



# Embozene Tandem® Microspheres

## Precisely Calibrated Drug-Eluting Microspheres

Precisely calibrated small microspheres for controlled embolization

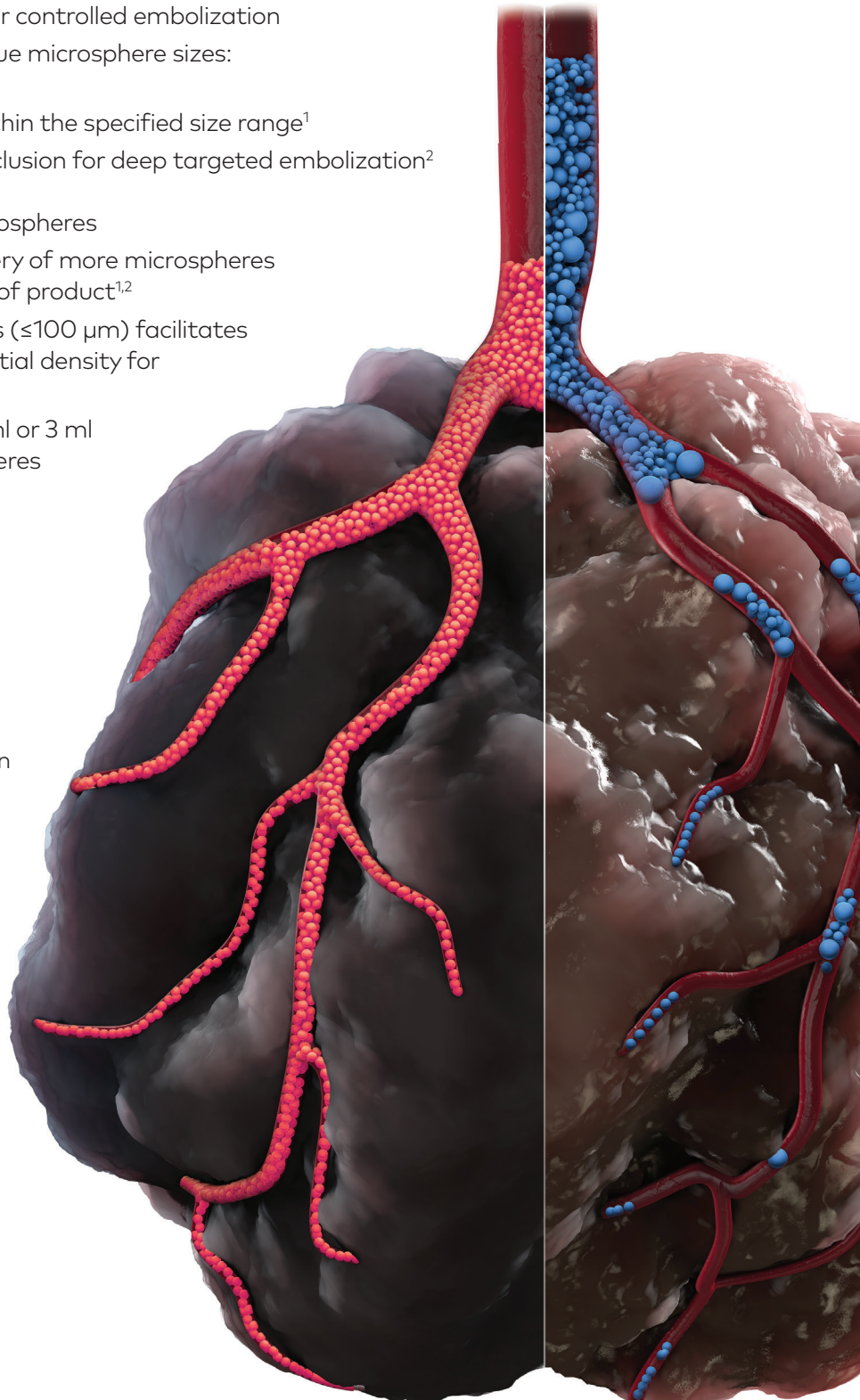
- Sized for tumor penetration with unique microsphere sizes: 40  $\mu\text{m}$ , 75  $\mu\text{m}$ , and 100  $\mu\text{m}$
- $\geq 95\%$  of Tandem Microspheres are within the specified size range<sup>1</sup>
- Decreases risk of premature vessel occlusion for deep targeted embolization<sup>2</sup>

Strength in numbers to deliver more microspheres

- Precise calibration allows for the delivery of more microspheres than competitors in the same volume of product<sup>1,2</sup>
- Greater number of small microspheres ( $\leq 100 \mu\text{m}$ ) facilitates deeper penetration and increased spatial density for homogenous tumor coverage<sup>2-4</sup>
- Single unit syringes are available in 2 ml or 3 ml options to deliver even more microspheres

Unique drug-eluting microspheres with a sustained drug release

- Fast drug loading time with a 50 mg/ml loading capacity<sup>1</sup>
  - $\leq 60$  minutes for doxorubicin and  $\leq 30$  minutes for irinotecan<sup>1</sup>
- Unique loading capacity of 150 mg for the 3 ml Tandem Microspheres option
- Precisely calibrated microsphere sizes remain stable after loading with drugs
  - Size change typically  $\leq 5\%$  with doxorubicin or irinotecan<sup>1,5</sup>
- Controlled drug elution may result in lower systemic drug levels<sup>2</sup>
- Sustained drug elution may lead to a prolonged and higher intratumoral concentration<sup>2,3,6</sup>

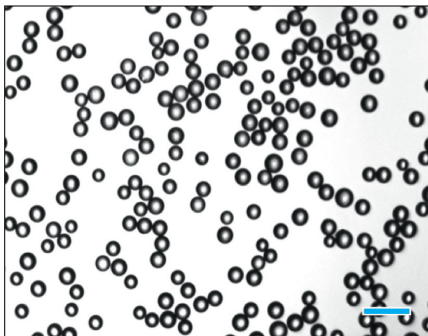


Size	Size Range	UPN (2 ml)	UPN (3 ml)
40 µm	40 ± 10 µm	05-0301-00402-06	05-0301-00403-06
75 µm	75 ± 15 µm	05-0301-00752-06	05-0301-00753-06
100 µm	100 ± 25 µm	05-0301-01002-06	05-0301-01003-06

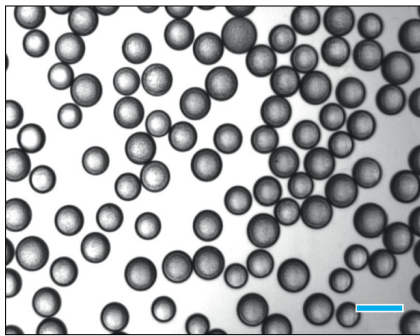


Tandem Microspheres are sold as single unit syringes with 2 ml or 3 ml of product and have a 3-year shelf life from date of manufacture<sup>1</sup>

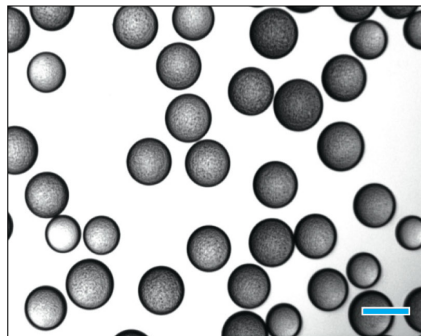
Tandem 40 µm



Tandem 75 µm



Tandem 100 µm



Optical micrographs (scale bar 100 µm)

Ref. 5

1. Date on file. Varian Medical Systems, Inc. 2020.
2. Delicque, J., et al., Liver chemoembolization of hepatocellular carcinoma using TANDEM(R) microspheres. *Future Oncol*, 2018. 14(26): p. 2761-2772.
3. Tanaka, T., et al., Pharmacokinetics and antitumor efficacy of chemoembolization using 40 µm irinotecan-loaded microspheres in a rabbit liver tumor model. *J Vasc Interv Radiol*, 2014. 25(7): p. 1037-1044 e2.
4. She, H.L., et al., In Vivo Proof of Superselective Transarterial Chemoembolization with 40-µm Drug-Eluting Beads in a Patient with Hepatocellular Carcinoma. *Cardiovasc Intervent Radiol*, 2016. 39(1): p. 137-40.
5. Blümmel, J., et al., Drug-eluting Beads in the Treatment of Hepatocellular Carcinoma and Colorectal Cancer Metastases to the Liver. *European Oncology and Haematology*, 2012. 8: p. 162-166.
6. Gnutzmann, D.M., et al., Evaluation of the plasmatic and parenchymal elution kinetics of two different irinotecan-loaded drug-eluting embolics in a pig model. *J Vasc Interv Radiol*, 2015. 26(5): p. 746-54.

**INDICATIONS FOR USE:** TANDEM Microspheres are indicated for embolization of blood vessels supplying primary hypervascular tumors or metastases in the liver.

**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:** 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.

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