

# Embozene<sup>®</sup> Microspheres

## Precisely Calibrated Microspheres

### Precise Calibration

Embozene Microspheres are available in 10 uniform sizes from 40  $\mu\text{m}$  to 1300  $\mu\text{m}$

- $\geq 95\%$  of Embozene Microspheres are within the specified size range,<sup>1</sup> resulting in greater confidence when performing superselective and targeted embolization procedures
- Compressible and robust to facilitate smooth catheter delivery
- Embozene Microspheres allow for a strong correlation between microsphere size and the diameter of vessel occlusion<sup>2</sup>
- Highly biocompatible hydrogel microspheres coated with Polyzene<sup>®</sup>-F<sup>3-5</sup>

### Enhanced Visualization

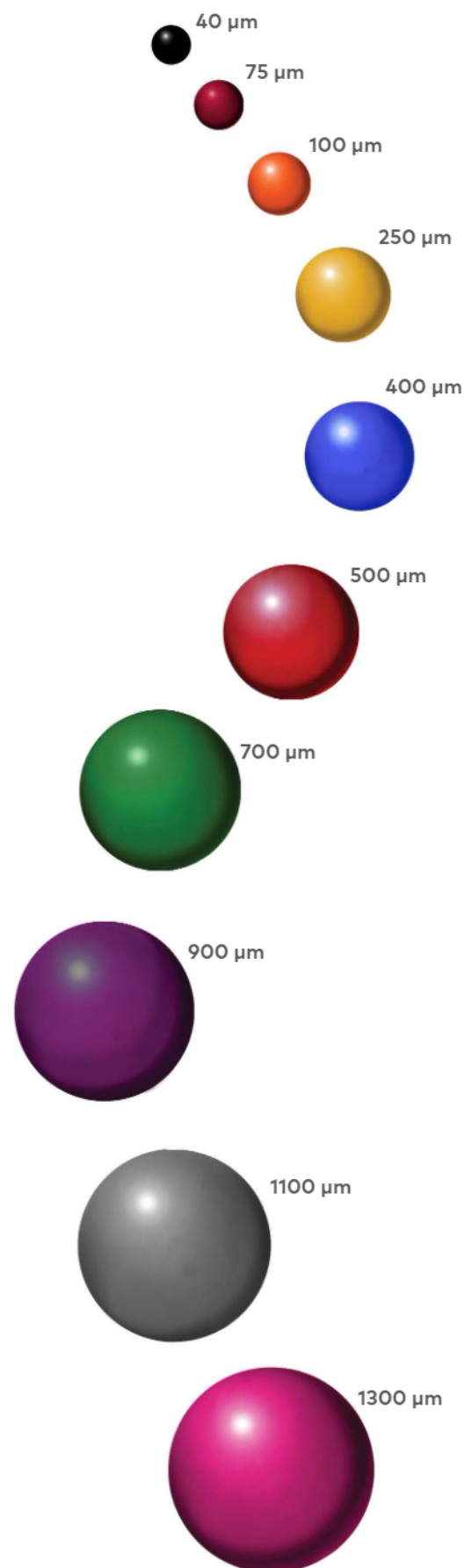
Embozene Microspheres are uniquely color-coded by size to enhance visualization

- Aids in size confirmation and ease of use
- Reduces confusion when multiple sizes are being used during a procedure

### Indications

Embozene Microspheres are indicated for the embolization of:

- Arteriovenous malformations
- Hypervascular tumors, including uterine fibroids and hepatoma
- Prostatic arteries for symptomatic benign prostatic hyperplasia (BPH)
- This device is not intended for neurovascular use



Size	Size Range	Color	UPN
40 µm	40 ± 10 µm	Black	01-0301-00402-11
75 µm	75 ± 15 µm	Burgundy	01-0301-00752-11
100 µm	100 ± 25 µm	Orange	01-0301-01002-11
250 µm	250 ± 50 µm	Yellow	01-0301-02502-11
400 µm	400 ± 50 µm	Blue	01-0301-04002-11
500 µm	530 ± 50 µm	Red	01-0301-05002-11
700 µm	700 ± 50 µm	Green	01-0301-07002-11
900 µm	900 ± 75 µm	Purple	01-0301-09002-11
1100 µm	1100 ± 75 µm	Gray	01-0301-11002-11
1300 µm	1300 ± 75 µm	Pink	01-0301-13002-11

Embozene Microspheres are sold as single unit syringes with 2 ml of product and have a 3-year shelf life from date of manufacture<sup>1</sup>



1. Data on file. Varian Medical Systems, Inc. 2020.
2. Stampfl, S., et al., Arterial distribution characteristics of Embozene particles and comparison with other spherical embolic agents in the porcine acute embolization model. J Vasc Interv Radiol, 2009, 20(12): p. 1597-607.
3. Stampfl, S., et al., Biocompatibility and recanalization characteristics of hydrogel microspheres with polyzene-F as polymer coating. Cardiovasc Intervent Radiol, 2008, 31(4): p. 799-806.
4. Stampfl, U., et al., Experimental liver embolization with four different spherical embolic materials: impact on inflammatory tissue and foreign body reaction. Cardiovasc Intervent Radiol, 2009, 32(2): p. 303-12.
5. Bates, M.C., et al., Translational Research and Early Favorable Clinical Results of a Novel Polyphosphazene (Polyzene-F) Nanocoating. Regenerative Engineering and Translational Medicine, 2019, 5(4): p. 341-353.

**INDICATIONS FOR USE:** Embozene Microspheres are intended for embolization of arteriovenous malformations and hypervascular tumors, including uterine fibroids (UFE) and hepatoma, and for embolization of prostatic arteries (PAE) for symptomatic benign prostatic hyperplasia (BPH). This device is not intended for neurovascular use.

**SAFETY STATEMENT:** Vascular embolization is a procedure that has inherent risk. The procedure should be performed by specialized physicians experienced in vascular embolization procedures. Risks include, but are not limited to, radiation exposure from fluoroscopy used to visualize the blood vessels during embolization, allergic reactions, tissue damage, complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgement, vasospasm, vessel trauma [e.g., dissection, perforation, rupture]), foreign body reactions (e.g., pain, rash, fever, inflammation), hemorrhage, development of alternative vascular pathways, recanalization with recurrence of symptoms, infection, ischemic infarction, neurological deficits, post-embolization syndrome, non-target vessel thrombosis, and death. For more information, please visit [www.varian.com/safety](http://www.varian.com/safety).

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

To order Varian Microspheres Product, please contact sales support at +1 888-272-1001 (Boston Scientific) through May 29, 2020. Starting June 1, 2020, please contact Varian's Interventional Solutions Customer support team +1 877-467-2009 or [vis.support@varian.com](mailto:vis.support@varian.com)

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