

LC BEAD LUMI™ Embolic Beads

Now available in smaller 40-90 µm size to support distal tumor penetration

LC Bead LUMI are precisely calibrated embolic beads developed using the same patented structure as the clinically proven LC Bead, but with the addition of a radiopaque component providing inherent, long-term radiopacity.

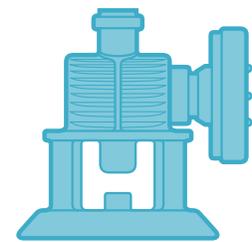


DESCRIPTION

- LC Bead LUMI are biocompatible, non-resorbable hydrogel beads offered in a variety of sizes.
- LC Bead LUMI are manufactured to be inherently radiopaque and visible under imaging (Computed Tomography [CT], Cone Beam Computed Tomography [CBCT] and Fluoroscopy).

PRESENTATION

- Each 10 ml vial contains approximately 2 ml of product in sterile phosphate buffered saline (total volume approximately 8 ml).
- Each vial of LC Bead LUMI is intended for single patient use only. Do not re-sterilize. Discard any unused material.



**Sterile 20mm ViaLok™
Vented Vial Access Device***
supplied in each package

* Yukon Medical LLC,
4021 Stirrup Creek, Durham, NC USA

STORAGE AND STABILITY

LC Bead LUMI™	Temperature	Shelf Life
Unopened	Room Temperature	24 months
Opened	2-8°C	24 hours
	Room Temperature	4 hours
Do not freeze LC Bead LUMI™		

ORDERING INFORMATION

	LC Bead LUMI™	
Size	40-90 µm	70-150 µm
Label Color	Orange	Black
Volume of Beads	2 ml	2 ml
Product Code	RO2L000	RO2L001
Catheter Compatibility	≥ 2.0 Fr (0.483 mm / 0.019 in)	≥ 2.0 Fr (0.483 mm / 0.019 in)

EXPLANATION OF SYMBOLS ON LC Bead LUMI PACKAGE LABELS

- REF** Catalogue number
- LOT** Batch number/Lot number
-  Do not reuse
-  Attention see instructions for use
-  Steam sterilized
-  Use-by date/Expiry
-  Protect from light/keep away from sunlight
-  Protect from moisture/keep dry
-  Do not freeze. Store at 2-25°C
-  Manufacturer

LUMI

INDICATIONS: • LC Bead LUMI™ are intended to be used for the embolization of hypervascular tumors and arteriovenous malformations (AVM). **CONTRAINDICATIONS:** 1. Patients intolerant to occlusion procedures. 2. Vascular anatomy or blood flow that precludes catheter placement or injection of embolics. 3. Presence or likely onset of vasospasm. 4. Presence or likely onset of hemorrhage. 5. Presence of severe atheromatous disease. 6. Lesion/tumor-feeding vessel with diameter smaller than any distal vessel(s) branching from it. 7. Presence of patent extra-to-intracranial anastomoses or shunts. 8. Presence of end arteries leading directly to cranial nerves. 9. Presence of arteries supplying the lesion/tumor not large enough to accept LC Bead LUMI™. 10. Vascular resistance peripheral to the feeding arteries precluding passage of LC Bead LUMI™ into the lesion/tumor. 11. Presence of collateral vessel pathways potentially endangering normal territories during the embolization procedure that cannot be coiled or blocked. 12. Presence of high-flow arteriovenous shunt with a diameter greater than the selected bead size that cannot be coiled or blocked. 13. Do not use LC Bead LUMI™ in the following applications: i. Embolization of arteriovenous (AV) shunts (i.e. where the blood does not pass through the arterial/capillary/venous transition but directly from artery to vein). ii. Any vasculature where LC Bead LUMI™ could pass directly into the internal carotid artery or other non-target territories. iii. Any neurovascular indication. 14. Do not use in the pulmonary arterial vasculature. **CAUTIONS:** • 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. • In case of hypersensitivity to contrast agents it is recommended not to use LC Bead LUMI™. • Non-target embolization may occur in the presence of arteriovenous anastomosis, branch vessels which lead away from the targeted embolization area, or emergent vessels not evident prior to embolization. The patient may experience severe complications as a result of non target embolization. Special care should be taken to avoid ischemia of non-tolerant, non-targeted tissue. • Patients with prior biliary surgery, bile duct dilation or vessels close to bile ducts may be at increased risk from infection (e.g. biloma/ liver abscess). • Consideration should be given to Tc99m-MAA scanning if there is suspicion of AV shunting, especially when using the smaller bead sizes. • Risks of radiation from angiography and fluoroscopy used to visualise the blood vessels during embolization which may include a radiation burn and risks to future fertility. **POTENTIAL COMPLICATIONS:** 1. Undesirable reflux or passage of LC Bead LUMI™ into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds, such as the pulmonary, internal carotid or coronary circulations. 2. Non-target embolization for example: • Pulmonary embolization • Pancreatitis • Deep vein thrombosis, or clotting of a deep vein in patient's leg(s) • Thrombosis of the artery at the incision site for arterial access 3. Ischemia at an undesirable location. 4. Capillary bed saturation and tissue damage. 5. Ischemic stroke or ischemic infarction. 6. Vessel or lesion/tumor rupture and hemorrhage. 7. Neurological deficits including cranial nerve palsies. 8. Vasospasm. 9. Recanalization. 10. Foreign body reactions necessitating medical intervention. 11. Infection necessitating medical intervention. 12. Clot formation at the tip of the catheter and subsequent dislodgement causing arterial thromboembolic sequelae. 13. Post embolization syndrome which may include nausea, fever, pain and increases in laboratory parameters such as elevated liver enzymes. 14. Allergic reactions to contrast agents or LC Bead LUMI™ in patients who are allergic or with known sensitivity to iodine / iodine containing substances. 15. Embolization of the wrong artery or migration of the beads to other parts of the body, which may necessitate further treatment. 16. Haematoma, or bruising or arterial aneurysm, at the arterial access incision site. 17. Liver abscess 18. Death.

Boston Scientific
Advancing science for life™

Peripheral Interventions
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

To order product or for more information
contact customer service at 1.888.272.1001.

© 2020 Boston Scientific Corporation
or its affiliates. All rights reserved.

PI-744207-AA