PATIENT INFORMATION LEAFLET

PLEASE PROVIDE TO THE PATIENT

EMBOSPHERE® MICROSPHERES

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DEVICE DESCRIPTION

The device Embosphere® Microspheres is an embolic material. Each microsphere is a small sphere which is about the size of a grain of sand. It is made of tris-acryl gelatin. This material is safe for use in the human body. The spheres are contained in a saline solution.

NOTE: It is a non-resorbable, permanent product.

INTENDED PURPOSE

Embosphere Microspheres are designed to occlude blood vessels, for therapeutic or preoperative purposes, in the following procedures:

- Embolisation of hypervascular tumours and processes, including uterine fibroids, meningiomas, liver tumours.
- Embolisation of the prostate arteries for relief of symptoms related to Benign Prostatic Hyperplasia.
- Embolisation of arteriovenous malformations.
- Haemostatic embolisation.

40-120 Qm microspheres are more specifically designed for embolisation of meningiomas and liver tumours.

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

Embolisation with Embosphere Microspheres is a minimally invasive treatment that is effective:

- For women with uterine fibroids for relief of related symptoms including heavy menstrual bleeding, pelvic pain or pressure, and/or urinary dysfunction, and for improvement of quality of life.
- For patients with hypervascular tumours, including liver tumours, for relief of related symptoms and for delay of the disease progression.
- For patients with meningioma, for reduction of intraoperative blood loss during resection procedure.
- For men with benign prostatic hyperplasia (BPH) for relief of related lower urinary tract symptoms (LUTS), such as urinary frequency, inability to urinate, incomplete emptying of bladder, difficulty starting urination, and straining to urinate or weak urine stream, and for improvement of quality of life.
- For patients with arteriovenous malformations for relief of related symptoms.
- For patients with haemorrhage for immediate and long-term bleeding control.

Embosphere is a long-term implantable device used to permanently occlude blood vessels. The microspheres stay in the human body for life. Therefore, there are no special instructions for the patient.

POTENTIAL COMPLICATIONS

ALL INDICATIONS

Vascular embolisation 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:

- Complications related to catheterization (e.g. haematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgement, nerve and/or circulatory injuries which may result in leg injury, infection)
- Vessel or lesion rupture and haemorrhage
- Occlusion of vessels in healthy territories
- Paralysis resulting from untargeted embolization or ischemic injury from adjacent tissue edema
- Stroke or cerebral infarction
- Ischaemia at an undesirable location, including ischaemic stroke, ischaemic infarction (including myocardial infarction), and tissue necrosis
- Blindness, hearing loss, loss of smell, and/or paralysis
- Capillary bed occlusion and tissue damage
- Death
- Undesirable reflux or passage of Embosphere 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 circulations
- Pulmonary embolism due to arterial venous shunting
- Vasospasm
- Recanalisation
- Foreign body reaction necessitating medical intervention
- Infection necessitating medical intervention
- Allergic reaction to medications (e.g. analgesics)
- Allergic reaction due to contrast media or embolic material
- Cutaneous irritations (e.g. rash), possibly delayed from the time of embolization
- Post-embolisation syndrome, such as transient pain, nausea, vomiting, fever, possibly delayed from the time of embolization
- Transient hypertensive episode
- Additional information is found in the Warnings section

UTERINE FIBROID EMBOLIZATION (UFE) SPECIFIC POTENTIAL COMPLICATIONS

Uterine fibroid embolization (UFE) is also known as uterine artery embolization (UAE).

- The most frequently anticipated post procedure complications are abdominal pain, discomfort, fever and/or nausea, collectively known as "Post-embolization Syndrome." Some patients may also experience constipation. This is generally managed with prescription or over-the-counter medications.
- Premature ovarian failure (i.e., menopause)
- Amenorrhea
- Infection of the pelvic region
- Uterine/ovarian necrosis
- Phlebitis
- Deep vein thrombosis with or without pulmonary embolism
- Vaginal discharge
- Tissue passage, fibroid sloughing, or fibroid expulsion post UFE
- Post-UFE intervention to remove necrotic fibroid tissue
- Vagal reaction
- Hysterectomy

PROSTATIC ARTERY EMBOLIZATION (PAE) SPECIFIC POTENTIAL COMPLICATIONS

- Non-targeted embolization of the rectum, bladder, scrotum, penis, or other areas
- The most frequent post-procedure complication includes "Post-PAE Syndrome", which includes nausea, vomiting, fever, pelvic pain, burning sensation, dysuria, and frequent or

urgent urination
- Skin burn (radiation exposure) from prolonged fluoroscopy time
- Blood in urine, semen, or stool
- Bladder spasm
- Urinary tract infection
- Urinary retention
- Constipation
- Urethral obstruction

NEUROLOGICAL SPECIFIC POTENTIAL COMPLICATIONS
- Ischemic stroke or ischemic infarction
- Neurological deficits, including cranial nerve palsies

Embosphere Microspheres are made of tris-acryl polymer impregnated with porcine gelatin and are magnetic resonance (MR) compatible.

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

Embosphere Microspheres is a long-term implantable device used to permanently occlude blood vessels. Biosphere Medical does not claim a specific lifetime for Embosphere Microspheres. The device lifetime of Embosphere Microspheres will exceed the patient life expectancy.

The polymeric acrylamide-gelatin microspheres that constitute Embosphere Microspheres are not considered degradable polymers. Polyacrylamide is a very rigid, indestructible polymer that will not degrade in a 37°C neutral environment.

MATERIALS AND SUBSTANCES INCLUDED IN THE DEVICE

IMPLANTABLE DEVICE MATERIALS TABLE		
Material	**Duration of exposure**	**Level of patient exposure** (maximum solid content by syringe)
Trisacryl Copolymer	Long-Term (> 30days)	159 ± 6 mg
Gelatin	Long-Term (> 30days)	23 ± 1 mg

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

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

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

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