Summary of Safety and Clinical Performance

for

LifePearl™ Microspheres

SSCPPT22-0006 Rev A

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DOCUMENT CHANGE HISTORY

SSCP Revision	Change Description	NB approved/verified
A	Initial Release	☐Yes ☐ No* Validation language:

*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]

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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 2.1 Device Identification and General Information

Device Names	
Device Trade Name	LifePearl Microspheres
Device Class	Class III
Basic UDI-DI	08402732LIFEPEARL3D
Year when first certificate (CE) was issued	2015
Legal Manufacturer	
Name & Address	MicroVention, Inc. 35 Enterprise Aliso Viejo, California, 92656 USA
Authorized Representative	
Name & Address	MicroVention Europe SARL 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 2.2 Intended Use

Intended Use	
Intended Purpose	LifePearl Microspheres are small gel spheres that are injected into a patient's blood vessel that supplies a tumor in your liver. LifePearl Microspheres swell and block the flow of blood supplying the tumor. LifePearl Microspheres is designed to remain in the body and not degrade. Your doctor may also decide to load LifePearl Microspheres with chemotherapy drugs.
Indications for Use	LifePearl Microspheres is designed to block the blood flow of blood vessels supplying liver tumors. Your doctor may also decide to load LifePearl Microspheres with chemotherapy drugs.
Intended Patient Group(s)	LifePearl Microspheres is intended for patients with liver cancer or a cancer that has spread from another site in the body to the liver.
Contraindications and/or Limitations	- LifePearl Microspheres is not intended to be used to block the blood vessels in the brain, spinal cord, or the major blood vessels of the heart. - Patients who cannot bear vascular occlusion procedures. - Blood vessels or blood flow that does not allow catheter placement or blocking (embolic) material injection. - Presence or likely onset of narrowing of the brain vessel or blocking of the blood flow (vasospasm) or heavy bleeding (hemorrhage). - Arteries with fatty blockage (atherosclerosis). - Presence of smaller feeding blood vessels branching from the main vessel. - Presence of secondary blood vessel branches that could possibly harm normal pathways when these blood vessels are blocked (embolization). - Presence of blood vessels supplying the tumor not large enough for the LifePearl particles to fit. - Presence of blood vessels that cannot handle the force of blockage by LifePearl Microspheres - Patient is pregnant - Patient has known allergies to radio-opaque contrast agent, drugs and their additives. - Do not use LifePearl Microspheres in the following applications: i. Blockage of non-malignant tumors. ii. Blockage of large, abnormal blood vessels (arteriovenous shunts) Any blood vessels where LifePearl Microspheres could pass directly into the wrong location.

1.3 Device Description

Table 2.3 Device Description

Device Description	
Description of the Device	LifePearl Microspheres are small gel spheres that swell in the presence of water. Your doctor may decided to load LifePearl Microspheres with chemotherapy drugs.
Materials or substances in contact with the patient's tissues	polyethylene glycol (PEG) 10k diacrylamide
Information about medicinal substances in the device	Your doctor may decide to load LifePearl Microspheres with chemotherapy drugs.
Description of how device achieves its intended mode of action	LifePearl Microspheres are injected into the blood vessels that supply a tumor with blood. The microspheres swell with water and block the blood supply to the tumor. Your doctor may choose to load BioPearl Microspheres with cancer drugs. LifePearl Microspheres are designed to remain in the body.
Description of Accessories	There are no accessories included with LifePearl Microspheres.
Description of other Devices or Products intended to be used in combination	Your doctor may decide to load LifePearl Microspheres with chemotherapy drugs.

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 manufacturer uses a standard process to predict a device's risk. The process gives an estimate of what might happen when the device is used. A list of possible risks and what might cause them is listed below. The Instructions 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

The procedure where blood flow is blocked to a tumor or an abnormal area of tissue (Vascular Embolisation) is a high-risk procedure that should be performed by a trained doctor. All known and foreseeable risks are accounted for.

- Warnings and precautions

  - Passage of LifePearl Microspheres particles into normal arteries next to the targeted artery or through the tumor into other arteries or arterial beds.
  - Blood vessel blockage that is not meant for treatment.
  - Blockage in the lungs
  - Inadequate blood supply to an organ or part of the body, especially heart muscles
  - Too many particles in the smallest blood vessels and tissue damage.
  - A lack of blood flow to a part of your brain (ischemic stroke) or the blood supply to part of the brain is interrupted or reduced, preventing brain tissue from getting oxygen and nutrients. (ischemic infarction).
  - A blood vessel or tumor bursts and bleeds heavily.
  - Brain damage including full or partial paralysis of the face, loss of sense of smell or eyesight.
  - Narrowing of the blood vessel, blocking flow (Vasospasm).
  - Death.
  - The need to restore blood flow (Recanalization).
  - Allergic reaction that need medical treatment.
  - Infection that needs medical treatment
  - Clot formation at the tip of the catheter and followed by it being forced out.
  - A collection of blood outside the blood vessel, or bruising, at the cut from the procedure
  - Abnormal bulge or ballooning in the wall of a blood vessel (Arterial aneurysm) at the where a cut was made during the procedure.
  - A medical condition that occurs when a blood clot forms in a deep vein (Deep vein thrombosis) or clotting of a deep vein in a patient's leg.
  - A medical condition that occurs when blood clots block veins or arteries (Thrombosis) of the artery at the cut from the procedure.
  - Allergic reaction
  - Risks of radiation from imaging used to see the blood vessels during the procedure, which may include radiation burns and risks to having future children.
  - DO NOT USE LifePearl Microspheres with blood blocking devices that use organic solvents such as rubbing alcohol (ethyl alcohol) and dimethyl sulfoxide (DMSO) at the same procedure site.

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

  There are no recalls or filed actions for LifePearl Microspheres.

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

- Clinical background of the device

LifePearl was first marketed in 2015.

- The clinical evidence for the CE-marking

There are 17 published clinical studies on patients with liver tumors treated with LifePearl Microspheres. The total 1,664 patients in these studies had good clinical outcomes.

The manufacturer has sponsored eight studies with a total of 681 patients. The patients in these studies had good clinical outcomes.

- Safety

The patients in the published and manufacturer-sponsored studies had overall safe outcomes. Adverse events in the studies included: pain, nausea, vomiting, loss of appetite, weakness, liver abscess, sepsis, liver function impairment, gall bladder inflammation, infection, bruising, dizziness, lowered white blood cell count, lowered platelet count, kidney failure, tumor rupture, and death.

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

Other treatments for liver tumors include chemotherapy drugs, antibody treatments, liver tumor removal surgery, liver transplant, and radio wave heat treatment of the tumor. Ask your doctor which treatment is right for you.

1.7 Suggested Training for Users

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