# PATIENT INFORMATION LEAFLET

**PLEASE PROVIDE TO THE PATIENT**

HEPASPHERE™ MICROSPHERES

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## DEVICE DESCRIPTION

HepaSphere™ device are microspheres made of an acrylic copolymer designed to offer controlled, targeted embolization.

HepaSphere is a non-resorbable, permanent product. The microspheres are hydrophilic, expandable, conformable, safe for use in the human body, and are available in a range of sizes.

The HepaSphere Microspheres can be loaded with doxorubicin HCl or irinotecan, and are able to release the drug locally at the embolization site.

HepaSphere Microspheres are contained in a sterile vial in dry form and must be reconstituted before use. They swell upon exposure to aqueous solutions.

## INTENDED PURPOSE

HepaSphere 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

HepaSphere Microspheres loaded with irinotecan are indicated for use in:

- Embolization of metastatic colorectal cancer (mCRC) to the liver.

## KIND OF PATIENT ON WHOM THE DEVICE IS INTENDED TO BE USED

The device HepaSphere Microspheres is intended for:

- Patients with intermediate hepatocellular carcinoma (HCC) (BCLC B disease according to Barcelona Clinic Liver Cancer staging system) that are not suitable for ablation intervention in Child-Pugh A or B cirrhotic with performance status 0–1. Approximately 90% of HCCs are associated with a known underlying aetiology, most frequently chronic viral hepatitis (B and C). The gender ratio is 70% of men for 30% of women with a mean age of 64 years old.
- Patients with metastases to the liver, including patients with metastatic colorectal cancer (mCRC) to the liver, which correspond to an advanced stage of primary tumors. The gender ratio is 70% of men for 30% of women with a mean age of 61 years old.

HepaSphere Microspheres are permanent surgically implantable devices and are designed for controlled, targeted arterial embolization. They stay in the human body for life. Therefore, there are no special instructions for the patient.

## INTENDED PERFORMANCE

- Delaying disease progression and improving survival in patients with hepatocellular carcinoma and metastases to the liver
- Delaying disease progression and improving survival in patients with metastatic colorectal cancer to the liver

## POTENTIAL COMPLICATIONS

Vascular embolization is a high-risk procedure. Complications may occur at any time during or after the procedure, and may include, but are not limited to, the following:

- Post-embolization syndrome (such as nausea, vomiting, pain, fever)
- Fatigue and loss of appetite
- Hypertension
- Liver disorders or failure (including liver enzyme anomalies and ascites)
- Complications related to catheterization (e.g. haematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgement, and nerve and/or circulatory injuries which may result in leg injury)
- Vessel or lesion rupture and hemorrhage
- Vasospasm
- Recanalisation
- Allergic reaction to medications (e.g. analgesics)
- Allergic reaction to non-ionic contrast media or embolic material
- Undesirable reflux or passage of HepaSphere Microspheres into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds, such as the internal carotid artery, pulmonary, or coronary circulation
- Pulmonary embolism due to arteriovenous shunting
- Pleural effusion
- Ischemia at an undesired location, including ischemic stroke, ischemic infarction (including myocardial infarction), and tissue necrosis
- Capillary bed occlusion and tissue damage (cholecystitis, cholangitis, pancreatitis)
- Paralysis resulting from untargeted embolization or ischemic injury from adjacent tissue oedema
- Blindness, hearing loss, and loss of smell
- Foreign body reactions necessitating medical intervention
- Infection necessitating medical intervention (including liver abscess)
- Death

HepaSphere Microspheres are made of an acrylic copolymer and are magnetic resonance imaging (MRI) compatible. There is no risk of magnetic field interference from resonance imaging devices or risk of electrical interference from electro surgical devices.

The product is a single-use implant device that does not require any examination, monitoring, or maintenance.

The product is a single-use implant device with no possibility of malfunction.

Any medical procedure carries some risks. Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

## EXPECTED DEVICE LIFETIME

HepaSphere Microspheres is a long-term implantable device used to permanently occlude blood vessels. Biosphere Medical does not claim a specific lifetime for HepaSphere Microspheres. The

device lifetime of HepaSphere Microspheres will exceed the patient life expectancy.

The microspheres are composed of a synthetic polymer that is designed to be compatible with the human body. They are non-resorbable, thus providing permanent vessel occlusion.

## MATERIALS AND SUBSTANCES INCLUDED IN THE DEVICE

| IMPLANTABLE DEVICE MATERIALS TABLE | | |
|---|---|---|
| **Material** | **Duration of exposure** | **Level of patient exposure** (for one vial) |
| Poly vinyl alcohol-co-sodium acrylate | Long-Term (> 30days) | 25 mg or 50 mg |

There are no manufacturing residuals that could pose a risk to the patient.

Any serious incident that occurs in relation to the HepaSphere Microspheres should be reported to the manufacturer and to the Therapeutic Goods Administration at www.tga.gov.au



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