PATIENT INFORMATION LEAFLET

PLEASE PROVIDE TO THE PATIENT

BEARING™ NSPVA

BEARING™ NSPVA

DEVICE DESCRIPTION

The device Bearing™ nsPVA are particles made of polyvinyl alcohol intended for embolization. This material is safe for use in the human body. Bearing nsPVA embolization particles are irregularly shaped, deformable and hydrophilic. They are in a dry form, packaged sterile in a glass vial. Each sterile vial is intended for single patient use only.

NOTE: It is a non-resorbable, permanent product.

INTENDED PURPOSE

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

Particles smaller than 355 microns cannot be used for the treatment of leiomyoma uteri.

KIND OF PATIENT ON WHOM THE DEVICE IS INTENDED TO BE USED

The device Bearing nsPVA is intended for patients with peripheral hypervascularized tumors, including leiomyoma uteri and peripheral arteriovenous malformations (AVMs).

Bearing nsPVA is a long-term implantable device used to permanently occlude blood vessels. The particles stay in the human body for life. Therefore, there are no special instructions for the patient.

INTENDED PERFORMANCE OF THE DEVICE

The intended performance of Bearing nsPVA device is:

- Relief of related symptoms and delay of disease progression in patients with peripheral hypervascularized tumors
- Reduction of fibroid volume, reduction of symptoms severity and improvement of quality of life in patients with uterine leiomyomas
- Improvement of symptoms in patients with peripheral arteriovenous malformations

POTENTIAL COMPLICATIONS

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:

- Postembolization syndrome
- 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 BEARING nsPVA 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 postprocedural 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
- Complications of misembolization include blindness, hearing loss, loss of smell, paralysis, pulmonary embolism and death

UTERINE FIBROID EMBOLIZATION (UFE) SPECIFIC POTENTIAL COMPLICATIONS

Uterine fibroid embolization (UFE) is also known as uterine artery embolization (UAE).
- 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)
- Necrosis of uterus, ovaries, buttocks, labia, cervix, and vagina
- Vesicovaginal or vesicouterine fistula
- Uterine Rupture
- Post-UFE Intervention to remove necrotic fibroid tissue
- Hysterectomy
- Phlebitis
- Deep vein thrombosis with or without pulmonary embolism
- Transient hypertensive episode
- Urinary Retention

Bearing nsPVA Embolization Particles are made of polyvinyl alcohol and are magnetic resonance imaging (MRI) compatible. There is no risk of magnetic field interference from resonance imaging devices or risk of electrical interference from electro surgical devices.

The product is a single-use implant device that does not require any examination, monitoring, or maintenance.

The product is a single-use implant device with no possibility of malfunction.

Any medical procedure carries some risks. Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

EXPECTED DEVICE LIFETIME

Bearing nsPVA is a long-term implantable device used to permanently occlude blood vessels. Biosphere Medical does not claim a specific lifetime for Bearing nsPVA. The device lifetime of Bearing nsPVA will exceed the patient life expectancy.

The particles are composed of cross-linked polyvinyl alcohol that is designed to be compatible

with the human body. They are non-resorbable, thus providing permanent vessel occlusion.

MATERIALS AND SUBSTANCES INCLUDED IN THE DEVICE

IMPLANTABLE DEVICE MATERIALS TABLE		
Material	Duration of exposure	Level of patient exposure (for one vial)
Polyvinyl alcohol	Long-Term (> 30days)	100 mg

There are no manufacturing residuals that could pose a risk to the patient.

Any serious incident that occurs in relation to the Bearing nsPVA device should be reported to the manufacturer and to the Therapeutic Goods Administration at www.tga.gov.au

407183002_001 ID072121