



HepaSphereTM

Microspheres

EXPERIENCE A DRUG-ELUTING
MICROSPHERE WITH THE
POWER OF CONFORMABILITY^{1,4}
FOR TACE FOR HCC.



HepaSphere™

Microspheres



FAST LOADING

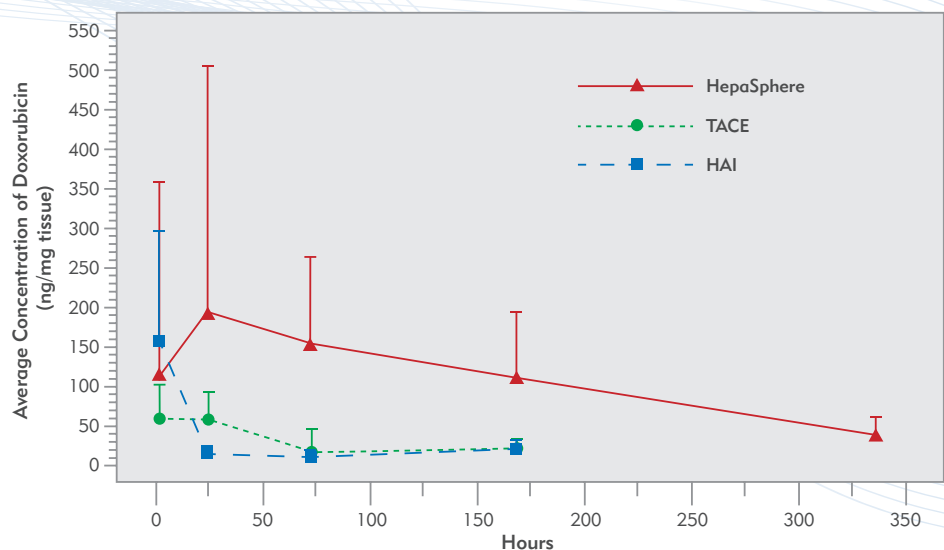
HepaSphere, also known as superabsorbent polymer (SAP) microsphere, is the only microsphere that:

- Is packaged dry and ready for reconstitution
- Works like a sponge and loads the drug throughout the microsphere
- Loads $\geq 90\%$ of 50mg Doxorubicin (powder prepared with normal saline) in <15 minutes^{*,8}
- Has a 15-day storage and stability lifetime once loaded with Doxorubicin^{**,8}
- Once reconstituted, swells to approximately 4x the size printed on the product label⁸
- Can absorb fluids up to 64x its dry-state volume⁵

THOROUGH LOADING⁸ & SUSTAINED ELUTION²

Doxorubicin is loaded throughout HepaSphere Microspheres and is retained by an ionic bond, providing a sustained release over 14 days², with peak intratumoral concentration of doxorubicin observed at 3 days.^{2,3}

DELIVER MORE DRUG DIRECTLY TO THE TUMOR FOR LONGER²



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 HepaSpheres Microspheres.

^{**}Loaded with lyophilized doxorubicin HCl reconstituted with preservative-free 0.9% sodium chloride and stored at 2-8°C.

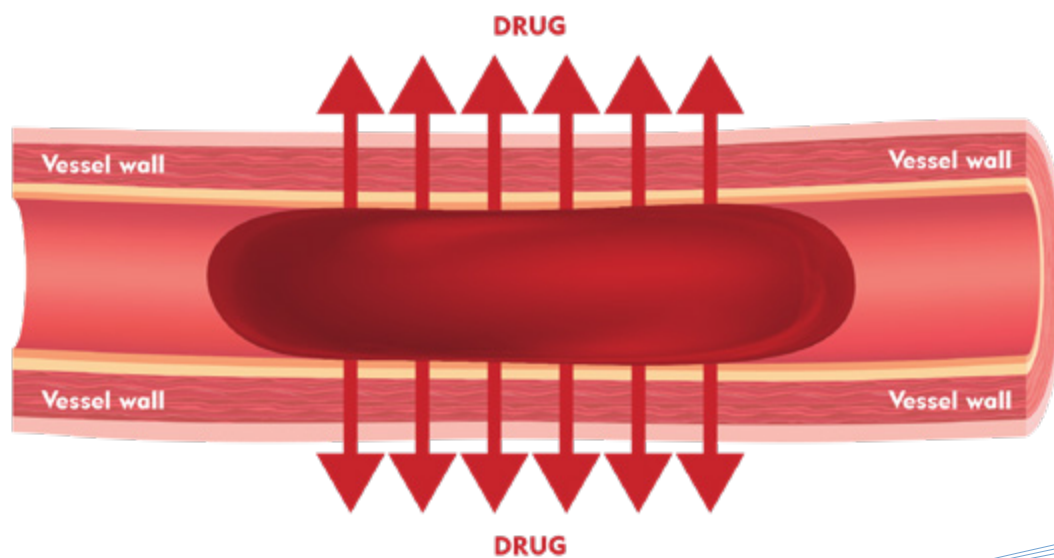
EXPERIENCE THE POWER OF CONFORMABILITY^{1,4}

HepaSphere is a drug-eluting microsphere that conforms to the vasculature for complete occlusion^{1,4}:

- Providing optimal contact between the microsphere surface and vessel wall, enabling high drug diffusion into the tumor and optimal embolization^{3,5,6}
- Enabling increased tumor necrosis³
- Decreasing the risk of vessel recanalisation^{1,4}
- Reducing the amount of product needed to reach embolisation endpoint^{4,7}

HIGH DRUG DIFFUSION

Because of its high conformability^{1,4}, HepaSphere provides optimal contact between the microsphere surface and vessel wall, enabling high drug diffusion into the tumor^{3,5,6}



HepaSphere™

Microspheres




TRUSTED & ESTABLISHED

HepaSphere Microspheres are supported by extensive research:

- with more than 25 peer-reviewed publications⁸
- over 1,173 patients treated⁸, and
- 20+ years of clinical use⁸



ORDERING INFORMATION

| | Q ² | 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 JL, de Círcolas 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 JL, de Luis E, García 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. Wang 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. 7. 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. 8. Data on file.



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



Understand. Innovate. Deliver.™

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