UNIVERSITY OF CALIFORNIA, SAN DIEGO
CONSENT TO PARTICIPATE IN RESEARCH

1. Study Title and Number

Title: The RELIEF Ureteral Stent – Assessment of Retrograde Urinary Reflux
Study # 809792

2. Principal Investigator

Seth Bechis, MD, MS
Associate Professor of Urology
Associate Director, UCSD-Kaiser Lap/Endourology Fellowship
Department of Urology
University of California, San Diego

3. Principal Investigator Phone Number, Research Team Number, and Emergency Contact Number

Principal Investigator Phone Number: 619-543-2869 *(available during business hours)*
Research Team Phone Number: 858-777-9721 *(available during business hours)*
24 Hour Contact Phone Number: 858-657-7000 *(for non-emergency issues after hours you may contact this number, press 0, tell them you are in a research study, and ask them to page the Urology Resident on-call)*
In the case of an emergency, dial 911 from any phone.

4. Study Sponsor

The Ureteral Stent Company, Inc., the study sponsor, is providing funding to UC San Diego to conduct this research study.

5. Study Overview

This research study is being conducted to evaluate the placement and adequacy of short-term drainage of the Relief stent.

We are inviting you to participate in a research study because you have chosen to pursue surgical treatment for your kidney stone.

This form explains the research so that you may make an informed decision about participating.

- Research is voluntary - whether or not you participate is your decision. You can discuss your decision with others (such as family, friends or another physician).
- You can say yes, but change your mind later.
- If you say no, we will not hold your decision against you.
- You can say no even if the person inviting you is part of your healthcare team.
- Your decision will not affect your health care or other benefits you may be entitled to.
- Please ask the study doctor or study team questions about anything that is not clear, and feel free to ask questions and mention concerns before, during, and after the research.
- You may consult with friends, family, a personal doctor, or anyone else before deciding whether or not to be in the study.
- You will be given a copy of this consent form and the Participant's Bill of Rights.

During surgery to treat kidney stones, it is considered standard of care - the treatment that your doctor would prescribe if you are not in the research study - to place a ureteral stent after ureteroscopy. The purpose of this

research study is to compare the Relief ureteral stent to the currently used double J (DJ) ureteral stent, and assess if there is a difference in post placement backflow of urine, pain or irritative symptoms.

Standard of care means treatment that is accepted by medical experts as the most appropriate for a certain type of disease or treatment and would be recommended if you are not participating in a research study.

You will first undergo baseline screening to determine if you are eligible for the study. If you are eligible, you will sign this Informed Consent Form and complete a preoperative questionnaire. You will then undergo surgical kidney stone removal as determined by you and your Urologist. You will be randomized to a type of stent. The type of stent you will receive will be decided by a computer program, not by you or your surgeon. The ureteral stent will be placed during surgery per Standard of Care. You will complete a postoperative questionnaire 12-30 hours after your procedure ends (Day 1). The same postoperative questionnaire will be given to you on postoperative Day 3 and 7, and the day of stent removal. You will have the ureteral stent removed during a Urology clinic appointment between postoperative Days 7-14.

The most serious risk is a breach of confidentiality, which, as explained later in the consent, is protected through several safety measures by the study team. Other risks include feeling uncomfortable while addressing some of the questions in the pain questionnaire.

A complete listing of possible risks and discomforts associated with this study can be found in Section 9 of this document.

There is a potential direct benefit to you or to others from you participating in this research. The Relief stent is suspected to provide relief from pain and discomfort during recovery after ureteroscopy. This is a potential direct benefit for the patients assigned to the Relief stent group. The knowledge to be gained from this research is whether the Relief stent provides improved pain and discomfort relief for patients who undergo kidney stone surgery. If the Relief stent provides improvement in symptoms, this will improve patient care and comfort.

Other options instead of participation in this study are to have the type of stent (either the Relief or double J (DJ) ureteral stent) that will be placed during your procedure will be decided by you and your surgeon.

More detailed information about this research study is provided below.

6. Whom can I talk to if I have questions?

If during your participation in the study you have questions or concerns, or if you think the research has hurt you, contact the research team at the numbers listed in Section 3 on the first page of this form. You should not agree to participate in this study until the research team has answered any questions you have about the study, including information contained in this form.

If before or during your participation in the study you have questions about your rights as a research participant, or you want to talk to someone outside the research team, please contact:

- UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu

7. How many people will take part?

We plan to study 50 people.

8. What happens if I take part in the research?

Here is what will happen to you if you agree to be in this study:

The RELIEF ureteral stent is an investigational device that has been approved by the Food and Drug Administration (FDA). It is being compared to a standard ureteral stent that has also been approved by the FDA. The researchers are interested in learning which device is more helpful in treating relieving urinary symptoms and pain from urine backflow (reflux) due to the ureteral stent.

As you read this form, ask questions if something is not clear.

After you are enrolled in the study via signing this Informed Consent Form, you will be randomized to one of two stent groups.

Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers choose which group you will be in. You will have a 50% chance of being placed in a specific group.

You will undergo your planned kidney stone procedure and have a ureteral stent placed per Standard of Care. The following procedures will be completed if you decide to participate in the study.

Screening/Enrollment:
- Sign Informed Consent Form
- Review and collection of demographic information, medication lists and review of medical records.

Day 0: Ureteroscopy and Stent Placement
- Medical chart review and medication record review
- Randomization to RELIEF stent or Standard of Care DJ stent

Day 1: Post-op Visit 1 (phone call)
- Medical chart review and medication record review
- Complete Ureteral Stent Symptom Questionnaire (USSQ) and 10-point pain scale surveys

Day 3: Post-op Visit 2 (phone call)
- Medical chart review and medication record review
- Complete USSQ and 10-point pain scale surveys

Day 7-10: Stent Removal (in-person)
- Medical chart review and medication record review
- Complete USSQ and 10-point pain scale surveys before removal

Day 9-12: Post-removal Visit 4 (phone call)
- Medical chart review and medication record review
- Complete USSQ and 10-point pain scale surveys

The USSQ is a questionnaire that will allow researchers to assess any possible symptoms related to the ureteral stent you will have placed.

Medical records to be reviewed include relevant labs, imaging, Urology clinic visit notes, and current medications related to your kidney stone condition.

If you decide not to participate in this research study, you will still have the ability to request that your surgeon use either the Standard of Care DJ stent, or the Relief stent.

Procedures	Screening/ Enrollment Day -90 to -1	Stent Placement (Day 0)	Post-Stenting Phone call Visit 1 (Day 1)	Follow up Phone call Visit 2 (Day 3)	Stent Removal In Person Visit 3 (Day 7-10)	Post-Stent Removal Phone Call Visit 4 (Day 9-12)
Informed consent	X					
Demographics	X					
Medications and medical history	X	X	X	X	X	X
Randomization		X				
Indicated for Ureteral Stenting	X					
Physical exam (including height and weight, vitals)		X		X	X	
Ureteral Stent Symptoms Questionnaire		X	X	X	X (before removal)	X
RELIEF Ureteral Stent or DJ Stent		X (placement)		X (removal)		

9. What are the risks and possible discomforts?

Participation in this study may involve risks or discomforts.

The standard of care surgical risks and risks with either of the stents should have been reviewed with you by your surgeon.

Risk of Randomization: If you participate in this study, you or your surgeon will not get to select the type of stent you will receive.

Risks of Loss of Confidential Information: There is also a risk that information about you could be released to an unauthorized party. To minimize this risk, we will limit access to study documents to study personnel only, use password protected documents, use encrypted databases, use a code on any specimens and information we collect and we will keep a link between the code and your identity in a different location.

Possible Unknown Risks: In addition, there might be risks that we cannot predict at this time. These unknown risks may be temporary, mild, and last only while you are actively participating in the research, or they may be serious, long-lasting, and may even cause death. You will be informed of any new findings that might affect your health or welfare, or might affect your willingness to continue in the research.

10. How will information about me be protected?

While we cannot guarantee complete confidentiality, we will limit access to information about you. Only people who have a need to review your information, documents, or specimens will have access. These people might include:

- Members of the research team and other staff or representatives of UCSD whose work is related to the research or to protecting your rights and safety.
- Representatives of the study sponsor or product manufacturer
- Representatives of Federal and other regulatory agencies who make sure the study is done properly and that your rights and safety are protected. The Food and Drug Administration (FDA) may inspect research records and learn your identity.

Study information will be labeled with a code instead of your name or other information that can easily identify you. The record linking your identifying information (name, address, etc.) and the code will be kept separate from the rest of the study information. Additionally, study record access will be restricted to study personnel only.

This consent form and some details of your study participation will be noted in your UC San Diego Health record. If you do not currently have a UC San Diego Health record, one will be developed for you. People involved with your medical care and insurance at UC San Diego or other organizations may become aware of these details. Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your UC San Diego Health record until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your research records.

The results of this study may be published once the study is completed. However, we will keep your name and other identifying information confidential. We expect this study will be completed in 1 year. This is only an estimate and the actual time to complete the study may be longer or shorter depending on a number of factors.

You will be asked to sign separate UC Health Insurance Portability and Accountability Act (HIPAA) Research Authorization form to use and disclose (share) your health information that identifies you for the purposes of this research study (see the separate authorization form for more information). Your permission as described in this informed consent and authorization form does not have an automatic expiration date.

11. Will I need to pay to participate in the research?

The Relief stent will be supplied at no cost while you take part in this study. If you decide to not take part in this study but still want to have the Relief stent placed, it will also be supplied to you at no cost. The cost of getting the Relief stent ready and giving it to you is also provided at no cost. It is possible that the Relief stent could not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your condition while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no cost. Before you decide to be in the study, you should check with your health plan/insurance company to find out exactly what they will pay for. Examples of procedures and drugs that may be billed include the following: Ureteroscopy, Percutaneous Nephrolithotomy, and any medications provided preoperatively and postoperatively.

12. What if I agree to participate, but change my mind later?

You can stop participating at any time for any reason, and it will not be held against you. Your choice will not affect any treatment relationship you have with healthcare providers at UC San Diego Health or any services you receive from them. No matter what you decide, there will be no penalty to you. You will not lose medical care or any legal rights.
If you stop participating, we may not be able to remove the information we have already collected about you or specimens we have already collected from you.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

In addition, the study doctor or sponsor may stop the study or take you out of the study at any time, even if you would like to continue. This could happen because it is in your best medical interest or you do not follow instructions given by the study personnel.

13. What will happen to information and/or biospecimens collected from me?

The data we collect with your identifiable information (for example, your name, medical record number, or date of birth) as a part of this study may be used to answer other research questions or may be shared with other investigators for other research. If we do so, we will remove all identifiable information before use or sharing. Once identifiers have been removed, we will not ask for your consent for the use or sharing of your data in other research.
While your privacy and confidentiality are very important to us and we will use safety measures to protect it, we cannot guarantee that your identity will never become known.

14. What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for: completing study questionnaires at expected time points (Day 0, 1, 3, 7, stent removal) and coming to the study visits and completing activities as described in section 8 of this form.

15. Will I be compensated for participating in the research?

If you agree to take part in this research, we will provide you up to $75 for your time and effort. You will be compensated $15 per study questionnaire, paid in full at your completion in the study.

16. What else is important for me to know?

You will be provided any clinically relevant information that may pertain to your health. You will not be provided a summary of the research findings.

If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Office of IRB Administration at 858-246-4777 or irb@ucsd.edu for more information about this, to inquire about your rights as a research participant, or to report research-related problems.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Signature Block for Adults Able to Provide Consent

Participant

I have received a copy of this consent document and a copy of the "Experimental Participant's Bill of Rights" to keep. I agree to participate in the research described in this form.

Printed Name of Participant

Signature of Participant Date

Person Obtaining Consent

I document that:

- *I (or another member of the research team) have fully explained this research to the participant.*
- *I have personally evaluated the participant's understanding of the research and obtained their voluntary agreement.*

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

Witness (if applicable)

I document that the information in this form (and any other written information) was accurately explained to the participant. The participant appears to have understood and freely given consent to join the research.

Printed Name of Witness

Signature of Witness Date

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CONSENT TO PARTICIPATE IN RESEARCH

Every individual asked to participate in a research study has the right to be:

1. Informed about the nature and purpose of the study.

2. Provided an explanation of the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.

5. Informed about of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. Told of the types of medical treatment, if any, available if complications should arise.

7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.

9. Provided a copy of the signed and dated written consent form and a copy of this form.

10. Given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study contact the researchers listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact:

- UC San Diego Office of IRB Administration at irb@ucsd.edu or 858-246-4777