Summary of Safety and Clinical Performance

for

Precipitating Hydrophobic Injectable Liquid PHIL™ System

SSCPPT23-0016

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: English
B	Revision – annual update to reflect the latest information. Any changes are made to: • Section 1.1: Device Identification & General Information • Section 1.2: Intended Use of the Device • Section 1.3: Device Description • Section 1.4: Risks & Warnings • Section 1.5: Summary of Clinical Evaluation & Post-Market Clinical Follow-Up • Section 1.6: Possible Diagnostic or Therapeutic Alternatives • Section 1.7: Suggested Training for Users	☐Yes ☒ No* Validation language

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

Sign Page

Document Author:

Signature: Date:

RA Approver:

Signature: Date:

Legal Approver:

Signature: Date:

TABLE OF CONTENTS

1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE [PATIENT VERSION] 5
1.1 Device Identification and General Information 5
1.2 Intended Use of the Device 5
1.3 Device Description 6
1.4 Risks and Warnings 7
1.5 Summary of Clinical Evaluation and Post-Market Clinical Follow-up 8
1.6 Possible Diagnostic or Therapeutic Alternatives 8
1.7 Suggested Training for Users 9

LIST OF TABLES

Table 1.1 Device Identification and General Information 5
Table 1.2 Intended Use 5
Table 1.3 Device Description 6

1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE [PATIENT VERSION]

Document Revision: B
Date Issued: October 2026

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 information presented below is intended for patients or lay people. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional if you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

1.1 Device Identification and General Information

Table 1.1 Device Identification and General Information

Device Names	
Device Trade Name	Precipitating Hydrophobic Injectable Liquid (PHIL) Liquid Embolic System
Device Class	III
Basic UDI-DI	37015174PHILKC
Year when first certificate (CE) was issued for the device	2014
Legal Manufacturer	
Name & Address	**MicroVention Europe SARL (MVE)** 30 bis, rue du Vieil Abreuvoir 78100 Saint Germain-en-Laye, France
Notified Body	
Name & Address	DQS Medizinprodukte GmbH August-Schanz-Straße 21 D-60433 Frankfurt am Main Germany

1.2 Intended Use of the Device

Table 1.2 Intended Use

Intended Use	
Intended Purpose	The PHIL device is used to treat blood vessel problems and some tumors.
Indications for Use	The PHIL device is used to treat blood vessel problems in the brain and other parts of the body. It may also be used to treat some tumors.

Intended Patient Group(s)	Doctors can use the PHIL device to treat problems with blood vessels in the brain and body. These problems include tangled blood vessels, bleeding, and some tumors.
Contraindications and/or Limitations	Doctors should not use the PHIL device if: • The person is very allergic to iodine (the substance in the device that helps it show up on X-rays). • The delivery microcatheter (tiny tube) can't be put in the right spot. • A test shows the person's body can't handle blocking a blood vessel. • Blood can't flow because the vessels are too tight. • The person is a very small baby (under 1,500 grams) or has serious liver or kidney problems.

1.3 Device Description

Table 1.3 Device Description

<table>
<tr><th colspan="3">Device Description</th></tr>
<tr><td>Description of the Device</td><td colspan="2">The PHIL device is a liquid material that is injected into a blood vessel to block blood flow. It contains iodine, which helps doctors see it on X-rays during treatment. After it is placed, the device stays in the body and remains in contact with blood and the blood vessel.
<table>
<tr><th>Key Functional Element</th><th>Materials</th></tr>
<tr><td>Flushing Solution</td><td>Dimethyl sulfoxide (DMSO)</td></tr>
<tr><td>PHIL Embolic Liquid</td><td>PHIL is a liquid material that contains a soft plastic-like substance mixed with DMSO, a liquid that helps it flow through the catheter. It also contains iodine, which helps doctors see it on X-rays.</td></tr>
<tr><td rowspan="6">Syringe</td><td>The barrel (the tube part) is made of strong glass called borosilicate glass, which doesn't break easily</td></tr>
<tr><td>The Luer (the small metal tip where the needle or tube connects) is made from strong stainless steel that doesn't rust</td></tr>
<tr><td>The stopper is made from a soft rubber-like material that helps seal the liquid inside and keeps it from leaking</td></tr>
<tr><td>The plunger is made from stainless steel, a strong metal that doesn't rust and helps push the liquid out</td></tr>
<tr><td>The cap is made from strong plastic that helps cover and protect the device</td></tr>
<tr><td>The finger grip is made from strong plastic (yellow or white) that helps you hold and control the device easily</td></tr>
<tr><td rowspan="4">Universal Adaptor</td><td>The hub is made from strong plastic and stainless steel, which helps connect parts and keeps them sturdy and rust-free</td></tr>
<tr><td>The Tuohy Borst body is also made from polypropylene, a strong plastic that helps hold the parts in place</td></tr>
<tr><td>The Tuohy Borst cap is made from polypropylene, a strong plastic that helps close and hold parts together</td></tr>
<tr><td>The Tuohy gasket is made from silicone, a soft, rubbery material that helps keep things sealed tight</td></tr>
<tr><td rowspan="4">Tray Packaging</td><td>The tray is made from polycarbonate, a tough plastic that doesn't break easily</td></tr>
<tr><td>The tray lid is made from Tyvek, a strong, paper-like material that keeps things clean and safe.</td></tr>
<tr><td>The insert (the paper piece inside the box) is made from the same strong, white cardboard as the box.</td></tr>
<tr><td>The box (carton) is made from strong, white cardboard called bleached paperboard</td></tr>
</table></td></tr>
<tr><td>Materials or substances in contact with the patient's tissues</td><td colspan="2">Two special chemicals are mixed in a liquid called DMSO. One help make things stick, and the other helps hold water</td></tr>
</table>

Information about medicinal substances in the device	The PHIL Embolic System does not have any medicine, animal parts, or blood in it.
Description of how device achieves its intended mode of action	Doctors use a tiny tube to send the PHIL liquid to the problem spot in the blood vessel. They watch where it goes using a special X-ray. The liquid works because it can mix with one kind of liquid (called DMSO), but not with water. When the PHIL liquid touches blood, it starts to turn solid. This helps block the blood vessel in just the right place. How well it works depends on how fast the liquid is given, how fast the blood is moving, and how big the blood vessel is. The outside of the liquid gets hard first, while the inside stays soft to help it go farther if needed.
Description of Accessories	The universal adapter is used with the PHIL device. It connects the syringe to the microcatheter, which is the small tube used to deliver the material. The adapter helps keep the PHIL material from mixing with other liquids before it is delivered. One adapter is used with each syringe.
Description of other Devices or Products intended to be used in combination	• Tiny metal coils can be put in a blood vessel to slow down the blood. This helps doctors add a special liquid to block the blood vessel. • Doctors use tiny tubes called microcatheters. Some new ones have tips that can come off, which helps doctors take the tube out more easily after the liquid gets hard. • Some tiny tubes have little balloons on them. These help keep blood vessels healthy and let the special liquid go deeper into the problem spot. Special balloon tubes, like the Scepter Mini, can send the liquid into small, far-away blood vessels and help keep it from going the wrong way.

1.4 Risks and Warnings

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

- **How potential risks have been controlled or managed**

  The company uses a standard process to predict device risk. The process gives a thorough estimate of what might happen when the device is used. A list of possible harm and what might cause them is compiled. The Instructions for Use also describes any warnings or precautions. These may be associated with remaining risk. Reports of any harm are tracked in a complaint database. Reports can come from users or other health care professionals or from publications. The database is assessed on a regular basis. Harms are investigated if rates are increasing or at a certain level. Actions such as changes in labelling or recall can be taken if needed.

- **Remaining risks and undesirable effects**

  Sometimes, problems can happen like bruising, blood clots, or bleeding if a blood vessel breaks. These problems might lead to serious issues like a blood clot moving to another part of the body, a stroke, or even death.

- **Warnings and precautions**

Warning:

Only trained doctors should use this device. They use special tools and imaging to place the material in the right area. If it is not used correctly, it may cause bleeding or other problems.

Cautions:

This device should only be used one time—don't reuse or try to clean it. Using it again could break it or make someone sick.

Precautions:

This device has not been studied in children, pregnant women, or some people with certain blood vessel conditions. Some people may notice a garlic-like taste or smell during treatment.

- **Summary of any field safety corrective action, (FSCA including FSN)**

During this period, one safety issue was reported for the PHIL devices. Ten improvements were also started. Eight were finished, and two were still being worked on.

1.5 Summary of Clinical Evaluation and Post-Market Clinical Follow-up

- **Clinical background of the device**

  These devices were first placed in the market in 2014.

- **The clinical evidence for the CE-marking**

- In 25 studies with 763 patients, doctors used the PHIL device to treat brain and body blood vessel problems, and most treatments worked very well. Many studies reported no problems and they rarely happened again. There were a few problems such as bleeding, heart problems, or issues with metal tubes and patient deaths, but none were caused by the PHIL device, showing that it works safely and effectively.

- **Safety**

  The PHIL device is as safe as other similar treatments. No new or unknown risks were found. The benefits are considered to outweigh the risks when used as intended.

1.6 Possible Diagnostic or Therapeutic Alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

- General description of therapeutic alternatives

There are other liquid materials like the PHIL device that doctors use to block off blood vessels. These include:

- Onyx™, made by a company called Medtronic

These devices are used to treat problems with blood vessels in the brain and other parts of the body. These problems include tangled blood vessels and some tumors.

- Onyx and PHIL are not sticky — they're more like rubber.

Doctors use different liquid materials to treat tangled blood vessels in the brain. These materials help block blood flow to the abnormal blood vessels. Each material has benefits and risks. Some harden quickly, while others allow doctors more time to control where the material goes. Some may also make it harder to see the treatment area on X-rays or may affect the tube used to deliver the material.

These materials have been used for many years. Doctors have learned a lot about how well they work and the risks they may have. This experience helps doctors choose the best treatment for each patient.

1.7 Suggested Training for Users

The PHIL device should only be used by doctors who are trained to treat blood vessel problems. These doctors have special training in using X-rays and other imaging tools to guide treatment.