Summary of Safety and Clinical Performance

for

BioPearl™ Microspheres

SSCPPT1102600A

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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]

Document Revision:
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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	BioPearlMicrospheres
Device Class	Class III
Basic UDI-DI	MVI: 08402732BIOPEARLM7
Year when first certificate (CE) was issued	2020
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 1.2 Intended Use

Intended Use	
Intended Purpose	BioPearl Microspheres are used to block large blood vessels supplying cancer cells or their spread in the liver. This device can also be loaded with cancer drugs. When used for drug loading, it should be done under doctor's direction.
Indications for Use	Blocking large blood vessels supplying cancer cells or their spread in the liver
Intended Patient Group(s)	Patients with liver cancer with large blood vessels and/or cancer spread from other cancers to the liver
Contraindications and/or Limitations	This device cannot be used in: • Blockage of blood vessels belonging to the central blood vessels (around the lung, heart, neck, and brain) • Patients who refuse blocking blood vessels procedures • Blood vessel structure or blood flow that prevents placing in tubes or injecting any object to block blood flow • Sudden narrowing of blood vessel or bleeding • Severe disease related to clogging of arteries • Back up blood vessels endangering normal areas during procedure • Blood vessels not large enough to accept the device • Blood vessel resistance to the feeding vessels preventing passage of the device into the area • Pregnant patient • Patient has known allergies to radio-opaque contrast agent, drugs and their additives Do not use this device if there is blockage in large areas between blood vessels or the device pass directly into other areas

1.3 Device Description

Table 1.3 Device Description

Device Description	
Description of the Device	BioPearl Microspheres are precisely sized and swell in the presence of water. This device can also load and release cancer drugs. The device is designed that the blood flow can increase after 2 weeks of procedure based on animal study. It is designed to degrade over time and be resorbed in the blood stream. The device will physically block blood flow to tumors. It can also be loaded with cancer drugs under doctor's supervision to stop the cancer cells from growing.

Materials or substances in contact with the patient's tissues	Glycerol mono-methacrylate, Dimethyl acrylamide monomers that are polymerized together with a sulfopropyl acrylate salt.
Information about medicinal substances in the device	This device can be loaded with cancer drugs. When used for drug loading, it should be done under the doctor's direction.
Description of how device achieves its intended mode of action	BioPearl 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. BioPearl Microspheres are designed to degrade and be reabsorbed into your bloodstream.
Description of Accessories	There are no accessories for BioPearl Microspheres.
Description of other Devices or Products intended to be used in combination	This device can be loaded with cancer drugs. When used for drug loading, it should be done under the doctor's direction.

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 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:

  - Undesirable passage of the device into normal arteries next to the targeted area or through the area into other arteries
  - Non-target blockage
  - Blockage of lung

- Reduced blood supply
- Saturation in network of small blood vessels and tissue damage
- Brain cell death
- Break in blood vessel and bleeding
- Damage in the nerves including brain nerve
- Sudden muscle tightness
- Death
- Restoring blood flow
- Bad body reactions requiring medical intervention
- Infection requiring medical intervention
- Clot formation at the end of the tube and subsequent failure in placement
- Localized bleeding at the site of device placement
- Bulge in the artery at the target site
- Clotting of a deep vein in a patient's leg
- Clotting of the artery at the target site
- Allergic reaction
- Risks of radiation from medical imaging used to visualize the blood vessels during the block, which may include radiation burn and risks to future pregnancy
- Do not use this device with other devices for blocking based on organic materials such as ethyl alcohol and dimethyl sulfoxide (DMSO) at the same target site

- Warnings and precautions

  There are some warnings and precautions with using the BioPearl Microspheres. All of these relate to the procedural steps done by the doctor. Your doctor will let you know if there are any actions you must take before the procedure.

  WARNINGS:

  Blocking the blood vessel is a high-risk procedure. The procedure should be performed by doctors who are trained. Side effects can occur at any time during or after the procedure such as:

  – Unwanted passage of the device into normal vessels next to the targeted area or to any other areas
  – Non-target blockage
  – Blockage in the lung
  – Reduced blood supply at unwanted location

- Saturation in a network of capillaries and tissue damage
- Reduced blood flow or death of tissue
- Vessel or lesion broken and bleeding
- Damage in the nervous system including dysfunction in cranial nerve
- Sudden narrowing of blood vessel
- Death
- Restored blood flow
- Body reactions needing urgent medical help
- Infection needing urgent medical help
- Clot at the edge of the rube
- Blood collection or skin discoloration at the incision site for arterial access
- Arterial aneurysm at the incision site for arterial access
- Deep vein thrombosis or clotting of a deep vein in a patient's leg
- Blood clot at the incision site (cut)
- Allergies
- Risks of radiation from medical imaging such as radiation burn and risks to future pregnancy
- Do not use this device with other devices based on organic solvents such as ethyl alcohol and dimethyl sulfoxide (DMSO) at the same blockage site

CAUTIONS:

- Do not use if the vial or cap looks damaged.
- Do not use this device in its original dry state. It should be reformed before use.
- The procedure with this device should only be done by a doctor who is trained.
- Each package of this device can only be used once for one patient. Dispose of any unused material**.** Do not clean again for another use.
- The doctor should carefully select the size and the quantity of this device based on his experience and expertise
- Doctors must decide the right time to stop the procedure.
- Slowing and termination of flow indicates that the vessel or the target area is blocked. Careful monitoring is required.
- Blocking small particles must be done slowly. The injection speed and manner must be controlled. If not done correctly, the device can block non-targeted tissue or organs.

- Do not use if the device is not kept properly
- If the connections between small vessels are not normal, it can block non-targeted areas and cause bad side effects to the patient.
- Particles smaller than 100 µm can move to distal anastomotic feeders and embolize circulation to distal tissue. For this reason, smaller particles have a greater likelihood of causing reduced blow flow. This should be considered before starting the procedure. Possible consequences include, but are not limited to, loss of motion, tissue death, swelling, abscess information, and severe side effects from cancer drugs.
- Reduced blood flow to tissue next to the target area may cause swelling. So special care should be taken to avoid such reduced blood flow.
- If there are side effects during injection, consider stopping the procedure. These symptoms may include changes in the patient's vital signs, such as low oxygen level or central nervous system changes.

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

There were no safety or corrective actions from the company for these microspheres.

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

- Clinical background of the device

BioPearl Microspheres were first placed on the market in 2020.

- The clinical evidence for the CE-marking

There is one study on BioPearl Microspheres. In this study, 13 patients were treated with BioPearl Microspheres (Iezzi et al., 2025). All 13 patients had successful tumor blockage.

- Safety

In this study, one of the thirteen patients experienced catheter blockage and two patients experienced collection of bile in their abdomen (biloma) that required surgery (Iezzi et al., 2025).

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 cancer include cancer 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.

References

IEZZI, R., POSA, A., BARGELLINI, I. & SPREAFICO, C. 2025. Transarterial Chemoembolization with BioPearls for the Treatment of Hepatocellular Carcinoma: A Preliminary Experience. *Pharmaceuticals*, 18, 307.