EmboCube™

English

Embolization Gelatin

INSTRUCTIONS FOR USE

℞ Only **Caution:** Federal (U.S.A.) law restricts this device to use by or on the order of a licensed physician.

INTENDED USE

EmboCube Embolization Gelatin is indicated for use in embolization of:

- Hypervascular tumors,
- Blood vessels to occlude blood flow to control bleeding / hemorrhaging in the peripheral vasculature.

DEVICE DESCRIPTION

EmboCube Embolization Gelatin consists of biocompatible, hydrophilic and dry pre-cut cubes of resorbable porcine gelatin packaged in a 10-mL syringe with a standard luer lock tip.

SPECIFICATIONS

EmboCube Embolization Gelatin is sold in two sizes (2.5 mm and 5.0 mm) and three weight configurations with the specification for each size listed below:

Order Number	Weight	Cube Hydrated Size	Recommended injection syringe volume	Minimum catheter ID	Color Code
EC2525	25 mg	2.5 mm	1 mL	0.024″ (0.61 mm)	Green
EC2550	50 mg	2.5 mm	1 mL	0.024″ (0.61 mm)	Green
EC25100	100 mg	2.5 mm	1 mL	0.024″ (0.61 mm)	Green
EC5025	25 mg	5.0 mm	3 mL	0.040″ (1.02 mm)	Red
EC5050	50 mg	5.0 mm	3 mL	0.040″ (1.02 mm)	Red
EC50100	100 mg	5.0 mm	3 mL	0.040″ (1.02 mm)	Red

Based on an animal model, EmboCube Embolization Gelatin showed signs of resorption at week 4.

CONTRAINDICATIONS

- Patients intolerant to occlusion procedures
- Vascular anatomy or blood flow that precludes catheter placement or embolic agent injection
- Presence of vasospasm
- Presence of severe atheromatous disease
- Presence of feeding arteries too small to accept the selected device
- Presence of collateral vessel pathways potentially endangering normal territories during embolization
- Presence of arteries supplying the lesion not large enough to accept the EmboCube Embolization Gelatin
- Vascular resistance peripheral to the feeding arteries precluding passage of the EmboCube Embolization Gelatin into the lesion
- In large diameter arteriovenous shunts (i.e. where the blood does not pass through an arterial/capillary/venous transition but directly from an artery to a vein)
- In the pulmonary vasculature
- Coronary and intracerebral vascular use
- Presence of patent extra-to-intracranial anastomoses or shunts
- Presence of end arteries leading directly to cranial nerves
- In any vasculature where EmboCube Embolization Gelatin could pass directly into the internal carotid artery, vertebral artery, intracranial vasculature or the above listed vessels
- Patients with known allergy to gelatin

WARNINGS

- EmboCube Embolization Gelatin contains gelatin of porcine origin, and therefore, could cause an immune reaction in patients who are hypersensitive to collagen or gelatin. Careful consideration should be given prior to using this product in patients who are suspected to be allergic to injections containing gelatin.
- The physician should be sure to carefully select the size of EmboCube Embolization Gelatin according to the size of the target vessels at the desired level of occlusion in the vasculature and after consideration of the arteriovenous angiographic appearance. Size should be selected to prevent passage from artery to vein.
- Because of the significant complications of non-target embolization, extreme caution should be used for any procedures involving the extracranial circulation encompassing the head and neck, and the physician should carefully weigh the potential benefits of using embolization against the risks and potential complications of the procedure. These complications can include blindness, hearing loss, loss of smell, paralysis and death.
- Serious radiation induced skin injury may occur to the patient due to long periods of fluoroscopic exposure, large patient diameter, angled x-ray projections, and multiple image recording runs or radiographs. Refer to your facility's clinical protocol to ensure the proper radiation dose is applied for each specific type of procedure performed. Physicians should monitor patients that may be at risk.
- Onset of radiation-induced injury to the patient may be delayed. Patients should be counseled on potential radiation side effects and whom they should contact if they show symptoms.
- Pay careful attention for signs of non-targeted embolization. During injection carefully monitor patient vital signs to include SaO2 (e.g. hypoxia, CNS changes). Consider terminating the procedure, investigating for possible shunting, or increasing EmboCube Embolization Gelatin size if any signs of non-target embolization occur or patient symptoms develop.
- Consider upsizing the EmboCube Embolization Gelatin if angiographic evidence of embolization does not quickly appear evident during injection of the EmboCube Embolization Gelatin.
- Post embolization swelling may result in ischemia to tissue adjacent to target area. Care must be given to avoid ischemia intolerant, nontargeted tissue such as nervous tissue.
- EmboCube Embolization Gelatin should not be used in the neurovasculature.

PRECAUTIONS

- Patients with known allergy to contrast medium may require prophylactic treatment prior to embolization.
- Additional evaluations or precautions may be necessary in managing periprocedural care for patients with conditions such as, but not limited to:
  - Bleeding diathesis or hypercoagulative state
  - Immunocompromise
- Do not use the EmboCube Embolization Gelatin if the syringe or packaging appear damaged.
- For single patient use only – Contents supplied sterile - Never reuse, reprocess or resterilize the contents of a syringe. Reusing, reprocessing or resterilizing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reusing, reprocessing or resterilizing may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. All procedures must be performed according to accepted aseptic technique.
- Do not connect the 10-mL syringe with EmboCube Embolization Gelatin directly to a microcatheter for embolic delivery.
- The syringe is intended for embolic use only. Do not use for any other application.
- Select the size and quantity of EmboCube Embolization Gelatin appropriate for the pathology to be treated.
- Embolization with EmboCube Embolization Gelatin should only be performed by physicians who have received appropriate interventional embolization training in the region to be treated.

POTENTIAL COMPLICATIONS

Vascular embolization is a high-risk procedure. Complications may occur at any time during or after the procedure, and may include, but are not limited to, the following:

- Paralysis resulting from non-targeted embolization or ischemic injury from adjacent tissue edema
- Undesirable reflux or passage of EmboCube Embolization Gelatin 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
- Pulmonary embolism due to arterial venous shunting
- Ischemia at an undesirable location including ischemic stroke, ischemic infarction (including myocardial infarction), and tissue necrosis
- Capillary bed occlusion and tissue damage
- Vessel or lesion rupture and hemorrhage
- Recanalization
- Foreign body reactions necessitating medical intervention
- Infection necessitating medical intervention

- Complications related to catheterization (e.g. hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgment, and nerve and/or circulatory injuries, which may result in leg injury)
- Allergic reaction to medications (e.g. analgesics)
- Allergic reaction to contrast media or embolic material
- Pain and/or rash, possibly delayed from the time of embolization
- Death
- Blindness, hearing loss, loss of smell, and/or paralysis
- Neurological deficits, including cranial nerve palsies
- Additional information is found in the Warnings section

STORAGE & STERILITY

- EmboCube Embolization Gelatin must be stored at room temperature in a dry and dark place in their original packaging.
- Use by the date indicated on the labeling.
- Do not resterilize.

CLINICAL PROCEDURE

The EmboCube Embolization Gelatin should be used by physicians trained on the procedures for which the device is intended. The techniques and procedures described do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient. All available data, including the patient's signs and symptoms and other diagnostic test results, should be considered before determining a specific treatment plan.

INSTRUCTIONS FOR USE

1. Prior to use, carefully inspect the EmboCube Embolization Gelatin packaging and components for damage.
2. Utilizing sterile technique, remove the EmboCube Embolization Gelatin from its packaging and transfer to the sterile field.
3. Carefully evaluate the vascular network associated with the lesion using high resolution imaging prior to beginning the embolization procedure.
4. Choose the appropriate size of EmboCube Embolization Gelatin that best matches the pathology (i.e., vascular target/vessel size) and provides the desired clinical outcome.
5. Choose a delivery catheter based on the size of the target vessel and the EmboCube Embolization Gelatin size being used.
6. 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.
7. Use caution in targeting the appropriate vessel or embolization endpoint.
8. Prepare the EmboCube Embolization Gelatin according to the following steps:
   A. Take an empty 10 mL syringe and aspirate 5 mL of contrast and 5 mL of 0.9% NaCl and connect it to the inline port of a luer lock 3-way stopcock.
   B. Remove any air in the saline/contrast syringe and 3-way stopcock by slowly pushing the syringe plunger while the syringe tip is vertically upright.
   C. Turn the 3-way stopcock to close the syringe with saline and contrast.
   D. Firmly compress the EmboCubes with the syringe plunger tip to remove air from the EmboCubes.
   E. Attach the EmboCube syringe to the side port of the 3-way stopcock.
   F. Open the 3-way stopcock to allow for transfer between the EmboCube syringe and the saline/contrast syringe and slowly transfer the saline/contrast solution into the EmboCube syringe.
   G. Slowly make two to five back and forth transfers in the syringes to hydrate the EmboCubes.
   H. Remove the 10-mL empty syringe and attach a 1 mL or 3 mL injection syringe to the 3-way stopcock.
   I. Draw the EmboCube Embolization Gelatin saline/contrast mixture into the injection syringe slowly and gently to minimize the potential of introducing air into the system.
   J. Purge all air from the system prior to injection.
   K. Inject the EmboCube Embolization Gelatin saline/contrast mixture from the delivery syringe into the delivery catheter under fluoroscopic visualization using a slow pulsatile injection while observing the contrast flow rate.
   L. Repeat the delivery process with additional injections of the EmboCube Embolization Gelatin saline/contrast mixture until the desired embolization endpoint is reached.
   M. Consider using larger sized EmboCube Embolization Gelatin if the initial injections do not alter the contrast flow rate.
9. Upon completion of the treatment, remove the catheter while maintaining gentle suction so as not to dislodge any residual EmboCube Embolization Gelatin still within the catheter lumen.
10. Discard any open, unused EmboCube Embolization Gelatin.

INFORMATION ON PACKAGING (SYMBOLS)

	Manufacturer: Name and Address
	Use by date: year-month-day
	Batch code
	Catalog number
	Do not resterilize
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Do not reuse
	Caution: Consult accompanying documents. Read instructions prior to use.
	Non-pyrogenic
STERILE R	Sterilized Irradiation

All serious or life-threatening adverse events or deaths associated with use of EmboCube Embolization Gelatin should be reported to the U.S. Food and Drug Administration under the MedWatch program and to the device manufacturer. Information about the MedWatch program and forms for reporting adverse events can be obtained at www.fda.gov/safety/medwatch/howtoreport/ucm053074.htm or by calling toll free 888-463-6332. Reports to Merit Medical, Inc. can be made by calling toll free 800-394-0295.

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