Austin HEALTH

Place Patient Label Here

Participant Information Sheet/Consent Form
Operating Room Participants

Interventional Study - *Adult providing own consent*

Title	A feasibility pilot study of the efficacy, reliability, safety and patient experience of the JiffyStent ureteric stent inserter
Short Title	Evaluation of the JiffyStent Inserter in patients requiring a ureteric stent.
Protocol Number	JSI001
Project Sponsor	JiffyStent Pty Ltd
Principal Investigators	Dr Marlon Perera
Associate Investigator(s)	Dr Patrick Gordon, Dr Gregory Jack
Location	Austin Health

Part 1 What does my participation involve?

1. Introduction and invitation to participate

You are invited to take part in this research project. This is because you require a ureteric stent as part of your standard urological procedure. The research project is testing a potential new device for inserting a ureteric stent. This new device is called JiffyStent Inserter.

This Participant Information Sheet/Consent Form tells you about the research project. It explains what is involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask your doctors or trial staff questions about anything that you find distressing, 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 may decline to participate for any reason including if you don't have enough time, are feeling too distressed or in too much discomfort. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project

- Consent to have the tests and procedures that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

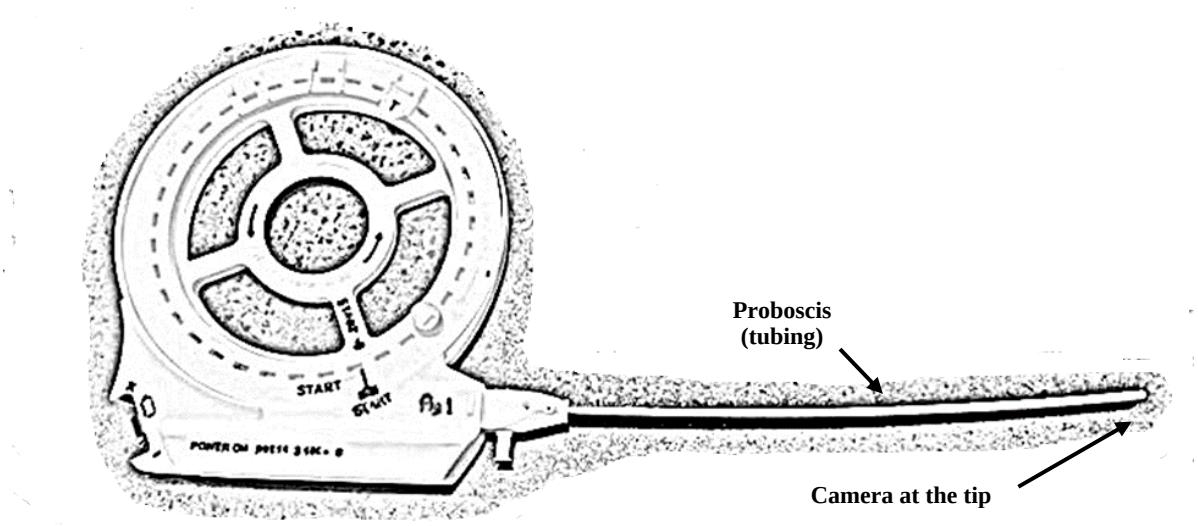
2. What is the purpose of this research?

People often come to the emergency room because they are in intense pain due to a kidney stone blocking the ureter (tube that connects the kidney to the bladder). To ease pain and to help clear the blockage, many people will require a ureteric stent.

Ureteric stents are usually inserted in the operating room with a large array of specialised equipment. There is often a long delay while waiting to get into the operating room for a stent insertion procedure.

This study is investigating a new medical device that allows a Urologist or Emergency Department Physician to insert a ureteric stent while the patient is in the emergency room. The purpose of this research project is to determine if the JiffyStent ureteric stent inserter is a safe, reliable and a feasible way of inserting a stent into the ureter.

The JiffyStent Inserter is a novel medical device that aims to provide visualisation of the ureteric orifice (opening) and facilitates the insertion of an already approved stent easily and safely in the emergency department without the need for an operating room. The stent insertion will follow hospital standard practice where the stent will be inserted via the urethra, bladder and ureteric orifice (opening).



The JiffyStent Inserter is experimental, which means that it is not an approved medical device in any country. **This is the first clinical trial using the JiffyStent Inserter in people requiring a ureteric stent.** You may not receive any health benefit from the study device; but there are risks of you having a device-related injury or illness

3. What does participation in this research involve?

This study involves two study groups:

1. Patients who are having a ureteric stent inserted in the operating room as a routine part of their urological procedure.
2. Patients who require a ureteric stent because they have presented to the emergency department with a kidney stone in their ureter causing severe pain.

You are being asked to participate in Group 1.

If you choose to participate in this study, you will be asked to see your study doctor for a total of up to 3 visits over the course of 1 month. As a study participant, you will be asked to undergo the following procedures/evaluations:

Visit 1 – Screening

Before any study-related procedures are commenced, the study doctor will explain the study to you and you will have time to read this Participant Information Sheet and Consent Form and ask any questions you may have. If you agree to participate in the study, you will need to sign and date this consent form.

During this visit, you will have the following assessments and procedures:

- Your doctor and the study team will review the results of tests, procedures and information you have previously had and/or provided, this includes:
    - Medical History including past Urological History (information will be collected about your history of medical and urology health and any other medically relevant health issues.)
    - Demographics (information about your birth date and gender)
    - Your imaging scan (CT or MRI) of your kidneys ureters and bladder
    - Clinical information from your urologist

Based on the information gathered during the screening process, your study doctor will decide if participating in this study is appropriate for you.

Visit 2 – Stent Insertion

This visit maybe conducted on the same day following your screening visit or may be conducted on a separate day. The procedure will be conducted in the operating room setting. You will be asked to complete a paper questionnaire to see if you have any pain before the procedure.

You will be administered general anaesthesia, the study doctor and/or anesthetist will discuss this with you prior to your procedure. You may also be administered a single dose of oral or intravenous (in the vein) antibiotics if deemed necessary by the study doctor.

The study doctor will insert the ureteric stent using the JiffyStent Inserter. This procedure is expected to take approximately 5-10 minutes.

Parts of the procedure may be recorded (in video format) by sponsor representatives or authorised study personnel. The recording will be de-identified, this means that there will not be any identifiable information on the recording, such as your name or any identifiable personal information. The recording will be provided to the sponsor with only a study identification number. Your identity will remain confidential, and the recording will be seen only by authorised study personnel for training, troubleshooting, or observational purposes. You will be asked whether you allow the above mentioned recording prior to the procedure in the consent section.

After the procedure is completed, you will be asked to complete a paper questionnaire to see if

you had any pain during the procedure and to rate your experience. A kidney, ureter and bladder (KUB) x-ray and/or renal ultrasound will be performed afterwards to confirm stent positioning.

Visit 3: Follow Up Visit

You will need to attend the study site for one (1) follow up visit 14 to 21 days post the stent insertion. During this visit, you will be asked to complete a paper questionnaire and the study doctor will review of your general health and how you are feeling.

Additional costs

There are no additional costs associated with participating in this research project, nor will you be paid. All medications, tests and medical care required as part of the research project will be provided to you free of charge.

4. What do I have to do?

If you decide to take part in this study, there are some rules you must follow. Some of the rules are listed below. There could be other rules that your study doctor will review with you.

- You must follow the study procedures and attend all the study visits. Please inform the study doctor if you will not be able to attend a visit.
- You must follow all instructions given to you while you are taking part in this study. If you do not, you may no longer be able to take part in the study. If you are unsure about what you are supposed to do, ask your study doctor.
- You must report any changes to your well-being, including any side effects, to the study doctor.
- You must be open and honest about your health history to protect your safety in this research study.
- You must tell the study staff about any other medication or non-medication therapy you are taking or if you have any changes to your medications or non-medication therapies during the study. Tell the study doctor before you start a new medication.
- You must inform the study doctor or staff if you decide not to participate in the research study anymore. You don't have to give a reason for your decision.
- You are not allowed to take part in any other research study while you are in this research study

5. Other relevant information about the research project

This research study will recruit up to 15 participants at the Austin Hospital.

6. What will happen to my data?

Data, including questionnaire data will be entered and stored in a secure online database hosted by Austin Health. This may be stored indefinitely. Only researchers directly associated with this research will be able to access the database. Each will have a unique login and all activities are auditable.

Any data extracted and analysed from the research will be de-identified so that your name, date of birth or other contact information never appears in any research analysis.

7. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Austin Health.

8. What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options (such as proceeding with standard hospital procedure for stent insertion) are available, and your study doctor will discuss these options with you before you decide whether or not to take part in this research project.

9. What are the possible benefits of taking part?

This is a study of a new device for the insertion of a ureteric stent. Possible patient benefits from the JiffyStent Inserter include:

- More rapid relief of pain
- Less time spent in hospital
- Quicker return to home and resumption of normal activities
- No need for a general anaesthetic

We cannot guarantee or promise that you will receive any benefits from this research; however, information from this project may help to improve the management of patients with kidney or ureteric stones in the future.

10. What are the possible risks and disadvantages of taking part?

Medical treatments/procedures often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate, or severe. If you have any of these side effects, or you are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms.

Risks for General Anaesthesia:

To keep you comfortable during your procedure, you will be given some form of general anaesthesia. Your study doctor will discuss with you the type or types of anaesthesia to be used. These types of medications are commonly used for other similar procedures. You might experience the following administration of anaesthesia:

- Nausea and vomiting
- Sore throat
- Awareness under anaesthesia
- Adverse drug reactions

- Dry mouth
- Itching
- Shivering reaction
- Postoperative delirium (confusion when regaining consciousness)
- In the most serious and extremely rare cases, anaphylactic shock

Risks for Insertion Procedures

Please discuss the risks associated with any stent ureteric insertion in particular with your health professional administering this informed consent. Inserting a ureteral stent (with or without the JSI), like any medical procedure, comes with potential risks. These can include:

- Puncture of the ureter (up to 1.67 millimetre diameter hole) from the guidewire and/or ureteric stent leading to ureteral stricture (scarring that narrows of the ureter). The potential long-term effects of a ureteric stricture may include an operation to repair the stricture, or a long-term ureteric stent, or loss of the kidney.
- The guidewire (flexible tread) may double-back (u-turn) in the ureter, making it difficult to pass through into the renal pelvis. This could lead to mis-positioning of the stent, and if this happens the stent retrieved and reinserted as per the standard procedure.
- Discomfort or pain in urethra or bladder
- Urinary Tract Infection

JiffyStent Inserter Risks

There is a risk that JiffyStent Inserter will prove mechanically inferior (less effective) to the standard procedure. This may result in the failure to insert the stent in the correct position in the ureter. If this occurs, the stent will be removed and you will be taken to the operating room for the standard insertion of a stent under general anaesthesia.

Imaging Risks – X-Ray

This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.5mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be very low.

If you experience any distress during your participation in this study, please tell the study doctor or study team, and they will assist you in contacting your GP for follow-up care.

11. What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. If you do withdraw, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

12. Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The device being shown not to be effective
- The device being shown to work and not need further testing
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities

Your study doctor may decide for your medical safety to stop your study treatment or take you off the study. You may be taken off the study if your study doctor learns you did not give a correct medical history or did not follow instructions for the study. If your study treatment is stopped, your study doctor will closely monitor your overall health.

13. What happens when the research project ends?

The study device will not be available after the end of the study. If your condition requires further treatment, your study doctor will help you decide what treatment is best for you after the end of the study. Your doctor will speak to you about your health care options.

When the study is completed at all the study sites, the data will be analysed. You will have an opportunity to learn of the study results. You may ask your study doctor for the results and to have them explained to you.

Results of the study are intended to be published in medical journals, used for scientific presentations and may also be shared with, or inspected by, health authorities worldwide. The confidentiality of all patients taking part will be maintained. You will not be identifiable in any reports or publications resulting from the study. If you would like to obtain a copy of any successfully published results, please ask your study doctor.

A description of this clinical trial will be available on www.anzctr.org.au. These websites will not include information that can identify you but could include a summary of study progress and results. You can search these websites at any time.

Part 2 How is the research project being conducted?

14. What will happen to information about me?

By signing the consent form, you give permission to the study doctor and relevant research staff accessing, collecting and using your personal information and health records for the research project. Information required for this study will be collected from your questionnaires and from information recorded in your medical record. Data will be entered and stored in a secure online database hosted by Austin Health. Any information obtained for the purpose of this research project and for future related research that can identify you will remain confidential. Your information will only be disclosed with your permission, except as required by law. Information about you may be obtained from your health records held at this and other health services for the purpose of this research.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, the institution relevant to this Participant Information Sheet, Austin Health, or as required by law. By signing the Consent Form, you

authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Information about your participation in this research project may be recorded in your health records. In accordance with relevant Australian and/or Victoria privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

15. Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

16. Who is organising and funding the research?

This research project is being conducted and funded by JiffyStent Pty Ltd.

Austin Health involved will receive a payment from JiffyStent Pty Ltd for undertaking this research project. However, no member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

JiffyStent Pty Ltd may benefit financially from this research project if, for example, the project assists Rivermark Medical to obtain approval for the JiffyStent Inserter.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to JiffyStent Pty Ltd, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

17. Who has reviewed the research 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.

18. Further information and who to contact

The person you may need to contact will depend on the nature of your query.

24-hour medical emergency is available by contacting 000 or going to your nearest hospital.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on *03 9496 5000* or any of the following people:

Clinical contact person

Name	Patrick Gordon
Position	Associate Investigator and Clinical Trials Coordinator Urology, Austin Health
Telephone	(03) 9496 5000
Email	Patrick.gordon@austin.org.au

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 4090 or (03) 9496 3248
Email	ethics@austin.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Name	Austin Health Human Research Ethics Committee
Position	Manager – Office for Research
Telephone	(03) 9496 5088
Email	ethics@austin.org.au

Consent Form - *Adult providing own consent*

Title	A feasibility pilot study of the efficacy, reliability, safety and patient experience of the JiffyStent ureteric stent inserter
Short Title	Evaluation of the JiffyStent Inserter in patients requiring a ureteric stent
Protocol Number	JSI001
Project Sponsor	JiffyStent Pty Ltd
Principal Investigator	Dr Marlon Perera
Associate Investigator(s)	Dr Patrick Gordon, Dr Gregory Jack
Location	Austin Health

Declaration by Participant

I am 18 years of age or older.

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Austin Health concerning my disease for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I give permission for my data to stored and used in future research.

I understand that I will be given a signed copy of this document to keep.

I understand that the recording of the procedure is optional and that recording will be de-identified, which means that there will not be any identifiable information on the recording.

Please mark the appropriate box below:

☐ I **DO** consent to allowing the procedure to be recorded

☐ I **DO NOT** consent to allowing the procedure to be recorded

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Witness to the informed consent process

Name (please print) _____

Signature _____ Date _____

* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print)

_____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

Title	A feasibility pilot study of the efficacy, reliability, safety and patient experience of the JiffyStent ureteric stent inserter
Short Title	Evaluation of the JiffyStent Inserter in patients requiring a ureteric stent.
Protocol Number	JSI001
Project Sponsor	JiffyStent Pty Ltd
Principal Investigator	Dr Marlon Perera
Associate Investigator(s)	Dr Patrick Gordon, Dr Gregory Jack
Location	Austin Health

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Austin Health.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.