SpaceOAR™ Hydrogel System

Quick Start Guide: Assembly instructions with vial adapter

These instructions demonstrate how to prepare the SpaceOAR Hydrogel kit using the vial adapter and identify the marked needle hub to facilitate correct orientation of the needle during the procedure. For details on the kit assembly and the procedure, refer to the product's Instructions for Use (IFU).

A. Accelerator Syringe
B. Diluent Syringe, with blue label
C. Y-Connector
D. Powder Vial, with blue label
E. Vial Adapter
F. Plunger Cap
G. Syringe Holder
H. 18G x 15cm Needle, with marked hub

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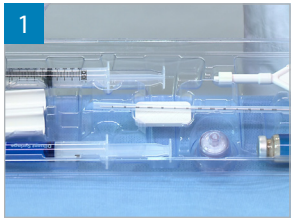
Prepare the Precursor Syringe

1



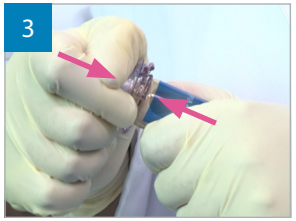
Transfer the contents of the SpaceOAR Hydrogel System onto the sterile field.

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

2

With one hand pick up the Powder Vial, with the other hand pick up the packaging cup that holds the Vial Adapter.

3



Attach the Vial Adapter in the cup to the Powder Vial by pushing together until fully seated.

4

Remove cup from vial assembly and discard.

5

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

6

Inject syringe contents into the vial and shake the assembly until the powder is completely dissolved and set aside for approximately one minute.

Note: The solution may appear to be milky with bubbles.

7

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

8

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.

9

Pull back 1 mL of air into each syringe.

10

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

11

With the syringes held upright, attach Syringe Holder to syringe barrels.

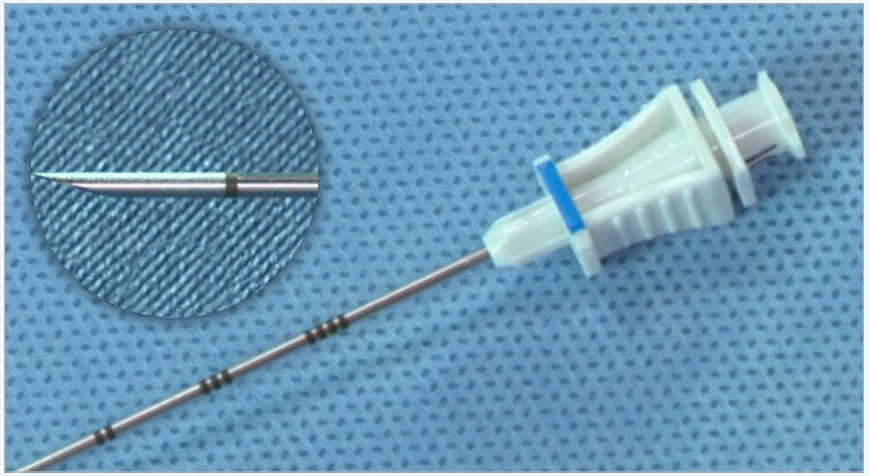
12

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

Assemble the Delivery System

An assembled delivery system will appear as above.

Identifying the Marked Needle Hub



During the procedure, the blue marking on the needle hub will be visible when correctly oriented, with bevel facing down.

Learn more by visiting **BostonScientific.eu/SpaceOAR**

SpaceOAR Hydrogel 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; and rectal urgency.

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.

Material not intended for use in France.

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IMPORTANT INFORMATION: These materials are intended to describe common clinical considerations and procedural steps for the use of referenced technologies but may not be appropriate for every patient or case. Decisions surrounding patient care depend on the physician's professional judgment in consideration of all available information for the individual case.

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