



Embosphere PRO™

Prostatic Artery Embolization Kit



FIRST AND ONLY FDA-CLEARED EMBOLIC INDICATED
FOR PROSTATIC ARTERY EMBOLIZATION

Predictable. Targeted. Established. Convenient.™

Embosphere PRO™

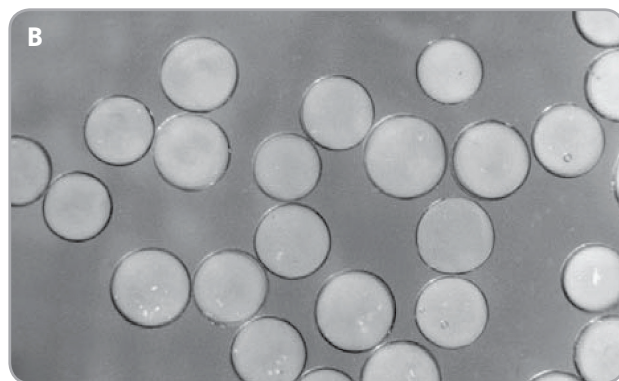
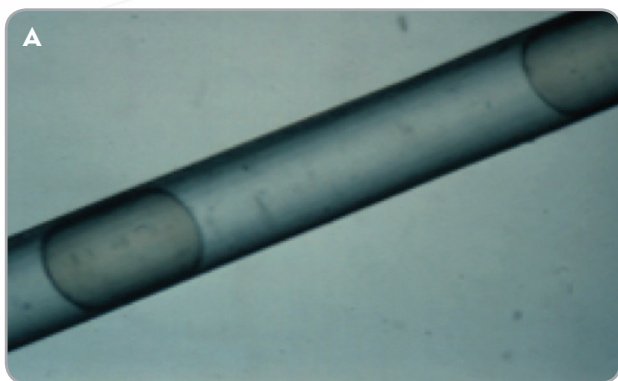
Prostatic Artery Embolization Kit

Prostatic artery embolization (PAE) is a technically challenging procedure that demands a predictable, targeted, and established microsphere like Embosphere® Microspheres.

The first and only embolic cleared by the U.S. Food & Drug Administration for PAE, Embosphere® Microspheres are available in Merit's exclusive Embosphere PRO™ Prostatic Artery Embolization Kit, which brings additional convenience to the power and predictability of Embosphere® Microspheres.

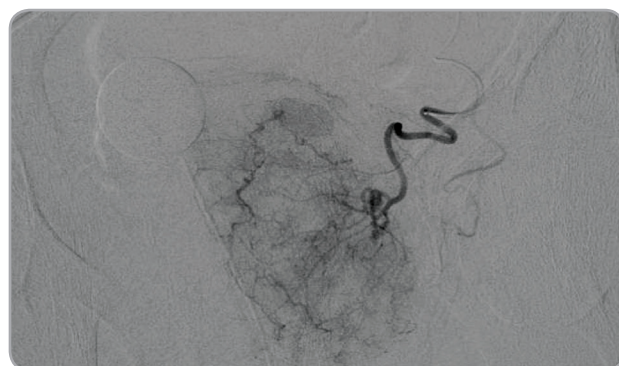
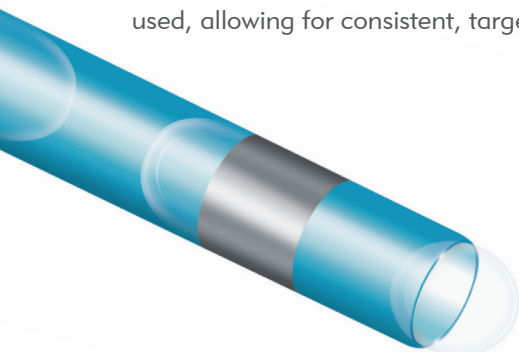
PREDICTABLE

Embosphere® Microspheres temporarily compress to facilitate smooth microcatheter passage (A).¹ Once through the microcatheter, Embosphere® Microspheres return to their original spherical shape and stated diameter (B) for predictable, targeted delivery.¹

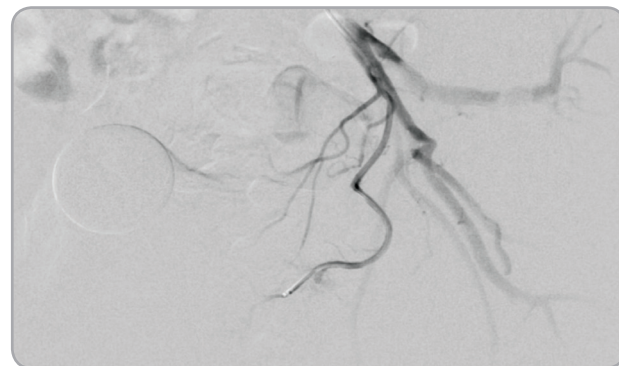


TARGETED

Embosphere® Microspheres have consistently demonstrated a direct correlation between the level of arterial occlusion and the size of the microspheres used, allowing for consistent, targeted occlusion.²⁻⁴



Pre-embolization



Post-embolization

ESTABLISHED

Embosphere® Microspheres are the most clinically studied and clinically utilized spherical embolic, having been proven:

- During more than 20 years of clinical use
- In more than 250 clinical articles, with more than 35 PAE-related⁵

PAE Clinical Summary with Embosphere® Microspheres⁵

A composite database of 286 patients who underwent PAE using Embosphere® Microspheres for treatment of symptomatic benign prostatic hyperplasia (BPH) was analyzed to evaluate clinical outcomes. All patients were suffering from lower urinary tract symptoms (LUTS) due to BPH with International Prostate Symptom Scores (IPSS) of moderate to severe.

Post embolization, 97% of patients reported a decrease in their IPSS by at least 3 points, and 90% of patients dropped at least 1 symptom category, from severe to moderate or moderate to mild.

Most patients also experienced improvement in their Quality of Life score and a substantial decrease in prostate volume.

Mean Prostate Volume at Baseline and Follow-Up

Time Window	Mean ± SD	n
Baseline	85.1 ± 38.3	265
1 to 3 months f/u	62.4 ± 27.1	193
9 to 16 months f/u	65.2 ± 28.6	118

Mean Quality of Life at Baseline and Follow-Up

Time Window	Mean ± SD	n
Baseline	4.8 ± 0.9	166
1 to 3 months f/u	1.4 ± 1.2	165
9 to 16 months f/u	1.4 ± 1.1	116

Mean IPSS at Baseline and Follow-Up

Time Window	Mean ± SD	n
Baseline	21.5 ± 6.8	251
1 to 3 months f/u	6.3 ± 5.8	190
9 to 16 months f/u	6.2 ± 5.8	136

For more information about the composite database and clinical outcomes, refer to the Embosphere PRO™ Prostatic Artery Embolization Kit Instructions for Use (IFU).

CONVENIENT

Merit Medical's new Embosphere PRO™ Prostatic Artery Embolization Kit combines the power and predictability of Embosphere® Microspheres with basic preparation and delivery tools for added convenience.

Each kit includes:

- (1) prefilled syringe of Embosphere® Microspheres, 300-500 µm or 100-300 µm
- (1) 10 mL Medallion® Syringe
- (1) 3 mL Medallion® Syringe
- (2) 1 mL Medallion® Syringes
- (1) 3-way Marquis® Stopcock, 1050 psi





Embosphere PRO™

Prostatic Artery Embolization Kit

First and only embolic indicated for PAE



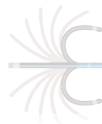
Ordering Information

Product Number	Item Description	Color Code
S220PRO	Embosphere PRO™ Prostatic Artery Embolization Kit with prefilled syringe of Embosphere® Microspheres, 100-300 µm, 2 mL volume	
S420PRO	Embosphere PRO™ Prostatic Artery Embolization Kit with prefilled syringe of Embosphere® Microspheres, 300-500 µm, 2 mL volume	

Sold 1 per box. It is recommended to use 300-500 µm Embosphere® Microspheres for PAE.

Navigate the Challenges of PAE

PAE is a technically demanding procedure because of complex anatomical variations and narrow prostatic arteries often blocked by atherosclerosis. PAE can also be time-consuming with long fluoroscopy time and multiple imaging such as conebeam computed tomography and digital subtraction angiography, which can lead to high radiation exposure to physicians and patients.⁶⁻⁸ With its steerable articulating tip, Merit Medical's SwiftNINJA® Steerable Microcatheter is designed to simplify and shorten the PAE procedure.



SwiftNINJA®

Steerable Microcatheter



Catheter Specifications

Part Number	Outer Diameter Proximal Portion	Outer Diameter Distal Portion	Usable Length	Hydrophilic Coating Length	Distance From Tip To 1 st Markerband	Distance Between 1 st and 2 nd Markerbands	Recommended Guide Cath. ID	Inner Diameter	Max. Guide Wire	Max. Injection Pressure	Max. Microsphere Size	Max. Coil Size	Cath. Vol.
MIV-20500	2.9F (0.97 mm)	2.4F (0.80 mm)	125 cm	80 cm	0.5 mm	13.5 mm	0.042" - 0.043" (1.07 mm - 1.09mm)	0.021" (0.54 mm)	≤ 0.018" (0.46 mm)	6,900 kPa (1,000 psi)	700 µm	.018" (0.46 mm)	0.49 mL

Before using, refer to Instructions for Use (IFU) for indications, contraindications, warnings, precautions, and directions for use.

REFERENCES

- Laurent A, et al. Trisacryl Gelatin Microspheres for Therapeutic Embolization, I: Development and In Vitro Evaluation. *Am J Neuroradiol* 1996 Mar; 17:533-540.
- Pelage JP, et al. Uterine Artery Embolization in Sheep: Comparison of Acute Effects with Polyvinyl Alcohol Particles and Calibrated Microspheres. *Radiol* 2002;224:436-45.
- Verret V, et al. The Arterial Distribution of Embosphere and Embosphere Microspheres in Sheep Kidney and Uterus Embolization Models. *J Vasc Interv Radiol* 2011 Feb;22(2):220-8.
- Yamamoto A, et al. Evaluation of Tris-acryl Gelatin Microsphere Embolization with Monochromatic X Rays: Comparison with Polyvinyl Alcohol Particles. *J Vasc Interv Radiol* 2006 Nov;17(11 pt 1):1797-802.
- Data on file.
- Garzón W, et al. Prostatic artery embolization: radiation exposure to patients and staff. *J Radiol Prot* 2016; 36:246-254.
- Laborda A, et al. Radiodermatitis after prostatic artery embolization: case report and review of the literature. *Cardiovasc Intervent Radiol* 2015; 38:755-759.
- Andrade G, et al. Radiation Exposure of Patients and Interventional Radiologists during Prostatic Artery Embolization: A Prospective Single-Operator Study. *J Vasc Interv Radiol* 2017; 28:517-521.



Understand. Innovate. Deliver.™

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