Summary of Safety and Clinical Performance

for

MicroPlex™ Coil System (MCS)

HydroCoil™ Embolic System (HES)

SSCPPT22-0005

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1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE [PATIENT VERSION]

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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 persons. 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 in case 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	MicroPlex Coil System (MCS) HydroCoil Embolic System (HES)
Device Class	III, Implantable
Basic UDI-DI	MCS: 08402732MCSSW HES: 08402732HESSB
Year when first certificate (CE) was issued	2008
Legal Manufacturer	
Name & Address	**MicroVention, Inc. (referred to as MVI)** 35 Enterprise Aliso Viejo, California 92656, USA
Authorized Representative	
Name & Address	**MicroVention Europe SARL (referred to as 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

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1.2 Intended Use of the Device

Table 1.2 Intended Use

Intended Use	
Intended Purpose	The MCS and HES (coils) are used to block blood vessels when there is an unusual bulge in the blood vessel of the brain or in the nerve. This can also be unusual connection between arteries and veins. These coils can also be used to block blood flowing into the bulge or other unusual blood vessels outside of the heart and brain, which can supply arms and legs. The V-Grip™ Detachment Controller (DC) is to be used with MCS and HES only. It separates these coils after the procedure.
Indications for Use	The MCS and HES (coils) are used to block blood vessels when there is an unusual bulge in the blood vessel of the brain or in the nerve. This can also be unusual connection between arteries and veins. These coils can also be used to block blood flowing into the bulge or other unusual blood vessels outside of the heart and brain, which can supply arms and legs. The V-Grip DC is to be used with MCS and HES only. It separates these coils after the procedure.
Intended Patient Group(s)	These coils are used in adult patients to block unusual blood flow in the brain.
Contraindications and/or Limitations	None

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1.3 Device Description

Table 1.3 Device Description

Device Description	
Device Description	The MCS and HES are insertable coils that are attached to a V-Trak™ (delivery pusher) by plastic materials. Both MCS and HES are made of metals, and they are available in various shapes and sizes. The V-Grip DC is designed to separate coils for blocking blood vessels into the arteries and veins outside of the heart and brain, which can supply arms and legs. The detachment controllers are powered by batteries (9V).
Materials or substances in contact with the patient's tissues	Implant: Platinum/Tungsten alloy and Platinum/Tungsten alloy/Hydrogel
Information about medicinal substances in the device	There are no medicinal substances.
Description of how device achieves its intended mode of action	The coiling of blood vessels with the bulge in the brain is done under medical imaging using the MCS and HES. These coils are delivered to the target area through standard surgical small tubes (microcatheters). The coils are separated from the delivery piece and after separation, the coil expands when exposed to the blood. Many coils are used until the blood flow is blocked. Over time, new tissue will cover the opening of the bulge and prevent it from growing or tearing.
Description of Accessories	The V-Grip Detachment Controller is used together with the MCS and HES. The detachment controller is powered by batteries, which provide energy for separating the coil from the delivery pusher. It is packaged and sold separately as a clean device for single patient only.
Description of other Devices or Products to be used together	There is no other device to be used together other than V-Grip Detachment Controller.

1.4 Risks and Warnings

Reach out to your doctor if you are going through side effects related to the device or its use or if you are worried about its risks. Do not use this document to replace doctor's consultation.

- **How potential risks have been managed**
    - The company uses a standard process to predict a device risk. The process gives a good estimate of what might happen when the device is used. A list of possible risks and what might cause them is listed below. The instruction for use also describes any warning or precautions. These may be associated with remaining risk. Reports of any risks are tracked in a complaint database. The reports can come from users or other workers in hospital or from journals. The database is assessed regularly. These risks are investigated if rates are increasing or at a certain level. Actions such as changes in labeling or recall can be taken if needed.
- **Remaining risks and undesirable effects**

  There is always a risk of unwanted side effects when you have any type of surgery. It can be difficult to know why the side effects are occurring. The device's instructions for use identified the following known side effects that can occur:

    - Accessory product is damaged, and a portion remains in the body
    - Break in the bulge of the artery in brain during and following separation
    - Biological risk
    - Coil and delivery pusher will not load into the small surgical tubes
    - Coil and delivery pusher will not track to the target area
    - Coil damage during removal
    - Coil placed incorrectly
    - Coils pulled into the parent vessel
    - Coil will not place
    - A blockage in the blood vessel during coil placement
    - Energy risk
    - Environmental risk
    - Too much movement of surgical small tubes
    - Foreign body blockage in the blood vessel
    - Coil moves outside of the bulge into the parent vessel
    - Used incorrectly
    - Unable to separate product
    - Unable to introduce the product into the surgical small tubes

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- Not enough visibility under medical imaging
- Incorrect therapy selected (not as planned)
- Incorrect therapy selected (not according to instruction for use)
- Not used correctly with accessories
- Loss of surgical small tubes access the bulge
- Partial separation of the coil from the pusher
- Early coil separation after introduction
- Early coil separation during preparation
- Product is not clean due to the production environment
- Product becomes unclean during shipping, distribution, or storage
- Product becomes unclean during use
- Product separates and a portion remains in the body
- Product is used again
- Stretch-resistant member breaks
- Subsequent coils unable or difficult to place
- Blockage in the blood vessels
- Distressed tip
- Sudden tightening of blood vessels due to vessel wall irritation

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- **Warnings and precautions**

  There are some warnings and precautions with using the MCS and HES. All of these relate to the surgical steps done by the doctor. Your doctor will let you know if there are any actions you must take before surgery.

  - The MCS/HES is clean and will not cause fever unless the unit package is opened or damaged.
  - Use the device only one time. Do not reclean and/or reuse it. After use, throw it away according to the rules at the hospital or local government. Do not use it if the packaging is damaged.
  - The device must be delivered only through a wire-based metal tube with a surface coating. If there is damage to the coil, remove both the coil and the metal tube from the patient.
  - High quality X-ray is required to place the coil correctly.
  - Do not move the V-Trak delivery pusher with too much power. When it is harder to move the pusher, find the reason and check any damage, then remove the coil.

- Move and pull the coil slowly and smoothly. Remove the entire coil if there is too much friction. IF there is too much friction with a second coil, check the metal tube for any damage.
- Take special care to pull the coil under X-ray with a direct matching movement with the pusher if it needs to be moved to a better position. If the coil does not move in a direct matching movement with the pusher, the coil may be stretched or broken. Gently remove and throw away the entire device.
- The coil may stretch when used sometimes because the blood vessel path is twisty and the shapes of the bulges in the brain are different. If the coil is stretched, it may break or move around in the area.
- If a coil must be taken back from the blood vessel after separating, do not take back the coil with a snare, into the delivery tube. This could damage the coil and result in device separation. Remove the coil, tube, and any device used to take back the coil.
- If there is resistance while withdrawing a coil that is at an acute angle to the tip of the tube, it is possible to avoid coil stretching or breaking by carefully repositioning the distal tip of the tube around the opening of the bulge. The coil will move back into the small tube.
- Delivery of multiple coils is usually required to achieve the desired blockage of bulges in the blood vessel. The desired procedural endpoint is angiographic occlusion.
- The long-term effect of this product on tissues outside of blood vessels is not clear so care should be taken to retain this device within the blood vessel.
- Always check at least two MicroVention V-Grip detachment controllers are available before starting the procedure.
- The device cannot be separated with any power source other than a MicroVention V-Grip detachment controller.
- Always move a correct sized wire through the metal tube after separating the coil and removing the pusher so no coil remains within the metal tube.
- Do not place the V-Trak delivery pusher on a bare metallic surface.
- Always use the V-Trak delivery pusher with surgical gloves.
- Do not use with radio frequency devices.
- Do not change this device.

- **Summary of any field safety corrective action, (FSCA including FSN) if applicable**
  - There were no safety or corrective actions from the company for these coils.

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

- **Clinical background of the device**
  - These coils were first placed in the market in 2008.
- **The clinical evidence for the CE-marking**
  - There are 21 studies with 3,833 patients found from a literature search where the MCS and HES were used. The company also did 15 studies including 2,087 patients to support the devices treating the bulge in the brain and other unusual activities in the nerves or blood vessels. Bad outcomes were studied to see how well the devices work, and the benefits and risks were fair. The combined clinical data is shown below.
  - Clinical Benefits – the MCS and HES coils support blocking blood flowing into unusual bulge in the brain as well as other nerves or blood vessels.
    - 93.3%-98.6% with successful use of the coils (success of the procedure or coil separation)
    - 100% successful rate of cure within 6 months
    - 16%-84% immediate complete block
    - 42.6%-100% immediate complete or near complete block
    - 91.3% complete block during first 30 minutes of arteries in the stomach
    - 53%-90.9% complete block at follow-up (6 months-60 months)
    - 61.1%-100% complete or near complete block at follow-up (6 months-60 months)
    - 76.8%-96.7% good clinical results (mRS 0-2) at follow-up (6 months-47.9 months)
- **Safety**
  - Using MCS and HES were just as safe and successful as using other similar coils. There are no new risks found and the rates of side effects were low and similar. There were more benefits than risks with using these coils.
  - Clinical Risks – the risks found from using MCS and HES coils from the journals and company's studies:
    - Occurred again in 4.4%-27.9% of patients
    - Restored unsual flow in 4.1%-23.6% of patients
    - Treating again in 0.8%-13.7% of patients
    - Break in the bulge in 0.2%-4.0% of patients
    - Water in brain in 1.6%-17.1% of patients
    - Break in wall of organ in 1.0%-4.0% of patients
    - Parent artery block in 0.9%-1.6% of patients
    - Blood collection outside of blood vessels in 1.0%-3.6% of patients
    - Dissection in 0.7%-1.6% of patients
    - Sudden tightening of blood vessel in 5.0%-9.7% of patients

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- Brain related side effects in 2.1%-14.9% of patients
- Brain bleed in 2.2%-10.0% of patients
- Brain cell death in 1.6%-3.7% of patients
- Blood supply block in brain in 1.6% of patients
- Blood clots in 1.6%-8.7% of patients
- Procedure related side effects in 3.8%-17.1% of patients
- Coil related side effects in 1.0%-6.0% of patients
- Illness/Unhealthy state in 0.5%-17.1% of patients
- Death in 0.7%-10.0% of patients
- Bad side effects in 6.3% of patients

- The company keeps a record of complaint data. From 01 October 2021 through 30 September 2022, there was 1 report of death. The company received 1,545 total product complaints with MCS and HES and that is 0.0091% complaint rate. These risks were consistent with the other similar coils.

1.6 Possible Diagnostic or Therapeutic Alternatives

Talk to your doctor about any other option to this device. They will know what is best for your overall condition.

- **General description of other choices:** Treatments other than surgeries may be best for some patients. You and your doctor will decide what is right for you. When symptoms are bad and surgeries do not work, blocking blood vessels or coiling procedure may be an option. There are advantages and disadvantages to each treatment option.

1.7 Suggested Training for Users

This device is not used directly by the patient. No training is required for the patient.

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