scepter Mini Balloon Microcatheter. *Interv Neuroradiol.* 2022. #volume#:15910199221128442
Vollherbst, D. F., Chapot, R., Wallocha, M., Saatci, I., Cekirge, S., Rouchaud, A., Mounayer, C., Kocer, N., Kizilkilic, O., Sourour, N. A., Shotar, E., Psychogios, M. N., Brehm, A., Bendszus, M., Möhlenbruch, M. A.. First clinical multicenter experience with the new Scepter Mini microballoon catheter. *J Neurointerv Surg*. 2021. 13:261-266
Ahn, J. H., Cho, Y. D., Kang, H. S., Kim, J. E., Cho, W. S., Jung, S. C., Kim, C. H., Han, M. H.. Endovascular treatment of ophthalmic artery aneurysms: Assessing balloon test occlusion and preservation of vision in coil embolization. *American Journal of Neuroradiology*. 2014. 35:2146-2152

Bibliography
Aydin, K., Stracke, P., Berdikhojayev, M., Barburoglu, M., Mosimann, P. J., Suleimankulov, N., Sarshayev, M., Sencer, S., Chapot, R.. Safety, Efficacy, and Durability of Stent plus Balloon-Assisted Coiling for the Treatment of Wide-Necked Intracranial Bifurcation Aneurysms. *Neurosurgery*. 2021. 88:1028-1037
Borota, L., Mahmoud, E., Nyberg, C., Lewén, A., Enblad, P., Ronne-Engström, E.. Dual lumen balloon catheter – An effective substitute for two single lumen catheters in treatment of vascular targets with challenging anatomy. *Journal of Clinical Neuroscience*. 2018. 51:91-99
Clarençon, F., Papagiannaki, C., Saleme, S., Rouchaud, A., Shotar, E., Rius, E., Burel, J., Boch, A. L., Sourour, N. A., Mounayer, C.. Balloon Pressure Technique with the Scepter Mini Balloon as Part of the Endovascular Strategy for Brain Arteriovenous Malformations Embolization: Preliminary Multicenter Experience. *Clinical Neuroradiology*. 2023. #volume#:#pages#
Dabus, G., Linfante, I., Martínez-Galdámez, M.. Endovascular treatment of dural arteriovenous fistulas using dual lumen balloon microcatheter: Technical aspects and results. *Clinical Neurology and Neurosurgery*. 2014. 117:22-27
Fiorella, D., Peeling, L.. Balloon-assisted guide catheter positioning to overcome extreme cervical carotid tortuosity: Technique and case experience. Journal of NeuroInterventional Surgery. 2013. 5:A27
Hafazalla, K., Baldassari, M. P., Sweid, A., Starke, R., Sajja, K., Lebovitz, J., Storey, C., Herial, N., Tjoumakaris, S., Gooch, M. R., Zarzour, H., Rosenwasser, R., Jabbour, P.. A comparison of dual-lumen balloon and simple microcatheters in the embolization of DAVFs and AVMs using onyx. *Journal of Clinical Neuroscience*. 2020. 81:295-301
Jagadeesan, B. D., Grande, A. W., Tummala, R. P.. Safety and Feasibility of Balloon-Assisted Embolization with Onyx of Brain Arteriovenous Malformations Revisited: Personal Experience with the Scepter XC Balloon Microcatheter. *Interventional Neurology*. 2018. 7:439-444
Jagadeesan, B. D., Siddiq, F., Grande, A. W., Tummala, R. P.. Modified balloon assisted coil embolization for the treatment of intracranial and cervical arterial aneurysms using coaxial dual lumen balloon microcatheters: Initial experience. *Journal of NeuroInterventional Surgery*. 2014. 6:704-707
Jang, C. K., Kim, B. M., Park, K. Y., Lee, J. W., Kim, D. J., Chung, J., Kim, J. H.. Scepter dual-lumen balloon catheter for Onyx embolization for dural arteriovenous fistula. *BMC Neurology*. 2021. 21:#pages#
Kular, S., Tse, G., Pahwa, B., Goddard, T., Saleem, N., Nagaraja, S., Dyde, R., Patankar, T.. Micro-balloon-assisted embolization of anterior cranial fossa dural arteriovenous fistula via a trans-ophthalmic approach — a technical report and case series. *Neuroradiology*. 2022. 64:1269-1274
Lebovitz, J., Storey, C., Sweid, A., Tjoumakaris, S., Gooch, M. R., Rosenwasser, R., Jabbour, P.. Onyx Embolization of Spinal Arteriovenous Fistula via Scepter Balloon. *World Neurosurgery*. 2020. 134:62-66
Martínez-Galdámez, M., Orlov, K., Kadziolka, K., Puthuran, M., Kalousek, V., Pabón, B., Escartín, J., Rodríguez, C., Chandran, A., Kislitsin, D., Berestov, V., Vega, P., Diaz, C., Dabus, G.. Safety and efficacy of

Bibliography
intracranial aneurysm embolization using the "combined remodeling technique": low-profile stents delivered through double lumen balloons: a multicenter experience. *Neuroradiology*. 2019. 61:1067-1072
Mendes, G. A. C., Silveira, E. P., Saleme, S., Losif, C., Ponomarjova, S., Caire, F., Mounayer, C.. Balloon-assisted microcatheter navigation for AVM embolization: Technical note. *Journal of Neurosurgery*. 2015. 123:1120-1124
Omura, Y., Imamura, H., Tani, S., Adachi, H., Fukumitsu, R., Sunohara, T., Fukui, N., Sasaki, N., Fukuda, T., Akiyama, T., Kajiura, S., Shigeyasu, M., Asakura, K., Horii, R., Sakai, N.. A Damp-and-Push Technique for the Copolymer (Onyx) Embolization of Dural Arteriovenous Fistula. *Journal of Stroke and Cerebrovascular Diseases*. 2021. 30:#pages#
Paramasivam, S., Niimi, Y., Fifi, J., Berenstein, A.. Onyx embolization using dual-lumen balloon catheter: Initial experience and technical note. *Journal of Neuroradiology*. 2013. 40:294-302
Rho, M. H., Kim, B. M., Suh, S. H., Kim, D. J., Kim, D. I.. Initial experience with the new double-lumen scepter balloon catheter for treatment of wide-necked aneurysms. *Korean Journal of Radiology*. 2013. 14:832-840
Rose, S. C., Berman, Z. T., Fischman, A. M., Young, L. B., Flanagan, S., Katz, M. D., Diiulio, M., Kuban, J. D., Golzarian, J.. Inline Balloon Occlusion–Assisted Delivery of Ethylene Vinyl Alcohol Copolymer for Peripheral Arterial Applications: A Multicenter Case Series. *Journal of Vascular and Interventional Radiology*. 2020. 31:986-992
Samaniego, E. A., Martínez-Galdámez, M., Abdo, G.. Treatment of direct carotid-cavernous fistulas with a double lumen balloon. *Journal of NeuroInterventional Surgery*. 2016. 8:531-535
Sirakov, A., Bhogal, P., Bogovski, S., Matanov, S., Minkin, K., Hristov, H., Ninov, K., Karakostov, V., Penkov, M., Sirakov, S.. Comaneci plus Balloon-assisted Embolization of Ruptured Wide-necked Cerebral Aneurysms. *Clinical Neuroradiology*. 2022. 32:773-782
Spiotta, A. M., Miranpuri, A., Hawk, H., Chaudry, M., Turk, A. S., Turner, R. D.. Balloon remodeling for aneurysm coil embolization with the coaxial lumen Scepter C balloon catheter: Initial experience at a high volume center. *Journal of NeuroInterventional Surgery*. 2013. 5:582-585
Takahira, K., Kataoka, T., Ogino, T., Endo, H., Nakamura, H.. Efficacy of a coaxial system with a compliant balloon catheter for navigation of the Penumbra reperfusion catheter in tortuous arteries: Technique and case experience. *Journal of Neurosurgery*. 2017. 126:1334-1338
Tao, Y., Niu, Y., Zhu, G., Chen, Z.. Endovascular treatment of a traumatic dural arteriovenous fistula of the superior sagittal sinus using dual lumen balloon microcatheter. *Neurosciences*. 2016. 21:158-160
Wallace, A. N., Kayan, Y., Delgado Almandoz, J. E., Fease, J. L., Milner, A. A., Scholz, J. M.. Endovascular Treatment of Wide-Necked Intracranial Aneurysms with the Scepter XC Balloon Catheter, with Low-Profile Visualized Intraluminal Support (LVIS) Jr. Deployment as a "Bailout" Technique. *World Neurosurgery*. 2019. 121:e798-e807

Bibliography

White, T. G., Shah, K. A., Turpin, J., Dehdashti, A. R., Link, T., Katz, J. M., Woo, H. H.. Single institution early clinical experience with the Scepter Mini balloon catheter. *Neuroradiology Journal*. 2021. 34:562-567

Zamponi, J. O., Trivelato, F. P., Rezende, M. T. S., Freitas, R. K., De Castro-Afonso, L. H., Nakiri, G. S., Abud, T. G., Ulhôa, A. C., Abud, D. G.. Transarterial treatment of cranial dural arteriovenous fistulas: The role of transarterial and transvenous balloon-assisted Embolization. *American Journal of Neuroradiology*. 2020. 41:2100-2106

Zhang, T., Cai, Y., Wang, L., Yang, L., Li, Z., Wei, W., Feng, Y., Xiong, Z., Zou, Y., Sun, W., Zhao, W., Chen, J.. Visualization balloon occlusion-assisted technique in the treatment of large or giant paraclinoid aneurysms: A study of 17 cases series. *Frontiers in Neurology*. 2023. 14:#pages#

Zhang, X., Guo, W., Shen, R., Sun, J., Yin, J., Chen, X., Gao, L., Chen, Z., Zhang, Q.. Combined use of Onyx and coils for transarterial balloon-assisted embolization of traumatic carotid-cavernous fistulas: A report of 16 cases with 17 fistulas. *Journal of NeuroInterventional Surgery*. 2016. 8:1264-1267

Machi, P, Costalat, Vincent, Lobotesis, K, Ruiz, C, Cheikh, YB, Eker, O, Gascou, G, Danière, F, Riquelme, C, Bonafe, Alain. LEO baby stent use following balloon-assisted coiling: single-and dual-stent technique—immediate and midterm results of 29 consecutive patients. *American Journal of Neuroradiology*. 2015. 36:2096-2103

Deniwar, Mohamed Adel, Ahmad, Saima, Eldin, Ashraf Ezz. Transarterial Embolization of Intracranial Arteriovenous Fistulas with Large Venous Pouches in the Form of Venous Outlet Ectasia and Large Venous Varix or Aneurysm: Two Centers Experience. *Journal of Korean Neurosurgical Society*. 2022. 65:30-39

Brzegowy, Paweł, Kucybała, Iwona, Krupa, Kamil, Łasocha, Bartłomiej, Wilk, Aleksander, Latacz, Paweł, Urbanik, Andrzej, Popiela, Tadeusz J. Angiographic and clinical results of anterior communicating artery aneurysm endovascular treatment. *Videosurgery and Other Miniinvasive Techniques*. 2019. 14:451-460

Park, Yu-jung, Roh, Jieun, Baik, Seung Kug, Yeom, Jeong A, Kang, Chul-Hoo, Jeong, Hee Seok, Lee, Sang Won. Single Center Experience of the Balloon-Stent Technique for the Treatment of Unruptured Distal Internal Carotid Artery Aneurysms: Sharing a Simple and Reliable Tip to Use Scepter-Atlas Combination. *Journal of the Korean Society of Radiology (Taehan Yŏngsang Ŭihakhoe chi).* 2021. 82:1258

Ito, Yoshiro, Matsumaru, Yuji, Hosoo, Hisayuki, Tanaka, Shun, Araki, Kota, Okune, Sho, Hirata, Koji, Marushima, Aiki, Hayakawa, Mikito, Ishikawa, Eiichi. Chronological Changes in Embolization for Cerebral Arteriovenous Malformations: Impact of Endovascular Treatment Device Advancements. Journal of Neuroendovascular Therapy. 2024. #volume#:oa. 2024-0041

Lee, S., Kubota, M., Tajima, Y., Kojima, I., Higuchi, Y.. Transarterial embolization of radicular arteriovenous fistula at the craniocervical junction. Radiology Case Reports. 2024. 19:1712-1717

351,Saal-Zapata, G., Durand-Castro, W., Valer-Gonzales, D., Flores-Quijaite, J. E. M., Rodriguez-Varela, R.. Endovascular trends in the treatment of intracranial aneurysms in a Peruvian reference center. Journal of Neurosciences in Rural Practice. 2023. 14:655-659

Bibliography
Su, X., Song, Z., Ma, Y.. An isolated Sinus Intracranial Dural Arteriovenous Fistula with Unusual Drainage Pattern. World Neurosurgery. 2024. 184:3-4