Embozene® Microspheres are spherical, tightly calibrated, biocompatible, non-resorbable, hydrogel beads coated with an inorganic perfluorinated polymer (Polyzene®-F) coating. They are available in a range of sizes suitable for embolic therapy. Embozene® Microspheres are available in individual 1ml or 2ml vials. Each 1ml vial contains 1ml of Embozene® Microspheres suspended in the same transport solution. The total volume of Embozene® Microspheres plus transport solution for both 1ml and 2ml of product is approximately 7ml per vial. Each vial of Embozene® Microspheres is packaged in a sterile, sealed, tray with a peel-away lid. A color-coded label indicates the specific size of the particle contained in the vial. 

### Table B. Product Specifications and Ordering Information for Non-Colored Beads

<table>
<thead>
<tr>
<th>Label</th>
<th>Minimum Inner Diameter Required</th>
<th>Ref Numbers 1ml Syringe</th>
<th>Ref Numbers 2ml Syringe</th>
<th>Ref Numbers 1ml Vial with Colored Beads</th>
<th>Ref Numbers 2ml Vial with Colored Beads</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purple</td>
<td>400 μm</td>
<td>400 μm</td>
<td>500 μm</td>
<td>75 μm</td>
<td>40 μm</td>
</tr>
<tr>
<td>Green</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>530 μm ± 50 μm</td>
<td>250 μm ± 50 μm</td>
<td>100 μm ± 25 μm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blue</td>
<td>75 μm ± 15 μm</td>
<td>75 μm ± 15 μm</td>
<td>75 μm ± 15 μm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red</td>
<td>530 μm ± 50 μm</td>
<td>250 μm ± 50 μm</td>
<td>100 μm ± 25 μm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 2. Presentation

**2.1 Syringes**

Embozene® Microspheres are offered in a 2ml syringe prefilled with 1.2ml of 2% gel. Each syringe contains 1.2ml of Embozene® Microspheres suspended in a non-pyrogenic, sterile transport solution of physiological saline. Syringes are available in a range of sizes suitable for embolic therapy. Each package of Embozene® Microspheres is packaged in a sterile, sealed, tray with a peel-away lid. A color-coded label indicates the specific size of the particle contained in the syringe. 

### 3. Indications and Contraindications

#### 3.1 Indications:

- **Embozene® Microspheres** are indicated for the embolization of hepatic arterial and arterial/venous malformations (HAML). 
- **Embozene® Microspheres** are indicated for the embolization of arterial-venous malformations (AVMs) of the central circulatory system, internal carotid artery, or other non-target territories (i.e., where the blood does not pass through the arterial/capillary/venous transition but directly from artery to vein).

#### 3.2 Contraindications:

- Presence of patent extra-to-intra-cranial anastomoses or shunts from the arterial to the venous circulation
- Vascular anatomy precludes correct catheter placement or embolic injection
- Patient is unable to tolerate vascular occlusion procedures
- Patient is pregnant
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- Vascular anatomy precludes correct catheter placement or embolic injection
- Patient is unable to tolerate vascular occlusion procedures
- Patient is pregnant

### 4. Warnings

#### 4.1 Warnings

Vascular embolization is a high-risk procedure. The procedure should be performed by experienced physicians trained in vascular embolization procedures. The physician must select the most appropriately sized microsphere for the patient’s vasculature.

- Do not use Embozene® Microspheres in patients with a history of allergy to perfluorocarbons or other substances
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### 4.2 Precautions

#### 4.2.1 Contraindications:

- Embolization with Embozene® Microspheres should only be performed by physicians who have received appropriate interventional radiology training and have demonstrated competence in performing such procedures.
- Safety and effectiveness of Embozene® Microspheres in the treatment of uterine fibroids has not been established.
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#### 4.2.2 Instructions for Use

- Each package of Embozene® Microspheres is intended for single patient use only. Discard any unused material. Do not resterilize.
- Following completion of the embolization procedure, flush the catheter with Embozene® Microspheres to ensure complete removal of the microspheres.
- Each package of Embozene® Microspheres is intended for single patient use only. Discard any unused material. Do not resterilize.
- Following completion of the embolization procedure, flush the catheter with Embozene® Microspheres to ensure complete removal of the microspheres.
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- Following completion of the embolization procedure, flush the catheter with Embozene® Microspheres to ensure complete removal of the microspheres.

### 5. Interaction with Pharmaceuticals

- There are no known interactions between Embozene® Microspheres and pharmaceuticals.
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### 6. Instructions for Use

- Embolization of the patient’s artery in the correct location and at the correct position is critical to the success of the treatment. Confirm the correct location of the vessel by radiographic imaging.
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For additional information, please refer to the manufacturer’s instructions for use.
6.1 Instructions for Use of Prefilled Syringe

Gently swirl the contents before opening the syringe.

Under continuous fluoroscopic control, slowly infuse Embozene® Microspheres into the bloodstream. Always inject under free flow conditions. To optimize injection through the catheter, it is recommended that the syringe remain in a horizontal position during injection.

Locate the volume of contrast medium needed to achieve the optimal desired effect. Under continuous fluoroscopic control, slowly infuse Embozene® Microspheres into the bloodstream. Always inject under free flow conditions. To optimize injection through the catheter, it is recommended that the syringe remain in a horizontal position during injection.

Avoid reflux of Embozene® Microspheres as this can induce immediate ischemia of the tissue or vessel.

At the end of the infusion, remove the catheter while maintaining gentle aspiration to avoid dislodging any residual Embozene® Microspheres still inside the catheter.

Once the clinical endpoint is reached, wait for 2–3 minutes to observe whether the beads redistribute themselves and re-establish flow to the target. If flow is re-established, inject an additional volume of microspheres until the final clinical endpoint is achieved. Continue infusion until the desired devascularization is obtained.

Discard any opened Embozene® Microspheres prefilled syringe units.

6.3 Catheter Selection

Embozene® Microspheres are designed to be used with a variety of catheters and microcatheters. Choose a delivery catheter based on the characteristics of the lesion and the effects desired.

Attach a 1ml injection syringe to one port of the luer-lock 3-way stopcock. Attach a delivery catheter to the remaining port on the stopcock. Under continuous fluoroscopic control, slowly infuse Embozene® Microspheres into the bloodstream. Always inject under free flow conditions.

If the desired microsphere size and concentration is undeliverable via the selected catheter, another catheter should be considered. At the end of the infusion, the vascular system will be maximally occluded. Embozene® Microspheres used under optimal conditions have been reported to provide the best possible revascularized area (Table C). The table lists the volume of contrast medium, the desired size of the microspheres, and the corresponding revascularized area.

If the selected size and concentration cannot provide the expected revascularized area (Table C), the highest volume of contrast medium has been used for the selected size. In all other cases, the microspheres will stay in suspension for several minutes.

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EXPLANATION OF SYMBOLS USED ON THE PACKAGE LABEL

9. Definitions

Note the Instruction for Use and Table C. Embozene® Microspheres Contrast Media Mixing Chart.