MERIT MEDICAL

FLEX & CONFORM

HepaSphere™

Microspheres

Experience a drug-eluting microsphere with the power of conformability for TACE for HCC.[1]

HepaSphere™
Microspheres

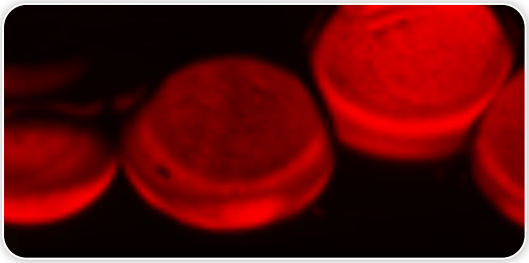
FAST LOADING

HepaSphere, also known as superabsorbent polymer (SAP) microsphere, is the only microsphere that:

- Is packaged dry and ready for reconstitution
- Works like a sponge and loads the drug throughout the microsphere
- Loads ≥90% of doxorubicin (liquid or powder prepared with normal saline) in <15 minutes*
- Has a 15-day storage and stability lifetime**
- Once reconstituted, swells to approximately 4x the size printed on the product label
- Can absorb fluids up to 64x its dry-state volume

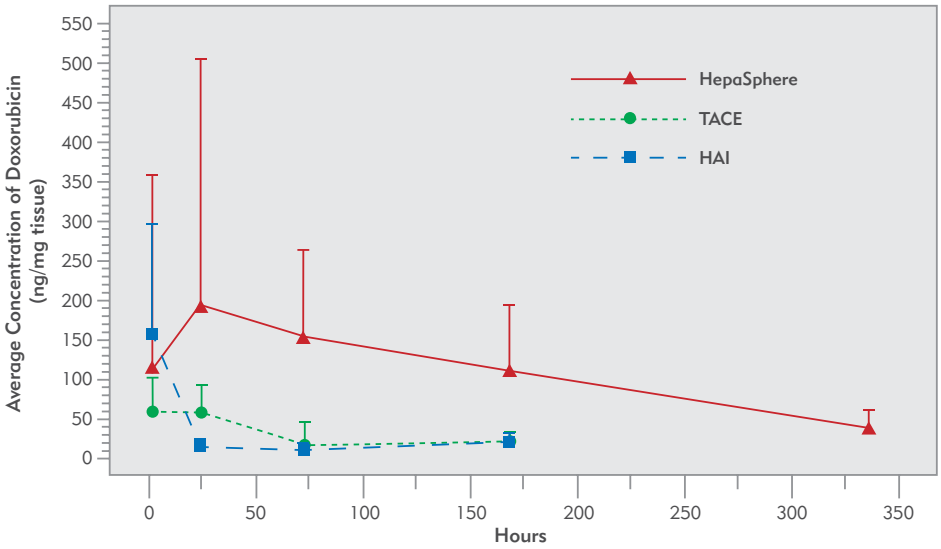
THOROUGH LOADING & SUSTAINED ELUTION

Doxorubicin is loaded throughout HepaSphere Microspheres and is retained by an ionic bond, providing a sustained release over 14 days[2], with peak intratumoral concentration of doxorubicin observed at 3 days.[3]



Photomicrograph of cross sections of HepaSphere Microspheres loaded with doxorubicin (original magnification, 20x). The red color indicates the presence of doxorubicin, which is loaded throughout the microsphere. Data on file.

DELIVER MORE DRUG DIRECTLY TO THE TUMOR FOR LONGER[2]



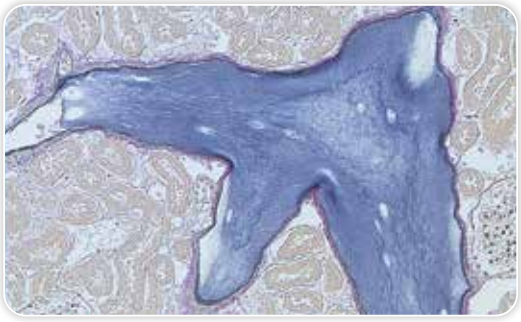
In the hepatic arterial infusion (HAI) and transarterial chemoembolization (TACE) groups, intratumoral doxorubicin levels declined to negligible levels at 1 and 3 days after treatment, while in the HepaSphere group, the intratumoral doxorubicin level was still detectable at 14 days after treatment and was higher than that in the other groups at 1, 3, and 7 days.

*Recommended loading time is 60 minutes for all sizes of HepaSphere Microspheres.
**Loaded with lyophilized doxorubicin HCl reconstituted with preservative-free 0,9% sodium chloride and stored at 2-8°C.

EXPERIENCE THE POWER OF CONFORMABILITY

HepaSphere is a drug-eluting microsphere that conforms to the vasculature for complete occlusion:

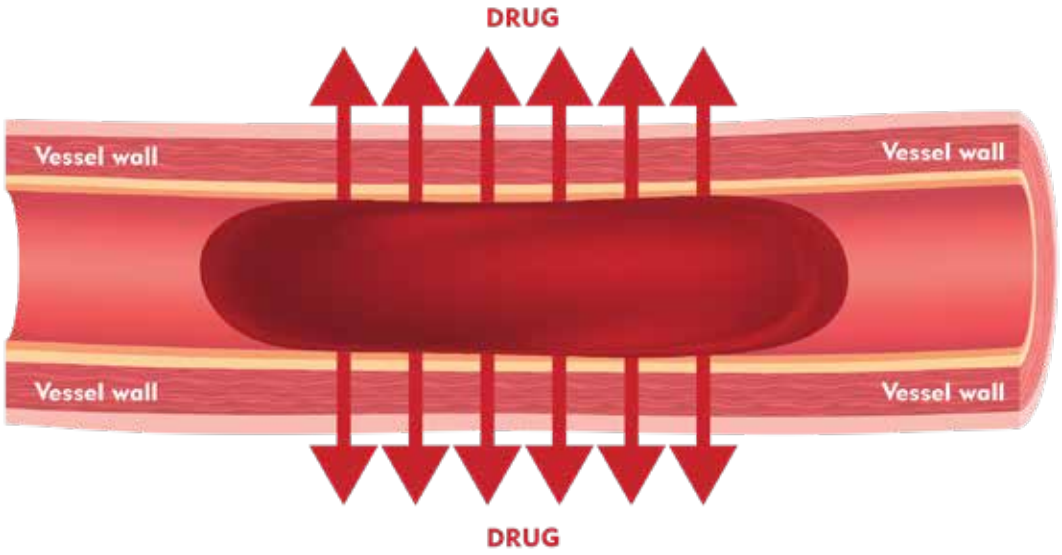
- Providing optimal contact between the microsphere surface and vessel wall, enabling greater drug diffusion into the tumor[3-5]
- Enabling greater tumor necrosis[6,7]
- Decreasing the risk of vessel recanalisation[4]
- Enhancing the embolic effect, reducing the amount of product needed to reach embolisation endpoint[4]



In vivo photomicrographs show the high conformability of HepaSphere Microspheres. Images courtesy of Dr. Keigo Osuga.

GREATER DRUG DIFFUSION

Because of its high conformability, HepaSphere provides optimal contact between the microsphere surface and vessel wall, enabling greater drug diffusion into the tumor.[3,5]



HepaSphere™
Microspheres

TRUSTED & ESTABLISHED

HepaSphere Microspheres are backed by extensive research, with more than 65 peer-reviewed publications and over 10 years' clinical use, demonstrating:

- Consistent Objective Response and Disease Control [8-11]
- Established Overall Survival data[10,11,13]
- Reduced systemic exposure compared to cTACE, minimising impact to healthy liver function and other drug-related toxicity[5,11]

ORDERING INFORMATION

	Q²	HepaSphere Microspheres	
Dry Size (µm)	20-40	30-60	50-100
Hydrated Size (µm)	80-160	120-240	200-400
Colour Code	Grey	Orange	Yellow
Order Number	**V125HS**	**V225HS**	**V325HS**

HepaSphere Microspheres are packaged dry; 25mg per vial; 1 vial per box. Must be reconstituted before use.

References

1. De Luis E, Bilbao JI, de Ciércoles JA, Martínez-Cuesta A, de Martino Rodríguez A, Lozano MD. (2008). In vivo evaluation of a new embolic spherical particle (HepaSphere) in a kidney animal model. Cardiovasc Intervent Radiol. 2008 Mar-Apr;31(2):367-76. **2.** Gupta S, Wright KC, Ensor J, et al. (2011). Hepatic arterial embolization with doxorubicin-loaded superabsorbent polymer microspheres in a rabbit liver tumor model. Cardiovasc Intervent Radiol, Oct;34(5):1021-30. **3.** Lee KH, Liapi E, Cornell C, et al. (2010). Doxorubicin-loaded QuadraSphere microspheres: plasma pharmacokinetics and intratumoral drug concentration in an animal model of liver cancer. Cardiovasc Intervent Radiol, Jun;33(3):576-82. **4.** Bilbao JI, de Luis E, Garcia de Jalón JA, et al. (2008). Comparative study of four different spherical embolic particles in an animal model: a morphologic and histologic evaluation. J Vasc Interv Radiol, Nov;19(11):1625-38. **5.** van Malenstein H, Maleux G, Vandecaveye V, et al. (2011). A randomized phase II study of drug-eluting beads versus transarterial chemoembolization for unresectable hepatocellular carcinoma. Onkologie, Jul;34:368-376. **6.** Lee KH, Liapi E, Vossen JA, et al. (2008). Distribution of iron oxide-containing Embosphere particles after transcatheter arterial embolization in an animal model of liver cancer: evaluation with MR imaging and implication for therapy. J Vasc Interv Radiol, Oct;19(10);1490-6. **7.**Wáng YXJ, De Baere, Idée JM, et al. (2015). Transcatheter embolization therapy in liver cancer: an update of clinical evidences. Chin J Cancer Res, 27(2):96-121. **8.** Grosso M, Vignali C, Quaretti P, et al. (2008). Transarterial chemoembolization for hepatocellular carcinoma with drug-eluting microspheres; preliminary results from an Italian multicentre study. Cardiovasc Intervent Radiol, Nov-Dec;31(6):1141-9. **9.** Dekervel J, Malenstein H, Vandecaveye V, et al. (2014). Transcatheter arterial chemoembolization with doxorubicin eluting superabsorbent polymer microspheres in the treatment of hepatocellular carcinoma: midterm followup. J Vasc Intervent Radiol, Feb;25(2):248-55. **10.** Malagari K, Pomoni M, Moschouris H, et al. (2014). Chemoembolization of Hepatocellular Carcinoma with Hepasphere 30-60µm. Safety and Efficacy Study. Cardiovasc Interv Radiol. Feb;37(1):165-175. **11.** Kucukay F, Badem S, Karan A, et al. (2015). A single-center retrospective comparison of doxorubicin-loaded HepaSphere transarterial chemoembolization with conventional transarterial chemoembolization for patients with unresectable hepatocellular carcinoma. J Vasc Intervent Radiol, Nov; 26(11):1622-1629. **12.** Zurstrassen CE, Gireli LPO, Tyng CJ, et al. (2017). Safety and efficacy of HepaSphere 50-100 µm in the treatment of hepatocellular carcinoma. Minim Invasive Ther Allied Technol, Aug;26(4):212-219. **13**. Grosso M, Pedrazzini F, Bongiovanni S, et al. (2016). Transcatheter Arterial Chemoembolization Using HepaSphere Microspheres: Experience in 251 Patients with Unresectable Hepatocellular Carcinoma. Intervent Onc 360, Dec.

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Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.

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