

Embozene Tandem® Microspheres

Precisely Calibrated Drug-Eluting Microspheres

Precisely calibrated small microspheres for controlled embolization

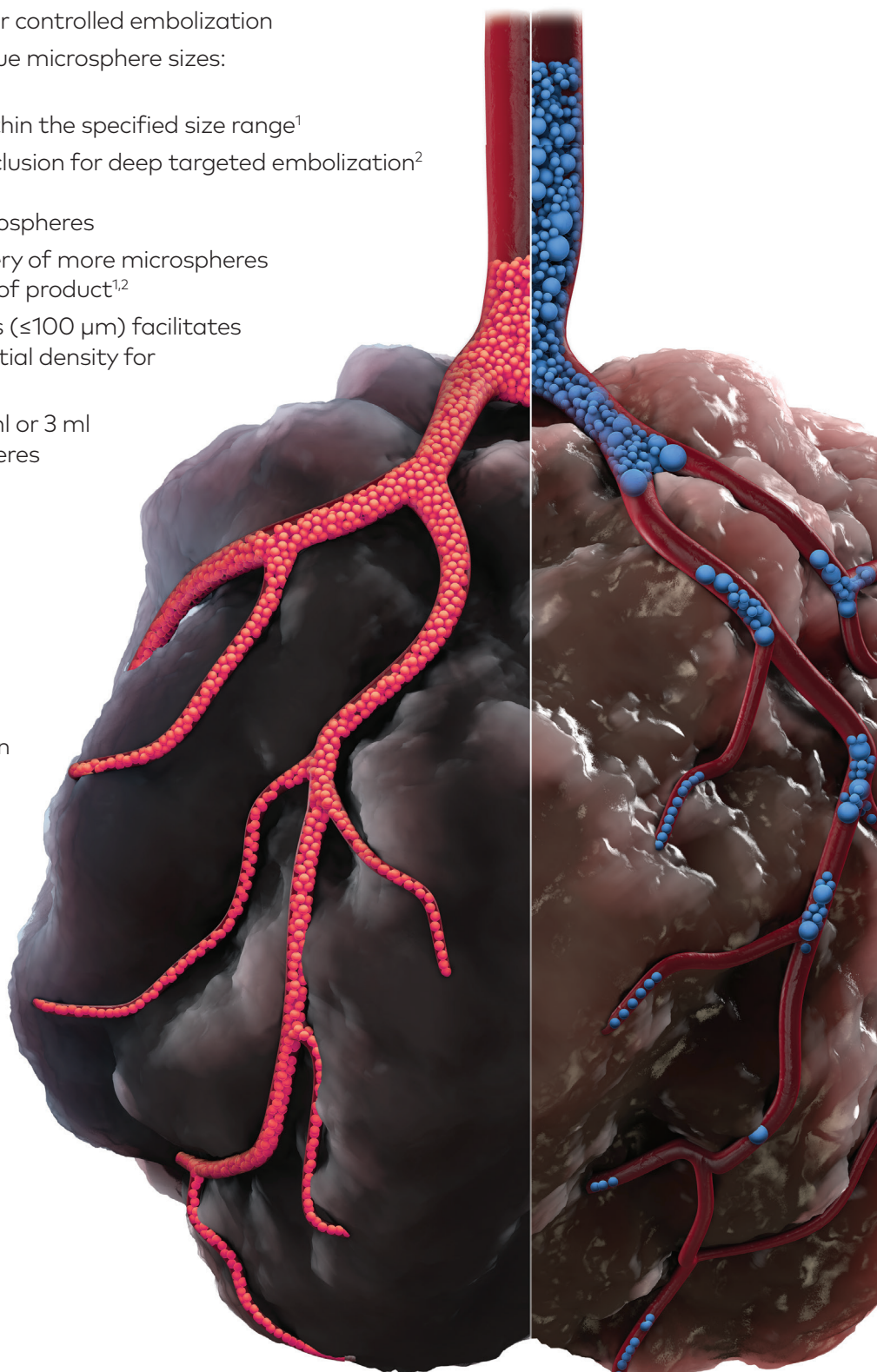
- Sized for tumor penetration with unique microsphere sizes: 40 μm , 75 μm , and 100 μm
- $\geq 95\%$ of Tandem Microspheres are within the specified size range¹
- Decreases risk of premature vessel occlusion for deep targeted embolization²

Strength in numbers to deliver more microspheres

- Precise calibration allows for the delivery of more microspheres than competitors in the same volume of product^{1,2}
- Greater number of small microspheres ($\leq 100 \mu\text{m}$) facilitates deeper penetration and increased spatial density for homogenous tumor coverage²⁻⁴
- 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 capacity¹
 - ≤ 60 minutes for doxorubicin and ≤ 30 minutes for irinotecan¹
- 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^{1,5}
- Controlled drug elution may result in lower systemic drug levels²
- Sustained drug elution may lead to a prolonged and higher intratumoral concentration^{2,3,6}

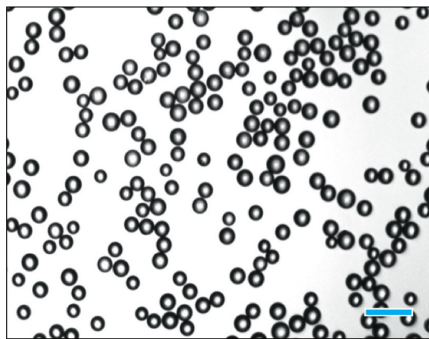


Size	Size Range	UPN (2 ml)	REF (2 ml)	UPN (3 ml)	REF (3 ml)
40 µm	40 ± 10 µm	05-0301-00402-10	10420-TSO	05-0301-00403-10	10430-TSO
75 µm	75 ± 15 µm	05-0301-00752-10	10720-TSO	05-0301-00753-10	10730-TSO
100 µm	100 ± 25 µm	05-0301-01002-10	11020-TSO	05-0301-01003-10	11030-TSO



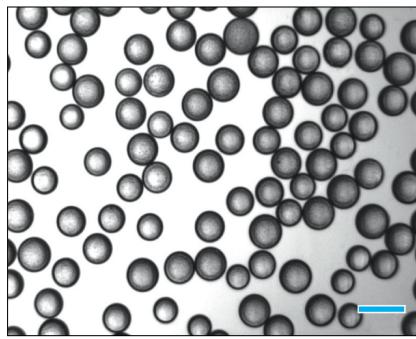
Tandem Microspheres are sold as single unit syringes with 2 ml or 3 ml of product and have a 3-year shelf life from date of manufacture¹

Tandem 40 µm

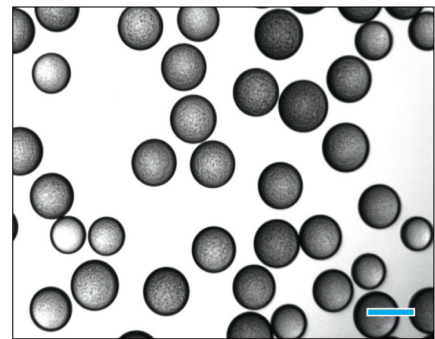


Optical micrographs (scale bar 100 µm)

Tandem 75 µm



Tandem 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 microm 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 the following conditions: hypervascular tumors, arteriovenous malformations, and unresectable hepatocellular carcinoma. 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.

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

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USA, Corporate
Headquarters

Varian Medical Systems
Palo Alto, CA
Tel: 650.424.5700
800.544.4636

Legal
Manufacturer

Boston Scientific
Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA

USA, Varian's
Interventional Solutions
Business Headquarters

Varian Medical Systems
Austin, TX
Tel: 877.467.2009



EU Authorized
Representative

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

vis.support@varian.com

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