residual flow. This end point generally corresponds to an angiographic image is generally described as complete stasis or near
The UFE specific end point

• At the discretion of the physician, pneumatic compression devices may
• The safety and effectiveness of BEARING nsPVA Embolization
PRECAUTIONS FOR ALL INDICATIONS
• Onset of radiation-induced injury to the patient may be delayed.
• An appropriate gynecologic work-up should be performed on all
(Specific for Treatment of Leiomyoma Uteri)
• The diagnosis of uterine sarcoma could be delayed by taking a non-
CONTRAINDICATIONS FOR ALL INDICATIONS
Do not use particles smaller than 355 microns for the treatment of
Peripheral hypervascularized tumors, including leiomyoma uteri and
V1100EP 1000-1180 Red 0.040” (1016 μm)
V400EP 355-500 Green 0.020” (508 μm)
PRODUCT DESCRIPTION
1. Vascular anatomy or blood flow precludes stable, selective BEARING
Use in the presence of:
CONTRAINDICATIONS SPECIFIC TO UTERINE FIBROID
1. Postembolization syndrome
12. Death
16. Transient hypertensive episode
11. Patients intolerant to occlusion procedures
1. Severe atheromatous disease
110. Patients with active endocarditis or septicemia
EMBOLIZATION (UFE)
Caution:
Rx Only Caution:
STORAGE AND STERILITY
Each vial contains BEARING nsPVA Embolization Particles saline/contrast mixture. Consider
syringe slowly and gently to minimize the potential of introducing air into
embolization particle size being used.

Obstruction may be a function of contrast dilution volume; ensure that enough
floating and not observed as aggregates.

10 mL of 0.9% NaCl. To ensure proper hydration and suspension, gently
the treatment site to avoid inadvertent occlusion of normal vessels.

Caution:

Para-clotting

“Clumping” of BEARING nsPVA Embolization Particles or catheter
Terminate infusion before complete vessel occlusion has occurred.
Continued infusion may result in inadvertent reflux into critical arteries, creating the potential for
alternative vascular pathways, recanalization or recurrence of symptoms.

100% of the treatment volume is delivered, proximal slowing or termination of BEARING
vessels at the precapillary level and to occlude unintended normal vessels;
these risks and potential complications of the procedure. These complications
include blindness, hearing loss, loss of smell, paralysis, and death.

Collateral pathways. Do not proceed with embolization unless these
failure which, in turn, may result in patient injury, illness or death. Reuse,
collateral pathways. Do not proceed with embolization unless these
risks and potential complications of the procedure. These complications
include blindness, hearing loss, loss of smell, paralysis, and death.

To, the following:

All serious or life-threatening adverse events or deaths associated with use
your facility’s institutional protocol to ensure the proper radiation dose
alternative vascular pathways, or recurrence of symptoms.

Authorization to practice radiology in the state in which embolization is to be performed.

To, the following:

Vaughn Cancer Institute
14750 North Central Freeway, Suite 800
Dallas, Texas  75244
Authorized Representative: Merit Medical South Jordan, Utah  84095
1600 West Merit Parkway
Parkmore Business Park West, Galway, Ireland
Authorized Representative: Merit Medical Ireland Ltd,
EC Customer Service +31 43 3588222
www.merit.com

FDA REGISTRATION NUMBER
Weight
Respawn to, the following:

1000cc, and patients that are overweight, to lower the risk of deep vein
thrombosis.

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