To All U.S. Customers,  
April 26, 2018

Boston Scientific’s Embozene Microspheres have received FDA clearance for an expanded indication to include the Prostate Artery Embolization (PAE) procedure for the treatment of symptomatic Benign Prostatic Hyperplasia (BPH). The full indication for Embozene Microspheres is as follows:

Embozene Microspheres are intended for the embolization of arteriovenous malformations and hypervascular tumors, including uterine fibroids (UFE) and hepatoma, and for embolization of prostatic arteries (PAE) for symptomatic benign prostatic hyperplasia (BPH).

In addition to the general embolization contraindications, warnings and adverse events, additional contraindications, warnings and adverse events specific to the PAE procedure have been added.

Embozene Microspheres Contraindications Specific for PAE:
Prostatic Artery Embolization (PAE) procedures for benign prostatic hyperplasia shall not be performed if:

- Evidence of prostatic cancer or bladder cancer
- Urethral stricture
- Prostate size (less than) 40 grams
- Active prostatitis
- Interest in the preservation of fertility
- Patients with renal impairment
- Peak urinary flow rate (greater than) 12 ml/sec
- Large bladder diverticuli or stones
- Neurogenic bladder
- Detrusor failure

Embozene Microspheres Warnings Specific for PAE:

- An appropriate urological work-up should be performed on all patients (e.g., urological history and appropriate testing, such as Prostate-Specific Antigen test and, when appropriate, biopsy to rule out carcinoma).
- The effect of prostatic embolization on male fertility has not been determined. Therefore, this procedure should only be performed on men who are willing to accept the risk of future infertility.
- Three-dimensional planning imaging (e.g., magnetic resonance angiography [MRA], computed tomographic angiography [CTA]) should be performed prior to embolization on patients who have had any previous invasive treatment to the prostate (e.g., surgery, ablation, etc.) or pelvic irradiation.

Embozene Microspheres Potential Adverse Events Specific to PAE:

- Acute urinary retention
- Bladder ischemia or necrosis requiring surgical intervention
- Diarrhea
- Hematuria/Hematospermia
- Rectal Bleeding
- Rectal or lower colonic strictures
- Sexual dysfunction or impaired fertility
- Urethral or anal burning sensation
- Urethral stricture
- Urinary incontinence
- Urinary symptoms (e.g. dysuria, urgency, frequency)

Embozene Microspheres will now be marketed with the PAE for BPH indication. For any questions regarding Embozene Microspheres or this new indication, please consult the Directions for Use.

Sincerely,

Michael Miller
Principal Product Manager
Peripheral Interventions