

BeadBlock™

Targeted and predictable embolisation

CE Mark-Approved
for UFE* and PAE*  0086



*Size restrictions apply to indication
Please see back page

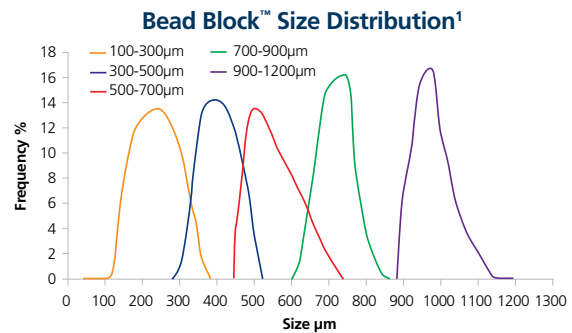


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The unique structure of Bead Block™ – PVA hydrogel crosslinked with acrylic polymer - ensures smooth delivery and targeted, effective embolisation

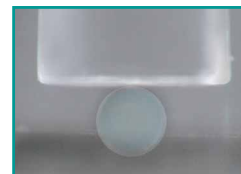
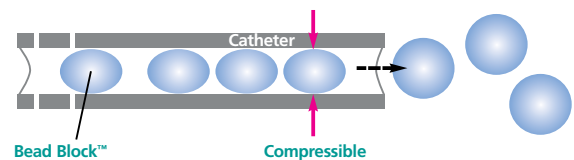
Accurate Sizing

Bead Block™ is precisely calibrated to offer reliable and consistent size distribution and predictable embolisation.



Compressibility with Rapid Shape Recovery

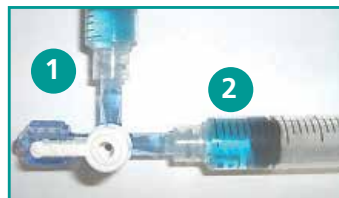
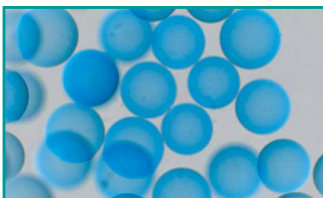
- Bead Block™ can be temporarily deformed to facilitate smooth passage through the catheter lumen.²
- Bead Block™ rapidly returns to its spherical shape once delivered from the catheter, facilitating travel to the target vessel and effective embolisation at the endpoint.²



Bead Block™: 100% shape recovery at 0.16 seconds from 70% compression

Spherical Integrity

- Studies show that, unlike other embolics, Bead Block™ does not aggregate or fragment, either of which may compromise the embolisation endpoint.³

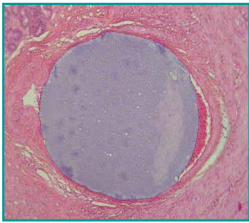


Bead Block™ after 20 transfers*: High resistance to fragmentation

*One transfer = entire contents of syringe 1 pushed through to syringe 2

Bilbao et al demonstrated that:

- Bead Block™ tends to locate in vessels of small size (eg arciform arteries) and appear individualised or in formed rows.³
- Most Bead Block™ specimens adapted perfectly to the vascular wall, completely occluding the vessel lumen.³
- Other bland embolic agents either did not adapt to the walls of the artery or demonstrated high rates of variability in the degree to which they adapted.³



Accurately sized Bead Block™ within targeted vessel provides a true mechanical embolisation⁴



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Please see table overleaf

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. (Fig A)
- 2 **Remove all air from the syringe.**
- 3 Gently invert the 20ml syringe several times to evenly suspend the Bead Block™/contrast solution.
Do not use a shaking motion. (Fig B)
- 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. Attach the injection syringe (1-5ml according to preference) to the second port. Attach the remaining port of the stopcock to the delivery catheter. (Fig C)

Ensure all air is purged from the system prior to injection.

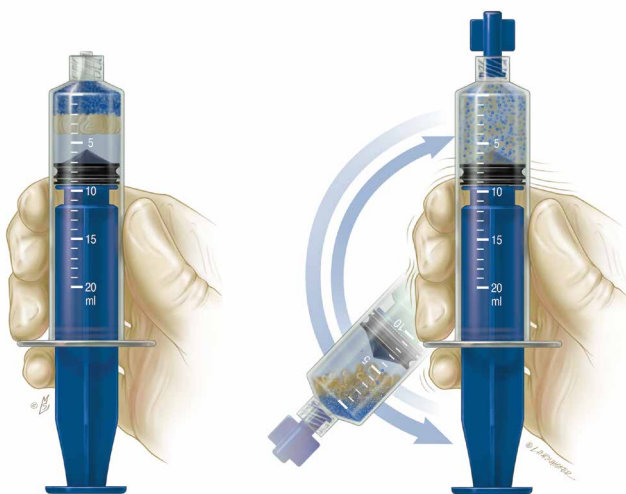


Fig A

Fig B

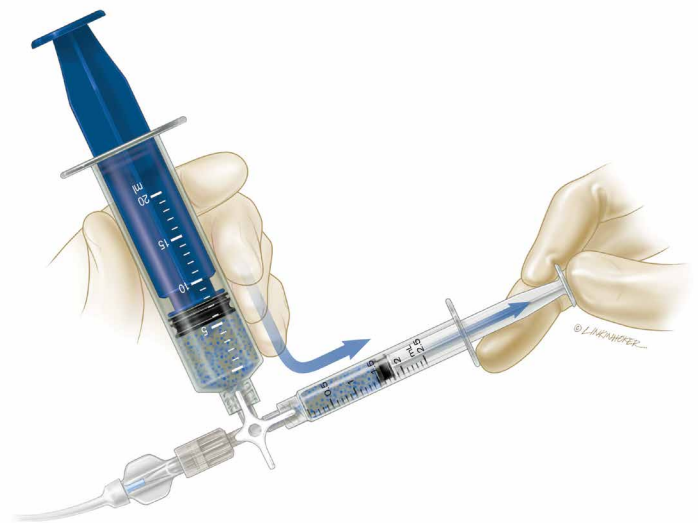
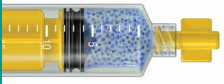
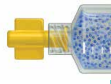
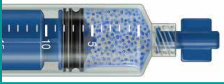




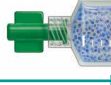
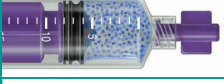
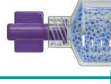


Fig C


Do not pass the content vigorously between syringes when obtaining suspension/re-suspension.
Exercise conservative judgment in determining the embolisation endpoint.

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Please see table overleaf

Bead Block™ indication, contrast media and suspension

	Size Range μm	Indication	Omnipaque™ 300	Isovue®-300	Optiray® 300	Visipaque™ 320	
	100 to 300	PAE*, Hypervascular Tumours	5.0 ml 1 min	5.0 ml 1 min	5.0 ml 1 min	5.0 ml 1 min	
	300 to 500	PAE*, Hypervascular Tumours	5.0 ml 2 min	5.0 ml 1 min	5.0 ml 1 min	5.0 ml 2 min	
	500 to 700	UFE*, Hypervascular Tumours	5.0 ml 3 min	5.0 ml 2 min	5.0 ml 2 min	4.0 ml 5 min	
	700 to 900	UFE*, Hypervascular Tumours	5.0 ml 5 min	5.0 ml 4 min	5.0 ml 4 min	2.0 ml 5 min	
	900 to 1200	UFE*, Hypervascular Tumours	2.0 ml 3 min	2.0 ml 3 min	2.0 ml 4 min	2.0 ml 6 min	
Key		Initial volume of contrast medium to add to achieve suspension for at least 45 seconds		Approximate time to achieve suspension, inverting several times every 20 seconds			

Bead Block™ catheter compatibility for easy delivery

Colour Code	Size Range μm	>0.040" >1020 μm				0.026"-0.040" 650-1020 μm								0.0205"-0.026" 520-650 μm				0.015"-0.0205" 380-520 μm		Size Range μm	Colour Code			
		Glidecath 4Fr	Glidecath 5Fr	Optritorque 4Fr	Optritorque 5Fr	Vasco +25 (3-8Fr)	PROGREAT 2.7Fr	PROGREAT 2.8Fr	Renegade High Flow 28	Vasco +25 (3Fr)	Vasco +28 (3-3Fr)	Rebar 027 (2-8Fr)	PROGREAT (2.4Fr)	Renegade	Vasco +18 (2-1Fr)	Vasco +21 (2-4Fr)	Rebar 18 (2-3Fr)	Echelon 10 (1-7Fr)	Echelon 14 (1-9Fr)			Nautica 14 XL (2-2Fr)	Rebar 10 (1-7Fr)	Rebar 14 (1-9Fr)
	100 to 300	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	100 to 300	
	300 to 500	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	300 to 500	
	500 to 700	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	500 to 700	
	700 to 900	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	700 to 900	
	900 to 1200	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	900 to 1200	

Bead Block™ is compatible with all 4F and 5F catheters (minimum ID of 0.040"/1040 μm)

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Please see table at the top of this page

Imagine where we can go.



Bead Block™

Bead Block™ Ordering Information

2ml Bead Block™ is suspended in 5ml physiological buffered saline in 20ml syringe and is packed singly.

Product Codes			Indication		
Bead Block™ Size	BTG Product Code	Label Colour	Hypervascular Tumours and Arteriovenous malformations	Uterine Fibroid Embolisation (UFE)*	Prostatic Artery Embolisation (PAE) for BPH*
Bead Block™ 100-300µm	EB2S103	Yellow	✓ Yes	✗ No	✓ Yes
Bead Block™ 300-500µm	EB2S305	Blue	✓ Yes	✗ No	✓ Yes
Bead Block™ 500-700µm	EB2S507	Red	✓ Yes	✓ Yes	✗ No
Bead Block™ 700-900µm	EB2S709	Green	✓ Yes	✓ Yes	✗ No
Bead Block™ 900-1200µm	EB2S912	Purple	✓ Yes	✓ Yes	✗ No

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France	Tel. +33-184884056	Spain	Tel. +34-911981738
Germany	Tel. +49-3030809275	Switzerland	Tel. +41-315280675
Ireland	Tel. +353-15134139	UK	Tel. +44-2033187881
Italy	Tel. +39-0694805067	Other countries: Please visit www.btg-im.com for details of your local distributor	

References:

1. Biocompatibles a BTG International group company, data on file: Ref: FAR-ES-0042.
2. Lewis A et al. In Vitro Evaluation of Microspherical Embolization Agents. J Mater Sci: Mater Med 17 (2006): 1193-204.
3. Bilbao, JI et al. Comparative Study of Four Different Spherical Embolic Particles in an Animal Model: A Morphologic and Histologic Evaluation. J Vasc Intervent Radiol 19 (2008) 1625-1638.
4. Photograph of Bead Block in an artery courtesy of JP Pelage, PhD, Hôpital Lariboisière, Paris, France.

Important Information

Indications:

Bead Block is intended to be used for the embolisation of hypervascular tumours, including uterine fibroids and arteriovenous malformations (AVMs). Bead Block is also intended to be used for the treatment of symptomatic Benign Prostatic Hyperplasia (BPH).

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.
2. Non-target embolization.
3. Pulmonary embolization.
4. Ischaemia at an undesirable location.
5. Capillary bed saturation and tissue damage.
6. Ischaemic stroke or ischaemic infarction.
7. Vessel or lesion rupture and haemorrhage.
8. Neurological deficits including cranial nerve palsies.
9. Vasospasm.
10. Death.
11. Recanalisation.
12. Foreign body reactions necessitating medical intervention.
13. Infection necessitating medical intervention.
14. Clot formation at the tip of the catheter and subsequent dislodgement.

UFE-Specific Potential Complications:

Potential post-procedure complications include:

1. Abdominal pain
2. Discomfort
3. Fever
4. Nausea
5. Constipation
6. Premature ovarian failure (ie menopause)
7. Amenorrhoea
8. Infection of the pelvic region
9. Uterine/ovarian necrosis
10. Phlebitis
11. Deep vein thrombosis with or without pulmonary embolism
12. Vaginal discharge
13. Tissue passage, fibroid sloughing, or fibroid expulsion post UFE
14. Post-UFE intervention to remove necrotic fibroid tissue
15. Vagal reaction
16. Transient hypertensive episode
17. Hysterectomy

PAE-Specific Potential Complications:

Potential post-procedure complications include:

1. Post procedural abdominal pain.
2. Transient polyuria.
3. Transient hematuria.
4. Transient urinary retention.

CE 0086

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