

Prostatic Artery Embolisation



 **Embosphere®**
MICROSPHERES

 **MERTMEDICAL™**

Results You Can Trust

Embosphere Microspheres, the most clinically studied round embolic, provide consistent and predictable results for effective embolisation in the treatment of uterine fibroids, hypervascular tumours, arteriovenous malformations and Benign Prostatic Hyperplasia (BPH).

Embosphere Microspheres' unique nonresorbable, resilient and cell-adhesive properties provide predictable outcomes procedure after procedure.

Embosphere Microspheres are backed by decades of research and are nonaggregating for predictable distribution. With several size ranges and volumes to choose from, Embosphere Microspheres allow precise targeted delivery.

Benign Prostatic Hyperplasia (BPH)

Moderate to severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) afflict approximately 50% of men aged 65 and older. At around age 50, the prostate gland—through which the urethra passes—grows large enough to constrict the urethra. For some patients, quality of life decreases due to frequent urges to urinate and insufficient voiding.

Prostatic Artery Embolisation (PAE) is a less invasive treatment option and selectively blocks blood flow to the prostate resulting in reduced prostate volume and reduced urethral stricture. Clinical data has demonstrated that patients achieve durable symptom relief while avoiding the complications and side effects associated with surgical or energy-based procedures and pharmacotherapy.¹

Nonaggregating Properties

The hydrophilic surface and spherical shape of Embosphere Microspheres prevent aggregation in the catheter lumen and in the vasculature.

Predictable Distribution

Because they are nonaggregating, Embosphere Microspheres distribute predictably after embolisation.

Targeted Delivery

Embosphere Microspheres are available in size ranges and volumes that allow the physician to select the right size spheres for the targeted tissue.



40-120 μm

100-300 μm

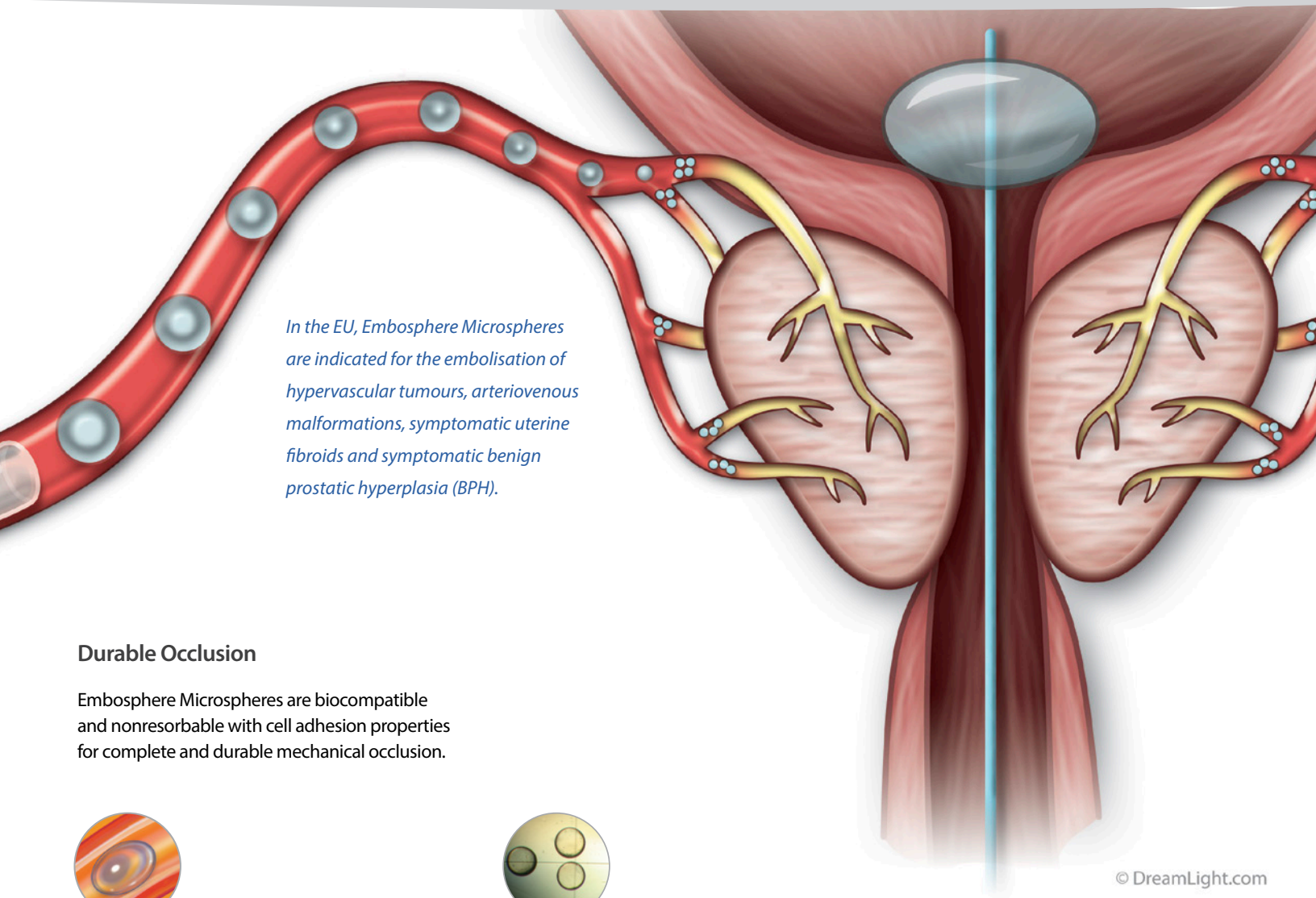
300-500 μm

500-700 μm

700-900 μm

900-1200 μm

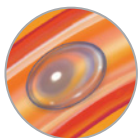
The Clear Choice for Embolisation



In the EU, Embosphere Microspheres are indicated for the embolisation of hypervascular tumours, arteriovenous malformations, symptomatic uterine fibroids and symptomatic benign prostatic hyperplasia (BPH).

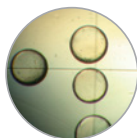
Durable Occlusion

Embosphere Microspheres are biocompatible and nonresorbable with cell adhesion properties for complete and durable mechanical occlusion.



Compressible and Resilient Material

Elastic properties allow temporary compression of up to 33%, facilitating smooth passage, even through microcatheters. Resilient material returns to original diameter after delivery, contributing to durable and targeted results.



Consistent Shape

Embosphere Microspheres exhibit a consistent cross-sectional diameter for targeted delivery. Their round shape matches the vessel lumen to help ensure occlusion.

© DreamLight.com

Embosphere Microspheres

The Clinically Proven Round Embolic

Trust Embosphere Microspheres, the world leader in microsphere embolisation.

¹Clinical References

Carnevale, FC, Antunes AA, da Motta Leal Filho JM, et al.

Prostatic artery embolisation as a primary treatment for benign prostatic hyperplasia: Preliminary results in two patients. *Cardiovasc Intervent Radiol.* 2010; 33(2): 355-361.

Carnevale, FC, da Motta Leal Filho JM, Antunes AA, et al.

Midterm follow-up after prostate embolisation in two patients with benign prostatic hyperplasia. *Cardiovasc Intervent Radiol.* 2011; 34(6): 1330-1333.

Carnevale, FC, da Motta Leal Filho JM, Antunes AA, et al.

Quality of life and clinical symptom improvement support PAE for patients with acute urinary retention caused by benign prostatic hyperplasia. *J Vasc Interv Radiol.* 2013. Epub 2013 Feb 20.

Embolisation Efficacy

Indications for Use:

Embosphere Microspheres are designed to occlude blood vessels, for therapeutic or preoperative purposes, in the following procedures:

- Embolisation of hypervascular tumours and processes, including uterine fibroids, meningiomas
- Embolisation of arteriovenous malformations
- Haemostatic embolisation
- Embolisation of the prostate gland for relief of symptoms related to benign prostatic hyperplasia (Only available in select markets*)

*CE marked by LNE/G-Med in compliance with the MDD 93/42/EEC amended by 2007/47/EC. Please refer to www.merit.com/pae to check if the above indication has been cleared in your country.

In the USA, Embosphere Microspheres are indicated for use in embolisation of arteriovenous malformations, hypervascular tumours, and symptomatic uterine fibroids. The indication for the embolisation of the prostate gland for relief of symptoms related to benign prostatic hyperplasia is not cleared by the FDA. The FDA has approved an Investigational Device Exemption for Merit Medical's international, multi-center, randomized clinical trial (NCT01789840) that will compare the results of prostatic artery embolisation to transurethral resection of the prostate (TURP) for treatment of BPH.

For full prescribing information, please refer to the Embosphere Microspheres Instructions for Use.

Embosphere Microspheres are available in six size ranges for targeted embolisation.

Now available with color coded syringes**

Embosphere Microspheres in a syringe**

Size Range (µm)	Color Code	1 ml*	2 ml*
40 - 120	Orange	---	S120GH
100 - 300	Yellow	S210GH	S220GH
300 - 500	Blue	S410GH	S420GH
500 - 700	Red	S610GH	S620GH
700 - 900	Green	S810GH	S820GH
900 - 1200	Purple	S1010GH	S1020GH

* Volume of Embosphere Microspheres supplied in sterile saline in 20ml syringes.

** Color coded syringes are not available in all markets and have a 3 - year shelf life. Please check with your local Sales Representative for availability.



Embosphere Microspheres in a sterile vial***

Size Range (µm)	Color Code	1 ml*	2 ml*
40 - 120	Orange	V110GH	V120GH
100 - 300	Yellow	V210GH	V220GH
300 - 500	Blue	V410GH	V420GH
500 - 700	Red	V610GH	V620GH
700 - 900	Green	V810GH	V820GH
900 - 1200	Purple	V1010GH	V1020GH

* Volume of Embosphere Microspheres supplied in sterile saline to a volume of 5 ml.

*** Vials are not available in all markets.

Please check with your local Sales Representative for availability.



Please refer to the product IFU before product use.

Packaged 5 per box (United States), individually in most other countries.
Contact your Merit Sales Representative for details.



www.merit.com

Merit Medical Systems, Inc. • 1600 West Merit Parkway • South Jordan, Utah 84095 • 1-801-253-1600 • 1-800-35-MERIT
 Merit Medical EUROPE, MIDDLE EAST AND AFRICA (EMEA) • Amerikalaan 42, 6199 AE Maastricht-Airport • The Netherlands • Tel: +31 43 358 82 22
 BioSphere Medical, S.A. • Parc des Nations - Paris Nord 2 • 383 Rue de la Belle Etoile • 95700 Roissy en France • France
 Free phone for specific country: Austria 0800 295 374 • Belgium 0800 72 906 (Dutch) 0800 73 172 (French) • Denmark 80 88 00 24 • France 0800 91 60 30
 Finland 0800 770 586 • Germany 0800 182 0871 • Ireland (Republic) 1800 553 163 • Italy 800 897 005 • Luxembourg 8002 25 22 • Netherlands 0800 022 81 84
 Norway 800 11629 • Sweden 020 792 445 • UK 0800 973 115