

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:

Size	Label Color
100 – 300 µm	Yellow
300 – 500 µm	Blue
500 – 700 µm	Red
700 – 900 µm	Green
900 – 1200 µm	Purple

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 onset 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.
8. Presence of collateral vessel pathways potentially endangering normal territories during embolisation.
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 (ie. 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.

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.
9. Death.
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.

PACKAGE LABEL:

REF	Catalogue number
LOT	Batch number/Lot number
	Do not reuse
	Attention see instructions for use
STERILE	Steam Sterilized
	Use before/Expiry
	Protect from light
	Protect from moisture
	Do not freeze

REFERENCES:

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3. Beaujeux R, Laurent A, Wassef M et al: Trisacryl gelatin microspheres for therapeutic embolization, II: Preliminary clinical evaluation in tumours and arteriovenous malformations. *AJNR*, 17: 541-548, March 1996.
4. Bendszus M, Klein R, Burger R, et al: Efficacy of trisacryl gelatin microspheres and polyvinylalcohol (PVA) particles in the preoperative embolization of meningiomas. Presented at the ASNR 36th Annual Meeting, May 17-21, 1998.
5. Chamsangavej C, Wallace S: Transcatheter regional therapy of extremity tumours. In: *Peripheral Vascular Intervention*.
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7. Derdyn C, Graves, V, Salamat M, Rappe A: Collagen-coated acrylic microspheres for embolotherapy: In vivo and in vitro characteristics. *AJNR*, 18:647-653, April 1997.
8. Deveikis JP: endovascular therapy of intracranial arteriovenous malformations: materials and techniques. *Neuroimaging Clin of N Am*, 8(2):401-424, 1998.
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12. Rose SC: Transcatheter occlusion of injured extremity and pelvic arteries. In: *Peripheral Vascular Intervention*.
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Patents

US 5,583,163

US 6,652,883

US 6,676,971

Other patents pending

Manufactured by:
Biocompatibles UK Limited
Chapman House
Farnham Business Park
Weydon Lane
Farnham
Surrey GU9 8QL
United Kingdom

Tel: +44 (0)1252 732 732
Fax: +44 (0)1252 732 777
<http://www.biocompatibles.com>