

STERILE - SINGLE USE ONLY - NON-PYROGENIC

Sterilised by steam

Do not use if the package is opened or damaged**DESCRIPTION:**

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

Size	Label Colour
100 – 300 µm	Yellow
300 – 500 µm	Blue
500 – 700 µm	Red
700 – 900 µm	Green
900 – 1200 µm	Purple

PRESENTATION:**Syringe**

- Syringe of 20 ml.
- Syringe is presented in a sterile, sealed pre-formed Tyvek® peel-away tray with a label coloured to denote the specific size range.
- Each syringe contains approximately 1 ml or 2 ml of Bead Block microspheres in non-pyrogenic, sterile, physiological buffered saline. Total volume of saline and Bead Block microspheres is 5 ml.
- Each syringe is intended for single patient use only. Do not resterilise. Discard any unused material.

INDICATIONS:

Bead Block microspheres are intended to be used for the embolisation of hypervascular tumours and arteriovenous malformations (AVMs).

CLINICAL APPLICATIONS:

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

CONTRAINDICATIONS:

1. Patients intolerant to occlusion procedures.
2. Vascular anatomy or blood flow that precludes catheter placement or emboli injection.
3. Presence or likely onset of vasospasm.
4. Presence or likely onset of haemorrhage.
5. Presence of severe atheromatous disease.
6. Presence of feeding arteries smaller than distal branches from which they emerge.
7. Presence of patent extra-to-intracranial anastomoses or shunts.
8. Presence of collateral vessel pathways potentially endangering normal territories during embolisation.
9. Presence of end arteries leading directly to cranial nerves.
10. Presence of arteries supplying the lesion 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.
12. Do not use Bead Block microspheres in the following applications:
 - i. Embolisation of large diameter arteriovenous shunts (ie. 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 Embolic Agent could

pass directly into the internal carotid artery or the above listed vessels.

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 embolising arteriovenous malformations with large shunts to avoid passage of the microspheres into the pulmonary or coronary circulation.

The colour of the Bead Block microspheres could be visible through the skin if injected into arteries feeding superficial tissues.

■ CAUTIONS:

- Do not use if the syringe or packaging appear damaged.
- Sterile and single use product. Do not reuse.
- Select the size and quantity of Bead Block microspheres appropriate for the pathology to be treated.
- Embolisation with Bead Block microspheres should only be performed by physicians who have received appropriate interventional occlusion training in the region intended to be embolised.

CAUTION:

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

■ POTENTIAL COMPLICATIONS:

1. Undesirable reflux or passage of Bead Block microspheres 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 embolisation.
3. Ischaemia at an undesirable location.
4. Capillary bed saturation and tissue damage.
5. Ischaemic stroke or ischaemic infarction.
6. Vessel or lesion rupture and haemorrhage.
7. Neurological deficits including cranial nerve palsies.
8. Vasospasm.
9. Death.
10. Recanalisation.
11. Foreign body reactions necessitating medical intervention.
12. Infection necessitating medical intervention.
13. Clot formation at the tip of the catheter and subsequent dislodgement.

■ CONSERVATION AND STORAGE:

- Bead Block microspheres must be stored in a cool, dry and dark place in its original packaging.
- Use by the date indicated on the syringe label.
- Do not freeze.

■ INSTRUCTIONS FOR USE:

- Carefully evaluate the vascular network associated with the lesion using high resolution imaging prior to beginning the embolisation procedure.
- Bead Block microspheres are available in a range of sizes. Care should be taken to choose the appropriate size Bead Block microspheres that best matches the pathology (ie. vascular target/vessel size) and provides the desired clinical outcome.
- When embolising arteriovenous malformations, choose a particle size that will occlude the nidus without passing through the AVM.
- Choose a delivery catheter based on the size of the target vessel. Bead

Block microspheres can tolerate temporary compression of 20% to 30% in order to facilitate passage through the delivery catheter.









- 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.
- Bead Block microspheres are not radio-opaque. It is recommended to monitor the embolisation under fluoroscopic visualisation by adding the desired amount of contrast medium to the physiologic suspension fluid.

■ TO DELIVER BEAD BLOCK MICROSPHERES.

Pre-Filled Syringe:

- o Directly aspirate 5 ml of contrast medium into the syringe to obtain an approximate 50% contrast and approximate 50% saline solution mix. Remove all air from the syringe. To evenly suspend the Bead Block microspheres/contrast solution, gently invert the 20 ml syringe several times. Attach the 20 ml syringe to one port of the luer-lock 3-way stopcock; and, if desired, a delivery catheter may be attached to the remaining port on the stopcock. Wait several minutes to allow the Bead Block microspheres to suspend properly. Draw the Bead Block microspheres/contrast solution 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. Inject the Bead Block microspheres/contrast solution from the injection syringe under fluoroscopic visualisation using a slow pulsatile action, while observing the contrast flow rate. If there is no effect on the flow rate, repeat the delivery process with additional injections of Bead Block microspheres/contrast solution or larger sized Bead Block microspheres may be considered. If the Bead Block microspheres/contrast solution requires re-suspension, gently invert the 20 ml syringe several times. Exercise conservative judgement in determining the embolisation endpoint.
- Upon completion of the treatment, remove the catheter while maintaining gentle suction so as not to dislodge Bead Block microspheres still within the catheter lumen.
- Discard any open, unused Bead Block microspheres in the Pre-Filled Syringe.

■ PACKAGE LABEL:

REF = Catalogue number	 = Use before/Expiry
 = Batch number/Lot number	 = Protect from light
 = Do not reuse	 = Protect from moisture
 = Attention see instructions for use	 = Do not freeze
 = Steam Sterilised	