

# SpaceOAR post-market registry study

<b>Submission date</b> 09/10/2025	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/11/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/01/2026	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Space OAR/SpaceOAR Vue Systems are biodegradable medical devices that are implanted between the prostate and rectum to temporarily move part of the rectal wall away from the prostate during radiation therapy for prostate cancer. Studies have shown these can lead to a reduced dose of radiation to the rectum and therefore reduce side effects from radiation. These spacers have been used in cancer treatment centres in the UK, as well as Europe and other countries, for over 6 years.

Recently, concerns have been raised by regulators that there is little data about the long-term safety of rectal hydrogel spacers for use in conjunction with radiotherapy treatment for prostate cancer. To address this, this study will collect data about the short-term side-effects and long-term safety of SpaceOAR and SpaceOAR Vue rectal hydrogel spacers in men who receive them in the UK and France. Men who have agreed to receive these spacers as part of their standard medical care will be asked to take part in the study whereby data about their treatment and health will be collected from their medical records and from members of the clinical team who deliver their treatment.

### Who can participate?

Men aged 18 years and over with a confirmed diagnosis of prostate cancer, who have been recommended to undergo radiation therapy, and are planning to undergo implantation of a SpaceOAR hydrogel spacer as part of their standard medical care

### What does the study involve?

During the study, participants will be asked to complete questionnaires over a maximum period of 36 months from the date they receive a spacer. The multiple-choice questionnaires will ask questions about quality of life which are related to participant's treatment for prostate cancer. The questionnaires and safety data will be collected and recorded before, during and after the implantation of the hydrogel spacer and radiotherapy treatment. Follow up appointments arranged by their hospital normally stop about 24 months after their cancer treatment. By taking part in the study, participants will be asked to continue to have these appointments for up to 36 months after their hydrogel spacer implantation.

Most of the questionnaires in this study will be completed remotely (online or via post, if needed). The first questionnaire will be when participants consent to take part in the study, and

then at 75 days, and 6, 12, 24 and 36 months after the hydrogel spacer implantation. The questionnaires will ask about your health and quality of life related to prostate cancer. Participation in the study will finish after your 36-month visit and questionnaire completion.

What are the possible benefits and risks of participating?

This study involves monitoring participants health at appointments which are 2 and 3 years their hydrogel spacer implantation. These are additional to the standard care normally received which may be seen as beneficial. Otherwise, participants will not physically benefit from participating in this study. However, medical science and future patients may benefit from their participation. We do not foresee any risks to participants who decide to take part in the study.

Where is the study run from?

Sheffield Hallam University (UK)

When is the study starting and how long is it expected to run for?

December 2024 to January 2030

Who is funding the study?

Boston Scientific Corporation (manufacturer of the SpaceOAR Systems)

Who is the main contact?

1. Dr Grace Price, grace.price@shu.ac.uk
2. Dr Saïd Ibeggazene, S.Ibeggazene@shu.ac.uk.

## Contact information

**Type(s)**

Scientific

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None OASIS Study Team

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## **Additional identifiers**

### **ClinicalTrials.gov (NCT)**

NCT07300631

### **Integrated Research Application System (IRAS)**

341038

### **Central Portfolio Management System (CPMS)**

68734

## **Study information**

### **Scientific Title**

OASIS: SpaceOAR post-market registry study: assessing the safety and acceptability of SpaceOAR use with prostate radiotherapy

### **Acronym**

OASIS

### **Study objectives**

To document the safety, acceptability and long-term outcomes of SpaceOAR and SpaceOAR Vue hydrogel rectal spacers in subjects undergoing radiation therapy (External Beam Radiotherapy or brachytherapy) to treat prostate cancer.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 03/09/2025, East of Scotland Research Ethics Service REC 1 (EoSRES, Tayside Medical Science Centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, UK; Tel: not provided; tay.eosres@nhs.scot), ref: 25/ES/0073

### **Study design**

Observational; Design type: Cohort study

### **Primary study design**

Observational

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Prostate cancer

### **Interventions**

#### **DESIGN**

This observational multi-centre, multi-national study uses a prospective cohort design. This design was chosen because the study is intended to act as an enhanced form of post-marketing surveillance for the SpaceOAR rectal spacer system with the primary purpose of assessing the safety of the system in usual care. This device is currently under a NICE special arrangements recommendation and collection of further safety data is warranted.

#### **RECRUITMENT**

Participants will be identified as those in routine clinical care offered radiotherapy with curative intent for prostate cancer during the recruitment period for the study. All patients offered curative-intent radiotherapy for prostate cancer will be recorded in a screening log to track whether they were offered spacer insertion, whether they chose to proceed with the procedure, and whether they consented to share their contact details with the research team at Sheffield Hallam University (SHU).

The OASIS study will offer participants enhanced monitoring of their experiences with the SpaceOAR device as part of their usual care. When patients are approached by their clinician regarding the possibility of spacer implantation, they will be informed that additional data collection is required for all participants receiving the device. To facilitate this process, a research team at Sheffield Hallam University (SHU) are conducting a formal study at certain NHS sites across the UK. Clinicians will explain that, if the patient chooses to proceed with the spacer, their routine safety data will be included in the study with their consent. Additionally, participants will be invited to complete questionnaires, which will provide valuable data if they are agreeable to this.

The participant's direct care team will first seek verbal consent to share their contact details to the research team at SHU. The direct care team will also provide the participant with a Patient Information Sheet and securely forward the patient's referral details to the SHU research team via encrypted email.

A member of the SHU research team will then contact the prospective participant by telephone to offer further information about the study and, if necessary, provide another copy of the Patient Information Sheet. The prospective participant will have opportunity to review the study materials and discuss any aspects of the study with the SHU research team, including questionnaire and data collection processes.

If the participant decides to take part, informed consent will be obtained over the telephone. The SHU researcher will then enrol the participant into the study during the same call.

## DATA COLLECTION

### PROMS:

Participants enrolled into the study will be asked to complete a series of Patients-Reported Outcome Measures (PROMs):

- prior to their spacer insertion (remotely - telephone - usually during the consent call)
- on the day of their spacer insertion (in person)
- on the day of radiotherapy initiation (in person)
- 75 days post-spacer insertion (remotely - online or post)
- 6 months post-spacer insertion (remotely - online or post)
- 12 months post-spacer insertion (remotely - online or post)
- 24 months post-spacer insertion (remotely - online or post)
- 36 months post-spacer insertion (remotely - online or post)

### PROMs include:

- EPIC-26: A 26-item multiple choice questionnaire assessing symptoms and quality of life impacts of prostate cancer treatment.
- Vaizey Incontinence Score: A 7-item scoring system to measure the severity of faecal incontinence
- International Prostate Symptoms Score (IPSS): A 8-item scoring tool evaluating urinary symptoms
- Symptoms Index: A 16-item scoring system to assess the impact of prostate cancer treatment.

Completion of the PROMs is expected to take approximately 10-20 min, based on feedback from a PPIE group. Those participants who choose to complete PROMS online will receive either login credentials or a secure unique web link, allowing them access the questionnaires from any internet-enabled device, such as a computer, tablet, or smartphone.

In addition to the above, participants will also be asked to complete a SpaceOAR-specific patient reported questionnaire immediately after their SpaceOAR insertion, or within 10 days of the procedure, prior to radiotherapy. Usual care for patients who have received a spacer insertion includes outpatient appointments at approximately 75 days, 6-month, 12-months post-procedure.

As part of the study, participant may be invited to attend additional follow-up appointments at 24 and/or 36 months post-spacer insertion to monitor and record any adverse events. These follow-ups may take the form of a brief telephone consultation with their direct care team, or an

outpatient appointment. These additional follow-ups are not typically part of standard care, however any clinical data collected will be used by the direct care team to inform the patient's ongoing care.

#### Case Report Forms:

The participant's direct care team and NHS site research staff will be responsible for completing CRFs for all consented participants to capture data on associated treatments, radiotherapy treatment plans and adverse events at each study timepoint. Additional study CRFs - such as SAE reports, study Withdrawal forms and Notification of Death -will also need to be completed by the NHS research team as required.

#### STUDY TIMELINE

Protocol finalisation, database development and internal review, ethical approval, site recruitment, site set-up, participant recruitment, 12-month recruitment report, follow-up data collection and monitoring, site closure, data analysis, preparation of final study report, archiving.

#### INTERIM REPORTING

A 12-month recruitment report is planned to be produced up to 15 months following the recruitment of participants in both the UK and France. No interim analysis is planned.

Researcher bias is not anticipated to be a concern in this study as the main data sources are routine clinical adverse event reporting and self-administered questionnaire data. Furthermore, the study research team and sponsor will be acting independently of the device manufacturer.

#### Intervention Type

Device

#### Phase

Not Applicable

#### Drug/device/biological/vaccine name(s)

SpaceOAR

#### Primary outcome(s)

1. Proportion of subjects experiencing symptoms (PROMs), adverse events (CTCAEv5.0) or abnormal imaging (MR/CT) related to the procedure of SpaceOAR/SpaceOAR Vue System hydrogel within 30 days of implantation (as adjudicated by the independent Clinical Events Committee)
2. The proportion of subjects with Grade  $\geq 2^*$  gastro-intestinal/ano-rectal (GI) toxicity (CTCAE v5.0) within 3 years of receiving radiation therapy

#### Key secondary outcome(s)

1. Proportion of subjects with relevant Grade  $\geq 2^*$  gastro-intestinal/ anorectal (GI) toxicity at 12, 24 and 36 months
2. Proportion of subjects with relevant Grade  $\geq 2^*$  genitourinary (GU) toxicity at 12, 24 and 36 months
3. Impact of treatment on bowel function as measured on the bowel domain of EPIC26 up to 3 years post radiation therapy (PROMs)
4. Impact of treatment on urinary, sexual, and overall Quality of Life (QoL) (EPIC26) assessments up to 3 years post radiation therapy (PROMs)
5. Physician rating of SpaceOAR/SpaceOAR Vue placement on a Likert scale of 1 (very difficult)

to 5 (very easy) at time of spacer insertion

6. Patient-reported perception of procedure relative to biopsy procedure at time of spacer insertion

7. Overall mortality and causes of mortality at 3 years

8. Selection criteria for placement of SpaceOAR/SpaceOAR Vue system

9. Onset time of Grade  $\geq 2^*$  gastro-intestinal/ano-rectal toxicity

10. Onset time of Grade  $\geq 2^*$  genito-urinary toxicity using EPIC-26 and IPSS

### **Completion date**

31/01/2030

## **Eligibility**

### **Key inclusion criteria**

1. All patients with a clinical diagnosis of prostate cancer planned to undergo treatment with curative intent at selected sites in the UK subject to SpaceOAR being used as usual standard of care

2. Age  $\geq 18$  years old

3. Capacity to provide verbal, informed consent for participation over the telephone

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

18 years

### **Upper age limit**

100 years

### **Sex**

Male

### **Total final enrolment**

0

### **Key exclusion criteria**

Patients lacking the capacity to provide informed consent, including those unable to understand verbal explanation or written information in English, or who have specific communication needs

### **Date of first enrolment**

24/11/2025

### **Date of final enrolment**

01/03/2027

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

**Chesterfield Royal Hospital NHS Foundation Trust**

Chesterfield Road

Calow

Chesterfield

England

S44 5BL

## Study participating centre

**Maidstone and Tunbridge Wells NHS Trust**

The Maidstone Hospital

Hermitage Lane

Maidstone

England

ME16 9QQ

## Study participating centre

**East and North Hertfordshire Teaching NHS Trust**

Lister Hospital

Coreys Mill Lane

Stevenage

England

SG1 4AB

## Study participating centre

**Royal Free London NHS Foundation Trust**

Royal Free Hospital

Pond Street

London

England

NW3 2QG

## Study participating centre

**Guy's and St Thomas' NHS Foundation Trust**  
St Thomas' Hospital  
Westminster Bridge Road  
London  
England  
SE1 7EH

**Study participating centre**  
**The Clatterbridge Cancer Centre NHS Foundation Trust**  
Clatterbridge Hospital  
Clatterbridge Road  
Bebington  
Wirral  
England  
CH63 4JY

**Study participating centre**  
**Norfolk and Norwich University Hospitals NHS Foundation Trust**  
Colney Lane  
Colney  
Norwich  
England  
NR4 7UY

**Study participating centre**  
**Burnley General Hospital**  
Casterton Avenue  
Burnley  
England  
BB10 2PQ

## **Sponsor information**

**Organisation**  
Sheffield Teaching Hospitals NHS Foundation Trust

**ROR**  
<https://ror.org/018hjpz25>

# Funder(s)

## Funder type

Industry

## Funder Name

Boston Scientific Corporation

## Alternative Name(s)

Boston Scientific, Boston Scientific Corp., BSC

## Funding Body Type

Government organisation

## Funding Body Subtype

For-profit companies (industry)

## Location

United States of America

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 2.0		28/10/2025	No	Yes