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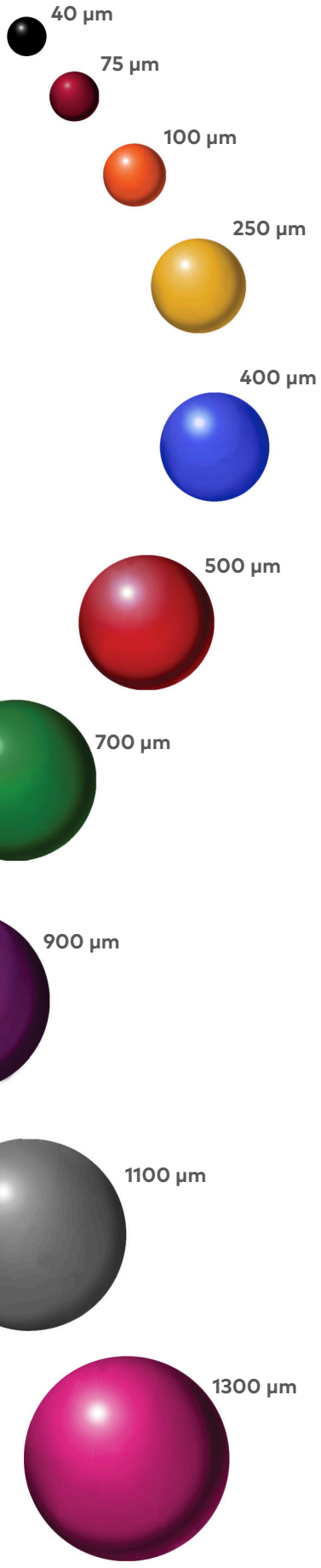
Embozene® Microspheres

Precisely Calibrated Microspheres



Precise Calibration

Embozene Microspheres are available in 10 uniform sizes from 40 µm to 1300 µm

- ≥95% of Embozene Microspheres are within the specified size range,[1] 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[2]
- Highly biocompatible hydrogel microspheres coated with Polyzene®-F[3-5]

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:

- Hypervascular tumors
- Arteriovenous malformations
- Uterine fibroids
- Hepatocellular carcinoma
- Benign prostate hyperplasia (BPH)
- Tumors of the head, neck, torso, and skeletal system
- Bleeding and trauma
- Pre-operative reduction of bleeding other than in the central nervous system
- This device is not intended for neurovascular use

Size	Size Range	Color	UPN (1 ml)	UPN (2 ml)
40 µm	40 ± 10 µm	**Black**	01-0301-00401-07	01-0301-00402-07
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 manufacture[1]

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 indicated for embolization of the following conditions: hypervascular tumors, arteriovenous malformations, uterine fibroids (UFE), hepatocellular carcinoma, benign prostatic hyperplasia (BPH), tumors of head, neck, torso, and skeletal system, bleeding and trauma, and pre-operative reduction of bleeding other than in the central nervous system. 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.

CAUTION: The law restricts these devices 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.

Information contained herein is for distribution outside the U.S. only.

To order Varian Microspheres Product, please visit www.varian.com/is
Consult your Varian representative for country- specific product availability.

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