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Imagine where we can go.

Bead Block® is intended to be used for the embolization of hypervascular tumors and arteriovenous malformations (AVMs).

Potential Complications:
1. Undesirable reflux or passage of Bead Block® 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.
2. Pulmonary embolization.
3. Ischemia at an undesirable location.
4. Capillary bed saturation and tissue damage.
5. Ischemic stroke or ischemic infarction.
6. Vessel or lesion rupture and hemorrhage.
7. Neurological deficits including cranial nerve palsies.
8. Vasospasm.
10. Recanalization.
11. Foreign body reactions necessitating medical intervention.
12. Infection necessitating medical intervention.
13. Clot formation at the tip of the catheter and subsequent dislodgement.

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

For more information or to order, please contact:
Customer Service
Biocompatibles, Inc.
Five Tower Bridge
Suite 810
300 Barr Harbor Drive
West Conshohocken, PA 19428
USA

Phone: (877) 626-9989
Fax: (877) 626-9910
Email: orders@btgplc.com
www.btg-im.com

Important Information

Indications:

Bead Block® is suspended in physiological buffered saline in 2ml syringes and is packed singly.

Product Codes

<table>
<thead>
<tr>
<th>Bead Block® Size</th>
<th>BTG Product Code</th>
<th>Label Colour</th>
</tr>
</thead>
<tbody>
<tr>
<td>100-300μm</td>
<td>EB25103</td>
<td>Yellow</td>
</tr>
<tr>
<td>300-500μm</td>
<td>EB25305</td>
<td>Blue</td>
</tr>
<tr>
<td>500-700μm</td>
<td>EB25507</td>
<td>Red</td>
</tr>
<tr>
<td>700-900μm</td>
<td>EB25709</td>
<td>Green</td>
</tr>
<tr>
<td>900-1200μm</td>
<td>EB25912</td>
<td>Purple</td>
</tr>
</tbody>
</table>

Imagine where we can go.

The only spherical embolic agent comprised of PVA hydrogel cross-linked with acrylic polymer.

References:
3. Hidaka K et al. Compression and relaxation tests are complementary to evaluate embolization microspheres. Composition of Embolembol, Embozene and Bead Block. CIRSE presentation, Valencia, Spain, October 2010.

Important Information
Bead Block®: The only spherical embolic agent comprised of PVA hydrogel cross-linked with acrylic polymer

1. Compressible
   - Reliable delivery in catheter and vessels.
   - Precise distal embolization.
   - More resistant to clogging.
   - No fragmentation.

2. Suspension and delivery
   - When using 5ml of Isovue®-300 contrast, Bead Block® stays in suspension more than twice as long as Embosphere® and Contour SE™.
   - This may allow for less clogging and a more uniform distribution and delivery of beads.

3. Precise calibration
   - Precise size calibration for targeted embolization.

4. Elastic
   - Shape recovery for reliable delivery.

5. Blue tint
   - Optimal visualization for enhanced handling and safety.

Imagine where we can go.
How does Bead Block® compare?

- **Bead Block®**
  - PVA hydrogel cross-linked with acrylic polymer

- **Embosphere®**
  - Acrylic polymer structure (Trisacyl®)

- **Contour SE™**
  - Macroporous PVA®

- **Embozene™**
  - Polyphosphazene-coated polymethylmethacrylate

What does this mean?

**Rigidity and fragmentation**

- Bead Block® is significantly less rigid than Embosphere®.
- An in-vivo animal study by Bilbao et al., published in JVIR in 2008, demonstrated that:
  - Bead Block® remained round or slightly oval and showed no fragmentation at 48 hours after embolization.
  - Embosphere had a large number of particles that showed a fragmented appearance at 48 hours after embolization.
- Trisacyl® gelatin microspheres (Embosphere®) have a high rigidity and deform slightly under a sustained compression since they have a high elasticity.
- Polyphosphazene-coated polymethylmethacrylate microspheres (Embozene™) are soft and deform considerably under sustained compression and are more viscous than Bead Block® and Embosphere®.
Bilbao et al reported that Embosphere® particles showed a tendency to cluster in groups within the arteries. This tendency of Embosphere® particles to aggregate within the arteries has been reported by other authors. Nonspherical PVA particles tend to aggregate in the hub of the micro-catheter, making irrigation with saline necessary to be able to use the micro-catheter. Nonspherical PVA particles have a tendency to clump as a result of particle aggregation, leading to proximal occlusion of the targeted blood vessels.

Suspension and delivery
- When using 5ml of Isovue®-300 contrast, Bead Block® stays in suspension more than twice as long as Embosphere® and Contour SE™.
- This may allow for less clogging and a more uniform distribution and delivery of beads.

Aggregation
- Bilbao et al reported that Embosphere® particles showed a tendency to cluster in groups within the arteries.
- Embosphere® particles showed a greater tendency to aggregate.
- This tendency of Embosphere® particles to aggregate within the arteries has been reported by other authors.
- Nonspherical PVA particles tend to aggregate in the hub of the micro-catheter, making irrigation with saline necessary to be able to use the micro-catheter.
- Nonspherical PVA particles have a tendency to clump as a result of particle aggregation, leading to proximal occlusion of the targeted blood vessels.

Complete vascular occlusion
- In the Bilbao study, Bead Block® tended to locate in vessels of small size (e.g., arciform arteries) and appeared individualized or formed rows.
- Most Bead Block® specimens adapted perfectly to the vascular wall, completely occluding the vessel lumen.
- Embosphere® particles do not adapt to the walls of the arteries.
- The degree of adaptability of Contour SE™ particles to the vascular wall is highly variable.

Endothelial inflammation
- Inflammatory and giant cell reactions after embolization procedures depend on the embolic material.
- The overall inflammatory reaction was low for spherical embolic agents. However, marked inflammation was associated with small Embosphere particles at 4 weeks, a finding that might be caused by the allogeneic overcoat.

Recanalization
- For many years polyvinyl alcohol (PVA) particles have been the most frequently used particle embolic agent. However, the irregular shape and variable granulometric sizes of these particles prevent correlation of the arterial occlusion level and the particle size. These properties may cause proximal large vessel occlusion and recanalization in the late period. This created the need for the search to find alternative embolizing agents with more targeted and distal occlusion.
- The highest extent of recanalization was observed with Contour SE particles at 4 weeks. This might be caused by its non-elastic deformation within the vessels, which renders the particles more susceptible to redistribution phenomena.

Bead Block®: The only spherical embolic agent comprised of PVA hydrogel cross-linked with acrylic polymer

Imagine where we can go.
Suspension and delivery

- When using 1mL of Isopaque-300 contrast, Bead Block® stays in suspension more than twice as long as Embosphere® and Contour SE®.
- This may allow for less clogging and a more uniform distribution and delivery of beads.

Aggregation

- Bilbao et al reported that Embosphere® particles showed a tendency to cluster in groups within the arteries.
- Embosphere® particles showed a greater tendency to aggregate.
- This tendency of Embosphere® particles to aggregate within the arteries has been reported by other authors.
- Nonspherical PVA particles tend to aggregate in the hub of the micro-catheter, making irrigation with saline necessary to be able to use the micro-catheter.
- Nonspherical PVA particles have a tendency to clump as a result of particle aggregation, leading to proximal occlusion of the targeted blood vessels.

<table>
<thead>
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<tbody>
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</tr>
</tbody>
</table>

Bead Block' preparation

1. Draw up contrast medium directly into the Bead Block®-pre-filled syringe. To obtain an even suspension, initially use 50:50 contrast to Bead Block® volume. If Bead Block® sinks, add more contrast. If Bead Block® floats, add more saline.
2. Remove all air from the syringe.
3. Gently invert the 20ml syringe several times. Do not use a shaking motion.
4. Wait to allow Bead Block® to suspend properly.
5. Attach the 20ml syringe to the side port of the luer-lock 3-way stopcock.
6. Attach the injection syringe (1-5ml according to preference) to the second port.
7. Attach the remaining port of the stopcock to the delivery catheter.
8. Ensure all air is purged from the system prior to injection.

Bead Block® contrast media and suspension

<table>
<thead>
<tr>
<th>Colour Code</th>
<th>Isovue®-300</th>
<th>Omnipaque™ 300</th>
<th>Optiray® 300</th>
<th>Visipaque™ 320</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 to 300</td>
<td>5.0 ml</td>
<td>5.0 ml</td>
<td>5.0 ml</td>
<td>5.0 ml</td>
</tr>
<tr>
<td>300 to 500</td>
<td>5.0 ml</td>
<td>5.0 ml</td>
<td>5.0 ml</td>
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<tr>
<td>500 to 700</td>
<td>5.0 ml</td>
<td>5.0 ml</td>
<td>5.0 ml</td>
<td>4.0 ml</td>
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<td>700 to 900</td>
<td>5.0 ml</td>
<td>5.0 ml</td>
<td>5.0 ml</td>
<td>2.0 ml</td>
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<tr>
<td>900 to 1200</td>
<td>2.0 ml</td>
<td>2.0 ml</td>
<td>2.0 ml</td>
<td>2.0 ml</td>
</tr>
</tbody>
</table>

Key

- Nonspherical PVA particles are more likely to aggregate in the hub of the micro-catheter, making irrigation with saline necessary to be able to use the micro-catheter.

Bead Block® administration

1. Inject the Bead Block®/contrast solution from the injection syringe under fluoroscopic visualization using a slow pulsatile action, while observing the contrast flow rate.
2. If there is no effect on the flow rate, repeat the delivery process with additional injections of Bead Block®/contrast solution or larger sized Bead Block® may be considered.
3. If the Bead Block®/contrast solution requires re-suspension, gently invert the 20ml syringe several times. Do not pass the content vigorously between syringes when obtaining suspension/re-suspension. Exercise conservative judgment in determining the embolization endpoint.

Bead Block® catheter compatibility for easy delivery

- Bead Block® is compatible with all 4F and 5F catheters (minimum ID of 0.040”/1040µm).
- Bead Block® is compatible with all 4Fr, 4Fr Optitorque, 4Fr Vasco +25 (3Fr), Vasco +21 (2.4Fr), Vasco +35 (3.8Fr), Rebar 027 (2.8Fr), Echelon 10...2.7Fr, PROGREAT (2.4Fr), Echelon 14 (1.9Fr), Renegade High Flow 2.8 Vasco +18. (2.1Fr), Rebar 10 (1.7Fr), Rebar 14 (1.9Fr).

- Inner Diameter (ID) >0.040”  >1020µm 0.026”-0.040”  650-1020µm  0.0205”-0.026”  520-650µm 0.015”-0.0205” 380-520µm


- Bead Block® is the only spherical embolic agent comprised of PVA hydrogel cross-linked with acrylic polymer.