

## User Guide to Endoscopic 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
- BioXmark® can be injected with standard endoscopic injection equipment
- This user guide focuses on handling and preparation of BioXmark® for endoscopic assisted 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 containing 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

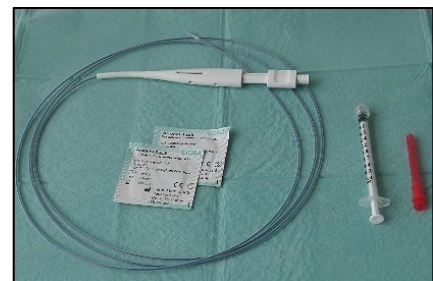


### 3. Equipment needed for injection

Depending on the intended number of markers to be implanted, volume per marker, and the dead volume of the injection needle (empty space within the injection needle that is filled with air before the injection needle is primed), more than one ampoule of BioXmark® and syringe may be needed.

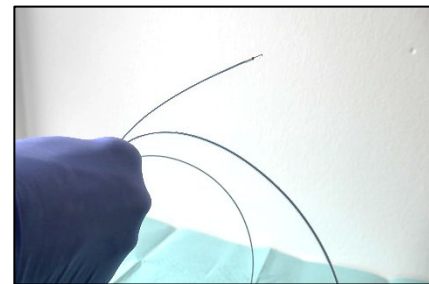
For endoscopic assisted implantation of BioXmark® you need:

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



#### 4. Preparation of equipment for injection

- Load the syringe(s) with the BioXmark® liquid from the ampoule(s) with the loading needle
- Loading needles do not need to be primed
- In case of a large dead volume in the injection needle you might need to use an additional BioXmark® ampoule
- Note that BioXmark® liquid is sticky and viscous
- Connect the syringe containing BioXmark® with your chosen endoscopic injection needle
- Push the needle tip out of the protection sheath
- Fill the dead-volume of the endoscopic needle with BioXmark® liquid by pressing the piston 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
- Retract the injection needle into the protection sheath and lock it



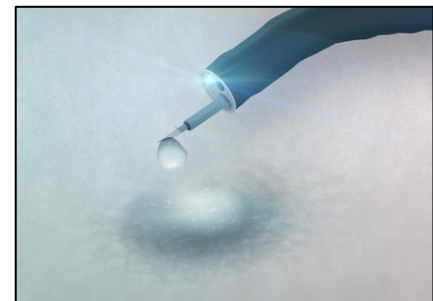
#### 5. Prepare the patient

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

#### 6. Implantation of BioXmark®

##### First target location:

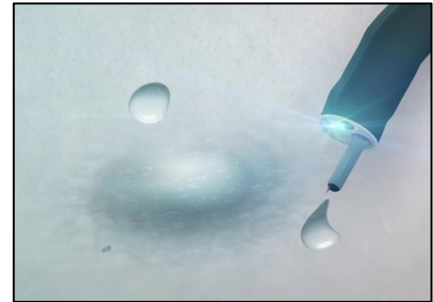
- After visual identification of the target via the endoscope the injection needle is inserted into the endoscope working channel
- The injection needle is guided to the first target site.
- Place the endoscopic needle at the target site. Push the injection needle out of the protection sheath and slowly inject the desired volume of BioXmark®
- Maintain a firm and constant pressure for additional 5-10 seconds to ensure that the total desired volume of BioXmark® has been 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
- The injection needle is retracted into the protection sheath

**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 endoscopic procedure the injection needle is pulled out of the working channel
- Immediately after retraction of the scope the working channel is flushed 3 times with at least 99.0 v/v% ethanol with a minimum of 10 mL to remove any residues of BioXmark®
- The endoscope is cleaned according to the manufacturer's guidelines
- The endoscopic BioXmark® implantation procedure is now completed. The patient will be ready for imaging for treatment planning one day after implantation.