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EMBOSPHERE® MICROSPHERES ARE PROVEN SAFE AND EFFECTIVE FOR UTERINE FIBROID EMBOLIZATION

Uterine fibroid tumors (leiomyomas) can adversely affect the quality of life for affected women. Common symptoms include heavy menstrual bleeding, pelvic pain, painful intercourse, anemia, pressure on the bladder, constipation, bloating, and an enlarged abdomen (*1*).

As many as 10 to 21 million women in the United States have uterine fibroids, and approximately 5.5 million seek treatment each year. Symptomatic uterine fibroids are responsible for 200,000 to 300,000 hysterectomies each year (*1*).

Nonsteroidal anti-inflammatory medications can control pain and birth control pills may control excessive menstrual bleeding. However, birth control pills are associated with hypertension, blood clots, and hepatic disease. In addition, some data suggest that fibroids may re-grow after pharmacologic treatment ends.

The U.S. Food and Drug Administration cleared **BioSphere Medical Inc.** (Rockland, MA), to market **Embosphere® Microspheres** for Uterine Fibroid Embolization (UFE) in November 2002. UFE is a nonsurgical, minimally invasive treatment that is effective on most fibroids. BioSphere Medical pioneered round embolic technology, and Embosphere Microspheres are the only round embolic on the market made with *tris*-acryl cross-linked with gelatin, a hydrophilic copolymer. Their smooth, round surface prevents aggregation within the catheter lumen and vasculature, facilitates accurate delivery, and allows predictable distribution after embolization. Their elastic properties allow temporary compression up to 33% for passage through small delivery systems, even microcatheters.

Richard A. Reed, MD, an interventional radiologist at Huntington Memorial Hospital (Pasadena, CA), has been using Embosphere Microspheres since they entered the embolic market. "Embosphere Microspheres are easy to use, very uniform in size, and allow for very efficient and effective embolization. Other products are mechanically different and may not provide a targeted and durable embolization," he said.

"Embospheres have a higher chance of effectiveness, meaning the symptoms of the fibroids are relieved, so patients do not need further treatment, such as a hysterectomy. We find it is the best small-particle embolic agent on the market today," Dr. Reed stated.

Durable Occlusion Backed By Research

The effectiveness of Embosphere Microspheres is backed by more published studies than all other spherical embolics combined—more than 65 publications to date (*2*).

A multicenter prospective study compared 102 patients undergoing UFE using Embosphere Microspheres with 50 having hysterectomy (*3*). UFE patients had a shorter mean hospital stay (0.83 days vs. 2.3 days, $p < .001$), a more rapid return to work (10.7 days vs. 32.5 days, $p < .001$), and significantly better reductions in blood loss scores ($p < .001$) and in menorrhagia questionnaire scores ($p < .001$). Complications were significantly more likely

to occur in the hysterectomy group (50% versus 27.5%, p = .01), with a trend toward more serious complications in the hysterectomy group. At 12 months, improvements in bulk symptoms, pelvic pain/discomfort, and urinary dysfunction were comparable between groups.

Recently, a limited randomized study compared uterine artery embolization for leiomyomas with Embosphere Microspheres versus treatment with spherical polyvinyl alcohol (PVA) particles. Thirty-six patients were treated and 35 had a 3-month clinical follow-up. Quality-of-life scores were more improved for the Embosphere group (49.0 vs. 27.9, p = .02). Of 25 patients undergoing MRI follow-up, Embosphere patients were significantly more likely to have complete infarction of all leiomyomas (6 vs. 1, p = .02), at least 90% tumor infarction (8 vs. 4, p = .03), and a lower mean percentage of residual perfused fibroid tumor tissue (9.6% versus 44.3%, p = .004). The authors concluded that spherical PVA particles result in an unacceptably high rate of failed tumor infarction (*4*).

Angiographic Results You Can Trust

Embosphere Microspheres consistently provide effective and durable embolization. Studies show that Embosphere Microspheres are compatible with multiple chemotherapy agents and can improve liver hypertrophy prior to resection (*5*) versus PVA particles in portal vein embolization.

BioSphere Medical, Inc., focuses on applying our proprietary microsphere technology to medical application, using embolotherapy techniques. Our principal focus is the treatment of symptomatic uterine fibroids, using uterine fibroid embolization. Our core technologies, consisting of patented bioengineered polymers and manufacturing methods, are used to produce miniature spherical beads with uniquely beneficial properties for the treatment of uterine fibroids, hypervascularized tumors, and arteriovenous malformations.

For more information concerning BioSphere Medical Inc., call 1-800-394-0295, or visit the company's Web sites at www.BioSpheremed.com and www.ask4ufe.com.

Embosphere® MICROSPHERES
Promoting Embolization Efficacy in UFE

ask4UFE™.com
Your Connection for the Treatment of Symptomatic Uterine Fibroids

BioSphere® Medical

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