Embosphere® Microspheres for Embolization

A Patient Information Guide

biosphere medical™
Innovating Embolotherapy
What is embolization?

Embolization is a minimally invasive procedure where the doctor uses tiny particles or embolics like *Embosphere Microspheres* to block the blood flow to tumors and abnormal connections between arteries and veins called vascular malformations. By blocking the blood flow, the doctor can often stop a tumor from growing and even destroy it. Vascular malformations are sometimes very serious, and embolization can often be used to treat them successfully.
In what parts of the body has embolization been done?

Embolization has been done in many parts of the body including the:

- Brain—tumors called meningiomas.
- Neck—abnormal connections between arteries and veins called arteriovenous malformations.
- Uterus
- Liver—liver tumors.
How is embolization done?

There are several steps in embolization:

First, the doctor uses a small needle to make a tiny hole or puncture in the skin next to a blood vessel. This is different from surgery where the doctor might make a large cut.

The doctor then puts a small tube called a catheter into the puncture and threads it through the blood vessels close to the tumor or other target.

Next, the doctor injects the tiny *Embosphere Microspheres* into the catheter. They travel through the catheter into the blood vessel and block the flow of blood to the tumor or other target. The catheter is then taken out.

It generally takes a short time, usually a few hours to complete the treatment. Typically, patients go home in 1–2 days and are back to normal activities in 4–7 days.
What kinds of doctors do embolization?

Embolization is usually done by interventional radiologists or interventional neuroradiologists. These are highly trained doctors who have become specialists in reading x-rays, MRI, ultrasound, and other ways of using “pictures” of your body to diagnose diseases. They have also learned how to use catheters and other tiny devices to treat diseases.
What are Embosphere Microspheres?

*Embosphere Microspheres* are the new class of embolic. They are round like the inside of the blood vessel vs other embolics which are irregular in shape. Their round shape is designed to individually fit the blood vessel to block any blood from getting to the tumor. Since other embolics aren’t round, they need to combine with a blood clot to block the blood flow.

*Embosphere Microspheres* are made of a material that biotechnology companies have used for many years to manufacture their products. They have been used for more than eight years worldwide for embolization in the brain, neck, liver, uterus and other parts of the body.

Are Embosphere Microspheres safe?

*Embosphere Microspheres* have an extensive history of clinical use in over 7,000 patients. This same material has been extensively used in the pharmaceutical industry in the preparation and purification of drug compounds.
The amount of material used in embolization is very small in comparison to most other implanted products. Examination of material that has been removed after as many as six years from human implant shows no indication of any long-term reaction and no measurable change in the implant material itself. Finally, the processes used to manufacture the material, and the final material itself, are carefully controlled to ensure that the product is fit for use.

Where are Embosphere Microspheres being used?

Embosphere Microspheres have been approved for use in many parts of the world. This includes the United States where they have been cleared by the Food and Drug Administration for the treatment of certain tumors and vascular malformations. They are also approved in Canada and Australia and were granted a “CE Mark” about four years ago which allows them to be sold throughout Europe.

Are there alternatives to embolization?

Most of the other treatments involve surgery, drugs or not doing anything at the present time. Generally, surgery is more painful; the patient has to stay in the hospital longer; and it takes longer to be able to go back to normal daily activities. Drugs can have side effects. The doctor will be glad to discuss all the treatment options, including potential benefits and risks, with the patient to make sure that the best treatment choice is made.
Presented as a service to patients and their physicians.