Participant Information and Consent Form

Short Name of Project	Single J Ureteric Stents following Ureteroscopy
Full Name of Project	Observing the migration rates and patient-reported stent-related outcomes of Single J Ureteric Stents following Ureteroscopy
Coordinating Principal Investigator	Joseph Ischia
Principal Investigator	Anthony Ta
Associate Investigator	Varun Buhariwalla
Project Sponsor	Nil
Austin Health	Austin Hospital

1. What am I being invited to do?

You are invited to take part in this research project. This is because you are having a Urological Surgical procedure as part of your standard of care that requires insertion of a ureteric stent. If you take part, we will ask you to answer a validated questionnaire about your symptoms and experience with a single-J ureteric stent which is a different form of the most common ureteric stent that is used.

Around 40 patients will take part in this project. They will be all be from Austin Health - Austin Hospital or the Heidelberg Repatriation Hospital
This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.
Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

2. What is the purpose of this project?

Following a Ureteroscopy that involve instrumentation of the ureters (tube which drains the kidney), such as laser fragmentation of kidney stones, it is gold-standard of practice in

Australia and across the world to insert a synthetic plastic-like stent which keeps your ureter open, patent and allows it to drain well in the instance of any swelling or debris. This stent unfortunately comes with some bothersome symptoms to patients such as discomfort, blood in the urine, and urgency or frequency of urine – all of which resolve with removal of the stent.

We are trialling a modified version of the standard double-J (double curl) stent which we aim to have fewer bothersome symptoms but provide the same safe standard of care after a Ureteroscopy. There is currently not a lot of research comparing the 2, and how it can possibly be a benefit to patients. A supplementary form with images of the common and new modified stent will be provided to you.

3. Do I have to take part and can I change my mind?

Your participation is entirely voluntary. You do not have to take part in this study, and if you choose not to take part you will receive the usual treatment/care. If you do agree to take part you are free to withdraw from the study at any time, without having to give a reason and this will in no way affect your current or future health care. You may refuse to participate or leave at any time without penalty or loss of benefits to which you are otherwise entitled.

Your participation in the study may be ended, by the study doctor or sponsor at any time and without your consent if:

- the study is stopped;
- if it is in your best interest;
- you fail to come to your regularly scheduled appointments;
- you participate in any other research projects without getting the approval of the doctor on the study.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

4. What do I have to do if I take part?

If you take part in this project, you will be in it for 2-4 weeks.
This table below outlines what you need to do in this project. For more information, please ask a member of the project team.

What part of the project?	What do I have to do?
When you start the project	Answer a single page Questionnaire (2 mins) about your symptoms with your current Double-J Stent inside
When you start treatment	Provide informed consent for the use of the modified stent in your standard care

During the project	Keep a mental track of your symptoms of urinary urgency, frequency, pain and blood in the urine – and how they compare to the previous stent
At the end of your project participation	Complete a repeat of the single page Questionnaire relating to your symptoms with the new stent. Report any adverse effects
After the project completes	Nothing more is required

Your time and expenses

You will be enrolled for approximately 2-4 weeks total in this study. And your only time commitment will be completing the short validated questionnaire twice which takes about 2-3 mins each time.

No financial incentives will be offered. Participation is voluntary and all stent procedures are part of standard care, aside from the investigational stent modification.

5. What are the benefits of taking part?

By taking part, you will help the researchers understand more about the safety and effectiveness of Single-J stents. This knowledge may help people in the future.
You may or may not directly benefit from taking part in this project. There is potential for reduced stent symptoms and discomfort. Contribution to research aimed at improving stent tolerability and quality of life for future patients.

6. What are the risks and discomforts of taking part?

There are some Known risks that will be there inherent to your procedure, regardless of your participation in the study and some additional risks specific to our modifications

Risks of Ureteroscopy, Ureteral Stenting

All ureteric stents have **known** side effects. The possible known side effects from the inherent procedure and stent you have are listed in the table below. Most of the side effects are rare. Some rare side effects may be serious. There may also be side effects that are unknown. Many side effects go away after you stop taking a medicine. Others can last a longer time or forever.

You should talk to a doctor urgently if you start to feel unwell during this project.

Very Common side effects	**Common side effects**	**Rare side effects**
More than one in 10 people will experience these side effects	More than one in 100 people will experience these side effects	People will only experience these side effects in unusual cases

Risks inherent to ureteroscopy (URS) and ureteral stenting include: • Haematuria (blood in urine) • Dysuria (painful urination) • Urinary tract infection (UTI) • Stent-related discomfort and pain	• Unknown impact on urinary symptoms compared to standard Double-J stent (DJS) • Urinary tract infection (UTI)	Risks specifically related to the **modified Single-J stent (SJS)**: • Because the Single-J stent has no lower curl in the bladder, there is a possibility that it may move out of position ("migrate"). Migration is rare with standard Double-J stents, but this study is being conducted specifically to investigate whether migration occurs more often with the Single-J design. • If migration does occur, it may require an additional procedure to replace or adjust the stent. • Other risks (such as infection or discomfort) are expected to be similar to those of standard stents.

7. How will my information be used for this project?

This section tells you how this project will collect, store, use, and share and/or dispose of your information. If you do not want us to collect this information, you cannot participate in this project.

Collecting your information
We will collect information for the project from your medical record, during your operation and directly from you

Keeping your information safe
To keep your information safe, we will:

- follow all relevant privacy requirements
- All study-related records, including electronic case report forms (eCRFs), will be securely stored in a REDCap (Research Electronic Data Capture) database hosted on a secure institutional server.
- take steps to prevent anyone from accessing information that identifies you unless they are authorised to do so, such as the project sponsor.
- give information and samples a code and keep them separate from your name or contact information.

You can ask us to tell you what information we have collected about you as part of this project. If your information is not correct, you can also ask us to change it. If you have any complaints about how we are managing your personal information, you can contact the Austin Health Complaints Officer

Physical documents such as signed consent forms will be stored in locked filing cabinets within restricted-access areas of the study site.

Data will be retained for a minimum of **15 years** following study completion, in accordance with institutional policies and relevant regulations.

After the retention period, data will be securely destroyed or anonymized to protect participant confidentiality.

Publishing project information

We will share certain information from this project so that others can use it and understand the study findings. This project information does not identify you individually/is limited to de-identified scores to make it hard to identify you. We will make this project information available through journal articles, presentations. **By being in this project, you agree to us sharing project information for these purposes**.

8. How will my information be shared for future research?

Sharing your Questionnaire scores and demographic data may help improve new research projects in the future. **We will also ask you to consider sharing your** Questionnaire scores and demographic **data, for 'future research'**. When we share your data, we will take steps to make it difficult for anyone to link this data back to you. This includes removing information that could easily identify you, like your name or contact information. There is still a small chance that someone could identify you again.

If you agree, we may share your data for research that is very similar to this project or research that is very different. The researchers may be in Australia or overseas. They may work for a commercial organisation like a pharmaceutical company or medical device company.

If you agree to share your data, you will not be told about the future research projects or any results from these projects.

If you change your mind, you have the option to ask us to stop sharing your data. However, if your data have already been shared, it may not be possible to retrieve or destroy them.

9. Who is running and paying for this project?

This project is being run and organised by Austin Health Urology Department
The site is receiving no funding

10. What happens if something goes wrong?

In an emergency, you should call 000 or go to the emergency department at your nearest hospital. If your injury is not urgent, you should contact us. We can help you organise medical care. If you experience any health problems while you are in this study, you should contact the research team immediately. All side effects or complications will be recorded and managed. Serious complications will also be reported to the hospital's Human Research Ethics Committee, who oversee the safety of participants in research.

If you are harmed because of taking part in this project, contact the Principal Investigator Dr Anthony Ta. We will talk about treatment options with you and your doctor. You may also be able to take action through the courts. You may wish to seek independent legal advice. If you are eligible for Medicare, you can receive the treatment you need to treat the harm free of charge as a public patient in any Australian public hospital.

11. Who has reviewed and approved this project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Austin Health.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2018). This statement has been developed to protect the interests of people who agree to participate in human research studies.

Comments or complaints about how this project is being run

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Complaints Officer
Telephone	03 9496 3566

Email	feedback@austin.org.au

12. Where can I find more information?

Thank you for taking the time to read this information about our project. You can contact a member of the project team at any time to ask questions.

- **In a medical emergency**: Call 000 or go to the nearest hospital emergency department.
- **If you feel unwell after hours and it is urgent but not life-threatening**: Call Austin Health switchboard (03 9496 5000) and ask for the on-call Urology Registrar.
- **For general study questions during business hours**: Contact Dr Anthony Ta (Principal Investigator) via Austin Health Urology Unit or email (anthony.ta@austin.org.au).

Clinical contact person

Name	Anthony Ta
Position	Primary Investigator
Telephone	Via Austin Urology Unit / Austin Switch Board 03 9496 5000
Email	Anthony.ta@austin.org.au

13. Signature Page

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Coordinating Principal Investigator	Joseph Ischia
Principal Investigator	Anthony Ta
Associate Investigator	Varun Buhariwalla
Site	Austin Health

Consent to take part in this project: This means you can say NO		
By signing this consent form, I acknowledge that: • I freely agree to take part in this project • I understand that I can stop taking part in the project at any time • I have read, or have had read to me, the information provided about this project and understand what is involved including the use of my personal information • I have had the opportunity to consider the information, ask questions and am satisfied with the answers I received		
Consent to future use of information and samples [Delete section if not relevant]	**Yes**	**No**
I agree to my individual data being collected, stored and shared for **any** future research	☐	☐

Person taking part in the project

Signature: _____ Date: _____

Name: _____

Person conducting the informed consent discussion

I have explained the research project, its procedures and risks to the potential participant and I believe they have understood that explanation.

Signature: _____ Date: _____

Name: _____

Witness (where decision-maker has required assistance to read this form)

Signature: _____ Date: _____

Name: _____

Each person must sign and personally date this consent form

Charter of Healthcare Rights

Your healthcare, safety and rights		رعايتك الصحية وسلامتك وحقوقك.	
Sự chăm sóc y tế, an toàn và quyền của quý vị		您的护理，安全和权利	
Η ιατρική σας φροντίδα, ασφάλεια και τα δικαιώματά σας		您的護理，安全與權利	
Ваша здравствена нега, безбедност и права		Vaša zdravstvena njega, bezbjednost i prava	
Вашата здравствена нега, безбедност и права		La vostra assistenza sanitaria, sicurezza e diritti	