

User Guide to Percutaneous Implantation of BioXmark®

1. Introduction

- BioXmark® is a liquid soft tissue marker for radiographically marking of soft tissue for image guided radiotherapy and proton therapy
- This User Guide focuses on handling and preparation of BioXmark® for percutaneous implantation and do not replace the BioXmark® instructions for use and your local guidelines
- Consult the instructions for use as needed during use of BioXmark®
- The BioXmark® instructions for use are included in each box of ampoules



2. Visual inspection and opening of the ampoule

- BioXmark® is delivered in one-point cut glass ampoules of 1 mL each
- Use gloves throughout the process
- Make a visual inspection ensuring the ampoule is intact and the liquid is clear and colorless to light yellow
- Open the BioXmark® ampoule by holding the ampoule with the colored dot on the ampoule head facing yourself. Then, break the ampoule neck by pulling the top of the ampoule head inward



3. Equipment needed for injection

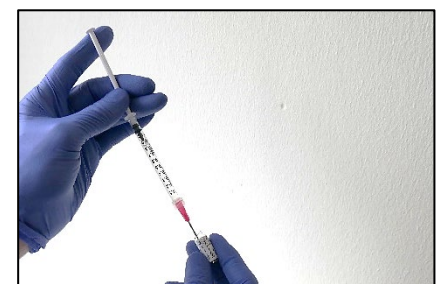
For percutaneous assisted insertion of BioXmark® you need:

- One standard syringe with Luer lock. We recommend to use a 1mL syringe for volume control
- One loading needle (18G-20G)
- One injection needle (19G-25G)
- Ethanol wipes

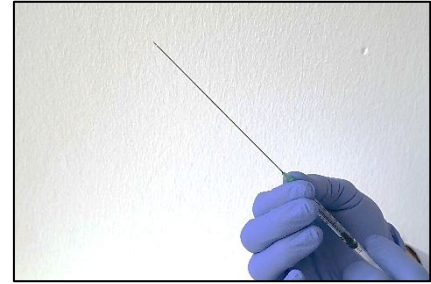


4. Preparation of equipment for injection

- Load the syringe with the BioXmark® liquid from the ampoule with the loading needle
- Loading needles do not need to be primed
- Note that BioXmark® liquid is sticky and viscous



- Connect the injection needle to the syringe
- Completely fill the injection needle with the BioXmark® liquid until the first drop of BioXmark® is visible at the tip of the needle
- Remove the drop by wiping the needle tip with an ethanol wipe
- The injection needle is ready to use for percutaneous injection of BioXmark®



5. Prepare the patient

- Prepare the patient for the percutaneous injection and disinfect according to your local guidelines

6. Implantation of BioXmark®

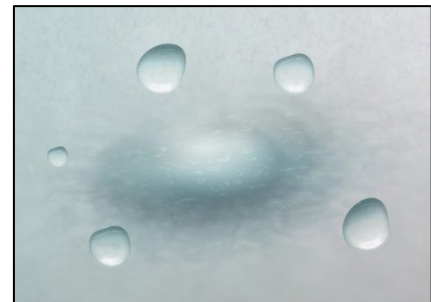
First target location:

- The injection needle is guided to the first target site
- Inject the desired volume of BioXmark® at the target site and keep a constant pressure until the total desired volume of BioXmark® is injected
- Use image guidance (such as fluoroscopy) to verify the intended marker placement and volume during the implantation of BioXmark®
- The volume of each marker can be customized during implantation



Additional target locations:

- The injection needle can now be guided to the next target site and the injection process can be repeated multiple times taking into account the available volume of BioXmark® in the syringe
- The number of markers can be customized for each procedure
- If a marker placement cannot be verified, a new marker can be implanted during the same procedure



7. Finalization of implantation

- After the percutaneous procedure the injection needle is retracted and the syringe and needle are disposed according to local guidelines
- The percutaneous BioXmark® implantation procedure is now completed. The patient will be ready for imaging for treatment planning one day after implantation.