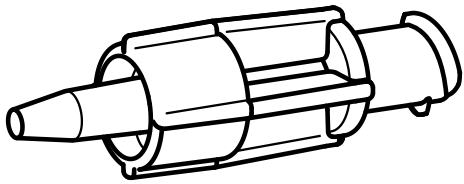
Torpedo™ Gelatin Foam

INSTRUCTIONS FOR USE

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

DEVICE DESCRIPTION
The Torpedo consists of biocompatible, hydrophilic and resorbable dry gelatin foam that is compressed into a cylindrical shape and preloaded into a cartridge with standard female and male luer fittings.



Based on an animal model, the gelatin foam Torpedo showed signs of resorption at week 4.

MAGNETIC RESONANCE IMAGING
The Torpedo is made of porcine gelatin and has no ferrous composition.

SPECIFICATIONS
The Torpedo is available in two diameters (2.5 mm and 5.0 mm) and two lengths (10 mm and 20 mm) with the specifications for each size listed below:

Part Number	Compressed / Dehydrated Torpedo Diameter	Uncompressed / Hydrated Torpedo Diameter	Torpedo Length	Recommended Injection Syringe	Minimum Catheter ID	Color Code
TOR2510	0.9 mm	2.5 mm	10 mm	1 ml	0.027″ (0.69 mm)	Yellow
TOR2520	0.9 mm	2.5 mm	20 mm	1 ml	0.027″ (0.69 mm)	Yellow
TOR5010	1.7 mm	5.0 mm	10 mm	3 ml	0.040″ (1.02 mm)	Purple
TOR5020	1.7 mm	5.0 mm	20 mm	3 ml	0.040″ (1.02 mm)	Purple

The Torpedo is designed for use with a catheter with an inner diameter large enough to allow delivery of the Torpedo through the catheter to the target vasculature via syringe injection.

INDICATION
The Torpedo is indicated for use in the embolization of hypervascular tumors.

Torpedo Gelatin Foam size 2.5 mm occludes vessels up to 2.5 mm and Torpedo Gelatin Foam size 5 mm occludes vessels up to 5 mm.

CONTRAINDICATIONS
- Patients with known allergy to gelatin
- Patients intolerant to occlusion procedures
- Vascular anatomy or blood flow that precludes catheter placement or embolic agent injection
- Presence of vasospasm
- Presence of hemorrhage
- 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 selected size of the device
- Vascular resistance peripheral to the feeding arteries precluding passage of the device 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 the device could pass directly into the internal carotid artery, vertebral artery, intracranial vasculature or the above listed vessels

WARNINGS
- The Torpedo 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 the Torpedo 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 the size of the Torpedo if any signs of non-target embolization occur or patient symptoms develop.
- Consider upsizing the Torpedo if angiographic evidence of embolization does not quickly appear evident during injection of the Torpedo device.
- Post embolization swelling may result in ischemia to tissue adjacent to target area. Care must be given to avoid ischemia intolerant, non-targeted tissue such as nervous tissue.
- If air is not fully purged from the system prior to injection, air embolism may occur.

PRECAUTIONS
- Do not use the Torpedo if the packaging is damaged.
- For single patient use only—contents supplied sterile—never reuse, reprocess or resterilize the contents of the Torpedo packaging. 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.
- Select the size and quantity of Torpedo appropriate for the pathology to be treated.
- Do not expose the Torpedo to liquid prior to deployment. Exposing the Torpedo to liquid prior to deployment may cause premature swelling of the Torpedo, which may inhibit deployment.
- Deliver each Torpedo within five (5) minutes of debubbling the Torpedo cartridge to prevent premature swelling of the Torpedo, which may inhibit deployment.
- In the event the delivery catheter becomes obstructed, do not attempt to flush the catheter with excessive pressure as fracture and/or reflux of the Torpedo may occur resulting in non-target embolization.
- Only one (1) Torpedo should be delivered at a time. Delivery more than one (1) Torpedo at a time may result in non-target embolization.
- 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
- Embolization with Torpedo 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 the device 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

DEVICE PACKAGING
Package contains:
- Three (3) Torpedo cartridges
- One (1) blunt stylet to assist with loading the Torpedo into a catheter for delivery

The contents of each package have been sterilized using Gamma irradiation.

Other items required but not provided:
- 1 mL or 3 mL delivery syringe
- 50:50 contrast/saline sterile mixture for delivery
- Catheter with an inner diameter equal to or greater than the minimum I.D. listed for delivery of the selected Torpedo size

STORAGE & STERILITY
- The Torpedo 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

PREPARATIONS FOR USE
Embolization with the Torpedo should only be performed by physicians who have received appropriate interventional embolization training in the region to be treated.
1. Prior to use, carefully inspect the Torpedo packaging and components for damage.
2. Utilizing sterile technique, remove the Torpedo cartridges and blunt stylet from their 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 Torpedo 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 Torpedo 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.

DEPLOYMENT PROCEDURE

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.

THE TORPEDO CAN BE DELIVERED WITH OR WITHOUT THE USE OF BLUNT STYLET.

OPTION 1: TORPEDO DELIVERY WITHOUT BLUNT STYLET

1. Attach the female luer end of the Torpedo to the male luer of a 1 mL or 3 mL delivery syringe filled with 50:50 contrast/saline sterile mixture.
   Precaution: Only one (1) Torpedo should be delivered at a time. Delivering more than one (1) Torpedo at a time may result in non-target embolization.
2. With the delivery syringe and attached Torpedo standing upright, gently depress the plunger of the delivery syringe to remove air. The Torpedo cartridge has a debubbling channel designed for air-free injection. Gently and slowly depress the plunger of the delivery syringe until 2-5 drops of the contrast/saline sterile mixture come out of the Torpedo tip.
3. Make an air-free connection between the Torpedo (still connected to the delivery syringe) and the hub of the catheter that is positioned in the vasculature for embolization.
4. Firmly depress the plunger on the delivery syringe to deliver the contrast/saline sterile mixture and the Torpedo through the catheter and into the vasculature, observing the delivery of the Torpedo under fluoroscopy. If the Torpedo does not exit after depleting the entire volume of fluid in the delivery syringe, refill the delivery syringe with 50:50 contrast/saline sterile mixture and continue to deliver fluid until the Torpedo exits the catheter.
5. If further embolization is desired, repeat steps 1-4 with additional Torpedoes.
6. Discard any empty Torpedo cartridges or unused devices, including the blunt stylet.

OPTION 2: TORPEDO DELIVERY WITH BLUNT STYLET

1. Attach the Torpedo to the hub of the delivery catheter that is positioned in the vasculature for embolization.
   Precaution: Only one (1) Torpedo should be delivered at a time. Delivering more than one (1) Torpedo at a time may result in non-target embolization.
2. Using the blunt stylet, slowly push the gelatin foam Torpedo out of the cartridge and into the delivery catheter.
3. Remove the empty Torpedo cartridge (with the blunt stylet still attached) from the catheter hub.
4. Using a wet-to-wet connection, attach a 1 mL or 3 mL delivery syringe filled with 50:50 contrast/saline sterile mixture to the catheter hub.
5. Firmly depress the plunger on the delivery syringe to deliver the contrast/saline sterile mixture and the Torpedo through the catheter and into the vasculature, observing the delivery of the Torpedo under fluoroscopy. If the Torpedo does not exit after depleting the entire volume of fluid in the delivery syringe, refill the delivery syringe with 50:50 contrast/saline sterile mixture and continue to delivery fluid until the Torpedo exits the catheter.
6. If further embolization is desired, repeat steps 1-5.
7. Discard any empty Torpedo cartridges or unused devices, including the blunt stylet.

INFORMATION ON PACKAGING (SYMBOLS)

	Manufacturer: Name and Address
	Use By: YYYY-MM-DD
	Lot Number
	Catalog Number
	Do Not Re-sterilize
	Do Not Use if Package is Damaged
	Keep away from sunlight
	Keep dry
	Single Use
	Caution: Consult accompanying documents. Read instructions prior to use.
	Non-pyrogenic
	Sterilized Irradiation

All serious or life-threatening adverse events or deaths associated with the use of the Torpedo 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.

www.merit.com

Biosphere Medical SA
Parc des Nations - Paris Nord 2
383 rue de la Belle Etoile
95700 Roissy en France
France

Manufacturered For:
Merit Medical Systems, Inc.
1600 West Merit Parkway,
South Jordan, Utah 84095 U.S.A.
1-801-253-1600
U.S.A. Customer Service 1-800-356-3748

404996001EN_001 ID 2019-07-10