

Embozene™ Microspheres

Precisely calibrated Microspheres

Precise Calibration

The largest array of precisely calibrated microsphere sizes

- 10 uniform sizes are available from 40 µm to 1300 µm
- Biocompatible hydrogel microspheres coated with Polyzene®-F¹⁻³
- ≥95% of Embozene Microspheres are within the specified size range,⁴ resulting in greater confidence when performing super selective and targeted embolization procedures
- Compressible to facilitate smooth passage through delivery catheters
- Embozene Microspheres have a strong correlation between microsphere size and the diameter of vessel occlusion⁵

Enhanced Visualization

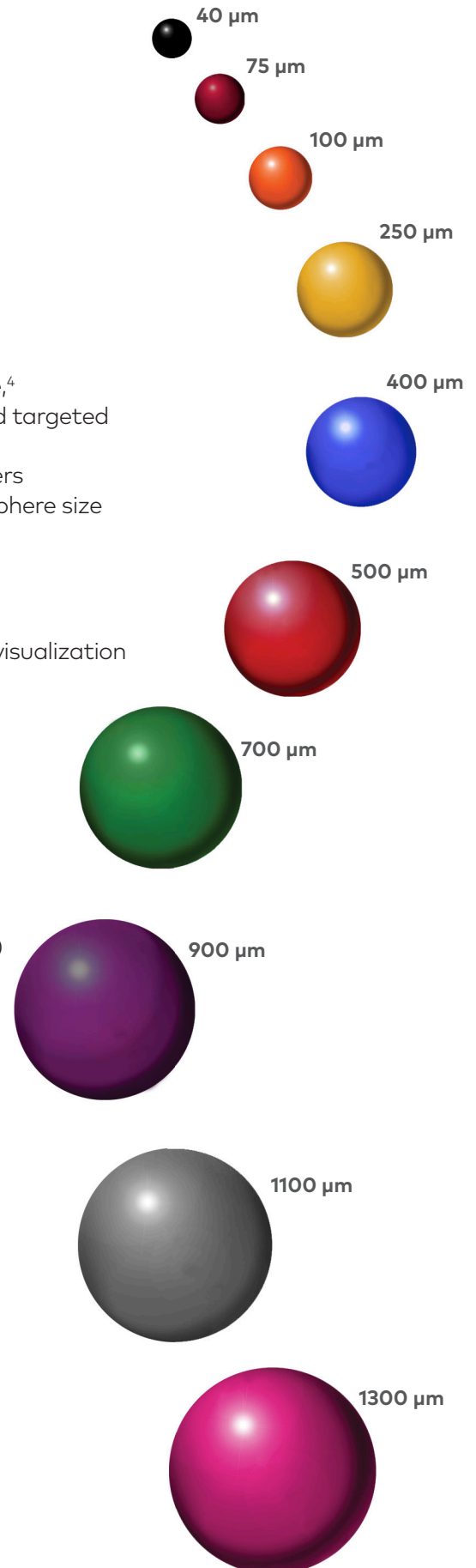
Embozene microspheres are uniquely color-coded by size to enhance visualization

- Visualization aids in size confirmation and ease of use
- Eliminates 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 hepatomas
- Prostatic arteries for symptomatic benign prostatic hyperplasia (BPH)



Size	Size Range	Color	UPN (1ml)	UPN (2ml)
40 µm	40 ± 10 µm	Black	01-0301- 00401-07	01-0301- 00401-07
75 µm	75 ± 15 µm	Burgundy	01-0301- 00751-07	01-0301- 00752-07
100 µm	100 ± 25 µm	Orange	01-0301- 01001-07	01-0301- 01002-07
250 µm	250 ± 50 µm	Yellow	01-0301- 02501-07	01-0301- 02502-07
400 µm	400 ± 50 µm	Blue	01-0301- 04001-07	01-0301- 04002-07
500 µm	530 ± 50 µm	Red	01-0301- 05001-07	01-0301- 05002-07
700 µm	700 ± 50 µm	Green	01-0301- 07001-07	01-0301- 07002-07
900 µm	900 ± 75 µm	Purple	01-0301- 09001-07	01-0301- 09002-07
1100 µm	1100 ± 75 µm	Gray	01-0301- 11001-07	01-0301- 11002-07
1300 µm	1300 ± 75 µm	Pink	01-0301- 13001-07	01-0301- 13002-07

Embozene Microspheres are sold as single unit syringes with 1 ml or 2 ml of product and have a 3-year shelf life from date of manufacture⁴

1. Stampfl, S., et al., Biocompatibility and recanalization characteristics of hydrogel microspheres with polyzene-F as polymer coating. Cardiovasc Intervent Radiol, 2008. 31(4): p.
2. 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.
3. 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.
4. Data on file. Varian Medical Systems, Inc. 2020.
5. 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.



INDICATIONS FOR USE: Embozene Microspheres are intended for the 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). The device is not intended for neurovascular use.

CONTRAINDICATIONS: The contraindications of Embozene Microspheres include the presence of vasculature where Embozene® Microspheres could pass directly into the central nervous system, central circulatory system, internal carotid artery, or other non-target territories. Procedures should not be performed if vascular anatomy precludes correct catheter placement or embolic injection.

WARNINGS AND PRECAUTIONS: 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.

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

A complete list of indications, contraindications, warnings and precautions are described in Embozene® Microspheres Instructions for Use. Please consult these before using the product.

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Not all features or products are available in all markets and are subject to change.

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