Boston Scientific
Advancing science for life™

CONTOUR™ PVA Particles

OCCLUDE MORE WITH LESS

Contour PVA Particles occluded the uterine artery with 67% less product and equivalent clinical results as compared to Merit Medical Embosphere Microspheres.[1]

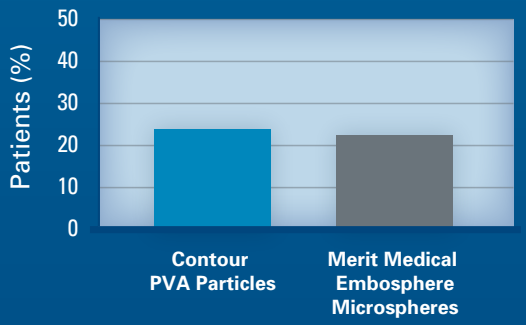
9 mL – Merit Medical Embosphere Microspheres

3 mL – Contour PVA Particles

EQUIVALENT CLINICAL RESULTS
AT A FRACTION OF THE COST[2]

Contour PVA Particles offered equivalence in frequency of uninfarcted fibroids, symptom score improvement, patient satisfaction, and quality of life improvement for uterine fibroid embolization, according to randomized comparative data against Merit Medical Embosphere Microspheres.[1]

Presence of Uninfarcted Uterine Fibroids Three Months After Treatment

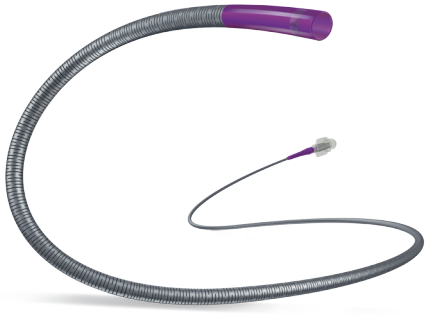


1. Spies, et al. PVA Particles vs. Tris-acryl Microspheres for UAE, JVIR Aug 2004
2. Cost claim based on 2014 List Prices. Negotiated actual prices may vary.

Merit Medical Embosphere Microspheres are available in packages of 2 ml and 1 ml, which are both contained in a 20 ml syringe. The image is meant to show nine 1 ml syringes but pictured are syringes with 2 ml of product.

PORTFOLIO OF PRODUCTS

Contour™ Embolization Particles



Direxion™ Torqueable Microcatheters

Fathom™ Steerable Guidewire

Product UPN	Particle Size (microns)	Vials/Box	Minimum Compatible Catheter ID
M0017600121	45-150	2	0.53 mm (0.021 in) (e.g. Direxion Torqueable Microcatheter, Renegade™ 18 Microcatheter, Renegade STC Microcatheter)
M0017600151	45-150	5	
M0017600221	150-250	2	
M0017600251	150-250	5	
M0017600321	250-355	2	
M0017600351	250-355	5	
M0017600421	355-500	2	
M0017600451	355-500	5	
M0017600621	500-710	2	0.69 mm (0.027 in) (e.g. Direxion HI-FLO™ Torqueable Microcatheter, Renegade HI-FLO Microcatheter)
M0017600651	500-710	5	
M0017600821	710-1000	2	
M0017600851	710-1000	5	1.12 mm (0.044 in) (e.g. Imager™ II Diagnostic Catheter)
M0017601151	1000-1180	5	

Contour™ Embolization Particles

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: The Contour Embolization Particles are used for the embolization of peripheral hypervascular tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs). Do not use particles smaller than 355 microns for the treatment of leiomyoma uteri.

CONTRAINDICATIONS: Contraindications Specific to All Peripheral Indications • Vascular anatomy or blood flow precludes stable, selective Contour Embolization Particles or catheter placementPresence of vasospasm • Presence of hemorrhage • Presence of severe atheromatous disease • Presence of feeding arteries smaller than distal branches from which they emerge • Presence of collateral vessel pathways potentially endangering normal territories during embolization • Presence of arteries supplying the lesion not large enough to accept Contour Embolization Particles • Vascular resistance peripheral to the feeding arteries precluding passage of Contour Embolization Particles into the lesion • In large diameter arteriovenous shunts • In the pulmonary vasculature • Patient intolerance to occlusion procedures

Contraindications Specific to Uterine Fibroid Embolization (UFE): 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 AND PRECAUTIONS: Warnings Applicable to All Peripheral Indications

PRIOR TO EMBOLIZATION, PROSPECTIVE PATIENTS OR THEIR REPRESENTATIVES MUST BE PROVIDED AN INFORMED CONSENT DESCRIBING THE POSSIBLE COMPLICATIONS ASSOCIATED WITH THE USE OF THIS DEVICE. WRITTEN ACKNOWLEDGMENT IS WARRANTED. The safety and effectiveness of Contour Embolization Particles for neurovascular use have not been established. • As with any embolization device, patient injury, permanent disability or death may occur as a result of its use. • Vascular occlusion should only be performed by physicians possessing skilled interventional occlusion experience in the territory intended to be embolized. • A thorough evaluation of a patients medical condition, vascular pathways and the desired embolization goal is necessary to achieve successful occlusion. This evaluation should include baseline angiography to determine the presence of potentially dangerous collateral pathways.• Postprocedural patient follow-up to assess the continued level of vascular occlusion is necessary. Angiography may be indicated.

Precautions Applicable to All Indications: Patients with known allergy to contrast medium may require pre-medication prior to embolization.• Additional evaluations or precautions may be necessary in managing periprocedural care for patients with the following conditions: A. Bleeding diathesis or hypercoagulative state; B. Immunocompromised. • The use of sophisticated imaging equipment is necessary for successful embolization therapy. • Appropriate facilities should be available to treat potential complications of the procedure. • While it is anticipated that long-term embolization of vascular structures with Contour™ Embolization Particles will be achieved, no guarantee of permanence, cure or benefit can be made.

UFE Specific Warnings for Pregnancy (Specific for Treatment of Leiomyoma Uteri): UFE is not intended for women who desire future pregnancy. The effects of UFE on the ability to become pregnant and carry a fetus to term, and on the development of the fetus, have not been determined. Therefore, this procedure should only be performed on women who do not intend future pregnancy. • Women who become pregnant following UFE, should be aware that they may be at increased risk for preterm delivery, cesarean delivery, malpresentation (incorrect positioning of the baby), and postpartum hemorrhage (post-delivery bleeding). • Devascularization of uterine myometrium resulting from UFE may put women who become pregnant following UFE at increased risk of uterine rupture.

Other UFE Specific Warnings: Devascularization of uterine myometrium resulting from UFE may put women at increased risk of uterine rupture. • The diagnosis of uterine sarcoma could be delayed by taking a non-surgical approach (such as UFE), to treat uterine fibroids. Conduct a more thorough work-up for patients with warning signs for sarcoma (e.g., prior pelvic radiation, MRI findings, rapid tumor growth, postmenopausal with new uterine enlargement). Recurrent or continued tumor growth following UFE should be considered a potential warning sign for sarcoma and surgery should be considered.

UFE Specific Precautions: It is recommended that patients undergoing embolization of leiomyoma uteri be provided a clear understanding of who will provide post-procedure care prior to the embolization procedure. • UFE should only be performed by physicians who have received appropriate training for treatment of uterine leiomyomata (fibroids).• There is an increased chance of retro-migration of Contour Embolization Particles into unintended blood vessels as uterine artery flow diminishes. Embolization should be stopped when the vasculature surrounding the fibroid can no longer be visualized but before complete stasis in the uterine artery.

POTENTIAL COMPLICATIONS: Complications specific to embolization include, but may not be limited to: • Foreign body reactions (i.e. pain, rash) necessitating medical intervention • Allergic reaction to contrast media • Infection necessitating medical intervention • Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgment, vasospasm and nerve and/or circulatory injuries, which may result in leg injury) • Undesirable reflux or passage of Contour™ Embolization Particles into arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds • Ischemia at an undesirable location • Incomplete occlusion of vascular beds or territories may give rise to the possibility of post procedural hemorrhage, development of alternative vascular pathways, recanalization or recurrence of symptoms • Vessel or lesion rupture and hemorrhage • Recurrent hemorrhage • Ischemic stroke or myocardial infarction • Death

Potential Complications Specific to UFE: Postembolization syndrome • Vaginal Discharge • Tissue passage, fibroid sloughing or fibroid expulsion post-UFE • Temporary or permanent stopping of menstrual bleeding • Infection of the pelvic region • Endometrial atrophy with amenorrhea despite normal ovarian function • Complications to pregnancy • Premature Ovarian Failure (i.e., menopause) • Uterine/Ovarian necrosis • Uterine Rupture • Post-UFE Intervention to remove necrotic fibroid tissue • Hysterectomy REV AA

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To order product or for more information contact customer service at 1.888.272.1001.

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