

What are the risks and complications associated with UFE?

Overall, UFE is a safe procedure for treating symptomatic fibroids with minimal risk. Infrequent complications that have been reported following UFE are listed below. You should talk to your doctor about the likelihood that you may experience any of these risks.

SHORT TERM

- "Post-embolization syndrome," which may include abdominal pain/cramping, nausea and/or fever, and generally occurs soon after embolization
- Pain or rash, which may occur after a delayed time period
- Vaginal discharge or infection
- Vaginal passage of the fibroid tissue, which may require intervention by your doctor to remove the tissue
- Urinary tract infection
- Allergic reaction to contrast media, medications, or embolic material
- Bruising or nerve injury to your groin area from the catheterization procedure
- Temporary suspension of menstruation
- Inflammation of skin overlying blood vessels
- Low blood pressure and fainting during or after procedure
- Temporary increase in blood pressure during the procedure

LONG TERM

- Permanent stop in menstruation or damage to your ovaries, which may result in early menopause
- Additional treatment for your fibroids due to insufficient improvement in fibroid-related symptoms

The incidence of serious risks reported for this procedure are extremely low.

However, you should be aware that there have been rare reports of the following complications following embolization:

- Hysterectomy or removal of ovaries due to infection or other tissue damage
- Migration of embolization particles to other pelvic organs resulting in damage to healthy tissue
- Blood clots that could migrate to the lungs (pulmonary embolism)
- Damage to blood vessels that may result in excessive bleeding
- Loss of blood flow to healthy tissue such as the leg, which may result in injury
- Skin injury (burns) due to excessive x-ray exposure during embolization, which may not appear for a delayed period after treatment. You should discuss the potential symptoms of radiation burns with your doctor and know whom to call if you experience these symptoms.
- If you should become pregnant following UFE, you should be aware that you may be at increased risk for complications such as preterm delivery, incorrect positioning of the baby, cesarean delivery, post-delivery bleeding, and tearing of the uterus.
- Death-4 deaths have been reported out of approximately 150,000 UFE procedures worldwide.

If you have any questions concerning risks and complications of the procedure, you should discuss them with your doctor. If you decide to undergo UFE, you should discuss any complications that you experience following the procedure with your doctor. You should also report all device-related adverse events or problems to the device manufacturer, Biosphere Medical, Inc., using their toll-free number, 800-394-0295.