

Contour[®] PVA Embolization Particles

Product Information

UPN	Order Number	Particle Size Range (Microns)	Box Size
M0017600121.....	760012.....	45 -150	2 Vials Per Box
M0017600121.....	760012.....	45 -150	2 Vials Per Box
M0017600151.....	760015.....	45 -150	5 Vials Per Box
M0017600221.....	760022.....	150 - 250.....	2 Vials Per Box
M0017600251.....	760025.....	150 - 250.....	5 Vials Per Box
M0017600321.....	760032.....	250 - 355.....	2 Vials Per Box
M0017600351.....	760035.....	250 - 355.....	5 Vials Per Box
M0017600421.....	760042.....	355 - 500.....	2 Vials Per Box
M0017600451.....	760045.....	355 - 500.....	5 Vials Per Box
M0017600621.....	760062.....	500 - 710.....	2 Vials Per Box
M0017600651.....	760065.....	500 - 710.....	5 Vials Per Box
M0017600821.....	760082.....	710 -1000	2 Vials Per Box
M0017600851.....	760085.....	710 -1000	5 Vials Per Box
M0017601121.....	760112.....	1000 -1180	2 Vials Per Box
M0017601151.....	760115.....	1000 -1180	5 Vials Per Box

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Refer to the Directions for Use for complete instructions for use.

Indications:

Contour Embolization Particles are used for the embolization of peripheral hypervascular tumors and peripheral arteriovenous malformations (AVMs).

Contraindications:

1. Patient intolerance to temporary occlusion procedures
2. Vascular anatomy or blood flow precludes stable, selective Emboli or catheter placement
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 patient extra-to-intracranial anastomoses or shunts
8. Presence of collateral vessel pathways potentially endangering normal territories during embolization
9. Presence of end arteries leading directly to cranial nerves

Contraindications (cont.):

10. Presence of arteries supplying the lesion not large enough to accept Emboli
11. Vascular resistance peripheral to the feeding arteries precluding passage of Emboli into the lesion

Contour[®] PVA Embolization Particles

Warnings:

As with any embolization device, patient injury, permanent disability or death may occur as a result of its use.

Vascular occlusion should only be performed by physicians possessing skilled interventional occlusion experience in the territory intended to be embolized.

The use of sophisticated imaging equipment is necessary for successful embolization therapy.

PRIOR TO EMBOLIZATION, PROSPECTIVE PATIENTS OR THEIR REPRESENTATIVES MUST BE PROVIDED AN INFORMED CONSENT DESCRIBING THE POSSIBLE COMPLICATIONS ASSOCIATED WITH THE USE OF THIS DEVICE. WRITTEN ACKNOWLEDGMENT IS WARRANTED.

Potential Adverse Effects:

Complications specific to embolization include, but may not be limited to:

1. Foreign body reactions necessitating medical intervention
2. Infection necessitating medical intervention
3. Clot formation at the tip of the catheter and subsequent dislodgment
4. Undesirable reflux or passage of Emboli 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
5. Ischemia at an undesirable location
6. Capillary bed saturation and tissue damage
7. Ischemic stroke or ischemic infarction
8. Vessel or lesion rupture and hemorrhage
9. Recurrent hemorrhage
10. Neurological deficits, including cranial nerve palsies
11. Vasospasm
12. Death
13. Recanalization
14. RETREATMENT MAY BE REQUIRED

COMPLICATIONS MAY EXIST WHICH ARE CURRENTLY UNKNOWN OR UNFORESEABLE.

15. 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)
16. Allergic reaction to pain medications
17. Allergic reaction to contrast media or embolic material
18. Pain and/or rash, possibly delayed from the time of embolization.
19. Incomplete occlusion of vascular beds or territories may give rise to the possibility of post procedural hemorrhage, development of alternative vascular pathways, or recurrence of symptoms.
20. Recurrence of symptoms requiring re-treatment
21. Pulmonary Embolism

Contour[®] PVA Embolization Particles

Warnings and Precautions:

1. PRIOR TO EMBOLIZATION, PROSPECTIVE PATIENTS OR THEIR REPRESENTATIVES MUST BE PROVIDED AN INFORMED CONSENT DESCRIBING THE POSSIBLE COMPLICATIONS ASSOCIATED WITH THE USE OF THIS DEVICE. WRITTEN ACKNOWLEDGMENT IS WARRANTED.
2. As with any embolization device, patient injury, permanent disability or death may occur as a result of its use.
3. Vascular occlusion should only be performed by physicians possessing skilled interventional occlusion experience in the territory intended to be embolized.
4. A thorough evaluation of a patient's medical condition, vascular pathways and the desired embolization goal is necessary to achieve successful occlusion. This evaluation should include baseline angiography to determine the presence of potentially dangerous collateral pathways and visible shunts. Do not proceed with embolization unless these pathways and shunts can be protected.
5. The use of sophisticated imaging equipment is necessary for successful embolization therapy.
6. Appropriate facilities should be available to treat potential complications of the procedure.
7. Ensure cleanliness and attention to technique during preparation of the device to avoid introducing contaminants.
8. The appropriate size Emboli must be chosen based upon the lesion to be treated and the measurements taken from the baseline angiography.
9. Smaller Emboli may be more likely to result in cranial nerve palsies and ischemic infarction because of the potential to block vessels at the precapillary level; however, Emboli of all sizes share this potential.
10. Typically the artery will accept less Emboli as the treatment progresses. Proximal slowing or termination of Emboli passage may occur when the vessel or malformation is occluded by prior Emboli, or in the presence of severe atheromatous disease. Continued infusion may result in inadvertent reflux into critical arteries, creating the potential for undesirable ischemic infarction.
11. Avoid the use of a tapered tip delivery catheter. Emboli may lodge at the catheter tip creating an obstruction.
12. Should catheter obstruction occur, remove the catheter from the patient. Do not use forceful injection, guidewires or other instruments to dislodge the blockage. Do not continue using a catheter which has been obstructed as damage to the device may have occurred.
13. Incomplete occlusion of vascular beds or territories may give rise to the possibility of post procedural hemorrhage, development of alternative vascular pathways, or recurrence of symptoms.
14. The relationship between embolization and the appearance of cerebral lesions is unknown.
15. Postprocedural patient follow-up to assess the continued level of vascular occlusion is necessary. Angiography may be indicated.
16. While it is anticipated that long-term embolization of vascular structures with Contour Embolization Particles will be achieved, no guarantee of permanence, cure, or benefit can be made.
17. 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.
18. 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.
19. Patients with known allergy to contrast medium may require corticosteroids prior to embolization.
20. Additional evaluations or precautions may be necessary in managing periprocedural care for patients with the following conditions:
 - A. Bleeding diathesis or hypercoagulative state;
 - B. Immunocompromised.
21. Do not use if the vial, screw cap, or tray package appears damaged.

Contour[®] PVA Embolization Particles

Warnings and Precautions (cont.):

22. Select the size and quantity of Contour Embolic Particles appropriate for the pathology to be treated.

**Boston
Scientific**
Delivering what's next.™

Boston Scientific Corporation
Oncology
100 Boston Scientific Way
Marlborough, MA 01752-3238
www.bostonscientific.com

©2007 Boston Scientific Corporation
or its affiliates. All rights reserved.
MIO130WEB