Study name: OASIS: SpaceOAR PoSt – Market Registry Study: assessing the safety & acceptability of SpaceOAR use with prostate radiotherapy
Study site: <insert name of **Study site** where Study procedure will take place>
Study Site Principle Investigator: <insert Study PI name>

We'd like to invite you to take part in our research study.

- Your hospital is taking part in a new study to collect information about hydrogel rectal spacers in patients undergoing radiation therapy for prostate cancer.
- Before you decide whether to take part, we (the study team) would like you to understand what this involves.
- Please read this information carefully and take time to decide whether you would like to take part. You can also discuss it with your relatives or friends if you wish.
- You are free to decide whether or not to take part. If you choose not to it will not affect your care in any way.
- You can keep this information sheet to remind you about the study.
- If you have any questions, please contact the study team using the details on this page.

Thank you for reading this information sheet

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How to contact us

If you have any questions about this study, please contact:

OASIS study research team
Sheffield Hallam University (SHU)
Telephone: 01142253586
Email: sth.oasis@nhs.net

Summary

- **In this research study we will use information from you and your medical records.**
- **We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study.**
- **Everyone involved in this study will keep your data safe and secure. We will also follow all appropriate privacy rules**
- **At the end of the study, we will save some of the data in case we need to check it, and for future research.**
- **We will make sure no-one can work out who you are from the reports we write.**
- **This information pack tells you more about this.**

1 – Why are we doing this study?

The purpose of this study is to collect information about patients' experiences with the Space OAR/SpaceOAR Vue Systems (hydrogel rectal spacers). 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. We want to collect further information about the side effects that people get after radiotherapy to treat prostate cancer when they have a spacer inserted, and the long-term safety of these spacers. We aim to collect information about urinary, sexual, and bowel side effects and overall quality of life for prostate cancer patients undergoing radiation therapy with a hydrogel rectal spacer.

It is now a requirement by the National Institute of Care Excellence (NICE) that updated information about the safety and long-term outcomes of SpaceOAR and SpaceOAR Vue hydrogel rectal spacers in patients undergoing radiation therapy to treat prostate cancer, needs to be collected. This study will provide information for this NICE requirement across multiple hospitals in the UK.

2 - Why am I being asked to take part?

Your hospital clinic /cancer treatment centre has joined the study, and you are being asked to participate in this study because you have a confirmed diagnosis of prostate cancer, your doctor has recommended you undergo radiation therapy, and you are planning to undergo implantation of a SpaceOAR hydrogel spacer. This study aims to collect data from people like you who are receiving a SpaceOAR hydrogel spacer as part as your standard healthcare treatment about your treatment experience. Your decision to take part in this study or not only affects if we collect information from you and your healthcare team and will not change the care you receive.

3 - What will happen if I decide to take part in the study?

Do I have to take part?

No, your participation is voluntary, and you may withdraw your consent to take part at any time, without giving us a reason. Withdrawal from the study will not affect the standard of care that you receive.

If you would like to withdraw from the study, please contact the OASIS research team on 01142253586 or sth.oasis@nhs.net or a member of your clinical care team at your hospital. If you choose to withdraw you can stop taking part immediately and no further data will be collected from you.

You may also withdraw from the collection of study questionnaires only – in this case we would continue to collect and monitor your safety data only.

What will happen to me if I agree to take part?

During one of your routine appointments, your clinical team may tell you about the OASIS study. If you are interested, and give your permission, your clinical team will share your contact details with the OASIS research team at Sheffield Hallam University. A researcher from Sheffield Hallam University will contact you to arrange a convenient time to discuss the study in more detail. They will also send you this information sheet, if you have not already received it from your clinical team.

You will have the opportunity to ask any questions you may have about the study. The researcher will then check your eligibility. If you decide to take part, they will go through the consent process with you over the phone. The researcher will read through a series of questions regarding your participation in the study and record your responses on the form on your behalf. A copy of the completed consent form will be sent to you for your record, a further copy will be sent to your clinical team to be filed in your medical notes.

As part of this phone call, the researcher will also ask you a few questions about your medical history and invite you to complete some short multiple-choice questionnaires about your health and prostate cancer symptoms.

If you consent to take part and are found to be eligible, your health care team will be notified. If, for any reason, you are not eligible or decide not to participate in the study, your health care team will be kept informed.

During the study, you will be asked to complete questionnaires over a maximum period of 36 months from the date you receive a spacer, and your doctor or health care professional will record health and safety data in your notes, which is part of standard care. The multiple-choice questionnaires will ask questions about your quality of life which are related to your 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 your radiotherapy treatment. Follow up appointments arranged by your hospital normally stop about 24 months after your cancer treatment. These are often telephone appointments with a doctor or a nurse to monitor your health after radiotherapy. By taking part in the study, you will be asked to continue to have these appointments up to 36 months after your 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 you consent to take part in the study, and then at 75 days, and 6, 12, 24 and 36 months after the hydrogel spacer implantation. You will be sent reminders to complete the questionnaires at the appropriate time points. The questionnaires will ask you about your health and quality of life related to prostate cancer. In most cases you will only have one six page questionnaire booklet to complete which can take 10-20 minutes to complete. If you would prefer a paper questionnaire booklet, this can be sent out to you for completion and returned via the post. We can help you to complete the questionnaires over the phone if required. You will also complete questionnaires during two hospital visits: when you have the hydrogel spacer implanted, and when you start your radiotherapy. Your participation in the study will finish after your 36-month visit and questionnaire completion.

We would like to collect data about you from your medical records to avoid asking you more questions about your recent care. Your medical records are held by your hospital and will only be accessed by a member of your local health care team to collect key information to support study outcomes. We send and receive data via secure methods that maintain confidentiality. Your data will be sent to the study team at Sheffield Hallam University who are coordinating and analysing the data on behalf of the NHS investigators.

If you do not wish to complete questionnaires during the study but are willing to only allow us to collect data from your medical records, you can choose to take part in the study on this basis. If you do not wish to continue to complete questionnaires, then please contact the research team on 01142253586 or sth.oasis@nhs.net.

The Participant Journey

At your hospital appointment to discuss your hydrogel spacer implant	• You have given verbal consent for a research to contact you to discuss the study further.
After your appointment	• A researcher from Sheffield Hallam University will contact you by phone to discuss the study. • If you agree take part in the study, they will document your consent & ask you questions about your medical history. • You will be sent some short questionnaires to complete, by post or online, as you prefer.
At your spacer implantation appointment	• Your doctor or nurse will ask you to complete some study questionnaires during the appointment. • Your doctor or nurse will record relevant information in your medical notes and some of this information will be sent to the research team.
At your first appointment to have radiotherapy	• Your doctor or nurse will ask you to complete some study questionnaires during the appointment. • Your doctor or nurse will record safety information in your notes and some of this information will be sent to the research team.
75 days, and 6, 12, 24, and 36 months after your spacer implantation	• You will have a hospital appointment either in person or on the phone and your doctor or nurse will record safety information in your notes. • You will be sent a questionnairebooklet to complete by the research team.

You will not receive any additional treatments, medicines or blood tests if you take part in this study. This study is about the collection of information only.

4 - What are the benefits and risks of taking part?

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

5 - How will we use information about you?

We will need to use information from you and from your medical records, for this research project. For example, details regarding the clinical care you receive and changes to your health that are potentially related to your standard treatments

This information will include your NHS number, name, month of birth and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Sheffield Teaching Hospitals NHS Foundation Trust is the sponsor of this research and are responsible for looking after your information. We will share your information related to this research project with the following types of organisations:

- UK University team (Sheffield Hallam) responsible for delivering the research
- Research database provider based outside of the UK (in France)

We will keep all information about you safe and secure by:

- Only transferring data using secure methods
- Hosting study data in a secure database

- Only allowing people who work on the study to access study data
- Anonymising your data so that only your care team or the study research team can identify you from the study dataset

International transfers

As above, we will need to share data about you outside the UK for research related purposes to:

- Research database providers for hosting the study data in a secure database

We will only share the data that is needed. We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when this is legally required. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website: https://ico.org.uk/for-organisations/report-a-breach

How will we collect this information?

Data from me:

We will ask you to complete a total of eight questionnaire booklets over 36 months. The first booklet would be completed by you once you have verbally consented to take part in the study. You will be asked to complete questionnaires at your hospital appointments when the hydrogel spacer is implanted and when your radiotherapy starts. We will also contact you again at 75 days, and 6, 12, 24 and 36 months after you had your hydrogel spacer

implantation, to ask you to fill in another set of questionnaires. Please let us know if your personal details change during the study (address/email/phone). If you would like any help in completing the questionnaires we can arrange for a researcher to contact you. You will also be sent reminders, by your preferred method of contact, to complete the questionnaires at the appropriate time points.
Most questionnaire booklets will take about 10-20 minutes to complete but the questionnaires you complete at your two hospital appointments may take up to 25 minutes.

Data about me:

We would like to collect data about you from your medical records to avoid asking you more questions about your recent care. Your medical records are held by your hospital, and we will ask a member of your local health care team to collect key information to help us answer the study questions only.

We send and receive data via secure methods. Your data will be sent to Sheffield Hallam University and hosted and processed on a secure study database by our external database provider (Medsharing).

6 - Will my information be kept confidential?

Yes. Your name or personal details will not be known to anyone other than the study team and your healthcare team. No information from this research will be given to anyone outside of the study team. Your responses will be treated confidentially and remain anonymous to those outside the study team. The information will be treated as strictly confidential, and will be securely kept by the study team at Sheffield Hallam University and managed in accordance with the General Data Protection Regulation (GDPR) and all necessary clinical and research governance procedures. Any publications produced from this study will ensure participant names and other identifiable information will not be included.

The information needed for the study will be collected on electronic forms and sent by secure methods to the study team at Sheffield Hallam University (in some cases paper forms will be required and these will be sent by

standard Royal Mail post). Information may also be completed by you online and stored at Sheffield Hallam University. You will be allocated a study number, which will be used along with your initials, and month/year of birth to identify you on each paper and online form. The connection between your code and your name will be kept secured at Sheffield Hallam University.

Although the information we collect about you is confidential, should you disclose anything to us which we feel puts you or anyone else at risk, we may feel it necessary to report this to the appropriate persons.

What will happen to my data?

During this study, your personal data (such as age, gender, date of birth or other information that could identify you) and medical information will be collected by the study team and processed for the purpose of the study. Research is a task that we perform in the public interest. All information collected during this study will be kept strictly confidential in line with good clinical practice guidelines. Sheffield Teaching Hospitals (STH) NHS Foundation and Sheffield Hallam University (SHU) will act as joint Data Controllers for this study under the General Data Protection Regulations (GDPR). This means that we, as Sheffield Teaching Hospitals and Sheffield Hallam University, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. Where anonymisation of documentation is required, your hospital is responsible for ensuring only the instructed identifiers are present before sending to Sheffield Hallam University.

Sheffield Hallam University (SHU), Sheffield Teaching Hospitals (STH) will use your name and contact details to contact you about the research study and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from SHU, STH and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The people who analyse the information collected in the study will not be able to identify you and will not be able to find out your name or contact details.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 15 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team:
- by sending an email to sth.oasis@nhs.net
- by ringing us on 01142253586

How will my information be accessed and stored?

Your hospital will collect information from you and/or your medical records for this research study in accordance with our instructions. Your hospital will make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the study team, sponsor or regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your hospital will pass your name, address, email address (if applicable), and phone number to the study

team along with the information collected from you and your medical records. They will keep identifiable information about you from this study for 15 years after the study has finished.

Information collected about you will be securely entered and stored with strict arrangements about who can access the information. All email communication, and all digital data collection forms that are transferred to or from Sheffield Hallam University will be via secure, GDPR-compliant electronic systems (e.g. nhs.net email accounts). Any paper copies of data collection forms will only include study ID numbers and two identifiers, usually initials and month/year of birth.

Both electronic and paper data will be stored in keeping with Good Clinical Practice in line with National regulations after the end of the study, when paper data will be disposed of with confidential waste and electronic data no longer required for analysis, will be deleted. Participating hospitals will be expected to maintain a file of essential study documentation, with a template provided by the study sponsor for a duration in line with National Regulations. We will keep identifiable information about you for a maximum of 6 months after the study has finished and use these to send you information about the study results. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at Sheffield Hallam University or your hospital site after the end of the study, in case we need to check it, or check the results of the study. The study data will then be fully anonymised and securely archived for up to 15 years or destroyed. We will write our reports in a way that no-one can work out that you took part in the study.

We will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. When your data is shared outside the UK, it will be with the following sorts of organisations: a data hosting service that maintains the study database. Anyone who accesses your data outside the UK must do what we tell them, so that your data has a similar level of protection as it does under UK law.

You can stop being part of the study at any time (section 7), without giving a reason, but we will keep the information about you that we already have. You have the right to ask us to remove, change or delete data we

hold about you for the purposes of the study. We might not always be able to do this as we need to manage your information in specific ways in order for the research to be reliable and accurate and if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop.

To safeguard your rights, we will use the minimum personally-identifiable information possible. Further available at:
https://www.sheffieldclinicalresearch.org/for-patients-public/how-is-your-information-handled-in-research

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. You can find out more about how we use your information by contacting the study team using the contact details on the front of this form.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research. The Health Research Authority has published information for research participants at: www.hra.nhs.uk/patientdataandresearch

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). Our Data Protection Officer can be contacted using the following details:
Sponsor: sth.infogov@nhs.net
Study Team: dpo@shu.ac.uk

Future research

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. The information we collect about your health and care may be made available to other researchers, in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used to conduct research in accordance with relevant legislation, ethics and NHS research policy requirements. It will not be used to make decisions about future services available to you, such as insurance.

You will be specifically asked about whether you want your data to be used in future research. If you say no, you will still be able to participate in this study.

7 - More information about taking part.

Will I be reimbursed for my participation?

No payment will be made to you for your participation in this study. We purposely designed the study visits to coincide with your standard medical care and any follow-ups after your standard care visits end can mostly be done over the telephone, therefore you should not incur any extra costs by taking part in this study.

What happens at the end of the study?

After you have completed all of the evaluations during the 36 months of this study, you will have completed the study and will continue standard of care visits with your doctor.

What will happen if I don't want to carry on with the study

Your participation in the study is voluntary. You may choose not to be in the study, and you may withdraw from the study at any time. If you choose not to be in the study or to stop being in the study at any time, there will not be any negative impact to the care or treatment you receive, or any loss of benefits to you. In addition, if you withdraw from the study, it may be necessary for us to continue using the information collected about you up to the point that you withdraw, in accordance with your study consent. Any participant can withdraw from

providing more data at any point during the study without providing reason nor justification. All data collected up to that point will be included. All safety reporting will be continued by your doctor or health care professional and included in the final analysis, in line with clinical safety data collection. By signing this consent form, you agree to be contacted and/or to have your medical records and public records accessed by these parties to confirm your health status.

Who is sponsoring this study?

Sheffield Teaching Hospitals Foundation Trust (STH) is the sponsor for this study.

Who has reviewed the study?

This study has been reviewed and approved by the East of Scotland Research Ethics Committee. The refence number of the review is IRAS 341038 - 25/ES/0073

Who is funding the study?

The OASIS Study is being funded by Boston Scientific, manufacturer of the SpaceOAR Systems.

What if there is a problem?

Sheffield Teaching Hospitals (STH) is insured to protect research participants. Your well-being will always be our priority. We believe that this study is safe and do not expect you to suffer any harm or injury because of your participation. However, Sheffield Teaching Hospitals has agreed that if you are harmed as a result of your participation in the study, you will be compensated. In such a situation, you will not have to prove that the harm or injury which affects you is anyone's fault. These special compensation arrangements apply where harm is caused to you that would not have occurred if you had not taken part in the study. These arrangements do not affect your rights to pursue a claim through legal action.

What if I have some questions about the study?

If you would like to talk to someone in more detail or have any questions, then please contact the study team using the details listed on the first page of this document. You can also contact any of the following team members:

Dr Said Ibeggazene	Dr Grace Price	Professor Derek Rosario
Project Manager	Project Co-ordinator	Chief Investigator
01142255562	01142255839	0114 2261399
S.ibeggazene@shu.ac.uk	Grace.price@shu.ac.uk	derek.rosario@nhs.net
Sheffield Hallam University, Collegiate Campus, Collegiate Cres, Broomhall, Sheffield S10 2BP		Sheffield Teaching Hospitals, Royal Hallamshire Hospital, Glossop Rd, Broomhall, Sheffield S10 2JF

Thank you for taking the time to read this information.