SpaceOAR™ Hydrogel Implantation Procedure

Equipment Required for SpaceOAR Hydrogel Injection

- ☑ Side-fire Transrectal Ultrasound (TRUS) with sagittal and axial views
- ☑ Stepper stabilizer
- ☑ 10 or 20 cc syringe
- ☑ Sterile saline
- ☑ Sterile drape and gloves (for device assembly)
- ☑ Stand-off balloon (recommended)

Procedure Setup

The needle must be inserted using an aseptic transperineal approach under ultrasound guidance.

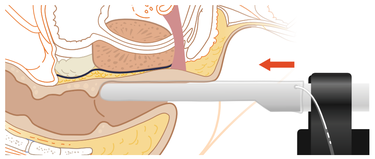
If the patient is not sedated, a local anesthetic may be used for patient comfort.

NOTE: If placing fiducials, do so prior to the SpaceOAR Hydrogel injection using a transperineal approach.

Needle Alignment and Placement

Step 1

Place stand-off balloon on TRUS probe, attach and secure onto stepper. Insert the probe into the rectum. Adjust probe position to obtain ultrasound coupling with the anterior rectal wall.



TRUS with Stand-off Balloon and Stepper

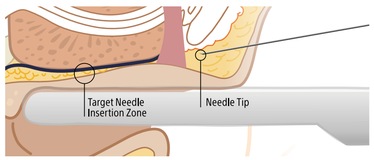
Note: On the ultrasound image, locate the perirectal fat between the prostate and the rectum to determine needle position for hydrodissection.

Step 2

Attach the 18G x 15cm needle (provided) to a syringe containing saline (not provided). Prime the needle.

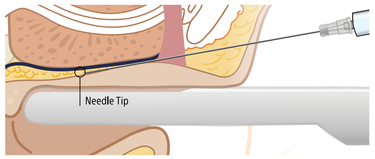
Step 3

Insert the needle approximately 1-2 cm above the TRUS probe. During the procedure, the blue marking on the needle hub will be visible when correctly oriented, with bevel facing down. Angle the needle as needed to reach the perirectal fat between the anterior rectal wall and the prostate. If needed, lower probe to reduce pressure on anterior rectal wall and prostate, allowing for creation of perirectal space.



Step 4

Advance the needle through the rectourethralis muscle to the perirectal fat approximately mid-gland. Confirm needle position in sagittal and axial views, and verify that the needle tip is in the perirectal fat.



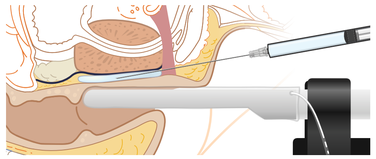
Note: Ensure the needle is on the midline when advancing.

Hydrodissection

Hydrodissection is used to separate the Denonvilliers' fascia and rectal wall and to verify proper needle placement at mid-gland prior to injecting the SpaceOAR Hydrogel.

Step 5

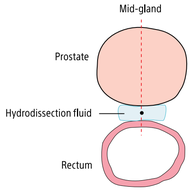
Inject small amounts of saline to hydrodissect the space between the Denonvilliers' fascia and anterior rectal wall.



Note: The perirectal space may not open during hydrodissection, e.g., scar tissue. If the perirectal space does not open with saline, do not inject the SpaceOAR Hydrogel.

Step 6

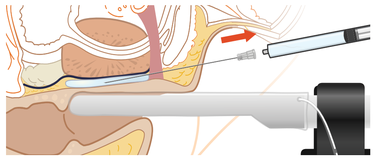
Access axial ultrasound view to confirm correct needle position (mid-gland and centered) and aspirate to confirm the needle is not intravascular.



Warning: If needle has penetrated the rectal lumen, do not proceed with procedure (to avoid infection).

Step 7

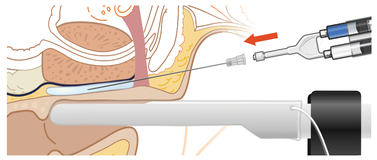
While maintaining the desired position at prostate mid-gland, carefully disconnect the syringe from the 18G needle.



Hydrogel Injection

Step 8

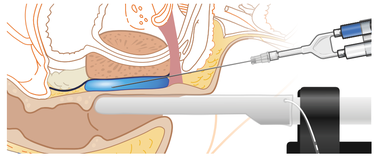
Being careful to maintain needle position, attach the SpaceOAR System delivery assembly to the 18G needle.



Note: Do not inject the SpaceOAR Hydrogel if you cannot confirm correct needle position prior to injecting.

Step 9

Under ultrasound guidance in the sagittal view, use a smooth, continuous injection technique to dispense the SpaceOAR Hydrogel into the space between the Denonvilliers' fascia and rectum. Inject entire syringe contents without stopping.



Note: The SpaceOAR Hydrogel injection should proceed uninterrupted, without stopping. Stopping during injection may result in device clogging, requiring the preparation of a replacement device.

Step 10

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

Note: If assembly becomes clogged, discard and prepare replacement device as needed.

SpaceOAR is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR Hydrogel to reduce the radiation dose delivered to the anterior rectum.

As with any medical treatment, there are some risks involved with the use of SpaceOAR Hydrogel. Potential complications associated with SpaceOAR Hydrogel 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 the 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.

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

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. This material not intended for use in France.

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A. Preparing the Precursor Syringe

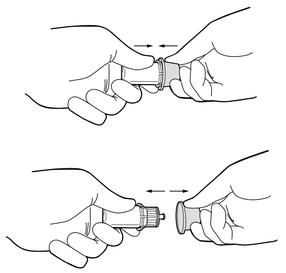
NOTE: Use of device must occur within 1 hour of preparation of the Precursor.

Using sterile technique, transfer the tray components and open on a sterile field.

Note: Do not remove the Vial Adapter from the packaging cup.

Step 1

With one hand pick up the Powder Vial, with the other hand pick up the packaging cup that holds the Vial Adapter. Attach the Vial Adapter in the cup to the Powder Vial by pushing together until fully seated. Remove the cup from vial assembly and discard.



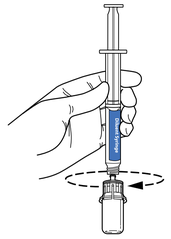
Step 2

Remove the blue cap from the Diluent Syringe and discard. Attach the Diluent Syringe to the Powder Vial.

Step 3

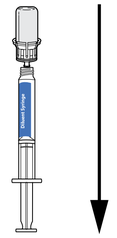
Inject syringe contents into the vial.

Shake the vial/syringe assembly until the powder is completely dissolved and set aside for at least one minute to help dissipate bubbles (bubbles may interfere with ultrasound visibility). The solution may appear to be milky with bubbles.



Step 4

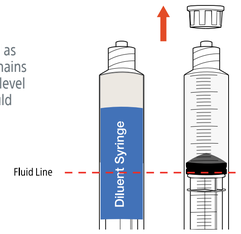
Invert the vial/syringe assembly and draw 5 mL of Precursor back into the syringe. Unscrew the syringe from the Powder Vial and discard the vial. This is the Precursor Syringe.



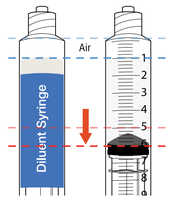
B. Assembling the delivery components for injection

Step 1

Remove the Accelerator Syringe cap. Expel liquid as needed so that 5 mL remains in the syringe. The fluid level in the two syringes should be equal.



Then pull back 1 ml of air into each syringe, to help avoid fluids from inadvertently entering Y-connector.

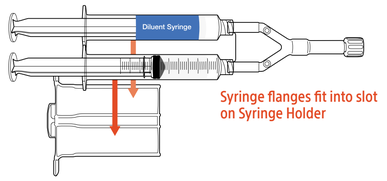


Step 2

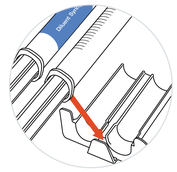
With the syringes held upright, attach Precursor and Accelerator Syringes to the Y-Connector. Use caution not to depress either syringe plunger so as to avoid fluids entering the Y-Connector.

Step 3

Attach the Syringe Holder to the two syringe barrels.

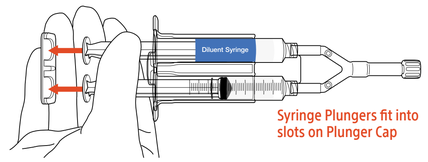


Syringe flanges fit into slot on Syringe Holder

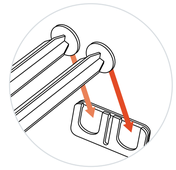


Step 4

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

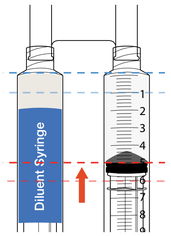


Syringe Plungers fit into slots on Plunger Cap



Step 5

Advance the syringe plungers to expel most of the air, but not all. Do not prime connectors. Do not allow fluids to enter Y-Connector at this time.



The syringe assembly is now ready to attach to the needle.

NOTE: When expelling air, do not allow fluids to enter the Y-Connector to avoid clogging.