

# Embosphere<sup>®</sup>

Microspheres

Prostatic Artery Embolisation



THINK EMBOLICS. DISCOVER MERIT.™

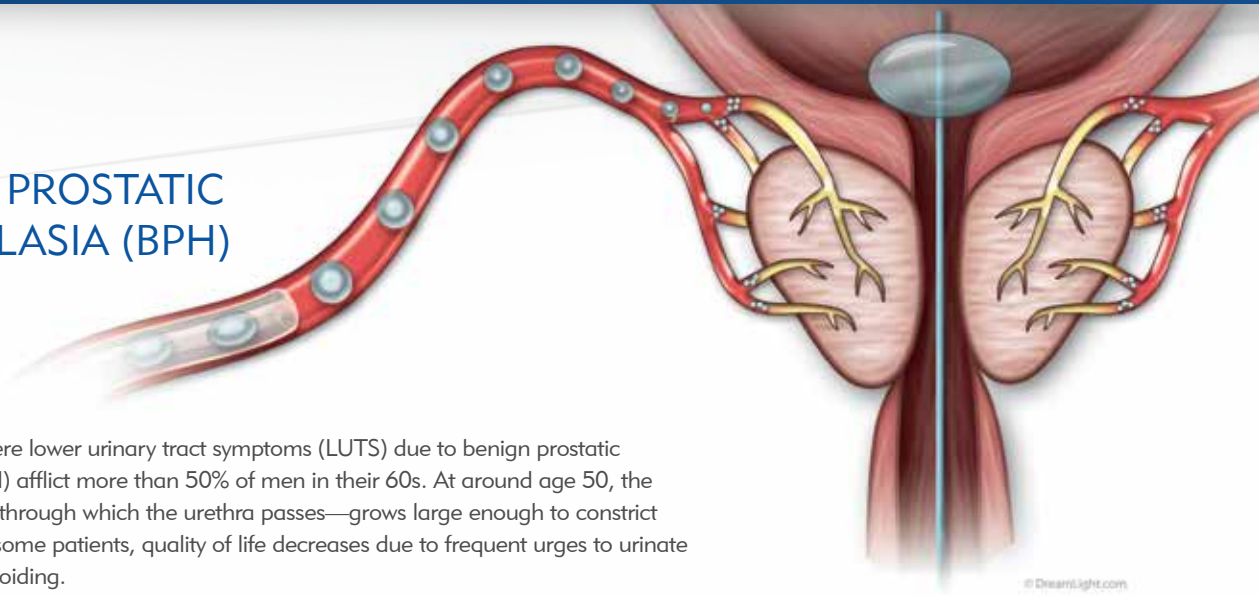
# Embosphere®

Microspheres

## BENIGN PROSTATIC HYPERPLASIA (BPH)

Moderate to severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) afflict more than 50% of men in their 60s. 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 have demonstrated that patients achieve durable symptom relief while avoiding the complications and side effects associated with surgical or energy-based procedures and pharmacotherapy.



### Safe mechanical occlusion

Non-resorbable, biocompatible.

### No catheter / proximal clogging: enhanced efficacy

Hydrophilic, compressible, smooth injection.

### Consistent & predictable results: enhanced safety

Resilient; size of the particles matches the size of the embolised vessels. No migration. Final endpoint at a glance.

## 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).



40-120 µm  
FOR: TACE / TAE



100-300 µm  
FOR: TACE / TAE



300-500 µm  
FOR: PAE / TACE



# PROSTATIC ARTERY EMBOLISATION FAQS

## What is Benign Prostatic Hyperplasia (BPH)?

It is the normal, ongoing growth of the prostate gland that happens naturally in most men as they age. Because this normal growth constrains the urethra, which passes through the prostate gland, men experience symptoms such as difficult urination as they age.

## What is Prostatic Artery Embolisation (PAE)?

PAE selectively blocks blood flow to the prostate, resulting in reduced prostate volume and reduced urethral stricture.

## Are Embosphere Microspheres indicated for Prostatic Artery Embolisation (PAE) due to symptomatic Benign Prostatic Hyperplasia (BPH)?

Embosphere Microspheres were the first to receive CE Mark approval for embolisation of the prostate arteries for relief of symptoms related to BPH in the EU.

## What is the actual experience with Embosphere?

More than four years' experience with patients treated in Brasil, US and Europe.

## What clinical literature is currently available for the Embosphere Microsphere BPH indication?

Prostatic artery embolisation as a primary treatment for benign prostatic hyperplasia: Preliminary results in two patients. Carnevale, FC, Antunes AA, da Motta Leal Filho JM, et al. Cardiovasc Intervent Radiol. 2010; 33(2): 355-361.

Quality of life and clinical symptom improvement support PAE for patients with acute urinary retention caused by benign prostatic hyperplasia. Carnevale, FC, da Motta Leal Filho JM, Antunes AA, et al. J Vasc Interv Radiol. Epub 2013: Feb 20.

Prostatic Artery Embolization for Enlarged Prostates Due to Benign Prostatic Hyperplasia. How I Do It. Francisco C. Carnevale, Alberto A. Antunes. Cardiovasc Intervent Radiol Vol 36 (4) Aug 2013.

More literature available on [MeritEMEA.com/PAE](http://MeritEMEA.com/PAE)

## How does PAE compare to other embolisation procedures like Uterine Artery Embolisation (UAE)?

PAE procedures take longer to complete because the arteries are smaller and more tortuous.

PAE patients are men, typically between the ages of 50 and 70. The arteries feeding the prostate tend to be 200-400  $\mu\text{m}$ . Because PAE patients are older, their arteries often reflect normal signs of aging, such as atherosclerosis. Atherosclerosis can make vessel catheterisation very difficult.

By comparison, UAE is performed on relatively young, healthy women. The uterine artery is larger and much easier to catheterise than the arteries feeding the prostate.

## What kind of material is typically used?

Normally one 2 mL syringe of 300-500  $\mu\text{m}$  of Embosphere Microspheres is required for bilateral PAE.

The use of a microcatheter and wire is essential. Please consult the Merit catalogue for the embolics delivery systems.

## Why Embosphere Microspheres for PAE?

Embosphere is the only predictable embolic on the market, providing a rapid homogenous distribution in the targeted zone, with no proximal clogging, no distal migration, and low failure rate. The prostatic gland is homogeneously infarcted providing a sustainable symptom relief.

## What is Merit's support and where can I learn more about PAE?

Over the past six years, Merit Medical has facilitated BPH treatment by investing in PAE research, clinical studies, and trainings.

Our commitment includes:

- Plenary session / symposia at major congresses
- Single / multicentric clinical studies
- Centers of excellence training program

For more information, please contact us at [EMEAworkshop@merit.com](mailto:EMEAworkshop@merit.com) or talk to your Merit Medical sales representative.



500-700  $\mu\text{m}$   
FOR: UAE / UFE



700-900  $\mu\text{m}$   
FOR: UAE / UFE



900-1200  $\mu\text{m}$   
FOR: UAE / UFE



## EMBOSPHERE MICROSPHERES ARE AVAILABLE IN SIX SIZE RANGES FOR TARGETED EMBOLISATION.



### Embosphere Microspheres in a syringe\*\*

Size Range (µm)	Colour Code	1 mL*	2 mL*
40 - 120	Orange	S110GH	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 20 mL syringes.  
 \*\* Colour 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)	Colour 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 and have a 3-year shelf life. Please check with your local Sales Representative for availability.

PAE

Please refer to the product IFU before product use.  
 Packaged 1 per box.

### SUSPENSION

1. Inject an equivalent amount of contrast to the NaCl provided in the syringe (50/50).
2. Spheres will begin to float after the injection.
3. Gently invert the syringe; after 3 minutes you will get a durable suspension.



### 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 arteries for relief of symptoms related to benign prostatic hyperplasia



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