BENIGN PROSTATIC HYPERPLASIA (BPH)

Moderate to severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) affect 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.

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).

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.
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?

More literature available on 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 µm. 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 µm 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 homogenously 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 or talk to your Merit Medical sales representative.
## Embosphere Microspheres

### 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

### 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.

### Contact Information

- Merit Medical Europe, Middle East & Africa
  - Amerikalaan 42, 6199 AE Maastricht-Airport, Netherlands
  - +31 43 358 82 22
- Merit Medical Ireland Ltd.
  - Parkmore Business Park West, Galway, Ireland
  - +35 39 170 37 33
- Merit Medical France
  - 136 Ave. Joseph Kessel, 78960 Voisins Le Bretonneux, France
  - +33 (0) 30 57 24 24
- Merit Medical Systems, Inc.
  - 1600 West Merit Parkway, South Jordan, UT, 84095 USA
  - +1 801 253 1600
- Asia, Pacific Rim, Latin America, Caribbean & Canada
  - +1 801 208 4438

The information presented here should not be construed as specific medical advice, diagnosis, treatment, or recommendation. Risks and complications are set forth on Merit Medical’s website or the product’s Instructions for Use. This material is not a substitute for a consultation of physical examination by a physician. Only discussion of your individual needs with a qualified physician will determine the best method of treatment for you. Merit Medical assumes no responsibility for a patient’s success, as results may vary.

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### Embosphere Microspheres in a Syringe

<table>
<thead>
<tr>
<th>Size Range (µm)</th>
<th>Colour Code</th>
<th>1 mL*</th>
<th>2 mL*</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 - 120</td>
<td>Orange</td>
<td>S110GH</td>
<td>S120GH</td>
</tr>
<tr>
<td>100 - 300</td>
<td>Yellow</td>
<td>S210GH</td>
<td>S220GH</td>
</tr>
<tr>
<td>300 - 500</td>
<td>Blue</td>
<td>S410GH</td>
<td>S420GH</td>
</tr>
<tr>
<td>500 - 700</td>
<td>Red</td>
<td>S610GH</td>
<td>S620GH</td>
</tr>
<tr>
<td>700 - 900</td>
<td>Green</td>
<td>S810GH</td>
<td>S820GH</td>
</tr>
<tr>
<td>900 - 1200</td>
<td>Purple</td>
<td>S1010GH</td>
<td>S1020GH</td>
</tr>
</tbody>
</table>

* 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

<table>
<thead>
<tr>
<th>Size Range (µm)</th>
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<tr>
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</tr>
</tbody>
</table>

* 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.

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Please refer to the product IFU before product use.

Packaged 1 per box.

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**E.M.E.A.**