LC Bead™ Embolic Agent

INSTRUCTIONS FOR USE

STERILE • SINGLE USE ONLY • NON-PYROGENIC
Sterilized by steam. Do not use if the package is opened or damaged

DESCRIPTION:

LC Bead comprise a range of hydrogel microspheres that are biocompatible, hydrophilic, nonresorbable and precisely calibrated. LC Bead microspheres are produced from polyvinyl alcohol and are available in the following size ranges:

<table>
<thead>
<tr>
<th>Size</th>
<th>Label Color</th>
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</thead>
<tbody>
<tr>
<td>100 – 300 µm</td>
<td>Yellow</td>
</tr>
<tr>
<td>300 – 500 µm</td>
<td>Blue</td>
</tr>
<tr>
<td>500 – 700 µm</td>
<td>Red</td>
</tr>
<tr>
<td>700 – 900 µm</td>
<td>Green</td>
</tr>
<tr>
<td>900 – 1200 µm</td>
<td>Purple</td>
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</tbody>
</table>

PRESENTATION:

- Glass vial of 10ml
- Stopper sealed by an aluminum cap equipped with a colored cap
- Each vial contains approximately 1 ml or 2 ml of LC Bead in a non-pyrogenic sterile physiological buffered saline.
- Each vial is intended for single patient use only. Do not resterilise. Discard any unused material

INDICATIONS:

LC Bead microspheres are intended to be used for the embolisation of hypervascular tumors and arteriovenous malformations (AVMs).

CLINICAL APPLICATIONS:

The scientific literature provides extensive documentation of embolisation procedures using a wide variety of artificial agents in both neurological and peripheral vascular systems, including the head, neck, spine, liver, genitourinary tract, uterus, gastrointestinal system, limbs and lungs. A representative bibliography is provided following these instructions for use.

CONTRAINDICATIONS:

1. Patients intolerant to occlusion procedures.
2. Vascular anatomy or blood flow that precludes catheter placement or emboli injection.
3. Presence or likely onset of vasospasm.
4. Presence or likely on set of hemorrhage.
5. Presence of severe atheromatous disease.
6. Presence of feeding arteries smaller than distal branches from which they emerge.
7. Presence of patent extra-to-intracranial anastomoses or shunts.
9. Presence of end arteries leading directly to cranial nerves.
10. Presence of arteries supplying the lesion not large enough to accept LC Bead microspheres.
11. Vascular resistance peripheral to the feeding arteries precluding passage of LC Bead microspheres into the lesion.
12. Do not use LC Bead microspheres in the following applications:
   i. Embolisation 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).
   ii. The pulmonary arterial vasculature.
   iii. Any vasculature where the use of LC Bead Embolic Agent could pass directly into the internal carotid artery or the above listed vessels.

WARNING: Studies have shown that LC Bead microspheres do not form aggregates and, as a result, penetrate deeper into the vasculature as compared to similarly sized PVA particles. Care must be taken to choose a larger sized LC Bead Embolic Agent when embolising arteriovenous malformations with large shunts to avoid passage of the microspheres into the pulmonary or coronary circulation.

The color of the LC Bead microspheres could be visible through the skin if injected into arteries feeding superficial tissues.

CAUTIONS:

- Do not use if the vial or packaging appear damaged.
- Sterile and single use product. Do not reuse.
- Select the size and quantity of LC Bead microspheres appropriate for the pathology to be treated.
- Embolisation with LC Bead microspheres should only be performed by physicians who have received appropriate interventional occlusion training in the region intended to be embolised.

CAUTION:

Federal (USA) law restricts this device to sale by or on order of a physician.
In: Peripheral Vascular Intervention.

REFERENCES:


POTENTIAL COMPLICATIONS:

1. Undesirable reflux or passage of LC Bead microspheres into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds, such as the internal carotid artery, pulmonary, or coronary circulations.
2. Pulmonary embolisation.
3. Ischemia at an undesirable location.
4. Capillary bed saturation and tissue damage.
5. Ischaemic stroke or Ischaemic infarction.
6. Vessel or lesion rupture and hemorrhage.
7. Neurological deficits including cranial nerve palsies.
8. Vasospasm.
10. Recanalisation.
11. Foreign body reactions necessitating medical intervention.
12. Infection necessitating medical intervention.
13. Clot formation at the tip of the catheter and subsequent dislodgement.

CONSERVATION AND STORAGE:

- LC Bead microspheres must be stored in a cool, dry and dark place in its original packaging.
- Use by the date indicated on the vial label.
- Do not freeze.

INSTRUCTIONS FOR USE:

- Carefully evaluate the vascular network associated with the lesion using high resolution imaging prior to beginning the embolisation procedure.
- LC Bead microspheres are available in a range of sizes. Care should be taken to choose the appropriate size LC Bead microspheres that best matches the pathology (ie. vascular target/vessel size) and provides the desired clinical outcome.
- When embolising arteriovenous malformations, choose a particle size that will occlude the nidus without passing through the AVM.
- Choose a delivery catheter based on the size of the target vessel. LC Bead microspheres can tolerate temporary compression of 20% to 30% in order to facilitate passage through the delivery catheter.
- 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.
- LC Bead microspheres are not radio-opaque. It is recommended to monitor the embolisation under fluoroscopic visualization by adding the desired amount of contrast medium to the physiologic suspension fluid.

To deliver LC Bead microspheres:

- After shaking the bottle containing the LC Bead, dilute them with contrast medium either in a metallic/stainless steel cup or directly in the vial. Take care to ensure proper suspension of the microspheres in the contrast medium to enhance distribution during injection. Draw the LC Bead into a syringe needle of a size greater than or equal to 19 gauge (1.07 mm). Slowly inject LC Bead into the delivery catheter under fluoroscopic visualization while observing the contrast flow rate. If there is no effect on the flow rate, choose a larger microsphere size and repeat the delivery process. 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 LC Bead microspheres still within the catheter lumen.
- Discard any open, unused LC Bead in the Vial.

REFERENCES:

It is recommended that the solution be slowly injected. If there is no evidence of plugging, then:

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Patents

US 5,583,163
US 6,652,883
US 6,676,971
Other patents pending

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