

What are the indications for HepaSpheres Microspheres?

- HepaSpheres Microspheres are CE marked and indicated for use in embolization of blood vessels with or without delivery of doxorubicin HCl for therapeutic or preoperative purposes in the following procedures:
 - Embolization of hepatocellular carcinoma
 - Embolization of metastases to the liver.

Are HepaSpheres Microspheres approved by the FDA?

- HepaSpheres Microspheres are not currently available for sale or distribution in the United States.



HepaSpheres Microspheres are CE marked and indicated for use in embolization of blood vessels with or without delivery of doxorubicin HCl for therapeutic or preoperative purposes in the following procedures: Embolization of hepatocellular carcinoma; Embolization of metastases to the liver. MR11-077 Rev. C 402423001/B ID 120312

Can HepaSpher[®] Microspheres load fluorouracil?

- HepaSpher[®] Microspheres are indicated for use in embolization of blood vessels with or without delivery of doxorubicin HCl for therapeutic or preoperative purposes in the following procedures:
 - Embolization of hepatocellular carcinoma
 - Embolization of metastases to the liver.
- HepaSpher[®] Microspheres are not indicated for use with fluorouracil.

Can HepaSpheres Microspheres load epirubicin?

- HepaSpheres Microspheres are indicated for use in embolization of blood vessels with or without delivery of doxorubicin HCl for therapeutic or preoperative purposes in the following procedures:
 - Embolization of hepatocellular carcinoma
 - Embolization of metastases to the liver.
- HepaSpheres Microspheres are not indicated for use with epirubicin.

Can HepaSpheres Microspheres load cisplatin/oxaliplatin?

- HepaSpheres Microspheres are indicated for use in embolization of blood vessels with or without delivery of doxorubicin HCl for therapeutic or preoperative purposes in the following procedures:
 - Embolization of hepatocellular carcinoma
 - Embolization of metastases to the liver.
- HepaSpheres Microspheres are not indicated for use with platins.





How are HepaSpheres Microspheres packaged?

HepaSpheres Microspheres are packaged in a 10 mL glass vial.

- The vial has a vacuum.
- Each vial contains 25 mg of HepaSpheres Microspheres.
- The vial is stopper-sealed by an aluminum cap equipped with a color-coded lid.
- Each vial is single-use only.
- The vial should not be re-sterilized and any unused material should be properly discarded.



HepaSphere Microspheres come in what size ranges?

Ordering Information				
Label Color	Sphere Size (Dry)	Sphere Size (Hydrated in 0.9% NaCl or Non-Ionic Contrast Media)	Dosage of Spheres	Catalog Item
Orange 	30-60 μm	120-240 μm	25 mg	V225HS
Yellow 	50-100 μm	200-400 μm	25 mg	V325HS
Blue 	100-150 μm	400-600 μm	25 mg	V525HS
Red 	150-200 μm	600-800 μm	25 mg	V725HS

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How many microspheres are there per vial of HepaSpheres Microspheres?

Number of Spheres per Vial (25mg)*		
Sphere Size (Dry)	Sphere Size (Hydrated)	Number of Spheres
30-60 μm	120-240 μm	815,000
50-100 μm	200-400 μm	139,000
100-150 μm	400-600 μm	28,100
150-200 μm	600-800 μm	9,400

*Calculation based on the mean diameters of microspheres and weight/volume ratio. Data on file at Biosphere[®] Medical.

Why are HepaSpheres Microspheres packaged dry?

- HepaSpheres Microspheres are packaged dry because this allows for loading of aqueous-based solutions mechanically.
- HepaSpheres Microspheres also have a negative charge that ionically attracts the positive charge of doxorubicin.
- In original packaging, HepaSpheres Microspheres have a 36-month shelf life.

How do I reconstitute HepaSphere Microspheres?

- Use 0.9% saline or non-ionic contrast medium.
- **NEVER USE PURE WATER TO RECONSTITUTE HEPASPHERE MICROSPHERES OR TO RECONSTITUTE DOXORUBICIN WITH HEPASPHERE MICROSPHERES.**
- Please refer to the package insert for reconstitution instructions.

How do HepaSpheres Microspheres load doxorubicin?

There are 2 mechanisms of loading

- Ionic: The doxorubicin is loaded into HepaSpheres Microspheres and eluted by a “reversible ionic exchange mechanism.”
 - The negatively charged HepaSpheres Microspheres interact with the protonated (positive) amine of the doxorubicin hydrochloride.
- Mechanical: HepaSpheres Microspheres mechanically absorb aqueous-based solutions whether or not they are positively charged.

What is doxorubicin?

- Doxorubicin is indicated for the treatment of several cancers, including bladder, breast, leukemia (some types), liver, lung, lymphomas, mesothelioma, multiple myeloma, neuroblastoma, and uterine.
- Doxorubicin is an anti-cancer chemotherapy drug.
- Doxorubicin is classified as an anthracycline antibiotic.
- Chemotherapy drugs work by damaging the RNA or DNA that tells the cell how to copy itself in division.
- If the cells are unable to divide, they die.

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What is the loading protocol for HepaSphere Microspheres with doxorubicin?

- There are two loading protocols for HepaSphere Microspheres: powdered doxorubicin and pre-solubilized doxorubicin.
- Please refer to the IFU and mixing charts for loading instructions.

How long does it take to load HepaSpheres Microspheres with doxorubicin?

- Please refer to the IFU and mixing charts for more information.

Type of Doxorubicin	Loading Time*
Powdered Doxorubicin (5 mg/mL reconstituted from powder)	60 minutes
Pre-solubilized Doxorubicin	120 minutes

*Loading time for 50 mg or 75 mg of doxorubicin

How much doxorubicin can be loaded in a vial of HepaSpheres Microspheres?

- The maximum amount of doxorubicin that can be loaded into a vial of HepaSpheres Microspheres is 75 mg.

What is the appearance of HepaSpheres Microspheres during and following loading with doxorubicin?

- When loading HepaSpheres Microspheres with doxorubicin, the sphere color changes to dark red.
- Please note that after the required loading time, the solution may retain some red coloration. This is normal. It is not an indication that HepaSpheres Microspheres failed to load.



What type of contrast should I use with HepaSphere Microspheres?

- Always use non-ionic contrast medium.

Can I use Lipiodol®?

- When using HepaSpheres Microspheres, you do not need to add Lipiodol.

Are there any peer-reviewed publications for HepaSphere Microspheres?

- For a comprehensive list of peer-reviewed publications, please refer to our bibliography. Below are some key publications regarding HepaSphere Microspheres.
- Peer-reviewed Clinical Data
 - Grosso et al. Transarterial chemoembolization for hepatocellular carcinoma with drug-eluting microspheres: preliminary results from an Italian multicentre study. CardioVascular and Interventional Radiology. 2008 Nov/Dec ; 31(6) 1141-9.
 - Poggi et al. Transhepatic arterial chemoembolization with oxaliplatin-eluting microspheres (OEM-TACE) for unresectable hepatic tumors. Anticancer Research. 2008 Nov/Dec; 28(6B):3835-42.
 - Sottani et al. Validation of an LC-MS/MS method for the determination of epirubicin in human serum of patient undergoing drug eluting microsphere transarterial chemoembolization (DEM-TACE). Journal of Chromatography. 2009 Nov; 877(29): 3543-8.
- Animal Data
 - Bilbao et al. In vivo evaluation of a new embolic spherical particle (hepaSphere) in a kidney animal model. CardioVascular and Interventional Radiology. 2008 Mar; 31(2): 367-76.
 - Gupta et al. Hepatic arterial embolization with doxorubicin-loaded superabsorbent polymer microspheres in a rabbit liver tumor model. CardioVascular and Interventional Radiology. 2011 Aug; 34(5): 1021-1030.
 - Lee et al. Doxorubicin-loaded quadrasphere microspheres: plasma pharmacokinetics and intratumoral drug concentration in an animal model of liver cancer. CardioVascular Interventional Radiology. 2010 Jun; 33(3): 576-82.
 - Khankan et al. Embolic effects of superabsorbent polymer microspheres in a rabbit renal model: comparison with tris-acryl gelatin microspheres and polyvinyl alcohol. Radiation Medicine. 2004 Nov/Dec; 22(6):384-90.
- In Vitro Data
 - Kos et al. Elution characteristics of doxorubicin-loaded microspheres differ by drug-loading method and microsphere size. Journal of Vascular and Interventional Radiology. 2011 Mar; 22(3):361-68.

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