

Uterine Fibroid Embolization (UFE)

A Patient's Guide



Uterine Fibroid Embolization (UFE)— A Patient’s Guide

Uterine fibroid embolization is a less invasive treatment option for uterine fibroids. This pamphlet provides some answers to questions that patients and their families may have about uterine fibroid embolization. Additional information is available at www.Fibroids1.com.

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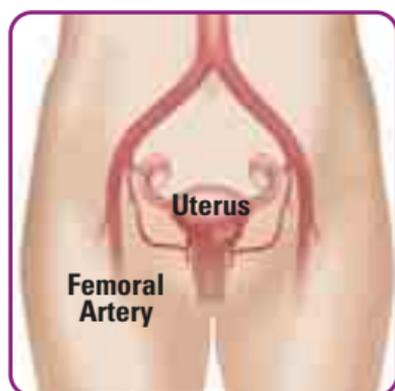
What is uterine fibroid embolization?

Uterine fibroid embolization (UFE) is a relatively new approach to the treatment of uterine fibroids. First performed in the early 1990s, UFE is a less invasive technique intended to block the flow of blood to fibroids, depriving them of the oxygen and nutrients they require to grow.

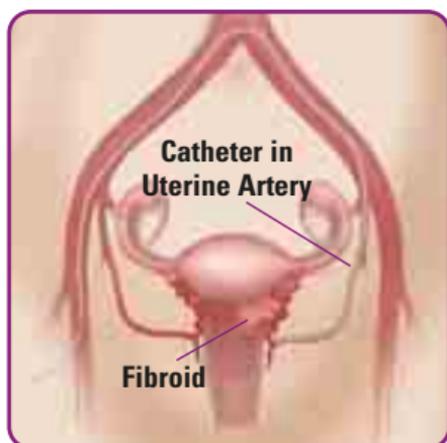
UFE is a procedure that is now available in many hospitals and medical centers. It is usually performed by an interventional radiologist—a specially trained physician who uses x-ray imaging to guide the procedure.

At the beginning of the procedure, you will be given medication to relax you. You will be awake but will be drowsy and should feel no pain.

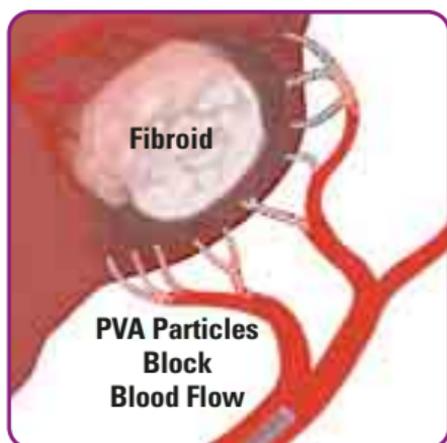
The skin in your groin area is cleaned, a local anesthetic is injected and a tiny incision is made. A small flexible tube called a catheter is inserted through the skin and into a blood vessel called the femoral artery.



The physician then steers the catheter up to your uterine artery—a blood vessel that branches from your femoral artery and supplies the fibroids. X-rays will be taken as the catheter is moved forward to make sure that it is placed correctly.



Once the catheter is in place, the physician injects a special dye to examine the fibroids. Then, small PVA particles are injected through the catheter. These particles—or “emboli”—flow into



the branches of your uterine artery, blocking the vessel and preventing blood from reaching the fibroids.

The catheter is removed and the procedure is repeated on the other side, ensuring that there is complete blockage of the blood flow. Deprived of oxygen and nutrients, your fibroids should shrink, potentially relieving your symptoms.

After the procedure is complete, small dressings are placed over the incisions in your groin.

What happens after the procedure?

UFE usually requires a hospital stay of one night. However, some women do go home on the day of the procedure.

Medications will be prescribed for you to control any pain, swelling and cramping that you may experience after the procedure. Occasionally, a fever may occur.

Before you leave the hospital, you should ask your doctor about your medications and the care of your dressings. You should also ask about any restrictions in activity. In most cases,



women who have had this procedure are able to return to light activity within a few days. They are usually back to work and normal activity within 7 to 10 days.

After you are discharged from the hospital, it will be important to contact your doctor if you develop a fever or if you experience pelvic pain that increases over time and lasts more than 24 hours. You should also immediately call if you notice a foul-smelling discharge.

How successful is UFE?

Embolization to treat uterine fibroids has been shown to be successful. Studies published or presented at scientific meetings show that the majority of women who have had UFE experienced significant or total relief from heavy bleeding, pain and other symptoms of their fibroids.⁵⁻¹³ The procedure can also be effective for treatment of multiple fibroids.



Because UFE is a fairly new procedure, significant long-term results are not yet available. For example, it is not yet known if fibroids can eventually re-grow. However, data available from women with at least 3-year follow-up are promising.¹⁴

Although UFE is a relatively new procedure, embolization of arteries in the uterus is not a new procedure. The technique has been used by interventional radiologists for more than 20 years to treat heavy bleeding after childbirth and due to other causes.¹⁻⁴

As an alternative to surgery or hormone therapy, UFE can decrease menstrual bleeding, urinary frequency, pelvic pain and pressure. As a less invasive technique, there is commonly little blood loss and recovery is generally much faster than after a surgical procedure. Many women have reported a significant improvement in their quality of life after UFE.

How successful is UFE?

(continued)

Boston Scientific Corporation, the manufacturer of Contour[®]-PVA Embolization Particles and Contour SE[™] Microspheres, conducted a prospective, multi-center clinical trial in the United States to evaluate the safety and effectiveness of UFE as an alternative to surgery for the management of uterine fibroids. The trial was designed to evaluate the improvement in fibroid-related symptoms that occurred up to 6 months after the procedure.

A validated quality of life questionnaire—an instrument used to assign a “score” to the women’s view of their quality of life—was used in this study. Primarily, the study evaluated the improvement in the score on the “Overall Fibroid Symptom” component of the questionnaire.

The UFE trial consisted of three arms. There were two UFE arms (Contour-PVA Embolization Particles and Contour SE Microspheres) and a surgical control arm (myomectomy).

At the completion of the first arm of the study—the Contour-PVA Embolization Particles arm—a total of 209 women were treated for symptomatic uterine fibroids. Of these, 149 women were treated with UFE using Contour-PVA Embolization Particles and 60 women, who formed the control arm of the study, were treated with myomectomy, a surgical approach.

The results listed below are based on 6-month follow-up of the UFE patients and myomectomy patients in the Contour[®]-PVA Embolization Particles study:

- The UFE patients treated with Contour-PVA Embolization Particles had an Overall Fibroid Symptom score success rate of 81% compared to the 74% success rate of those patients treated with myomectomy. The difference in success rate was not statistically different ($p=0.07$).
- The patients treated with UFE using Contour-PVA Embolization Particles experienced a significant reduction in dominant fibroid size. After 3 months, their dominant fibroid size was reduced by a median of 39%. After 6 months, it was reduced by a median of 52%.
- The patients treated with UFE using Contour-PVA Embolization Particles returned to normal activities in a median of 9.5 days. This was a significantly shorter period of time than the median of 39 days required for the myomectomy patients to return to normal activities. This difference is statistically significant ($p<0.05$).

How successful is UFE?

(continued)

At the completion of the second UFE arm of the study—the Contour SE™ Microspheres arm—and the completion of the control arm, myomectomy, there were a total of 146 women treated for symptomatic uterine fibroids. Of these, 77 women were treated with UFE using Contour SE Microspheres and 69 women, who formed the control arm of the study, were treated with myomectomy.

The results listed below are based on 6-month follow-up of 65 out of 77 UFE-treated patients and 69 myomectomy-treated patients in the Contour SE Microspheres study arm. There were 12 UFE patients who were not due for their 6-month follow-up visit at the time the data listed below was submitted to the FDA.

- The UFE patients treated with Contour SE Microspheres had an Overall Fibroid Symptom score success rate of 86% compared to the 74% success rate of those patients treated with myomectomy. The difference in success rate was not statistically different ($p=0.08$).
- The patients treated with UFE using Contour SE Microspheres experienced a significant reduction in dominant fibroid size. After 3 months, their dominant fibroid size was reduced by a median of 38%. After 6 months, their dominant fibroid size was reduced by a median of 44%.

- The patients treated with UFE using Contour SE™ Microspheres returned to normal activities in a median of 7 days. This was a significantly shorter period of time than the median of 37 days required for the myomectomy patients to return to normal activities. This difference is statistically significant ($p < 0.05$).

The women who participated in the two UFE arms of the study will continue to be followed annually for up to three years to assess their long term outcomes.

The results of this trial suggest that at 6 months after the procedure, both Contour®-PVA Embolization Particles and Contour SE Microspheres are safe and effective for the treatment of symptomatic uterine fibroids in women who desired to avoid surgery.

What are the risks and complications associated with UFE?

Though studies have demonstrated the safety and effectiveness of UFE, there are some associated risks, as there are with almost any medical procedure.

Most patients experience “post-embolization syndrome” including discomfort (pain) and cramping in the first several hours following the procedure. Some patients experience nausea and fever. These symptoms are controlled with medications and most are substantially improved by the next morning. However, there may be some discomfort and cramping for several days after the procedure.

Published studies show UFE has a low complication rate.^{9, 12, 15} Complications may include infection; allergic reactions to the dye, particles or medications; delayed pain or rash; or injury at the catheter entry site in the groin area. Other short term complications associated with UFE may include vaginal discharge; vaginal passage of fibroid tissue; or temporary stop in menstruation. As with other medical procedures, there is also a risk of a temporary change in blood pressure or fainting during or after the procedure. The incidence of serious or long term complications is low but may include injury to the uterus which may require hysterectomy; injury to pelvic organs due to migration of particles; skin burns due to excessive x-ray exposure; permanent stop in menstruation; damage to ovaries which may

result in early menopause; and additional fibroid treatment due to insufficient improvement of fibroid-related symptoms. As with other procedures and surgery, other long term complications may include pulmonary embolism due to migration of a blood clot to the lungs; loss of blood flow to healthy tissues; or death. If you would like additional information about potential complications, please consult your physician.

When the Contour[®]-PVA Embolization Particles arm was compared to the control arm in a clinical trial, 40% of myomectomy patients experienced a complication. This was a significantly higher rate than the 22% of UFE patients who experienced a complication. This difference is statistically significant ($p < 0.05$).

When the Contour SE[™] Microspheres arm was compared to the control arm, 42% of myomectomy patients experienced at least one complication. This was a significantly higher rate than the 26% of UFE patients who experienced at least one complication. This difference is statistically significant ($p < 0.05$).

There were no reports of complications related to the embolic particles in any of the UFE patients treated with either Contour-PVA Embolization Particles or Contour SE Microspheres.

What are the risks and complications associated with UFE?

(continued)

There were six UFE patients (4%) in the Contour[®]-PVA Embolization Particles arm who experienced a complication that was considered a major complication. Three of these (2%) were classified as related to the procedure, one was classified as not related to the procedure and two were classified as a new onset of a pre-existing condition. At the time this UFE arm was compared to the myomectomy arm, there was one myomectomy patient (2%) who experienced a major complication, which was classified as procedure-related.

There were no UFE patients (0%) in the Contour SE[™] Microspheres arm who experienced a major complication. When this UFE arm was compared to the myomectomy arm, there were two myomectomy patients (3%) who experienced a major complication which was classified as procedure-related.

Will my fertility be affected?

If you are pregnant, you should not have UFE. UFE is also not intended for women who desire future pregnancy. The effects of UFE on the ability to become pregnant and carry a baby to term, and on the development of the baby, have not been determined.

There have been a few women whose menstrual periods have stopped after UFE, which would result in infertility. Although it is not known if this effect was a result of the procedure, for some patients, premature menopause is a possible complication after UFE (most of these women were near the age of menopause at the time of the procedure).

If you should become pregnant following UFE, you may be at increased risk for complications. These include premature delivery; incorrect positioning of the baby; post-delivery bleeding; and rupture of the uterus. You may also be at increased risk for a Cesarean section delivery.

Who will provide my care after UFE?

It is important that you and your physician discuss who will provide your care after your procedure. You will need to know about follow-up office visits and who to contact in case of an emergency.



Commonly used terms

Catheter

A small flexible tube.

Complication

An unintended and undesirable experience or result associated with a patient and/or procedure.

Emboli

Particles that block flow within a blood vessel.

Femoral Artery

An artery in the leg which leads to the uterine artery.

Fibroid

A benign (non-cancerous) tumor in the uterus.

Interventional Radiologist

A specially-trained physician who uses x-ray imaging to guide procedures.

Median

The middle score in a set of scores. The median is the point that divides the set into two equal halves.

Myomectomy

A surgical procedure that removes fibroids from the wall of the uterus.

Pulmonary Embolism

Blockage of blood flow in the vessels that supply the lungs.

PVA

Polyvinyl alcohol. PVA particles have been used in embolization procedures for about thirty years.

Quality of Life Questionnaire

A tool that assesses the effects an illness and its therapy have on a patient. Completion of the questionnaire yields a “score” which reflects the patient’s view of his/her quality of life after taking into consideration any health-related issues that may affect it.

Statistically Significant

In medical studies, differences are said to be “statistically significant” if there is a probability of 5% or less that the result is due to chance. These statistics are illustrated by a “p value”—for example, $p < 0.05$.

Uterine Artery

The blood vessel that supplies the fibroid with the oxygen and nutrients required for growth.

Uterine Fibroid Embolization

Injection of particles to block the flow of blood to a fibroid.

Uterus

The womb.

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INDICATIONS: Contour®-PVA Embolization Particles are used for the embolization of hypervascular tumors and arteriovenous malformations. Contour SE™ Microspheres may be used for the embolization of hypervascular tumors including leiomyoma uteri and arteriovenous malformations (AVMs). **CONTRAINDICATIONS:** Include patient intolerance to occlusion procedures, vascular anatomy or blood flow precludes stable, selective emboli or catheter placement, presence or likely onset of vasospasm, presence or likely onset of hemorrhage, presence of severe atheromatous disease, presence of feeding arteries smaller than distal branches from which they emerge, presence of patient extra-to-intracranial anastomoses or shunts, presence of collateral vessel pathways potentially endangering normal territories during embolization, presence of end arteries leading directly to cranial nerves, presence of arteries supplying the lesion not large enough to accept emboli, vascular resistance peripheral to the feeding arteries precluding passage of emboli into the lesion. **CONTOUR SE MICROSPHERES UFE SPECIFIC CONTRAINDICATIONS:** Include pregnant women, suspected pelvic inflammatory disease or any other active pelvic infection, any malignancy of the pelvic region, endometrial neoplasia or hyperplasia, presence of one or more submucosal fibroid(s) with more than 50% growth into the uterine cavity, presence of pedunculated serosal fibroid as the dominant fibroid(s), fibroids with significant collateral feeding by vessels other than the uterine arteries. **WARNINGS & PRECAUTIONS:** Include smaller emboli may be more likely to result in cranial nerve palsies and ischemic infarction because of the potential to block vessels at the pre-capillary level, however, embolic devices of all sizes share this potential, the relationship between embolization and the appearance of cerebral lesions is unknown, and while long-term embolization of vascular structures with Contour SE Microspheres and Contour-PVA Embolization Particles will be achieved, no guarantee of performance, cure or benefit can be made. Patients with known allergy to contrast medium may require corticosteroids prior to embolization. **CONTOUR SE MICROSPHERES UFE SPECIFIC WARNINGS:** Not intended for women who desire future pregnancy, devascularization of uterine myometrium resulting from UFE may put women at increased risk of uterine rupture. **PRECAUTIONS:** Should only be performed by physicians who have received appropriate training for treatment of uterine leiomyomata (fibroids). Complete warnings and precautions relating to the use of Contour-PVA Embolization Particles and Contour SE Microspheres are included in the manufacturer's direction for use and can be explained by your physician.

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