

INSTRUCTIONS FOR USE
LifePearl™ Microspheres
STERILE • SINGLE USE ONLY • NON-PYROGENIC

Carefully read all instructions prior to use.

MRI Compatibility: MR Safe

DESCRIPTION:

LifePearl device comprises a range of embolizing microspheres that are biocompatible, hydrophilic, precisely calibrated and capable of loading and releasing chemotherapeutic agents (such as Doxorubicin and Irinotecan) in a controlled manner.

LifePearl Microspheres are produced from a biocompatible hydrogel comprising of polyethylene glycol and are available in the following size ranges:

Size Range	Label Color
100 ± 25 µm	Black
200 ± 50 µm	Yellow
400 ± 50 µm	Blue

Qualitative Implant Material Information	
Implant Material	Limit
Polyethylene glycol 10k	< 75 ppm
Diamino propane hydrochloride	< 25 ppm
Sulfopropyl acrylate potassium	< 25 ppm
Tetramethylethylenediamine	< 10 ppm
Hexane	< 12 ppm
Dye Colorant	< 10 ppm

PRESENTATION:

- LifePearl Microspheres are offered in a 20 ml syringe pre-filled with 2 ml of product suspended in a non-pyrogenic, sterile transport solution of physiological buffered saline.
- Total volume of physiological buffered saline and LifePearl Microspheres is approximately 6 ml.
- Prefilled syringes of LifePearl Microspheres are packaged in a sterile, sealed tray with a peel-away lid.
- A color-coded label indicates the specific size of the microspheres contained in the syringe.
- Permanent implant. Follow-up required at the discretion of the physician.

INTENDED PURPOSE/INDICATIONS:

LifePearl Microspheres are indicated for embolization of blood vessels supplying primary hyper-vascular tumors or metastases in the liver.

Note: LifePearl Microspheres can be loaded with chemotherapeutic drugs. When used for drug loading, drug loading should be done under a physician's direction, choice and responsibility, based on type and dose of drug most beneficial to the patient.

CONTRAINDICATIONS:

- Targeted embolization of blood vessels belonging to the central vascular system (arteriae pulmonales, aorta ascendens, arcus aorta, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior)
- Patients intolerant to vascular occlusion procedures.
- Vascular anatomy or blood flow that precludes catheter placement or embolic agent injection.
- Presence or likely onset of vasospasm or hemorrhage.
- Presence of severe atheromatous disease.
- Presence of feeding arteries smaller than distal branches from which they emerge.
- Presence of collateral vessel pathways potentially endangering normal territories during embolization.
- Presence of arteries supplying the lesion not large enough to accept LifePearl Microspheres.
- Vascular resistance peripheral to the feeding arteries precluding passage of LifePearl Microspheres into the lesion.
- Patient is pregnant
- Patient has known allergies to radiopaque contrast agent, drugs and their additives.
- Do not use LifePearl Microspheres in the following applications:
 - i. Embolization of non-malignant tumors.
 - ii. Embolization of large diameter arteriovenous shunts (i.e., where the blood does not pass through the arterial/capillary/venous transition but directly from artery to vein).
 - iii. Any vasculature where LifePearl Microspheres could pass directly into non-target territories.

CLINICAL BENEFIT:

LifePearl Microspheres are intended for embolization of blood vessels supplying primary hyper-vascular tumors or metastases in the liver. The embolization with cytotoxic chemotherapeutic drugs results in ischemic necrosis of the tumor.

CAUTIONS:

- Do not use if the syringe or packaging appears damaged.
- Do not use LifePearl Microspheres that have been improperly stored or mishandled.
- Select the size and quantity of LifePearl Microspheres appropriate for the pathology to be treated.

- Embolization with LifePearl Microspheres should only be performed by a physician with appropriate interventional training.
- Each package of LifePearl Microspheres is intended for single patient use only. Discard any unused material. Do not re-sterilize.
- The physician should carefully select the size and the quantity of the LifePearl Microspheres according to the lesion to be treated, based on the physician's education, training and currently available scientific evidence.
- Physicians must decide the appropriate time to stop the infusion of LifePearl Microspheres.
- Proximal slowing and termination of flow may indicate that the vessel or the target area is occluded. Careful fluoroscopic monitoring is required.
- Microparticle embolization must be performed slowly. The injection speed and manner must be controlled. Excessive injection rate may result in retrograde flow in the vessel leading to non-targeted embolization of healthy tissue or organs.
- If arteriovenous anastomoses, branch vessels which lead away from the targeted embolization area, or emergent not evident prior to embolization are present, it can lead to non-targeted embolization and cause severe complications for the patient.
- Particles smaller than 100 μm can migrate to distal anastomotic feeders and embolize circulation to distal tissue. For this reason, smaller particles have a greater likelihood of causing unwanted ischemic injury. This should be considered prior to starting the embolization procedure. Possible consequences include, but are not limited to, paralysis, necrosis, swelling, abscess formation and severe post-embolization syndrome.
- Ischemia of tissue adjacent to the target area may result from post-embolization swelling. Therefore, special care should be taken to avoid such ischemia of non-tolerant, non-targeted tissue such as a nervous system.
- If there are any symptoms of unwanted embolization during injection, consider stopping the procedure to evaluate the possibility of shunting. Such symptoms may include changes in patient's vital signs, such as hypoxia or central nervous system changes.

POTENTIAL COMPLICATIONS / WARNINGS

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State or Local Health Authority in which the user and/or patient is established.

Vascular Embolization is a high-risk procedure. The procedure should be performed by physicians trained in vascular embolization procedures. Complications can occur at any time during or after the procedure and may include, but not limited to

- Undesirable reflux or passage of LifePearl Microspheres into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds.
- Non-target embolization.
- Pulmonary embolization.
- Ischemia at an undesirable location.

- Capillary bed saturation and tissue damage.
- Ischemic stroke or ischemic infarction.
- Vessel or lesion rupture and hemorrhage.
- Neurological deficits including cranial nerve palsies.
- Vasospasm.
- Death.
- Recanalization.
- Foreign body reactions necessitating medical intervention.
- Infection necessitating medical intervention.
- Clot formation at the tip of the catheter and subsequent dislodgement.
- Hematoma, or bruising, 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.
- Thrombosis of the artery at the incision site for arterial access.
- Allergic reaction
- Risks of radiation from angiography and fluoroscopy used to visualize the blood vessels during embolization, which may include radiation burn and risks to future fertility.
- DO NOT USE LifePearl Microspheres in conjunction with embolization devices based on organic solvents such as ethyl alcohol and dimethyl sulfoxide (DMSO) at the same embolization site.

INTERACTIONS WITH PHARMACEUTICALS

- There are no known chemical interactions between LifePearl Microspheres and pharmaceuticals.

DRUG SELECTION AND LOADING:

- LifePearl Microspheres can load and deliver drugs that may be useful in the treatment of diseases in which embolization is also effective.
- For drug loading please refer to attached instructions for drug loading.

INSTRUCTIONS FOR USE

- Prior to the embolization procedure, evaluate the vascular anatomy associated with the lesion using high resolution imaging.
- LifePearl Microspheres are designed to be used in a variety of micro-catheters and catheters.
- Select a delivery catheter of appropriate size, suitable for the dimensions of target vessels.
- LifePearl Microspheres are available in a range of sizes. Care should be taken to choose the appropriate size of LifePearl Microspheres that best matches the pathology (i.e., vascular target/vessel size) and provides the desired clinical outcome.

- Choose a delivery catheter with an outer diameter that is smaller than the target vessel. LifePearl Microspheres can tolerate temporary compression of 20% to 30% in order to facilitate passage through the delivery catheter.
- Utilize catheter's minimum inner diameter measurement to determine the catheter compatibility with the microspheres. Carefully evaluate the vascular network associated with the lesion using high resolution imaging prior to beginning the embolization procedure.
- Introduce the delivery catheter into the target vessel according to standard techniques. Position the catheter tip as close as possible to the treatment site to avoid inadvertent occlusion of normal vessels.
- LifePearl Microspheres are not radiopaque. It is recommended to monitor the embolization under fluoroscopic visualization by adding the desired amount of contrast medium to the suspension fluid.
- Take care to ensure proper suspension of the LifePearl Microspheres in the contrast medium to enhance distribution during injection.
- Slowly inject LifePearl Microspheres into the delivery catheter under fluoroscopic visualization while observing the contrast flow rate. Exercise conservative judgment in determining the embolization endpoint.
- Upon completion of the treatment, remove the catheter while maintaining gentle suction so as not to dislodge LifePearl Microspheres still within the catheter lumen.
- Discard any unused LifePearl Microspheres.

CONSERVATION AND STORAGE:

- Store unopened LifePearl Microspheres in its original packaging. Keep dry and away from sunlight.
- Use by the date indicated on the label.
- Do not freeze.






















DISPOSAL:

Dispose of device/syringe in accordance with hospital policy and local regulations for biohazardous waste.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The Summary of Safety and Clinical Performance (SSCP) for the device will be accessible in the European database on medical devices after the launch of the European Database on Medical Devices (EUDAMED) (EUDAMED: <https://ec.europa.eu/tools/eudamed>). The SSCP will be linked to the Basic UDI-DI in the EUDAMED public website. A patient implant card is included in the package. This card should be completed and provided to the patient.

SYMBOLS:

	Catalog number
	Sterilized using steam or dry heat
	Keep dry
	Batch code
	Use-by-date
	Consult Instructions for Use
	Do not reuse
	Keep away from sunlight
	Manufacturer
	Do not use if package is damaged and consult instructions for use
	Medical Device
	UDI
	Single sterile barrier system
	Contents
	Authorized representative in the European Community/European Union
	Non-Pyrogenic
	Importer
	Distributor
	Do not resterilize
	MR Safe
	Country and Date of Manufacture

WARRANTY

MicroVention and Terumo warrant that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning, and sterilization of the device, as well as factors relating to the patient, diagnosis, treatment, surgical procedure, and other matters beyond MicroVention or Terumo's control, directly affect the device and the results obtained from its use. MicroVention or Terumo's sole obligation under this warranty is limited to the repair or replacement of this device through its expiration date, and MicroVention and Terumo shall not be liable for any incidental, indirect, special, or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Neither MicroVention nor Terumo assumes, or authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Neither MicroVention nor Terumo assumes any liability with respect to devices reused, reprocessed, or re-sterilized and makes no warranties, expressed or implied, including, but not limited to, merchantability or fitness for intended use, with respect to such devices.

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MicroVention, Inc.
35 Enterprise
Aliso Viejo, CA 92656, USA
PH: +1.714.247.8000
www.terumoneuro.com

EC|REP

MicroVention Europe, S.A.R.L.
30 bis, rue du Vieil Abreuvor
78100 Saint-Germain-en-Laye
France
PH: +33 (0)1 39 21 77 46



Terumo Europe N.V.
Interleuvenlaan 40
3001 Leuven Belgium
www.terumo-europe.com

CE 0297