

U.S. Food and Drug Administration

FDA Talk Paper

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FDA CLEARS DEVICE TO TREAT FIBROIDS

The Food and Drug Administration (FDA) has cleared the use of a medical device to treat uterine fibroids (benign uterine tumors) by shrinking them instead of surgically removing them. This procedure could save many women from having myomectomies (surgery to remove fibroids that leaves the uterus intact) or hysterectomies (surgery to remove the uterus).

The device is intended to treat symptomatic uterine fibroids in women who no longer intend to become pregnant.

Many women have fibroids without any symptoms and do not need treatment. However, in many other women, fibroids cause heavy bleeding, severe pelvic pain, cramps and frequent urination. These women are currently treated with medication or surgery. The newly cleared use of the device provides another option for these women.

The device is a material called Embosphere Microspheres, made by Biosphere Medical, Inc., of Rockland, Mass. It is used in uterine artery embolization (UAE), a less invasive procedure than surgical removal of fibroids. Embolization is the introduction of an agent into an artery to block blood flow.

In UAE procedures, a catheter is inserted into the femoral artery in the groin. After the catheter is moved to the appropriate location using x-ray video for visualization, the tiny embolic particles are injected through the catheter into the bloodstream just above the fibroid, cutting off its blood supply. Over a period of days to weeks, the fibroids tend to shrink. The embolic particles remain in the body permanently.

FDA cleared the device for UAE based on a clinical study of its safety and effectiveness conducted by Biosphere Medical. FDA also reviewed data on UAE procedures in the medical literature, in FDA's problem reporting database, and in a patient registry maintained by the Cardiovascular and Interventional Radiology Research and Education Foundation.

In the clinical study, 132 women who had problems with uterine fibroids were treated with the Embosphere Microspheres at seven medical centers in the United States. After six months, 65 percent of women had experienced a 50 percent or more reduction in bleeding. All had significant pain requiring intravenous or oral pain medication for one or two days following the procedure, and in four cases the pain persisted beyond that period. Six percent of women (6%) experienced an allergic reaction during or following the procedure. These reactions were generally judged by the treating physicians not to be related to the embolic particles. Nine percent of women experienced either no improvement or a worsening of their bleeding following UAE.

FDA's decision to clear the product for this new use was based on six months follow up, but it is not known whether or how often the fibroids will return after the procedure. Biosphere Medical will continue to follow the patients from the study for at least three years to address this question.

FDA's review of medical literature, the agency's problem reports, and the patient registry highlighted several other, more serious, risks from UAE procedures. These include premature menopause, stoppage of menstrual periods, pelvic infection, destruction of the uterus, hysterectomy, pregnancy complications and delayed diagnosis of uterine cancer that would have been detected sooner if the patient had undergone surgery. In addition, there have been four reported deaths following UAE out of 25,000 to 30,000 procedures performed worldwide. The incidence of these complications is relatively low, but they are nonetheless significant.

FDA's review also showed that women who have hysterectomies or myomectomies also face a small risk of significant complications.

An estimated 600,000 hysterectomies are performed in the U.S. annually, and at least one-third are for fibroids.

Although embolization procedures have been performed for more than 25 years, the Embosphere Microspheres material is the first embolic agent to be cleared specifically for uterine fibroid embolization. Two years ago, FDA cleared this device for two other types of conditions (arteriovenous malformations and hypervascular tumors). FDA's latest decision gives an additional indication, that of treating symptomatic uterine fibroids.

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Please note: This FDA talk paper includes a [correction](#) made Nov. 27, 2002.

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