



Summary of Safety and Clinical Performance
For
HydroPearl™ Microspheres
SSCPPT22-0004

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

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

DOCUMENT CHANGE HISTORY

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

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1 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE [PATIENT VERSION]

Document Revision: A

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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	HydroPearl Microspheres
Device Class	IIb
Basic UDI-DI	37015174HYDROPEARL7K (MDR MVE) 08402732HYDROPEARL5X (MDR MVI)
Year when first certificate (CE) was issued	2015
Legal Manufacturer	
Name & Address	MicroVention, Inc. (referred to as MVI) 35 Enterprise Aliso Viejo, CA 92656, USA MicroVention Europe SARL (referred to as MVE) 30 bis, rue du Vieil Abreuvoir 78100 Saint Germain-en-Laye, France
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-Str. 21 60433 Frankfurt am Main, Germany

1.2 Intended Use of the Device

Table 1.2 Intended Use

Intended Use	
Intended Purpose	HydroPearl Microspheres are micro beads that doctors use to block blood vessels on purpose. This helps treat certain health problems by stopping blood flow to areas that don't need it or are causing trouble.

Intended Use	
	<p>They can be used to help treat:</p> <ul style="list-style-type: none"> Cancer with lots of blood flow, like some liver and body tumors Liver cancer (called hepatocellular carcinoma) Uterine fibroids (non-cancer growths in the uterus) Big prostates (also called benign prostatic hyperplasia or BPH) Abnormal blood vessel connections (called arteriovenous malformations) Tumors in the neck, chest, and bones Bleeding and injuries To reduce bleeding before surgery
Indications for Use	<p>HydroPearl Microspheres are micro beads that doctors use to block blood vessels on purpose. This helps treat certain health problems by stopping blood flow to areas that don't need it or are causing trouble.</p> <p>They can be used to help treat:</p> <ul style="list-style-type: none"> Cancer with lots of blood flow, like some liver and body tumors Liver cancer (called hepatocellular carcinoma) Uterine fibroids (non-cancer growths in the uterus) Big prostates (also called benign prostatic hyperplasia or BPH) Abnormal blood vessel connections (called arteriovenous malformations) Tumors in the neck, chest, and bones Bleeding and injuries To reduce bleeding before surgery
Intended Patient Group(s)	<p>Doctors use HydroPearl Microspheres (micro beads) to block blood flow in certain parts of the body to treat different health problems, such as:</p> <ul style="list-style-type: none"> Cancers with lots of blood flow Liver cancer Uterine fibroids (non-cancer lumps in the uterus) Enlarged prostate (BPH) Abnormal blood vessels (called AVMs) Tumors in the neck, chest, and bones Bleeding or injury To reduce bleeding before surgery
Contraindications and/or Limitations	<p>HydroPearl Microspheres should not be used in certain situations because they could cause serious problems.</p> <p>General Reasons:</p> <ul style="list-style-type: none"> In big blood vessels near the heart, lungs, or brain (like the aorta, pulmonary artery, or carotid artery). If the beads could accidentally travel into the brain or spinal cord. If the patient can't handle blocked blood vessels. If the doctor can't safely get the beads to the right place. If the patient has narrow or spasming blood vessels, or is bleeding. If blood vessels are too damaged or too small. If there are extra vessel pathways that might let the beads reach healthy areas by mistake. If the tumor's blood supply is too small for the beads to fit. If blood pressure in the vessels is too high and the beads can't get to the target. If there's a large blood vessel problem where blood skips the usual path and goes straight from artery to vein. In lung blood vessels. If the patient is allergic to the contrast dye used during the procedure. If the patient is pregnant. <p>For Treating Uterine Fibroids (UFE)</p> <p>Don't use the device if the woman:</p> <ul style="list-style-type: none"> Is pregnant

Intended Use	
	<p>Has an infection in the pelvic area</p> <p>Has cancer or abnormal growths in the uterus</p> <p>Has fibroids that grow deep into the uterus or stick out on a stalk</p> <p>Has fibroids getting blood from vessels other than the main uterine arteries</p> <p>For Brain or Nerve Areas:</p> <p>Avoid using HydroPearl Microspheres if:</p> <p>There are open connections between brain and outside blood vessels</p> <p>The beads could go into nerves or brain arteries</p> <p>The beads might enter the carotid, vertebral, or brain arteries</p>

1.3 Device Description

Table 1.3 Device Description

Device Description	
Description of the Device	<p>HydroPearl Microspheres are micro, soft beads made from a safe, gel-like material. They are used by doctors to block blood flow in small blood vessels as part of a medical treatment. These beads are designed to plug blood vessels that feed things like tumors, fibroids, or other abnormal tissue. By cutting off the blood supply, the target tissue shrinks or dies, which helps treat the condition. The beads come in a sterile (germ-free) syringe, ready to use. They are pre-sized and color-coded so doctors can easily choose the right one. Sizes range from very micro to larger beads, depending on the size of the blood vessel. Doctors inject the beads through a thin, flexible tube (called a microcatheter) that's placed inside the blood vessel.</p> <p>Before injection, the beads are mixed with a special liquid that shows up on X-ray, so the doctor can watch exactly where the beads go. This helps them place the beads precisely in the right spot.</p>
Materials or substances in contact with the patient's tissues	Polyethylene glycol hydrogel
Information about medicinal substances in the device	The device does not have any medicine inside them
Description of how device achieves its intended mode of action	HydroPearl Microspheres block small blood vessels. Doctors put them into the blood through a tiny tube. The microspheres travel to the right spot and get stuck there. This stops blood from going to certain parts of the body, like a tumor or a place that is bleeding.
Description of Accessories	Not applicable.
Description of other Devices or Products intended to be used in combination	The HydroPearl Microspheres device comes in a syringe with a special tip that fits easily with standard hospital tools—like micro tubes (microcatheters) and valves (3-way stopcocks)—used to prepare and deliver the beads during a procedure.

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 harms and what might cause them is compiled. The Instructions of Use also describes any warning or precautions. These may be

associated with remaining risk. Reports of any harms 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

There is always a risk of undesirable side effects when you have any type of surgery. It can be difficult to know the exact source of some side effects.

Sometimes, problems can happen during or after the procedure. These may include bleeding, infection, pain, or the micro beads going to the wrong place in the body. For women getting treatment for fibroids, there may also be changes in periods, pain, or the need for more treatment.

- Warnings and precautions

General Warnings:

- Don't mix HydroPearl beads with other special liquids like alcohol or DMSO at the same spot in the body.
- We don't know for sure if this treatment (called UFE) affects a woman's ability to get pregnant or have a healthy baby in the future.
- This treatment is not meant for women who want to have children later.
- If a woman becomes pregnant after UFE, there may be a higher chance of:
 - Heavy bleeding after birth
 - Early delivery
 - Needing a C-section
 - The baby being in the wrong position
- Also, the uterus might be weaker after this treatment, which could increase the chance of it tearing during pregnancy (called uterine rupture).

UFE-Specific Warnings:

- Don't use HydroPearl beads smaller than 500 microns for UFE.
- All women should get a full check-up before having UFE. This includes:
 - Medical history
 - Pictures of the fibroids (imaging)
 - A test of the uterine lining (especially if bleeding is unusual), to make sure there's no cancer.
- If doctors try UFE without surgery, it may delay finding serious diseases like uterine sarcoma (a rare cancer). Signs like fast-growing fibroids or new growth after menopause should be taken seriously. If the fibroids keep growing after UFE, surgery might be needed.

Other Important Safety Tips (Precautions):

- Don't use the HydroPearl beads if the package looks damaged.
- The doctor should choose the right size and amount of beads depending on what needs to be treated.

- Only trained doctors should do this procedure

Extra Notes for UFE:

- Sometimes the beads can go into the wrong blood vessels if flow in the uterus slows down. This can cause problems.
- The long-term results of UFE are still unknown, so doctors and patients need to watch closely over time.
- Summary of any field safety corrective action, (FSCA including FSN) if applicable
During the time of review (01 November 2020 to 31 October 2024), there was one safety action taken for HydroPearl Microspheres.
 - On December 21, 2023, the company MicroVention sent out an urgent recall notice to customers.
 - One batch (Lot #00003420470) of HydroPearl Microspheres was accidentally shipped out even though it didn't fully follow the proper safety steps during production.
 - A part of the manufacturing process (called "aging") lasted five days too long, which was not what the rules said to do.
 - The company used FedEx to quickly notify doctors and hospitals about the recall so they would stop using that batch.

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

- Clinical background of the device

HydroPearl Microspheres are micro, round beads made from a soft, body-safe material. These beads come in different sizes and colors to help doctors tell them apart. They are stored in a clean, sealed syringe ready to use. Doctors use these beads to block blood flow to certain parts of the body—like tumors, fibroids, or other unwanted growths. Blocking the blood causes the area to shrink or die, which helps treat the problem. The device was placed in the market in 2015.

- The clinical evidence for the CE-marking

Doctors have used HydroPearl Microspheres to treat fibroids, prostate problems, and some types of cancer in 247 patients, and the studies showed good results. The research shows the treatment works well and is generally safe. Some studies also used the treatment for knee pain, but that use is not officially approved.

- Safety

Some patients had problems like burning, nausea, or pain after the treatment. A few had issues like trouble peeing, infections, or changes in their periods. These side effects happened at about the same rate as with similar treatments.

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

Different expert groups around the world have shared advice on using small beads (called microspheres) to block blood flow to treat health problems like liver cancer, big prostates, and fibroids. This is called embolization.

For Liver Cancer

Doctors can use different types of embolization treatments. Some use micro beads with medicine in them, and others use plain beads. Experts say both ways work well, and if the first or second treatment doesn't help, the doctor might need to try a different method.

For Enlarged Prostate (BPH)

There is a treatment called PAE that uses beads to shrink the prostate. It can help men who can't or don't want surgery. But it's a hard procedure and only doctors with special training should do it. Right now, it's not used as often as other treatments.

For Fibroids in the Uterus

A procedure called UAE uses beads to shrink fibroids by cutting off their blood supply. Many medical groups say it's a good option instead of surgery, but it's not for women who want to have babies, because we don't know enough yet about how it affects pregnancy. Doctors should talk to patients about the risks and benefits before doing it.

Other Similar Devices:

- Embosphere: Microsphere balls that stay in the body and help block blood to tumors or fibroids. They work really well and are safer than some older materials. Some people may feel chest pain or trouble swallowing, but these usually go away on their own.
- Embozene: Specially made beads that are all nearly the same size. This helps doctors block blood vessels more precisely. They may work even better than some other beads for shrinking tumors, using less medicine.

1.7 Suggested Training for Users

Only doctors who are trained to block blood flow in certain areas of the body should use HydroPearl Microspheres.