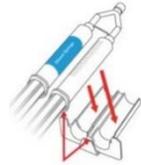


SpaceOAR® System
Product Code SO-3101
INSTRUCTIONS FOR USE



Indication:

SpaceOAR System is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy in prostate cancer patients without evidence of posterior extracapsular extension. In creating this space it is the intent of SpaceOAR System to reduce the radiation dose delivered to the anterior rectum. The SpaceOAR System is composed of biodegradable material and maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

Contraindications:

None known

Overview:

The SpaceOAR System consists of components for preparation of a synthetic, absorbable hydrogel spacer and a delivery system packaged for single use. The *in situ* formed hydrogel spacer creates a temporary space between the prostate and rectum during radiation therapy. The spacer is formed by mixing two solutions, the Precursor and the Accelerator. The Precursor solution is formed through the mixing of the Diluent solution (Trilysine buffer solution) with the PEG powder. The Accelerator solution is a salt buffer solution. When mixed together, the solutions cross-link to form a soft hydrogel. The mixing of the solutions is accomplished as the materials pass through a static mixer in the Y-Connector prior to passing through the injection needle. SpaceOAR hydrogel implant is MR Safe.

The hydrogel spacer maintains space for approximately 3 months and is absorbed in about 6 months, sufficient time to support the intended use.

The SpaceOAR System is provided sterile and consists of the following components:

Powder Vial, with blue label	
Diluent Syringe, with blue label	
Accelerator Syringe	
Y-Connector	
Syringe Holder	
Plunger Cap	
18G x 15cm Needle	

* No components are comprised of any latex material.

Required Equipment:

For this procedure a side-fire transrectal ultrasound (TRUS) probe and a stepper are required; a stand-off balloon is recommended.

Warnings:

- SpaceOAR System must only be administered via an aseptic transperineal route. Do not administer transrectally.
- The SpaceOAR needle tip must be at the prostate midline during SpaceOAR hydrogel injection to avoid lateral hydrogel formation. In the US Clinical Study incorrect hydrogel placement was observed in 0.7% of subjects.
- The SpaceOAR needle should be inserted under ultrasound guidance to maintain needle tip visibility and prevent rectal wall penetration. In the US Clinical Study inadvertent rectal wall needle penetrations were experienced in 1.4% of subjects.
- If the needle enters the rectal lumen at any time during the procedure, abandon the procedure to avoid infection.
- The perirectal space may not open during hydrodissection, e.g., scar tissue. If the perirectal space does not open with saline do not inject SpaceOAR.

Precautions:

- SpaceOAR Hydrogel System procedures should only be performed by physicians who have received appropriate training for proper hydrogel spacer deployment technique.
- Users of SpaceOAR System should be familiar with ultrasound needle placement during transperineal procedures.
- The SpaceOAR System is provided sterile. Do not use if packaging or seal has been damaged or opened. Do not re-sterilize.
- Do not use if the PEG powder is not free flowing.
- All system components are intended for single-use only. SpaceOAR components cannot be re-used.
- Discard opened and unused product.
- Use only with delivery system provided. Appropriate mixing of the Precursor and Accelerator solutions will not occur if the supplied Y-Connector is not used.
- Use within 1 hour of preparing the Precursor solution. Discard entire system if not used within 1 hour.
- If placing fiducials, do so with a transperineal approach prior to SpaceOAR hydrogel injection.
- SpaceOAR System injection should proceed uninterrupted, without stopping. Stopping during injection may result in device plugging, requiring the preparation of a replacement system.

Risks:

Potential complications that may be associated with the use of SpaceOAR System include, but are not limited to: pain associated with SpaceOAR hydrogel injection; pain or discomfort associated with SpaceOAR hydrogel; needle penetration of the bladder, prostate, rectal wall, rectum, or urethra; injection of SpaceOAR hydrogel into bladder, prostate, rectal wall, rectum, or urethra; local inflammatory reactions; infection; injection of air, fluid, or SpaceOAR hydrogel intravascularly; urinary retention; rectal mucosal damage, ulcers, necrosis; bleeding; constipation; and rectal urgency

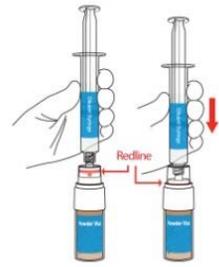
Detailed System Preparation

The use of SpaceOAR System consists of three steps:

- Preparing the Precursor Syringe
- Assembling the delivery components for injection
- Positioning the needle and injection of SpaceOAR hydrogel

A. Preparing the Precursor Syringe

- Using sterile technique, transfer the contents of the SpaceOAR System onto the sterile field.
- Remove the blue cap from the Diluent Syringe and discard.
- Attach the Diluent Syringe (blue label) to the Powder Vial (blue label)



- Without depressing the syringe plunger, pierce the vial seal by pushing the syringe into the vial cap until it is fully depressed (twisting not required). The entire reference line should disappear below the vial rim.



- Inject syringe contents into the vial.

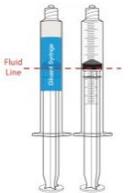
- Shake the vial/syringe assembly until the powder is completely dissolved and set aside for approximately one minute. The solution may appear to be milky with bubbles.

- Invert the vial/syringe assembly and draw 5 mL of Precursor back into the syringe.

- Unscrew the Syringe from the Powder Vial and discard the vial. This is the Precursor Syringe.

B. Assembling the Delivery Components for Injection

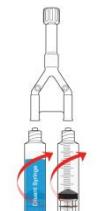
- Remove the cap from the Accelerator Syringe and expel liquid as needed so that 5 mL remains in the syringe. Check that the Diluent and the Accelerator Syringe fluid levels are equal.



- Pull back 1 mL of air into each syringe.

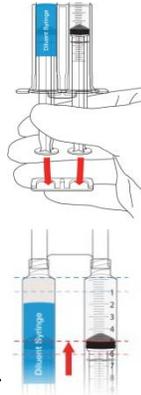


- With the syringes held upright attach Precursor and Accelerator Syringes to the Y-Connector.

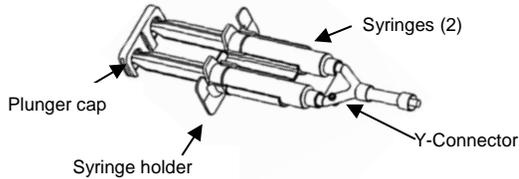


- Attach Syringe Holder to syringe barrels.

- Carefully attach the Plunger Cap to the plungers of both syringes while holding the plungers to avoid dispensing solutions into the Y-Connector.



SpaceOAR Delivery System prior to needle attachment

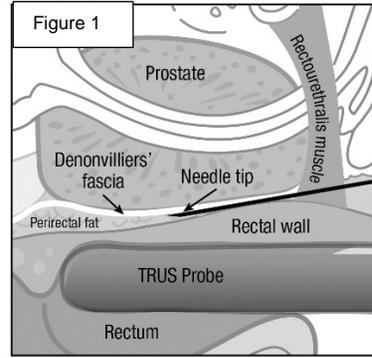


Detailed Procedure Instruction

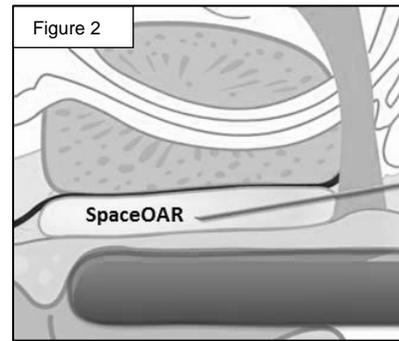
C. Positioning the Needle and Injection of SpaceOAR hydrogel

- Position the TRUS probe to enable visual guidance of the needle into the space between the prostate and rectum. Maintain visualization of the SpaceOAR needle tip at all times to prevent rectal wall penetration. If needed, lower probe to reduce pressure on anterior rectal wall and prostate, allowing for creation of perirectal space.
- Attach the 18G x 15cm needle (provided) to a syringe containing saline (not provided).
- Insert the needle approximately 1-2 cm above the anal opening. Angle the needle as needed to reach the perirectal fat between the anterior rectal wall and the prostate.
- Advance needle through the rectourethralis muscle to the perirectal fat approximately midgland. (Figure 1). Confirm midline

needle position in sagittal and axial views and verify that the needle tip is in the perirectal fat.



- Inject small amounts of saline to hydrodissect the space between Denonvilliers' fascia and anterior rectal wall.
- Access axial view to confirm needle is in the correct location (mid-gland and centered) and aspirate to ensure needle is not intravascular.
- While maintaining the desired needle position, carefully disconnect the syringe from the 18G needle.
- Being careful to maintain needle position, attach the SpaceOAR delivery system to the 18G needle.
- Under ultrasound guidance in the sagittal view, and with the needle tip at the prostate midline, use a smooth, continuous injection technique to dispense the SpaceOAR hydrogel into the space between the prostate and rectal wall (Figure 2). Inject entire syringe contents without stopping.



- Withdraw the needle/syringe assembly and discard the SpaceOAR System using appropriate precautions for sharp objects.



Consult Instructions For Use



Single Use Only



Not Made With Natural Rubber Latex



Temperature Limit



Sterilized using Irradiation



CAUTION: Federal law restricts this device to sale by or on the order of a physician.

SpaceOAR System must be stored at or below 25°C (77°F) in order to maintain product performance.



SpaceOAR is a registered trademark of Augmenix, Inc.