



Summary of Safety and Clinical Performance
for
SOFIA™ Catheter Family
SSCP22-0003

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DOCUMENT CHANGE HISTORY

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B	Updating using content provided in CER21-0000D, addition of SOFIA 88 information	☒ Yes ☐ No* Validation language: English
C	External standard references were revised per section 1.8. Add various missed sections to align with template.	☐ Yes ☒ No* Validation language:
D	Revision update to reflect the latest template and information	☐ Yes ☒ No* Validation language:
E	Section 1.8: External standard references were revised.	☐ Yes ☒ No* Validation language:
F	Section 1.8: External standard references revised.	☐ Yes ☒ No* Validation language:
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*Annual entries must be included. An entry stating such must be added if a revision is not required.

TABLE OF CONTENTS

1	SUMMARY OF SAFETY AND CLINICAL PERFORMANCE.....	4
1.1	Device Identification and General Information	4
1.2	Intended Purpose of the Device	5
1.3	Device Description.....	6
1.4	Risks and Warnings	8
1.4.1	Residual Risks and Undesirable Effects	8
1.4.2	Warnings and Precautions.....	8
1.4.3	Potential Complications / Adverse Effects	12
1.4.4	Other Aspects of Safety	13
1.5	Summary of the Clinical Evaluation and PMCF	13
1.5.1	Equivalent Device Clinical Data.....	13
1.5.2	Pre-CE-Mark Clinical Data.....	13
1.5.3	Clinical Data	13
1.5.4	Clinical Performance and Safety	14
1.5.5	Post-Market Clinical Follow-up	14
1.6	Possible Diagnostic or Therapeutic Alternatives	14
1.6.1	Treatment Options and Interventions.....	14
1.6.2	Available Technologies	16
1.7	Suggested Profile and Training for Users	16
1.8	Reference to any Harmonized Standards and CS	16
1.9	References.....	19

LIST OF TABLES

Table 1.1	Device Identification and General Information	4
Table 1.2	Intended Use	5
Table 1.3	Device Description	6
Table 1.4	Benefits/Risk of Standard of Care	14
Table 1.5	Similar Devices.....	16
Table 1.6	Harmonized Standards.....	17

1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

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

The following information is intended for users/healthcare professionals.

1.1 Device Identification and General Information

Table 1.1 Device Identification and General Information

Device Names	
Device Trade Name	SOFIA Catheter , SOFIA EX Catheter
EMDN Code	SOFIA Catheter: C0104020207 Peripheral Thrombectomy and Thromboaspiration Systems SOFIA EX Catheter: C0104020204 Peripheral Angiography Guide Catheters
Medical Device Nomenclature (EMDN)	C0104020207 Peripheral Thrombectomy and Thromboaspiration Systems C0104020204 Peripheral Angiography Guide Catheters
Device Class	Class III
Basic UDI-DI	37015174SOFIAJ9 (MicroVention Europe [MVE]) 08402732SOFIAGZ (MicroVention, Inc. [MVI])
Year when first certificate (CE) was issued for the device	SOFIA Catheter: 2013 SOFIA EX Catheter: 2019
Legal Manufacturer (MVI)	
Name & Address	MicroVention, Inc. 35 Enterprise Aliso Viejo, California, 92656 USA
Manufacturer SRN	US-MF-000016658
Authorized Representative	
Name & Address	MicroVention Europe SARL (referred to as MVE) 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye, France
Authorized Representative SRN	FR-AR-000004448
Legal Manufacturer (MVE)	
Name & Address	MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye, France
Manufacturer SRN	FR-MF-000004449
Notified Body	
Name & Address	DQS Medizinprodukte GmbH August-Schanz-Straße 21 D-60433 Frankfurt am Main Germany
Notified Body Identification Number	0297

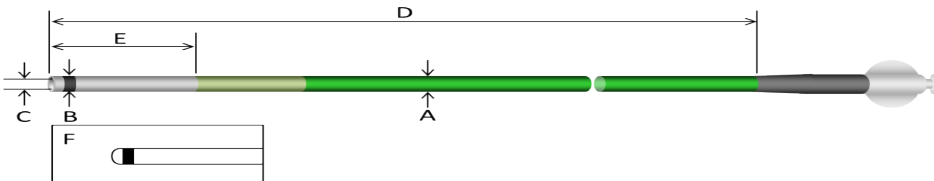
1.2 Intended Purpose of the Device

Table 1.2 Intended Use

Intended Purpose	
Intended Purpose	SOFIA Catheters: - The SOFIA Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA Catheter can be used to facilitate introduction of diagnostic or therapeutic agents. The SOFIA Catheter is not intended for use in coronary arteries. Moreover, the SOFIA Catheter is intended for use in removal/aspiration of emboli and thrombi from selected blood vessels in the arterial system, including the peripheral and neuro vasculatures. SOFIA EX Catheters: - The SOFIA EX Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA EX Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA EX Catheter is not intended for use in coronary arteries.
Indications for Use	SOFIA Catheters: - The SOFIA Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA Catheter can be used to facilitate introduction of diagnostic or therapeutic agents. The SOFIA Catheter is not intended for use in coronary arteries. Moreover, the SOFIA Catheter is intended for use in removal/aspiration of emboli and thrombi from selected blood vessels in the arterial system, including the peripheral and neuro vasculatures. SOFIA EX Catheters: - The SOFIA EX Catheter is indicated for general intravascular use, including the neuro and peripheral vasculature. The SOFIA EX Catheter can be used to facilitate introduction of diagnostic agents or therapeutic devices. The SOFIA EX Catheter is not intended for use in coronary arteries.
Target Population	SOFIA Catheters: - The intended patient population are those who need introduction of diagnostic or therapeutic agents in the vessels or removal of emboli or thrombi from vessels. The anatomic area of use of SOFIA Catheter is peripheral and neuro vasculature. The device is not used in the coronary arteries. SOFIA EX Catheters: - The intended patient population are those who need introduction of diagnostic or therapeutic agents in the vessels. The anatomic area of use of SOFIA EX Catheter is peripheral and neuro vasculature. The device is not used in the coronary arteries.
Contraindications and/or Limitations	There are no known contraindications.

1.3 Device Description

Table 1.3 Device Description

Device Description																																																						
Description of the Device	Design and Specifications The SOFIA Catheters are braid plus coil reinforced, single lumen, variable stiffness catheters with a shapeable distal segment. The distal segment is designed to facilitate vessel selection with a hydrophilic coating for navigation through the vasculature. A radiopaque marker is located at the distal end of the catheters for visualization under fluoroscopy (See figure below). The SOFIA EX Catheters are single-lumen, flexible catheters equipped with a coil and braid reinforcement. The distal segment is designed to facilitate vessel selection with a hydrophilic coating for navigation through the vasculature. A radiopaque marker is located at the distal end of the catheters for visualization under fluoroscopy (See figure below).																																																					
																																																						
	<table><tr><th></th><th>Parameter</th><th>SOFIA 5F</th><th colspan="2">SOFIA 6F</th><th>SOFIA EX</th><th>SOFIA 88</th></tr><tr><td>A</td><td>Diameter (outer), proximal</td><td>0.068 in / 1.7 mm</td><td colspan="2">0.0835 in / 2.1 mm</td><td>0.071 in / 1.8 mm</td><td>0.108 in / 2.74 mm</td></tr><tr><td>B</td><td>Diameter (outer), distal</td><td>0.067 in / 1.7 mm</td><td colspan="2">0.0825 in / 2.1 mm</td><td>0.068 in / 1.7 mm</td><td>0.102 in / 2.59 mm</td></tr><tr><td>C</td><td>Diameter (inner)</td><td>0.055 in</td><td colspan="2">0.070 in</td><td>0.058 in</td><td>0.088 in / 2.2 mm</td></tr><tr><td>D</td><td>Working length</td><td>115 - 125 cm</td><td>115 – 135 cm</td><td>95 – 105 cm</td><td>105, 115 cm</td><td>115, 120 cm</td></tr><tr><td>E</td><td>Distal section</td><td>17 cm</td><td>19 cm</td><td>6 cm</td><td>9 cm</td><td>14 cm</td></tr><tr><td>F</td><td>Tip configuration</td><td colspan="3">Straight Shapeable</td><td>Straight</td><td>Straight</td></tr></table>							Parameter	SOFIA 5F	SOFIA 6F		SOFIA EX	SOFIA 88	A	Diameter (outer), proximal	0.068 in / 1.7 mm	0.0835 in / 2.1 mm		0.071 in / 1.8 mm	0.108 in / 2.74 mm	B	Diameter (outer), distal	0.067 in / 1.7 mm	0.0825 in / 2.1 mm		0.068 in / 1.7 mm	0.102 in / 2.59 mm	C	Diameter (inner)	0.055 in	0.070 in		0.058 in	0.088 in / 2.2 mm	D	Working length	115 - 125 cm	115 – 135 cm	95 – 105 cm	105, 115 cm	115, 120 cm	E	Distal section	17 cm	19 cm	6 cm	9 cm	14 cm	F	Tip configuration	Straight Shapeable			Straight
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Design Characteristics of the Device	SOFIA Catheters The catheter body is constructed with a coil over the inner liner. Braiding covers the coil on the entire length of the catheter. A platinum/iridium alloy radiopaque marker band is located at the distal tip. The catheter outer distal layer is lined with polyolefin elastomer (Engage) and has a hydrophilic coating for lubricious insertion and delivery. The distal lumen is lined with PTFE. The catheter inner diameter is 0.055” (1.4 mm) or 0.070” (1.78 mm). The semi-rigid proximal section transitions to a flexible distal section to facilitate advancement through vessels. A luer fitting on the catheter hub is used for the attachment of accessories. The hub/strain relief provides for the kink resistance from the proximal end. A steam shaping mandrel is provided with the catheter to be used by the physician for tip shaping for SOFIA 5F and 6F Catheters. An introducer sheath is included to introduce the catheter into the y-connector. The SOFIA Catheters are provided sterile and for single use. The catheters are placed in a dispenser tube (HDPE) and is placed on a packaging card (polyethylene) that is provided in a sterile barrier Tyvek pouch and placed in a carton box. The introducer is the accessory that is provided on the packaging card. It is made of polyether block amide																																																					

Device Description	
	(Pebax). The purpose is to provide support when introducing the distal tip of the catheter into the hemostatic valve. Once the SOFIA Catheter distal shaft is placed inside the patient body, the introducer is removed by peeling it away from the system. The introducer sheath is not intended for use inside the patient body. SOFIA EX Catheters The catheter body is constructed with a nitinol coil over the inner lumen liner comprised of polytetrafluoroethylene (PTFE). To provide additional shaft support, a stainless-steel wire braiding has been added over the nitinol coil from the proximal end to the distal end. A platinum/iridium alloy radiopaque marker band is located at the distal tip. This is all covered by an outer layer of varying durometers of materials. The outer layer consists of a range of durometers and lengths of polyolefin, polyurethane (Pellethane) and polyether block amide (Pebax) – distal and proximal, respectively. The most proximal outer shaft section consists of polyamide (Grilamid). The outer surface of the catheter (distal 55-65 cm) is coated with a hydrophilic coating to reduce friction during navigation in the vasculature. A luer fitting on the catheter hub is used for the attachment of accessories. The hub-strain relief provides for kink resistance from the proximal end. An introducer sheath (Pebax) is also included to facilitate the introduction of the catheter into the y-connector. The SOFIA EX Catheters are provided sterile and for single use. The catheters are placed in a dispenser tube (HDPE) and is placed on a packaging card (polyethylene) that is provided in a sterile barrier Tyvek pouch and placed in a carton box. The introducer is the accessory that is provided on the packaging card. It is made of polyether block amide (Pebax). The purpose is to provide support when introducing the distal tip of the catheter into the hemostatic valve. Once the SOFIA EX Catheter distal shaft is placed inside the patient body, the introducer is removed by peeling it away from the system. The introducer sheath is not intended for use inside the patient body.
Previous Generations or Variants, if applicable	The following SOFIA and SOFIA EX Catheter device configurations/variants are CE-Marked and are commercialized in the European Union: • SOFIA Distal Access Catheter • SOFIA Select Catheter • SOFIA PLUS Catheter • SOFIA Flow PLUS Catheter • SOFIA Guiding Catheter • SOFIA Flow Catheter • SOFIA EX Intracranial Support Catheter
Single use – sterilization method	Single use, EtO Sterilized
Description of Accessories	The SOFIA Catheter comes packaged and sterilized with a steam-shaping mandrel and an introducer sheath. The SOFIA EX Catheter comes packaged and sterilized with an introducer sheath. The SOFIA EX Catheter does not include a steam-shaping mandrel since the tip is not shapeable. The physician may use the steam-shaping mandrel to shape the tip of the catheter. The introducer provides support when introducing the distal tip of the catheter into the hemostatic valve. Once the SOFIA Catheter distal shaft is placed inside the patient body, the introducer is removed by peeling it away from the system. The introducer sheath is not intended for use inside the patient body.
Description of other Devices or Products intended to be used in combination	The SOFIA Catheter is designed to be compatible with standard accessory devices for neurointerventional techniques, which include 6F or larger guiding sheath, ≤ 0.035" guidewire, and common rotating hemostasis valves (RHVs) and stopcocks. The SOFIA Catheter (not SOFIA EX) is also compatible with Class-I sterile (Is) aspiration accessory kits that provide a vacuum source for aspiration. The kits are

Device Description	
	manufactured by Merit Medical and distributed by MicroVention. Along with the catheter, these devices provide a vacuum source for the aspiration of emboli. The SOFIA Catheter includes IFUs for usage in conjunction with the Aspiration Tubing Kit and the Aspiration Syringe Kits.

1.4 Risks and Warnings

1.4.1 Residual Risks and Undesirable Effects

Hazards associated with the use of the SOFIA Catheter Family 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.

Undesirable effects associated with the SOFIA Catheter Family are addressed in the IFU as potential complications, which include but are not limited to the following:

- Vessel or aneurysm perforation
- Vasospasm
- Hematoma at the site of entry
- Embolism
- Ischemia
- Intracerebral/intracranial hemorrhage
- Pseudo aneurysm
- Seizure
- Stroke
- Infection
- Vessel dissection
- Thrombus formation
- Death

1.4.2 Warnings and Precautions

Warnings

SOFIA Catheters excluding SOFIA 88 Catheter:

- The SOFIA Catheter should only be used by physicians who have received appropriate training in interventional techniques.
- The SOFIA Catheter is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.
- Inspect the SOFIA Catheter prior to use. Do not use the device if any damages or irregularities are observed.
- Appropriate anti-coagulation and anti-platelet therapy should be administered per standard medical practice.

- The SOFIA Catheter 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 the SOFIA Catheter with Ethiodol or Lipiodol contrast media or other such contrast media which includes the components of those agents.
- Do not use organic solvents as the device may be damaged.
- Do not exceed 2070 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may damage the device or injure the patient. Carefully monitor placement of the distal tip when using a power injector to infuse.
- Do not make more than 90 degree angle on the Shaping Mandrel. Steaming of the distal tip with more than 90 degree angle may result in damage to the device.
- Do not steam the same device more than once, which may result in damage to the device.
- Torquing the SOFIA Catheter excessively while kinked may damage the device resulting in separation of the device. Withdraw the entire device (the device, microcatheter, and guidewire) if the device is severely kinked.
- The Introducer Sheath is not intended for use inside the patient body. Ensure that the Introducer Sheath is removed from the SOFIA Catheter once the distal shaft of the SOFIA Catheter is placed inside the patient body.
- Excessive aspiration with the distal tip of the SOFIA Catheter covered by the vessel wall may cause vessel injury. Carefully investigate location of the distal tip under fluoroscopy prior to aspiration.
- Do not attempt to clear the inner lumen of the SOFIA Catheter by infusion while keeping the device in the patient body.
- When flow from the lumen stops or becomes stagnant during aspiration, do not attempt to clear the inner lumen of the SOFIA Catheter by infusion while keeping the device in the patient body.

SOFIA 88 Catheter:

- The SOFIA Flow 88 Aspiration Catheter should only be used by physicians who have received appropriate training in interventional techniques.
- The SOFIA Flow 88 Aspiration Catheter is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.
- Inspect the SOFIA Flow 88 Aspiration Catheter prior to use. Do not use the device if any damages or irregularities are observed.
- Appropriate anti-coagulation and anti-platelet therapy should be administered per standard medical practice.
- The SOFIA Flow 88 Aspiration Catheter 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 the SOFIA Flow 88 Aspiration Catheter with Ethiodol or Lipiodol contrast media or other such contrast media which includes the components of those agents.
- Do not use organic solvents as the device may be damaged.
- Do not use automated high-pressure contrast injection equipment with the SOFIA Flow 88 Aspiration Catheter as it may damage the device.
- Do not exceed 2070 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may damage the device or injure the patient.
- Torquing the SOFIA Flow 88 Aspiration Catheter excessively while kinked may damage the device, resulting in separation of the device. Withdraw the entire device (the device, Compatible Catheter, and guidewire) if the device is severely kinked.
- The Introducer Sheath is not intended for use inside the patient body. Ensure that the Introducer Sheath is removed from the SOFIA Flow 88 Aspiration Catheter once the distal shaft of the SOFIA Flow 88 Aspiration Catheter is placed inside the patient body.
- Excessive aspiration with the distal tip of the SOFIA Flow 88 Aspiration Catheter covered by the vessel wall may cause vessel injury. Carefully investigate location of the distal tip under fluoroscopy prior to aspiration.
- Do not attempt to clear the inner lumen of the SOFIA Flow 88 Aspiration Catheter by infusion while keeping the device in the patient body.
- When flow from the lumen stops or becomes stagnant during aspiration, do not attempt to clear the inner lumen of the SOFIA Flow 88 Aspiration Catheter by infusion while keeping the device in the patient body.

SOFIA EX Catheters:

- The SOFIA EX Catheter should only be used by physicians who have received appropriate training in interventional techniques.
- The SOFIA EX Catheter is provided sterile and non-pyrogenic. Do not use if the packaging is breached or damaged.
- Inspect the SOFIA EX Catheter prior to use. Do not use the device if any damage or irregularities are observed.
- Appropriate anti-coagulation and anti-platelet therapy should be administered per standard medical practice.
- The SOFIA EX Catheter must be used 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 the SOFIA EX Catheter with Ethiodol or Lipiodol contrast media or other such contrast media which includes the components of those agents.
- Do not use organic solvents as the device may be damaged.
- Do not exceed 2070 kPa (300 psi) maximum recommended infusion pressure. Excess pressure may damage the device or injure the patient. Carefully monitor placement of the distal tip when using a power injector to infuse.

- Torqueing the SOFIA EX Catheter excessively while kinked may damage the device resulting in separation of the device. Withdraw the entire device (the device, microcatheter, and guidewire) if the device is severely kinked.
- The Introducer Sheath is not intended for use inside the patient body. Ensure that the Introducer Sheath is removed from the SOFIA EX Catheter once the distal shaft of the SOFIA EX Catheter is placed inside the patient body.

Precautions

SOFIA Catheters (SOFIA 55/70/Flow 88 Catheter):

- Exercise care in handling the SOFIA Catheter to reduce the chance of accidental damage.
- Verify compatibility of the SOFIA Catheter when using other ancillary devices commonly used in intravascular procedures. The physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.
- Use caution when manipulating the SOFIA Catheter in tortuous vasculature to avoid damage. Avoid advancing or withdrawal against resistance until the cause of resistance is determined.
- Presence of calcifications, irregularities, or other devices may damage the SOFIA Catheter and potentially affect its insertion or removal.
- Maintain perfusion of heparinized saline for inner lumen of the SOFIA Catheter to prevent thrombus formation.
- If removed from the patient, the hydrophilic coating on the SOFIA Catheter should be hydrated with heparinized saline. Do not allow the coating to dry.

SOFIA EX Catheters:

- Exercise care in handling the SOFIA EX Catheter to reduce the chance of accidental damage.
- Verify compatibility of the SOFIA EX Catheter when using other ancillary devices commonly used in intravascular procedures. The physician must be familiar with percutaneous, intravascular techniques and possible complications associated with the procedure.
- Use caution when manipulating the SOFIA EX Catheter in tortuous vasculature to avoid damage. Avoid advancing or withdrawal against resistance until the cause of resistance is determined. Torqueing the device against resistance may result in damage to the vessel or device.
- Presence of calcifications, irregularities, or other devices may damage the SOFIA EX Catheter and potentially affect its insertion or removal.
- Maintain perfusion of heparinized saline for inner lumen of the SOFIA EX Catheter to prevent thrombus formation.

- If removed from the patient, the hydrophilic coating on the SOFIA EX Catheter should be hydrated with heparinized saline. Do not allow the coating to dry as this may impact the coating safety and performance.
- Avoid pre-soaking devices for long durations when the device is not in use as this may impact the coating safety and performance.
- Avoid wiping the device with dry gauze as this may damage the device coating. Avoid excessive wiping of the coated device.
- Excessive torquing of the catheter may cause damage which could result in kinking and possible separation along the catheter shaft. Should the system become severely kinked, withdraw the entire system if this occurs (SOFIA EX catheter, guidewire and catheter sheath introducer).
- Limit the exposure to X-ray radiation doses to patients and physicians by using sufficient shielding, reducing fluoroscopy times, and modifying X-ray technical factors, when possible. The risk of X-ray radiation exposure complications may increase as procedure time and number of procedures increase.

1.4.3 Potential Complications / Adverse Effects

The potential complications / adverse effects for the SOFIA Catheter Family are listed below per the IFU for each device.

SOFIA Catheters (SOFIA 55/70/Flow 88 Catheter) and SOFIA EX Catheter:

Potential complications include, but are not limited to:

- Vessel or aneurysm perforation
- Vasospasm
- Hematoma at the site of entry
- Embolism
- Ischemia
- Intracerebral/intracranial hemorrhage
- Pseudo aneurysm
- Seizure
- Stroke
- Infection
- Vessel dissection
- Thrombus formation
- Death.

In addition for the EX catheters: Potential X-ray radiation exposure related adverse events include but are not limited to

- Alopecia

- Burns ranging in severity from skin reddening to ulcers
- Cataracts
- Delayed neoplasia
- Tissue necrosis
- Risks associated with contrast dye.

1.4.4 Other Aspects of Safety

During the evaluation period of 01 January 2022 to 31 December 2025, there were no field safety actions.

1.5 Summary of the Clinical Evaluation and PMCF

1.5.1 Equivalent Device Clinical Data

Clinical safety and performance were determined by the collection and analysis of available clinical data on the SOFIA Catheter Family products and did not rely on equivalence with any other product.

1.5.2 Pre-CE-Mark Clinical Data

There were no pre-market clinical investigations conducted for the SOFIA Catheter Family. SOFIA Catheters and SOFIA EX Catheters are legacy devices and have been on the market since 2013 and 2019, respectively.

1.5.3 Clinical Data

Clinical evidence was identified, collected, and appraised from a variety of trusted sources including post-market studies and published peer reviewed literature.

There are five completed post-market clinical studies for SOFIA Catheter Family (SESAME, ETIS, SOFAST/RESTORE (Cohort I/II), STABILISE, and ERASER. The SESAME, ETIS, STABILISE, and ERASER studies are completed, and the clinical results have been published. Regarding the SOFAST (Cohort I) and RESTORE (Cohort II) studies, the SOFAST cohort has been completed and published. The RESTORE cohort is completed but the study results are not yet available.

A systematic literature search and review were conducted in accordance with the principles of MEDDEV 2.7/1 (Revision 4). The literature search identified 64 published peer-reviewed clinical articles that demonstrated clinical use of the SOFIA Catheter Family for aspiration and general intravascular use, including the neuro and peripheral vasculature in 5,431 patients with an average follow up of 90 days. There was 1 randomized controlled study, 7 prospective cohort studies, and 17 case series/reports, 36 retrospective studies, and 3 registries. The overall quality of the data from the published clinical studies was high.

1.5.4 Clinical Performance and Safety

Clinical data on the SOFIA Catheter Family from the published literature and the completed post market clinical studies have been reviewed to evaluate safety and performance of the device. The published clinical data show high rates of technical success (69.9%–100%), recanalization (TICI 2b-3, 57.9%–100%), first-pass effect (24.2%–100%), NIHSS score (median) change from admission/baseline (9–18) to discharge/24-hr (2–12), and good clinical outcomes at 90 days (mRS 0–2, 30%–100%). These rates are comparable to rates reported in the published literature for similar devices reporting rates of technical success (66%–100%), recanalization (TICI 2b-3, 66%–100%), first-pass effect (44%–100%), NIHSS score (median) change from admission/baseline (12.5–19) to discharge/24-hr (3.5–11), and good clinical outcomes at 90 days (mRS 0-2, 34%–63.2%).

Published safety outcomes for procedures in which the SOFIA Catheter Family was used include hemorrhagic complication (sICH $\leq$ 14.4%), vessel dissection/rupture/perforation ($\leq$ 3.3%), emboli to new territory ($\leq$ 14.3%), vasospasm ($\leq$ 9.8%), and mortality ($\leq$ 28.4%, with the exception of 47.4% in one small study of high risk patients); only minor vessel dissection and vasospasm were directly associated with catheter use. These safety events and rates are comparable to those reported in the published literature for procedures involving similar devices which showed similar rates. Thus, the benefit-risk ratio for the SOFIA Catheter is comparable to the benefit-risk ratio for the standard of care/ state of the art. There were no new risks identified for the SOFIA Catheter Family, and all risks were deemed acceptable through the risk management process.

1.5.5 Post-Market Clinical Follow-up

Based on the substantial clinical evidence for the SOFIA Catheter Family, the post-market clinical follow-up activities include ongoing review of the published clinical literature and post market surveillance data. In addition, MicroVention has initiated a post-market real-world evidence registry MAESTRO (NCT06494436) to collect clinical data on commercially available MicroVention neurovascular treatment devices, including the SOFIA Catheter Family, used in standard clinical practice.

1.6 Possible Diagnostic or Therapeutic Alternatives

1.6.1 Treatment Options and Interventions

The intended uses of the SOFIA Catheter Family are relevant to treatment of conditions such as ischemic stroke.

Treatment options for ischemic stroke are either endovascular or medicinal, and both techniques have undergone major development in recent years. The table below describes the benefits and risks of the available treatment options.

Table 1.4 Benefits/Risk of Standard of Care

Treatment Option	Pro/Benefit	Con/Risks	Notes
Thrombolytic Agents (i.e. Alteplase (tPA))	Effective in improving functional outcomes after ischemic stroke up to 4.5–9 hours after symptom onset	- Short half-life, low recanalization rate of 30–40% for proximal occlusions and of <5% for distal Internal Carotid Artery (ICA) occlusion - Its effectiveness may diminish with more proximal or larger occlusions	Intravenous thrombolysis (IVT) is the basic treatment for acute ischemic stroke (AIS) patients applicable to approximately 25–30% of the patient population in large stroke centers.
Antiplatelet therapy (Medications)	- Antiplatelet therapy is a crucial preventive intervention against stroke recurrence, ensuing vascular problems, and death. The most widely utilized medications include aspirin, clopidogrel, and combinations of antiplatelet therapy like aspirin and clopidogrel. - DAPT use after an ischemic stroke is more debatable and has recently been proven useful in certain situations.	- Early studies of chronic Dual Antiplatelet Therapy (DAPT) in stroke showed no additional benefit and increased bleeding over single antiplatelets. - Traditionally, antiplatelet drug use was thought to be associated with an increased risk of strictly lobar microbleeds and increased ICH incidence in individuals with Cerebral Microbleeds.	However, recent research indicates that DAPT may reduce stroke risk more than a single antiplatelet therapy because it more effectively inhibits platelet activation pathways. The use of DAPT can continue for 21 to 90 days following a mild stroke or TIA, according to the 2019 Guidelines for the Management of Acute Ischemic Stroke. After 90 days, it is unclear whether antiplatelet administration should continue as monotherapy or dual treatment.
Stent Retrievers (SR)	- High rates of good clinical outcomes (mRS 0-2) seen in these trials - A good outcome increased with better recanalization	- Invasive nature of the treatment - Carries procedural risks such as symptomatic intracranial hemorrhage (sICH), dissection, or death.	No significant difference was seen in safety and effectiveness between the thrombo-aspiration approach and stent-retrieval thrombectomy for treating people with AIS.
Aspiration	- No significant difference between the direct aspiration and the SR groups in the rate of successful recanalization - Some trials report fewer complications, such as intracranial hemorrhage	- Invasive nature of the treatment - Aspiration thrombectomy carries procedural risks such as sICH, dissection, or death.	Furthermore, the combined group did not show any obvious advantage over either intervention applied alone.
Combination of stent retriever & direct aspiration	Potentially enhance the rate of successful recanalization through a combination of SR thrombectomy and direct clot aspiration	- Invasive nature of the treatment - The combination treatment approach carries procedural risks such as sICH, dissection, or death.	

Treatment Option	Pro/Benefit	Con/Risks	Notes
Cyclic Aspiration	- Increased first pass recanalization rate - Easier and faster removal of thrombus, thus reducing the potential of mechanical damage to the arterial wall - Less blood loss in patients during operation, due to the reduced magnitude of aspiration pressure and not maintaining the aspiration pressure at the peak value all the time as happened in the constant pressure aspiration	- Incomplete clot removal - Fragmentation and distal embolization can limit efficacy - Procedure time may be prolonged - Limited evidence in distal occlusions	- Cyclic Aspiration is a novel technology, delivering high frequency pulsed vacuum forces to increase the efficiency of aspiration thrombectomy. - It alternates the pressure at the interface of the catheter opening and the clot between full vacuum and precise positive pressure. - More assessment is needed to assess safety and performance of this novel technology to treat AIS patients.

1.6.2 Available Technologies

Intermediate/distal access catheters and aspiration catheters are medical devices with various types and styles available from multiple manufacturers. Examples of catheters similar to the SOFIA Catheter Family are listed in **Table 1.5**.

Table 1.5 Similar Devices

Device	Manufacturer	Intended Use
Penumbra Reperfusion Catheter (ACE64/68)	Penumbra	Penumbra Reperfusion Catheters are intended for use in the revascularization of patients with acute ischemic stroke secondary to large vessel occlusion.
React™ 68 catheter	Medtronic	The React 68 Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

1.7 Suggested Profile and Training for Users

This device should only be used by physicians who have undergone training in the use of the SOFIA Catheter Family devices according to the instructions for use.

1.8 Reference to any Harmonized Standards and CS

The SOFIA Catheter Family devices were designed, developed, and tested following the standards listed in Table 1.6.

Table 1.6 Harmonized Standards

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 D4169	2023e1	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D4332	2022	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
ASTM F88	2023	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1886	2016	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929	2023	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096	2011R2019	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F1980	2016	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
EN ISO 10993-3	2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)

Standard Number	Edition	Standard Title (equivalent edition)
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
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)
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)
ASTM E855	2021	Standard Test Methods for Bend Testing of Metallic Flat Materials for Spring Applications Involving Static Loading
ASTM F640	2023	Standard test methods for determining radiopacity for medical use

Standard Number	Edition	Standard Title (equivalent edition)
ANSI T564	2021	Transparent Chart for the Estimation of Defect Size

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