

Summary of Safety and Clinical Performance (SSCP) for Embosphere Microspheres

Language: English

This document is for patient.

Doctors should read the document SSCP-0001-001.

This document does not give advice on how to treat a disease.

Please contact your doctor if you have questions about your disease or the product.

This document is not an implant card.

This document is not the instructions for use.

This document does not give information on the safe use of the product.



Table of content

- 1.0 Device identification and general information3
- 2.0 Intended use and contraindications3
 - 2.1 Magnetic Resonance Imaging (MRI)3
- 3.0 Device Description4
 - 3.1 Materials in Contact with Patient Tissues.....4
 - 3.2 Duration of exposure to the device.....4
 - 3.3 Patient Implant Card4
 - 3.4 Embolisation procedure5
- 4.0 Side effects / Risks and Warnings7
- 5.0 Summary of Clinical Evaluation and Postmarket Clinical Follow-up (PMCF)8
- 6.0 Therapeutic Alternatives9
- 7.0 Suggested profile and training for users9
- 8.0 Annex 1: Model numbers covered by this document 10
- 9.0 Annex 2: Revision History 11



1.0 Device identification and general information

| | | |
|---|--|--|
| Device trade name: | Embosphere® Microspheres | (see the model numbers covered by this document in Annex 1: Model numbers covered by this document) |
| Manufacturer Information: | Name: Biosphere Medical S.A. Address: Parc des Nations – Paris Nord II, 383, Rue de la Belle Etoile, 95700 Roissy en France, France | |
| Basic UDI-DI key: | Product in a syringe : 088445048565E2 Product in a vial : 088445048794EK | |
| Date of first marketing in European Union: | 2000 | |

2.0 Intended use and contraindications

| | |
|---|---|
| Intended Purpose: | The spheres are implants. They are used to block blood flow in aimed vessels. They are used by doctor to treat many diseases. |
| Intended patients: | Women affected by uterine fibroids. Patients with cancers, such as liver cancers. Men affected by prostate enlargement. Patients with vessels malformations with high risk of bleeding. Patients with bleeding. |
| Contraindications, not use the product if: | The treatment cannot be supported by the patient. The treatment cannot be made safely. Patients have known allergic reaction to gelatin. |

2.1 Magnetic Resonance Imaging (MRI)

Note There is no risk with magnetic resonance imaging (MRI safe).

3.0 Device Description

Embosphere Microspheres are an implant. Each microsphere is a small sphere. It 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.

3.1 Materials in Contact with Patient Tissues

Only the tris-acryl gelatin spheres will be in contact with your blood vessels.

| Material | Duration of exposure | Level of patient exposure |
|---------------------|----------------------|---------------------------|
| Trisacryl Copolymer | Forever | 159 ± 6 mg |
| Gelatin | Forever | 23 ± 1 mg |

3.2 Duration of exposure to the device

The spheres remain in the body forever.

3.3 Patient Implant Card

An implant card has been provided to you by the hospital after your treatment. You must keep it forever.

3.4 Embolisation procedure

- 1 The treatment consists in blocking the aimed vessels. It starts with a small cut in your thigh or your forearm. The Figure 1 shows a thigh access.
- 2 Using special equipment, the doctor passes a thin tube into a vessel in your thigh or your forearm.
- 3 Then the doctor guides the tube near the location of the aimed vessels.
- 4 At this location, the injection of the spheres starts.
- 5 The small spheres will block the blood flow around the aimed tissue or cancer.

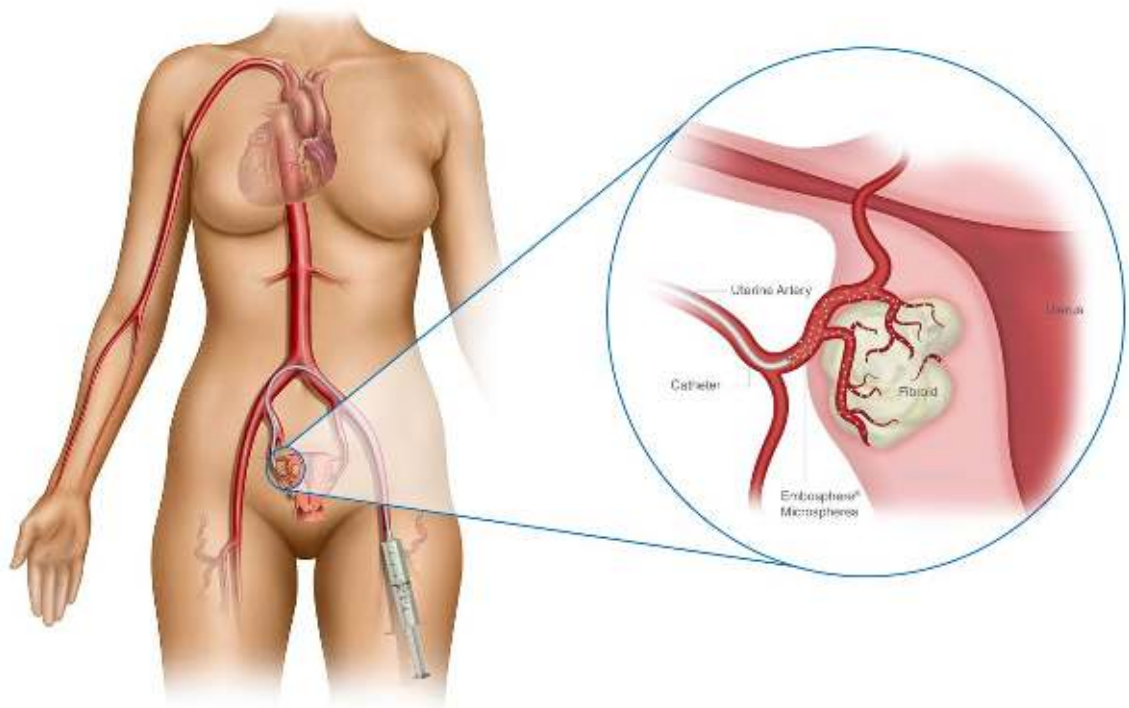


Figure 1. picture of a thigh access

Operating principle:

The small spheres block the vessels around the aimed tissue or cancer. Then, the blood flow cannot feed the tissue or cancer anymore. The lack of blood results in the size decrease of tissue or cancer.

In case of vessels malformations or bleeding, the blockage of the blood flow allows bleeding control.

In all cases, the spheres remain in the aimed vessels forever. The doctor removes the tube after treatment. The doctor will apply a pressure point to stop any bleeding. The treatment is usually an outpatient therapy. The patient may be back at home from 4 to 23 hours after treatment.

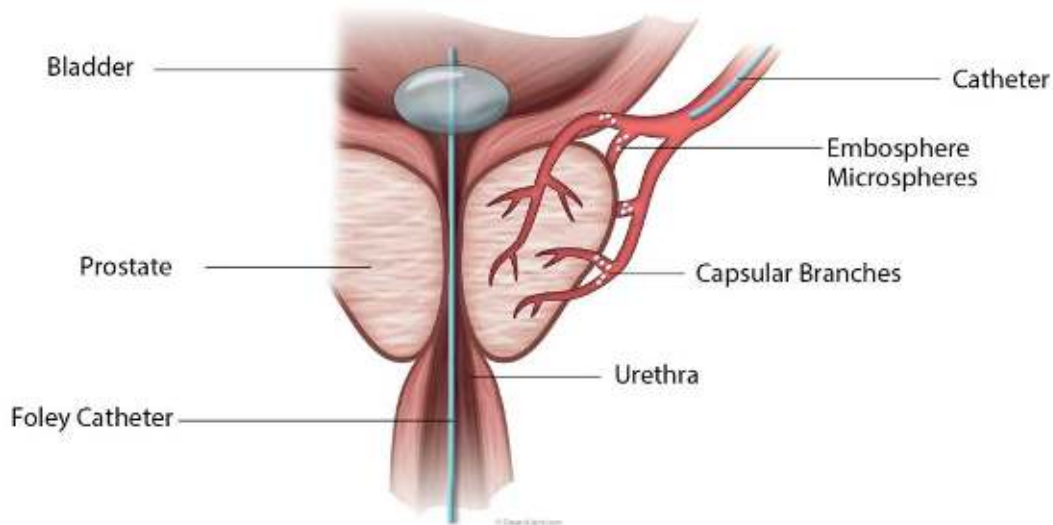


Figure 2. Use of Embosphere Microspheres in a prostate enlargement

4.0 Side effects / Risks and Warnings

Despite the low risk, potential side effects may be associated with the spheres. Contact your doctor if you have any concerns about the side effects. This document cannot replace a discussion with your doctor.

Side effects

Post-embolisation syndrome

Pain, fever, nausea, and tiredness. It happens in one case out of ten.

Allergic reactions

Allergic reaction to gelatin, or to other products and drugs used during the treatment. It happens in less than one out of hundred cases.

Risks related to catheter placing

Damage to the blood vessel, bleeding at the cutting site or infection. It happens in less than one out of hundred cases.

Non-targeted embolisation

The small spheres may unwillingly block the blood flow of other vessels. It happens in less than one out of hundred cases.

Side effects specifics to treatment of uterine fibroids

Lose small pieces of fibroid tissue

Fibroids may drop after treatment. Then, they leave the womb. It may require a specific treatment. The doctor will remove the fibroids. It will prevent bleeding or infection. It happens about one out of twenty women.

Infection or persistent symptoms

Infection or treatment failure may lead to removal of the womb. These events are rare. It happens in less than one out of hundred cases.

Menopause

Menstrual cycles resume usually. However, climacteric may occur. It happens about one out of hundred women. It is more frequent in women older than 45 years old.

Side effects specifics to treatment of prostate enlargement

Burning sensation

A burning sensation is common after treatment. It is due to radiation exposure during treatment. Doctor should monitor if you may be at risk. It happens about one out of five cases.

Bleeding

Blood may occur in urine, semen, or stool. It happens in less than four out of hundred cases.

Microsphere's migration

Few spheres may go to vessels of the rectum, bladder, or other. It happens in less than four out of hundred cases.



5.0 Summary of Clinical Evaluation and Postmarket Clinical Follow-up (PMCF)

Embosphere Microspheres have a strong clinical background. Doctors have treated a variety of diseases with the spheres for more than twenty years in Europe and worldwide.

The following table summarize the safety and performance information from the clinical evaluation.

| After treatment of | Performance analysis | Most frequent side effect | Serious side effect |
|---------------------------------|--|-------------------------------------|---|
| Uterine fibroid | Twelve months after treatment: Nine out of ten patients have symptoms decreased, as well as better quality of life. | Pain, fever, nausea, and tiredness. | Unwilling vessel blockage or infection. Less than two out of hundred cases. |
| Cancers (such as liver cancers) | Twelve months after treatment: Four out of ten patients have symptoms decreased. | Pain, fever, nausea, and tiredness. | Unwilling vessel blockage or infection. Less than two out of hundred cases. |
| Prostate enlargement | Twelve months after treatment: Nine out of ten patients have symptoms decreased, as well as better quality of life. | Pain, fever, nausea, and tiredness. | Unwilling vessel blockage or infection. Less than two out of hundred cases. |
| Vessels malformations | Six months after treatment: Six out of ten patients have symptoms decreased | Pain, fever, nausea, and tiredness. | Unwilling vessel blockage or infection. Less than one out of hundred cases. |
| Bleeding | Immediately after treatment: Nine out of ten patients have bleeding control. | Pain, fever, nausea, and tiredness. | Unwilling vessel blockage or infection. Less than one out of hundred cases. |
| | Six months after treatment: Nine out of ten patients have long-term bleeding control. | | |

The clinical evidence is based on over one hundred clinical studies where Embosphere Microspheres and the equivalent device EmboGold have been used to treat all the intended patients. EmboGold Microspheres are a coloured version of Embosphere Microsphere to facilitate visualisation during treatment.

Each year, Biosphere Medical collects additional information from the scientific literature to confirm the continued safety and performance of the Microspheres. Biosphere Medical is also conducting a clinical study to evaluate the long term effectiveness of the Microspheres for embolization of benign prostate hyperplasia (BPH).

6.0 Therapeutic Alternatives

Contact your doctor to discuss other treatments.

7.0 Suggested profile and training for users

Only trained doctors must use the product.

8.0 Annex 1: Model numbers covered by this document

| Nominal size | Colour code (labelling identifying line) | Reference code by volume | | |
|--|---|--------------------------|---------|--|
| | | 1 ml | 2 ml | |
| Embospheres Microspheres in syringe | | | | |
| 50-100 µm | Grey | S010GH | S020GH | |
| 40-120 µm | Orange | S110GH | S120GH | |
| 100-300 µm | Yellow | S210GH | S220GH | |
| 300-500 µm | Blue | S410GH | S420GH | |
| 500-700 µm | Red | S610GH | S620GH | |
| 700-900 µm | Green | S810GH | S820GH | |
| 900-1200 µm | Purple | S1010GH | S1020GH | |
| Embospheres Microspheres in Vial | | | | |
| 50-100 µm | Grey | V010GH | V020GH | |
| 40-120 µm | Orange | V110GH | V120GH | |
| 100-300 µm | Yellow | V210GH | V220GH | |
| 300-500 µm | Blue | V410GH | V420GH | |
| 500-700 µm | Red | V610GH | V620GH | |
| 700-900 µm | Green | V810GH | V820GH | |
| 900-1200 µm | Purple | V1010GH | V1020GH | |

9.0 **Annex 2: Revision History**

| SSCP revision | ECN Number | Date Issued | Change description | Author/PRRC | Revision validated by the Notified Body | Date of Notified Body approval |
|---------------|------------|-------------|--------------------|---|--|--------------------------------|
| 001 | PAR4029 | 12-Jan-2022 | Initial release | Author: Lionel Ekeidi Ngando Person Responsible for Regulatory Compliance: Rosène Amossé | <input checked="" type="checkbox"/> Yes Validation language: English <input type="checkbox"/> No | 21-Feb-2022 |