Bearing nsPVA Express™

EMBOLIZATION PARTICLES
NONSPHERICAL POLYVINYL ALCOHOL (NSPVA)

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

BEARING nsPVA™ Embolization Particles are irregularly-shaped, biocompatible, hydrophilic, nonresorbable particles produced from polyvinyl alcohol. These embolization particles are intended to provide vascular occlusion or reduction of blood flow within target vessels upon selective placement through a variety of catheters.

CONTENTS

• BEARING nsPVA Embolization Particles are packaged sterile in a 20 ml polycarbonate syringe with a standard luer lock connector, packaged individually in a sterile foil pouch.
• Each syringe contains 100mg of BEARING nsPVA Embolization Particles, packaged dry.
• Each sterile syringe is intended for single patient use only. Do not resterilize. Discard any opened, unused material.

SIZE RANGE & CATHETER COMPATIBILITY CHART

Order Number	Size Range (µm)	Color Code	Minimum Catheter ID
S100EP	45-150	Yellow	0.020" (508 µm)
S200EP	150-250	Purple	0.020" (508 µm)
S300EP	250-355	Dark Blue	0.020" (508 µm)
S400EP	355-500	Green	0.020" (508 µm)
S600EP	500-710	Orange	0.024" (610 µm)
S800EP	710-1000	Light Blue	0.027" (686 µm)
S1100EP	1000-1180	Red	0.040" (1016 µm)

INDICATIONS FOR USE

BEARING nsPVA Embolization Particles are used for the embolization of peripheral hypervascularized tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs).

Do not use particles smaller than 355 microns for the treatment of leiomyoma uteri.

CONTRAINDICATIONS FOR ALL INDICATIONS

Use in the presence of:
1. Vascular anatomy or blood flow precludes stable, selective BEARING nsPVA Embolization Particles or catheter placement
2. Vasospasm
3. Hemorrhage
4. Severe atheromatous disease
5. Feeding arteries smaller than distal branches from which they emerge
6. Collateral vessel pathways potentially endangering normal territories during embolization
7. Arteries supplying the lesion not large enough to accept BEARING nsPVA Embolization Particles
8. Vascular resistance peripheral to the feeding arteries precluding passage of BEARING nsPVA Embolization Particles into the lesion
9. Large diameter arteriovenous shunts (i.e. where the blood does not pass through an arterial/capillary/venous transition but directly from an artery to a vein)
10. Arterial pulmonary vasculature
11. Patients intolerant to occlusion procedures

CONTRAINDICATIONS SPECIFIC TO UTERINE FIBROID EMBOLIZATION (UFE)

1. Pregnant women
2. Suspected pelvic inflammatory disease or any other pelvic infection
3. Any malignancy of the pelvic region
4. Endometrial neoplasia or hyperplasia
5. Presence of one or more submucosal fibroid(s) with more than 50% growth into the uterine cavity
6. Presence of pedunculated serosal fibroid as the dominant fibroid(s)
7. Fibroids with significant collateral feeding by vessels other than the uterine arteries

POTENTIAL COMPLICATIONS FOR ALL INDICATIONS

Vascular embolization is a high-risk procedure. Complications may occur at any time during or after the procedure, and may include, but are not limited to, the following:
1. Postembolization syndrome
2. Foreign body reactions (i.e. pain, rash) necessitating medical intervention
3. Allergic reaction to contrast media
4. Infection necessitating medical intervention
5. 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)
6. Undesirable reflux or passage of BEARING nsPVA Embolization Particles into arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds
7. Ischemia at an undesirable location
8. Incomplete occlusion of vascular beds or territories may give rise to the possibility of postprocedural hemorrhage, development of alternative vascular pathways, recanalization or recurrence of symptoms
9. Vessel or lesion rupture and hemorrhage
10. Recurrent hemorrhage
11. Ischemic stroke or myocardial infarction
12. Death
13. Complications of misembolization include blindness, hearing loss, loss of smell, paralysis, pulmonary embolism and death

POTENTIAL COMPLICATIONS SPECIFIC TO UFE

1. Postembolization syndrome
2. Vaginal Discharge
3. Tissue passage, fibroid sloughing or fibroid expulsion post-UFE
4. Temporary or permanent stopping of menstrual bleeding
5. Infection of the pelvic region
6. Endometrial atrophy with amenorrhea despite normal ovarian function
7. Complications to pregnancy
8. Premature Ovarian Failure (i.e., menopause)
9. Necrosis of uterus, ovaries, buttocks, labia, cervix, and vagina
10. Vesicovaginal or vesicouterine fistula
11. Uterine Rupture
12. Post-UFE Intervention to remove necrotic fibroid tissue
13. Hysterectomy
14. Phlebitis
15. Deep vein thrombosis with or without pulmonary embolism
16. Transient hypertensive episode

17. Urinary Retention

WARNINGS FOR ALL 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 BEARING nsPVA Embolization Particles for neurovascular use have not been established.
- Because of the significant complications of misembolization, extreme caution should be used for any procedures involving the extracranial circulation encompassing the head and neck, and the physician should carefully weigh the potential benefits of using embolization against the risks and potential complications of the procedure. These complications include blindness, hearing loss, loss of smell, paralysis, and death.
- Neurologic deficit, ischemic stroke or ischemic infarct can occur from occlusion of normal vessels by this embolic.
- 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 patient's 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. Do not proceed with embolization unless these pathways can be protected.
- Do not use if protective sterile packaging is opened or damaged.
- Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- Smaller BEARING nsPVA Embolization Particles may be more likely to migrate distally and result in ischemic infarction because of the potential to block vessels at the precapillary level and to occlude unintended normal vessels; however, BEARING nsPVA Embolization Particles of all sizes share this potential.
- Typically the artery will accept less BEARING nsPVA Embolization Particles as the treatment progresses. Proximal slowing or termination of BEARING nsPVA Embolization Particles passage may occur when the vessel or malformation is occluded by prior BEARING nsPVA Embolization Particles, or in the presence of severe atheromatous disease. Continued infusion may result in inadvertent reflux into critical arteries, creating the potential for undesirable ischemic infarction.
- Exercise conservative judgment in determining embolization endpoint. Terminate infusion before complete vessel occlusion has occurred.
- "Clumping" of BEARING nsPVA Embolization Particles or catheter obstruction may be a function of contrast dilution volume; ensure that sufficient volume of the appropriate contrast/saline mix is utilized such that BEARING nsPVA Embolization Particles are free floating and not observed as aggregates.
- Should catheter obstruction occur, remove the catheter from the patient while maintaining gentle suction so as not to dislodge BEARING nsPVA Embolization Particles still within the catheter lumen. Do not use forceful injection, guidewires or other instruments to dislodge the blockage. Do not continue using a catheter which has been obstructed as damage to the device may have occurred.
- Incomplete occlusion of vascular beds or territories may give rise to the possibility of postprocedural hemorrhage, development of alternative vascular pathways, or recurrence of symptoms.
- Postprocedural patient follow-up to assess the continued level of vascular occlusion is necessary. Angiography may be indicated.
- Serious radiation-induced skin injury may occur to the patient due to long periods of fluoroscopic exposure, large patient diameter, angled x-ray projections, and multiple image recording runs or radiographs. Refer to your facility's institutional protocol to ensure the proper radiation dose is applied for each specific type of procedure performed. Physicians should monitor patients that may be at risk.
- Onset of radiation-induced injury to the patient may be delayed. Patients should be counseled on potential radiation side effects and whom they should contact if they show symptoms.
- While it is anticipated that long-term embolization of vascular structures with BEARING nsPVA Embolization Particles will be achieved, no guarantee of permanence, cure or benefit can be made.

PRECAUTIONS FOR ALL INDICATIONS

- DO NOT USE THIS PREFILLED SYRINGE TO DIRECTLY INJECT BEARING NSPVA PARTICLES. THIS IS A "RESERVOIR" SYRINGE. PLEASE REFER TO INSTRUCTIONS PARAGRAPH.
- 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.
- Sterile and single use product. Never reuse a syringe that has been opened. Do not use if the syringe, luer lock cap, or foil peel pouch appears damaged.
- Ensure cleanliness and attention to technique during preparation of the device to avoid introducing contaminants.
- The appropriate size particles must be chosen based upon the lesion to be treated and the measurements taken from the baseline angiography.
- The use of sophisticated imaging equipment is necessary for successful embolization therapy.
- Appropriate facilities should be available to treat potential complications of the procedure.
- The syringe is intended for embolic use only. Do not use for any other application.

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), postpartum hemorrhage (post-delivery bleeding), abnormal placentation and small-for-gestational-age infants.
- 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

- Do not use particles smaller than 355 microns.

- An appropriate gynecologic work-up should be performed on all patients presenting for embolization of uterine fibroids (e.g., endometrial sampling to rule out carcinoma for patients with abnormal bleeding).
- 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 BEARING nsPVA 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.
- At the discretion of the physician, pneumatic compression devices may be used for patients currently taking hormone therapy, uterine volume >1000cc, and patients that are overweight, to lower the risk of deep vein thrombosis.

INSTRUCTIONS FOR USE

Inspect packaging prior to use to ensure seal integrity for maintenance of sterility.

1. Carefully evaluate the vascular network associated with the lesion using high resolution imaging prior to beginning the embolization procedure.
2. Choose the appropriate size of BEARING nsPVA Embolization Particles that best matches the pathology (i.e., vascular target/vessel size) and provides the desired clinical outcome.
3. Choose a catheter based on the size of the target vessel and the embolization particle size being used.
4. Introduce the delivery catheter into the target vessel according to standard techniques. Position the catheter tip as close as possible to the treatment site to avoid inadvertent occlusion of normal vessels.
5. To deliver Bearing nsPVA Embolization Particles: Take an empty 20 mL syringe and aspirate 10 mL of non-ionic contrast and 10 mL of 0.9% NaCl and connect it to the inline port of a luer lock 3-way stopcock. Remove any air in the saline/contrast syringe and 3-way stopcock by slowly pushing the syringe plunger while the syringe tip is vertically upright. Turn the 3-way stopcock to close the syringe with saline and contrast. Remove the luer lock cap from the prefilled Bearing nsPVA Express syringe and break the tip seal by slightly pulling back on the plunger. Attach the Bearing nsPVA prefilled syringe to the side port of the 3-way stopcock. With the stopcock closed to the saline/contrast syringe, advance the Bearing nsPVA syringe plunger to remove air. Open the 3-way stopcock to allow transfer between the Bearing nsPVA Express syringe and the saline/contrast syringe and slowly transfer the saline/contrast solution into the Bearing nsPVA Express syringe. Slowly make several back-and-forth transfers in the syringes to hydrate the embolization particles and then wait 2-3 minutes prior to injection. Remove the 20 mL empty syringe and attach a 1 mL or 3 mL injection syringe to the 3-way stopcock. Use of a 1mL or 3mL syringe is recommended to provide more controlled embolic delivery. Draw the BEARING nsPVA Embolization Particles saline/contrast mixture into the injection syringe slowly and gently to minimize the potential of introducing air into the system. Purge all air from the system prior to injection. Inject the BEARING nsPVA Embolization Particles saline/contrast mixture into the delivery catheter under fluoroscopic visualization using a slow pulsatile injection while observing the contrast flow rate. If there is no effect on the flow rate, repeat the delivery process with additional injections of the BEARING nsPVA Embolization Particles saline/contrast mixture. Consider using larger sized BEARING nsPVA Embolization Particles if the initial injections do not alter the contrast flow rate. Exercise conservative judgment in determining the embolization endpoint.
6. Upon completion of the treatment, remove the catheter while maintaining gentle suction so as not to dislodge BEARING nsPVA Embolization Particles still within the catheter lumen.
7. Apply pressure to the puncture site or use an arterial closure device until hemostasis is complete.
8. Discard any open, unused BEARING nsPVA Embolization Particles.

The UFE specific end point is generally described as complete stasis or near stasis, with the main uterine artery remaining patent, but with negligible residual flow. This end point generally corresponds to an angiographic image of a patent uterine artery with all its distal branches occluded. As with any embolic particle, in order to avoid a false end point with early recanalization, the embolization end point should be confirmed by leaving the catheter in the uterine artery for approximately five minutes after the apparent conclusion of the procedure. The end point should then be confirmed with an injection of contrast and observation with fluoroscopy. Additional particles can then be administered to reach the stated endpoint if flow restoration due to redistribution is identified on this contrast injection.

Caution: "Clumping" of BEARING nsPVA Embolization Particles or catheter obstruction may be a function of contrast dilution volume; ensure that enough contrast is utilized such that BEARING nsPVA Embolization Particles are free floating and not observed as aggregates.

STORAGE AND STERILITY

- BEARING nsPVA Embolization Particles are best stored at room temperature in a dry and dark place in their original syringe and packaging.
- Use by the date indicated on the labeling.
- Do not resterilize.

UFE PATIENT COUNSELING INFORMATION:

- Patients should have a clear understanding prior to embolization of who will provide their post-procedure care and who to contact in case of an emergency after embolization.
- UFE candidates should have an understanding of the potential benefits, risks, and adverse events associated with UFE. In particular, patients should understand that there is a chance their fibroid-related symptoms will not improve following UFE.

INFORMATION ON PACKAGING

Symbol	Designation
	Date of manufacture: year-month-day
	Use by: year-month-day
LOT	Lot Number
REF	Catalogue Number
	Do not resterilize
	Do not use if package is damaged and Consult Instructions for Use.
	Keep away from sunlight
	Keep dry
	Single use
	Caution
	Non-pyrogenic
STERILE R	Sterilized using Irradiation
MD	Medical Device
UDI	Unique Device Identifier
	Single sterile barrier system with protective packaging inside
	Consult Instructions for Use
℞ ONLY	Caution: Federal (U.S.A.) law restricts this device to use by or on the order of a licensed physician

All serious or life-threatening adverse events or deaths associated with use of BEARING nsPVA Embolization Particles should be reported to the device manufacturer.

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