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ENGLISH

DESCRIPTION

Embosphere® Microspheres are biocompatible, hydrophilic, non-resorbable, precisely calibrated acrylic polymer microspheres impregnated with porcine gelatin.

They are available in a wide range of sizes and concentrations.

HOW SUPPLIED

8 mL glass vial closed with screw-top cap, individually packaged in blister tray sealed by a peel-away Tyvek® lid.

Contents: 1 mL or 2 mL of microspheres in pyrogen-free, sterile, NaCl 0.9% saline solution. Total volume of saline and microspheres: 5 mL.

INDICATIONS

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, etc.
- Embolisation of arteriovenous malformations.
- Haemostatic embolisation.
- Embolisation of the prostate arteries for relief of symptoms related to Benign Prostatic Hyperplasia.

40–120 µm microspheres are more specifically designed for embolisation of meningiomas and hepatic tumours.

CONTRAINDICATIONS

- Patients unable to tolerate vascular occlusion procedures.
- Vascular anatomy precluding correct catheter placement.
- Feeding arteries too small to accept the selected microspheres.
- Presence or suspicion of vasospasm.
- Presence of distal arteries directly supplying cranial nerves.
- Presence of patent extra-to-intracranial anastomoses.
- High-flow arteriovenous shunts or with a diameter greater than the selected microspheres.
- Use in the pulmonary vasculature.
- Severe atherosclerosis.
- Patients with known allergy to gelatin.

50–100 µm, 40–120 µm and 100–300 µm microspheres are not recommended for use in the bronchial circulation.

POTENTIAL COMPLICATIONS

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:

- Stroke or cerebral infarction
- Occlusion of vessels of healthy territories
- Vascular rupture and haemorrhage
- Neurological deficits
- Infection or haematoma at the injection site
- Allergic reaction, cutaneous irritations
- Transient pain and fever
- Vasospasm
- Death
- 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
- Additional information is found in the Warnings section

CAUTION

Embosphere Microspheres must only be used by specialist physicians trained in vascular embolisation procedures. The size and quantity of microspheres must be carefully selected according to the lesion to be treated, entirely under the physician's responsibility. Only the physician can decide the most appropriate time to stop the injection

of microspheres. Do not use if the vial, screw cap or tray package appears damaged. Never reuse a vial that has been opened. All procedures must be performed according to an aseptic technique.

For single patient use only - Contents supplied sterile.

Do not reuse, reprocess, or resterilise. Reusing, reprocessing or resterilising may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness or death. Reusing, reprocessing or resterilising may also create a risk of contamination of the device and/or cause patient infection or cross infection including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

WARNINGS

- Embosphere Microspheres contain gelatin of porcine origin, and, therefore, could cause an immune reaction in patients who are hypersensitive to collagen or gelatin. Careful consideration should be given prior to using this product in patients who are suspected to be allergic to injections containing gelatin stabilizers.
- Studies have shown that Embosphere Microspheres do not form aggregates, and as a result, penetrate deeper into the vasculature as compared to similarly sized PVA particles. Care must be taken to choose larger sized Embosphere Microspheres when embolising arteriovenous malformations with large shunts to avoid passage of the spheres into the pulmonary or coronary circulation.
- Some of the Embosphere Microspheres may be slightly outside of the range, so the physician should be sure to carefully select the size of Embosphere Microspheres according to the size of the target vessels at the desired level of occlusion in the vasculature and after consideration of the arteriovenous angiographic appearance. Embosphere Microspheres size should be selected to prevent passage from artery to vein.
- Because of the significant complications of misembolisation, extreme caution should be used for any procedures involving the extracranial circulation encompassing the head and neck, and the physician should carefully weigh the potential benefits of using embolisation against the risks and potential complications of the procedure. These complications can include blindness, hearing loss, loss of smell, paralysis and death.
- Because of the tortuous vessels and duplicative feeding arteries in the pelvic area, extreme caution should be used when performing embolisation for the treatment of symptomatic Benign Prostatic Hyperplasia. Complications of misembolisation may include ischaemia of the rectum, bladder, scrotum penis or other areas.
- Serious radiation-induced skin injury may occur to the patient due to long periods of fluoroscopic exposure, large patient diameter, angled x-ray projections, and multiple image recording runs or radiographs. Refer to your facility's clinical protocol to ensure the proper radiation dose is applied for each specific type of procedure performed. Physicians should monitor patients that may be at risk.
- Onset of radiation-induced injury to the patient may be delayed. Patients should be counseled on potential radiation side effects and whom they should contact if they show symptoms.
- Pay careful attention for signs of mistargeted embolisation. During injection carefully monitor patient vital signs to include SAO₂ (e.g. hypoxia, CNS changes). Consider terminating the procedure, investigating for possible shunting, or increasing microsphere size if any signs of mistargeting occur or patient symptoms develop.
- Consider upsizing the microspheres if angiographic evidence of embolisation does not quickly appear evident during injection of the microspheres

Warnings about use of small microspheres

- Careful consideration should be given whenever use is contemplated of embolic agents that are smaller in diameter than the resolution capability of your imaging equipment. The presence of arteriovenous anastomoses, branch vessels leading away from the target area or emergent vessels not evident prior to embolisation can lead to mistargeted embolisation and severe complications.
- Microspheres smaller than 100 microns will generally migrate distal to anastomotic feeders and therefore are more likely to terminate circulation to distal tissue. Greater potential ischaemic injury results from use of smaller sized microspheres and consideration must be given to the consequence of this injury prior to embolisation. The potential consequences include: swelling, necrosis, paralysis, abscess and/or stronger post embolisation syndrome.
- Post-embolisation swelling may result in ischaemia in tissue adjacent to target area. Care must be given to avoid ischaemia-intolerant, nontargeted tissue such as nervous tissue.

INSTRUCTIONS

- Position the catheter at the desired site and perform baseline angiography to evaluate the blood supply of the lesion.
- Embosphere Microspheres are available in a range of sizes. Because of the potential for misembolisation and the inherent variability in sphere sizes, the physician should be sure to carefully select the size of Embosphere Microspheres according to the size of the target vessels at the desired level of occlusion in the vasculature.
- Carefully select the size of microspheres according to the size of the vessels identified and the catheter used. Embosphere Microspheres are flexible particles that support temporary compression by 20 to 30 % to facilitate passage through microcatheters. Studies have shown a direct correlation between the size of microspheres and the size of occluded vessels.
- Check that the packaging is intact. The external surface of the vial is sterile.
- Gently swirl the opened vial, then pour into a sterile metal/ stainless steel cup.
- It is highly recommended to add contrast agent to monitor the injection radiologically. Do not exceed a maximum proportion of 50 % contrast agent – 50 % saline solution! To optimize diffusion of microspheres into the territory to be embolised, it is recommended to use a fairly dilute solution.
- To obtain a homogenous mixture, swirl the cup for about one minute. Do not use the syringe or any other instrument to obtain the suspension, as this could damage Embosphere Microspheres.
- Draw up the suspension using a small syringe (1 to 3 cc). Check that the desired quantity and concentration of microspheres are used.
- Under continuous fluoroscopic control, slowly infuse microspheres into the blood stream. Always inject under free flow conditions. Reflux of microspheres can induce immediate ischaemia of healthy tissues or vessels.
- Continue infusion until the desired devascularisation is obtained. Studies have shown that Embosphere Microspheres penetrate more distally into the lesion than PVA particles of similar size. Reduction of the arterial blood supply to the lesion is therefore more progressive.
- At the end of the infusion, remove the catheter while maintaining gentle aspiration to avoid dislodging any residual microspheres still inside the catheter.
- Discard any open vial or unused Embosphere Microspheres.

CONSERVATION AND STORAGE

Embosphere Microspheres must be stored in a cool, dry, dark place in their original vials and packaging. Use by the date indicated on the labels of the outer box and blister pack. Do not freeze.

Size Range (µm)	Color Code	1 mL	2 mL
50-100	Grey	V010GH	V020GH
40-120	Orange	V110GH	V120GH
100-300	Yellow	V210GH	V220GH
300-500	Blue	V410GH	V420GH
500-700	Red	V610GH	V620GH
700-900	Green	V810GH	V820GH
900-1200	Purple	V1010GH	V1020GH

Information on packaging:

All serious or life threatening adverse events or deaths associated with the use of Embosphere Microspheres should be reported to the device manufacturer.

Symbol	Designation
	Manufacturer: Name & Address
	Use by date: year-month-day
	Batch code
	Catalogue number
	Do not resterilize
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Do not re-use
	Caution - Refer to Instructions For Use
	Non-pyrogenic
	Sterilized using steam
	Lower limit of temperature
	EC mark logo - Notified body identification: 0459