**DESCRIPTION:**
Bead Block™ comprises a range of hydrogel microspheres that are biocompatible, hydrophilic, non-resorbable and precisely calibrated. Bead Block microspheres are produced from polyvinyl alcohol and are available in the following size ranges:

<table>
<thead>
<tr>
<th>Bead Size Range</th>
<th>Hypervascular Tumors/ Arteriovenous Malformations</th>
<th>Uterine Fibroid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal Bead Size</td>
<td>Label</td>
<td>Color</td>
</tr>
<tr>
<td>100-300 μm</td>
<td>Yellow</td>
<td>Yes</td>
</tr>
<tr>
<td>300-500 μm</td>
<td>Blue</td>
<td>Yes</td>
</tr>
<tr>
<td>500-700 μm</td>
<td>Red</td>
<td>Yes</td>
</tr>
<tr>
<td>700-900 μm</td>
<td>Green</td>
<td>Yes</td>
</tr>
<tr>
<td>900-1200 μm</td>
<td>Purple</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**PRESENTATION:**
1. Syringe of 20 ml presented in a sterile, sealed pre-formed polycarbonate tray with a peel-off Tyvek® lid.
2. Each syringe contains approximately 1 ml or 2 ml of Bead Block microspheres in non-pyrogenic, sterile, phosphate buffered saline.

**INDICATIONS:**
Bead Block microspheres are intended to be used for the embolization of hypervascular tumors, including uterine fibroids and arteriovenous malformations (AVMs).

**CLINICAL APPLICATIONS:**
The scientific literature provides extensive documentation of embolization procedures using a wide variety of artifical agents in both neurological and peripheral vascular systems, including the head, neck, spine, liver, gastrointestinal tract, uterus, gynecotogenous system, limbs and lungs. A representative bibliography is provided following these instructions for use.

**WARNING:**
Studies have shown that Bead Block microspheres do not form aggregates and, as a result, penetrate deeper into the vasculature as compared to similarly sized PVA particles. Care must be taken to choose a larger sized Bead Block Embolic Agent when embolizing arteriovenous malformations with large sheaths to avoid passage of the microspheres into the pulmonary or coronary circulation.

**CONTRAINdications:**
1. Patients intolerant to occlusion procedures
2. Vascular anatomy or blood flow that precludes catheter placement or injection of embolics
3. Presence or likely onset of vasospasm
4. Presence of severe atheromatous disease
5. Presence of lesion/tumor-feeding vessel with diameter smaller than any distal vessel(s) branching from it
6. Presence of patent extra-to-intracranial anastomoses or shunts
7. Presence of collateral vessel pathways potentially endangering normal territories during embolization
8. Presence of end arteries leading directly to visceral nerves
9. Presence of arterial supplying the lesion/tumor not large enough to accept Bead Block microspheres
10. Vascular resistance peripheral to the feeding arteries precluding passage of Bead Block microspheres into the lesion/tumor
11. Presence of patent extra-to-intracranial anastomoses or shunts
12. Do not use Bead Block microspheres in the following applications:
   i. Embolization of large diameter arteriovenous shunts (i.e. where the blood does not pass through the arterial/capillary/venous transition but directly from artery to vein)
   ii. The pulmonary arterial vasculature
   iii. Any vasculature where the use of Bead Block could pass directly into the internal carotid artery, the central circulatory system or other non-target territories

**POTENTIAL COMPLICATIONS:**
1. Undesirable reflux or passage of Bead Block microspheres into normal arteries adjacent to the targeted lesion/tumor or through the lesion/tumor into other arteries or arterial beds
2. Non-target embolization
3. Pulmonary embolism
4. Pancreatitis
5. Uterine Fibroid Embolisation (UFE) SPECIFIC PRECAUTIONS:
   i. Embolization of large diameter arteriovenous shunts (i.e. where the blood does not pass through the arterial/capillary/venous transition but directly from artery to vein)
   ii. The pulmonary arterial vasculature
   iii. Any vasculature where the use of Bead Block could pass directly into the internal carotid artery, the central circulatory system or other non-target territories

**Fibroids with significant collateral feeding by vessels other than the uterine arteries
**
6. Presence of lesion/tumor-feeding vessel with diameter smaller than any distal vessel(s) branching from it
7. Presence of patent 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 visceral nerves
10. Presence of arterial supplying the lesion/tumor not large enough to accept Bead Block microspheres
11. Vascular resistance peripheral to the feeding arteries precluding passage of Bead Block microspheres into the lesion/tumor
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   iii. Any vasculature where the use of Bead Block could pass directly into the internal carotid artery, the central circulatory system or other non-target territories

**UFE SPECIFIC WARNINGS:**
**Warnings about Life and Pregnancy:**
1. There are no long term data on the effects of UFE on the ability to become pregnant and carry a fetus to term, and on the development of the fetus
2. This procedure should only be performed on women who do not intend future pregnancy
3. Women who become pregnant following UFE may be at increased risk for the following:
   a. Preterm delivery
   b. Abnormal placation
   c. Preterm delivery
   d. Abnormal presentation at birth
4. Dissemination of the uterine myometrium resulting from UFE may increase the risk of uterine rupture of women who subsequently become pregnant following UFE
5. **OTHER UFE WARNINGS:**
   a. When using Bead Block for uterine fibroid embolization, do not use beads smaller than 700 microns.
   b. An appropriate gynecologic work-up should be performed on all patients presenting for embolization of uterine fibroids (e.g. gynecologic history, fibrinogen level, hematocrit, platelet count, etc.). Risk factors such as tumours, prior surgery, diabetes and obesity may increase the risk of complications.
   c. The diagnosis of uterine sarcoma could be delayed by taking a non-surgical approach (such as UFE) to treating fibroids. It is important to pay close attention to warning signs for sarcoma and for uterine cancer in patients with abnormal menstrual bleeding.
   d. UFE may increase the risk of uterine rupture of women who subsequently become pregnant following UFE

6. **OTHER UFE SPECIFIC CONTRAINDICATIONS:**
   a. There is an increased chance of reflux of Bead Block into unintended blood vessels as uterine artery flow diminishes. Compression of angiographic endpoint and infarction rate in individual patients indicates that best results were obtained with an endpoint close to the uterus.
   b. The long-term outcome of UFE is at present unknown.
   c. Uterine Fibroid Embolisation (UFE) SPECIFIC CONTRAINDICATIONS:
      1. Pregnancy
      2. Active or suspected pelvic inflammatory disease
      3. Malignancy of the pelvic region
      4. Endometrial neoplasia or hyperplasia
      5. Presence of submucous fibroids with greater than 50% growth into the uterine cavity
      6. Presence of pedunculated sessile fibroid as the dominant fibroid(s)
      7. Fibroids with significant collateral feeding by vessels other than the uterine arteries

**UFE SPECIFIC POTENTIAL COMPLICATIONS:**
Potential post procedure complications include:
1. Abdominal pain
2. Discomfort
3. Fever
4. Nausea
1. To obtain a homogeneous suspension, directly aspirate the contrast medium into the syringe containing the beads in phosphate buffered saline and

Bead Block™ has been tested and shown to be successfully delivered using the following combinations of microsphere size, contrast medium and

Recommended catheters and contrast agents:

<table>
<thead>
<tr>
<th>Product size range of Bead Block™</th>
<th>Recommended catheter (internal diameter)</th>
<th>Recommended contrast agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 – 500 μm</td>
<td>2.4 Fr (0.016 in/0.42 mm)</td>
<td>Omnipaque 350 (Iohexol 350)</td>
</tr>
<tr>
<td>300 – 500 μm</td>
<td>2.4 Fr (0.016 in/0.42 mm)</td>
<td>Omnipaque 350 (Iohexol 350)</td>
</tr>
<tr>
<td>200 – 300 μm</td>
<td>2.4 Fr (0.016 in/0.42 mm)</td>
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</tr>
</tbody>
</table>

**DELIVERY INSTRUCTIONS:**

1. To obtain a homogeneous suspension, directly aspirate the contrast medium into the syringe containing the beads in phosphate buffered saline and remove all air from the syringe. The volume of contrast medium to be added varies depending on the contrast medium viscosity and the bead size. As an example, the typical volume of contrast medium required for addition to the contrast medium volume ratio from 1:3 to 1:1 to achieve a contrast medium to product volume ratio ranging from approximately 40:60 (e.g. with Omnipaque 350 to 60:40 (e.g. with Niopam 330).

2. To evenly suspend the Bead Block microspheres/contrast medium, gently invert the 20 ml syringe several times.

3. Draw the Bead Block microspheres/contrast medium into the injection syringe slowly and gently to minimize the potential of introducing air into the system. Purge all air from the system prior to injection.

4. Inject the Bead Block microspheres/contrast medium from the injection syringe under fluoroscopic visualization using a slow pulsatile action, while observing the contrast medium flow rate. If there is no effect on the flow rate, repeat the delivery process with additional injections of Bead Block microspheres/contrast medium or larger sized Bead Block microspheres may be considered. If the Bead Block microspheres/contrast medium requires re-suspension, gently invert the 20 ml syringe several times.

5. Exercise conservative judgment in determining the embolization endpoint.

**REFERENCES:**