PetXmark™

US

Liquid fiducial marker

For use in dogs and cats

Read all sections of this instruction for use before using PetXmark™ for the first time

FOR PROFESSIONAL VETERINARIAN USE ONLY

PetXmark™ must be handled only by qualified health care professionals. Injection of PetXmark™ requires experience with implantation of fiducial markers or with taking biopsies from the tissue intended for the injection of PetXmark™.

1. DEVICE INFORMATION

1.1 DEVICE DESCRIPTION

- PetXmark™ is a single use, implantable medical device consisting of a sterile transparent liquid in a one-point-cut (OPC) glass ampoule.
- Each ampoule contains 1 ml liquid.
- Sterilized using steam.
- Magnetic Resonance (MR) safe.
- Upon injection of the PetXmark™ liquid into soft tissue, efflux of ethanol leads to the formation of a radiopaque, sticky and gel-like fiducial marker *in-vivo*.

1.2 DEVICE COMPONENTS

- The liquid is a mixture of ethanol, sucrose acetate isobutyrate (SAIB) and an iodinated and acylated derivative of sucrose (x-SAIB).
- The OPC glass ampoule consists of borosilicate.

1.3 STORAGE

- Store at 36-77°F (2–25 °C).
- Keep away from sunlight.

1.4 INJECTION VOLUME

The optimal injection volume depends on the intended target site, the planned treatment and the applied image modality as well as on the desired visibility and artefact level. In general, both visibility and artefacts increase with higher injection volumes.

- **CT and CBCT:** Injection volumes ≥ 0.010 ml usually form markers visible on computed tomography (CT) and cone beam computed tomography (CBCT).
- **MV X-ray:** PetXmark™ is not visible on megavoltage imaging.

Recommendation on maximum injection volumes

- The accumulated injection volume of multiple markers must be ≤ 0.300 ml for each patient

Up to 12 months toxicity studies in rats have demonstrated PetXmark™ to be safe and well tolerated when injected as five (5) markers of 0.060 ml each

Dimension and shape of a formed marker will vary depending on the injection volume and the anatomical implantation site.

2. INDICATIONS

- PetXmark™ is indicated for use to radiographically mark subcutaneous tissue in dogs and cats.

3. CONTRAINDICATIONS

- Do not use in patients with known hypersensitivity to iodine or any other component in PetXmark™.

4. WARNINGS

NOT FOR USE IN HUMANS

NOT FOR INTRAVASCULAR USE

- The PetXmark™ liquid may cause emboli if injected directly into the blood stream. Do not inject PetXmark™ liquid if excessive bleeding is observed. Do not inject near a lung vein as misplacement of a marker may result in emboli.

5. PRECAUTIONS

5.1 BEFORE USE

- Federal law restricts this device to sale by or on the order of a licensed veterinarian.
- The PetXmark™ liquid is **sticky and viscous**. It is recommended to allow sufficient time to get acquainted with PetXmark™ before first implantation in patients.
- Do not re-sterilize.
- Perform a visual inspection of PetXmark™ before use. Do not use if the ampoule is damaged. Do not use if the liquid is non-transparent.
- Use immediately after opening. Do not re-use.
- Cautions should be taken if the patient is treated with anti-coagulants, non-steroid anti-inflammatory drugs (NSAID) or other medication that can affect bleeding.

5.2 DURING INJECTION

- Avoid injections in necrotic tissue, highly vascularized tumor tissue and air-filled cavities e.g. tumor cavity as it may result in loss of markers and/or in the tissue not being marked properly.
- Do not fill the application needle with other liquids before, during or after filling it with the PetXmark™ liquid. It may impact the performance of PetXmark™.
- It is recommended to use the least invasive implantation procedure for the given indication.
- Injections may result in infection or trauma, such as bleeding. Use relevant concomitant treatments as needed.

6. ADVERSE EVENTS

The patient guardian shall be informed about the following possible adverse events related to the implantation of PetXmark™:

- Allergic reaction
- Bleeding
- Emboli
- Infection
- Local inflammatory response

7. PROCEDURE

7.1 PREPARATION

A. Prepare a syringe with a pressure resistant connection (e.g. Luer lock) and a loading needle (18-20G).
   Thinner needles may require longer time to fill the syringe.
B. Open the PetXmark™ ampoule and fill the syringe using the loading needle. The PetXmark™ liquid is **sticky and viscous**.
C. If a thinner needle is preferred for application, change the loading needle to an injection needle (19-25G):
   - Remove the loading needle.
   - Remove the stylet, if any, from the injection needle and attach the syringe containing the PetXmark™ liquid to the injection needle.
D. Completely fill the injection needle with the PetXmark™ liquid.
E. Wipe off the injection needle tip with an ethanol wipe to remove excess liquid.
   If PetXmark™ liquid is spilled, the spill on surfaces can be removed with ethanol wipes.

7.2 INJECTION

F. Place the injection needle in the intended position for tissue marking and inject the desired volume of the PetXmark™ liquid.
G. When placing the next marker, move to the intended position of this next marker and inject the desired volume of the PetXmark™ liquid.

7.3 DISPOSAL

- After use, syringes and needles may be potential biohazards. Dispose according to local procedures in line with applicable requirements.
- The ampoule and possible residual PetXmark™ liquid shall be disposed according to local procedures, e.g. as normal waste and glass.

7.4 FOLLOW-UP

- Monitor the patient for adverse reactions according to local procedures and national guidelines.

8. SYMBOL EXPLANATIONS

	Do not use if product sterile barrier system or its packaging (ampoule) is compromised
MR	MR safe
REF	Reference number / product code
LOT	Lot number
	Use-by date (expiry date)
36°F (2°C) 77°F (25 °C)	Lower temperature limit: 36°F (2°C). Upper temperature limit; 77°F (25 °C).
	Keep away from sunlight
	Consult instructions for use
STERILE	Sterilized using steam
	Do not re-use
	Manufacturer
STERILIZE	Do not resterilize
	Fragile, handle with care

9. CONTACT INFORMATION

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Product malfunction and adverse events must be reported by e-mail to urgent@nanovi.com. Please include your phone number in the subject line