

SPACEOAR™ SYSTEM

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use

SpaceOAR System 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 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.

Warnings

Carefully read all instructions prior to use. Observe all warnings and precautions noted throughout these and other instructions relevant to the procedure. Failure to do so may result in complications.

- 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.
- If SpaceOAR hydrogel is not seen in the perirectal space during injection, discontinue the procedure immediately. This could potentially indicate gel is in an unintended location (blood vessel). **Do not** inject additional SpaceOAR.
- Injection of air, fluid, or SpaceOAR hydrogel intravascularly could potentially lead to arterial or venous embolism. **Always aspirate** with the saline syringe to **verify the needle tip is not** in a blood vessel. If blood is aspirated, discontinue the procedure.
- The SpaceOAR product contains PEG. The use of this product in patients with documented PEG sensitivities or allergies has not been studied. The use of SpaceOAR in patients with a known allergy to PEG could potentially lead to allergic reaction (including anaphylaxis).

Adverse Events

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
- Local inflammatory reactions
- Infection (including abscess)
- Urinary retention

- Urgency (e.g. urinary and rectal)
- Constipation (acute, chronic, or secondary to outlet obstruction)
- Rectal tenesmus/muscle spasm
- Mucosal damage, ulcers
- Fistula
- Perforation (including prostate, bladder, urethra, rectum)
- Necrosis
- Allergic Reaction (includes localized or more severe reaction, such as anaphylaxis)
- Embolism (venous or arterial embolism is possible and may present outside of the pelvis, potentially impacting vital organs or extremities)
- Syncope
- Bleeding

The occurrence of one or more of these complications may require treatment or surgical intervention.

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.
- Use caution when attaching the powder vial to the sharp vial adapter component to avoid injury.
- 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 SpaceOAR System components are intended for single-use only. SpaceOAR System components cannot be re-used.
- 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.
- Air resulting from the SpaceOAR injection may distort ultrasound image.
- Maintain visualization of the SpaceOAR needle tip at all times to prevent injecting SpaceOAR into an unintended location, including the rectal wall, prostate, blood vessels, or other tissues. If needle tip visibility is distorted or compromised, **do not** inject SpaceOAR.
- Excessive resistance experienced during hydrodissection or SpaceOAR injection may indicate the needle tip is in an unintended location. Reassess needle position.
- Limit needle movement after hydrodissection and during SpaceOAR injection to avoid perforating unintended organs, such as the rectal wall, prostate, or blood vessels.

Precautions can be found in the product labeling supplied with each device.

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

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