English

EmboCube™

Embolization Gelatin

INSTRUCTIONS FOR USE

INTENDED USE
EmboCube Embolization Gelatin is indicated for use in embolization of blood vessels to occlude blood flow for controlling bleeding/hemorrhaging.

EmboCube Embolization Gelatin occludes vessels up to 5 mm.
EmboCube Embolization Gelatin is intended to be used in adults.

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.

MAGNETIC RESONANCE IMAGING
EmboCube Embolization Gelatin is made of porcine gelatin and has no ferrous composition.

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 4 weeks.

CONTRAINDICATIONS
- Patients unable to tolerate vascular occlusion procedures
- Vascular anatomy precluding correct catheter placement
- Feeding arteries too small to accept the selected EmboCube Embolization Gelatin
- Presence or suspicion of vasospasm
- Coronary and intracerebral vascular use
- Presence of distal arteries directly supplying cranial nerves
- Presence of patent extra-to-intracranial anastomoses
- High-flow arteriovenous shunts or with a diameter greater than the selected EmboCube Embolization Gelatin
- Use in the pulmonary vasculature
- Use in pre-operative portal vein embolization (PVE)
- Severe atherosclerosis
- 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 gelatin.
- Care must be taken when embolizing arteriovenous malformations with large shunts to avoid passage of the embolic into the pulmonary or coronary circulation.
- The physician should be sure to carefully select the size of EmboCube Embolization Gelatin according to the size of the catheter appropriate for 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.
- If air is not fully purged from the system prior to injection air embolism may occur.
- 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's vital signs to include SaO_2 (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.
- EmboCube Embolization Gelatin does not occlude vessels larger than 5 mm. If target vessel is larger than 5 mm, consider using other therapies.
- 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.
- CT/MRI/US imaging of treated anatomy prior to full resorption of implanted device may show findings that may be misinterpreted for other pathology.

CAUTIONS
- **DO NOT USE THIS PREFILLED SYRINGE TO DIRECTLY INJECT EMBOCUBE EMBOLIZATION GELATIN. THIS IS A "RESERVOIR" SYRINGE.** Use of a 1mL or 3mL syringe provides more controlled delivery and helps to avoid non-target embolization. **PLEASE REFER TO INSTRUCTIONS FOR USE PARAGRAPH.**
- EmboCube Embolization gelatin must only be used by specialist physicians trained in vascular embolization procedures. The size and quantity of EmboCube Embolization Gelatin must be carefully selected according to the lesion to be treated, entirely under the physician's responsibility. Only the physician can decide the most appropriate time to stop the injection of EmboCube Embolization Gelatin.
- 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.
- There is no testing done on using EmboCube with agents such as chemotherapies, sterile water, or lipiodol.

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:
- Stroke or cerebral infarction
- Occlusion of vessels in healthy territories
- Vascular rupture
- Neurological deficits
- Infection or haematoma at the injection site
- Allergic reaction, cutaneous irritations
- Transient pain and fever
- Vasospasm
- Death
- Ischaemia at an undesirable location, including ischaemic stroke, ischaemic infarction (including myocardial infarction), and tissue necrosis
- Blindness, hearing loss, loss of smell, and/or paralysis
- Post embolization syndrome (nausea, vomiting, fever and abdominal pain)
- Tumor lysis syndrome when the device is used to treat bleeding tumors
- 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 its 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 syringe from its pouch 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 catheter size appropriate for the target lesion (i.e., vascular target/vessel size). Please refer to the table in the Specifications section for catheter and EmboCube compatibility.
5. When embolizing arteriovenous malformations (AVMs), choose an EmboCube Embolization Gelatin size that will occlude the nidus without passing through the AVM.
6. Choose a delivery catheter appropriate to the size of the target vessel. The size of EmboCube Embolization Gelatin used should be based on selected catheter size. Please refer to the table in the Specifications section.
7. 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 non-target vessels.
8. Use caution in targeting the appropriate vessel or embolization endpoint.
9. Prepare the EmboCube Embolization Gelatin according to the following steps:
   A. Take an empty 10 mL syringe and aspirate 5 mL of non-ionic 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 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. Visually check the shape of the cubes through the transparent syringe. Cubes are appropriately hydrated when they have recovered their original shape.
      Note: the use of cubes that are not appropriately hydrated can result in catheter or microcatheter clogging.
   I. Remove the 10 mL empty syringe and attach a 1 mL or 3 mL injection syringe to the 3-way stopcock. Do not use the reservoir syringe to inject the embolization gelatin. Use of a 1mL or 3mL syringe provides more controlled delivery and helps to avoid non-target embolization.
   J. 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.
   K. Purge all air from the system prior to injection.
   L. Inject the EmboCube Embolization Gelatin saline/contrast mixture from the injection syringe into the delivery catheter under fluoroscopic visualization using a slow pulsatile injection while observing the contrast flow rate.
   M. Repeat the delivery process with additional injections of the EmboCube Embolization Gelatin saline/contrast mixture until the desired embolization endpoint is reached. Only the treating physician can determine when the desired endpoint is reached, and is based on the therapeutic goal.
   N. Consider using larger sized EmboCube Embolization Gelatin if the initial injections do not alter the contrast flow rate within the desired time.
10. 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.
11. Discard any open, unused EmboCube Embolization Gelatin.

INFORMATION ON PACKAGING (SYMBOLS)

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

All serious or life-threatening adverse events or deaths associated with use of EmboCube Embolization Gelatin should be reported to the device manufacturer.

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