Cleveland Clinic
Consent to Participate in a Research Study

Study Title: Prospective randomized comparison of 2 ureteral access sheaths during flexible retrograde ureteroscopy

Principal Investigator: Manoj Monga M.D.

Carefully review this consent document. The purpose of a consent document is to provide you with information to help you decide whether you wish to participate in research. Your decision is completely voluntary and will not affect your medical care if you choose not to participate. It is important for you to ask questions and understand the research risks, benefits and alternatives.

Please note:

- **You are being asked to participate in a research study**
- **Carefully consider the risks, benefits and alternatives of the research**
- **Your decision to participate is completely voluntary**

Your doctor may be an investigator in this research study, and as a research investigator, is interested in both your welfare and in the conduct of the research study. Before entering this study or at any time during this research, you may ask for a second opinion about your care from another doctor who is not involved with the research study. You are not under any obligation to participate in any research project offered by your doctor.

1. INFORMATION ON THE RESEARCH

Why Are You Being Asked To Take Part In This Research?

You are being asked to participate in this research study because you have been diagnosed with a kidney stone and are having an operation to remove it in a procedure called a "ureteroscopy".

Why Is This Study Being Done?

The purpose of this study is to investigate the effectiveness and safety of two ureteral access sheaths used in flexible retrograde reverse ureteroscopies which have already been approved for used by the U.S. Food and Drug Administration (FDA). This study will compare two such ureteral access sheaths that are both part of standard care and of equal value.

How Many People Will Take Part In The Study?

About 117 people will take part in this study.

What Is Involved In The Study?

You are already scheduled to have the procedure called a "ureteroscopy". Before your surgery begins, we will use chance selection (like flipping a coin) to decide which device will be used in your

ureteroscopy. You will be assigned to one of two devices. The device is a "ureteral access sheath" which is typically used in your procedure to increase the effectiveness of the procedure. Both of the "ureteral access sheaths" that could be used are U.S. Food and Drug Administration (F.D.A.) approved. Both of the "ureteral access sheaths" that could be used are devices that would normally be used for someone having the same procedure that is not involved in this study. Both of the "ureteral access sheaths" that could be used have the same cost. Both of the "ureteral access sheaths" that could be used are understood to have the same effectiveness. The research coordinator will assign you one of the two devices before your procedure begins. The research coordinator will notify all Operating Room personnel to ensure that the correct device is used. The device will be used during the procedure while you are under anesthesia.

After this type of procedure, it is standard of care that all patients have an x-ray to see if the procedure was effective in removing the kidney stone. This x-ray normally is taken 4 to 6 weeks after the procedure. You will be asked to come in for an x-ray which will help your doctor see the status of your kidney stone disease.

Visit	What procedures/tests that will be done at this visit?	What will need to be brought and/or done for this visit?
Visit 1 Your procedure	• Ureteroscopy	Do not eat after midnight the night before the visit. You must have a friend or family member accompany you to the hospital
Visit 2 4-6 weeks after procedure	• Follow-up x-ray of kidneys, ureters, and bladder	

How Long Will You Be In The Study?

Your participation in this study will last from the start of your ureteroscopy procedure until your follow-up x-ray.

2. RISKS AND DISCOMFORTS

What Are The Risks Of The Study?

The medical risks during your procedure will not have additional risks above the risks associated with standard care.

The major complication rate associated with ureteroscopy occurs in less than 1% of all procedures. Major ureteral wall perforations can occur. Ureteral wall trauma and stricture formation may also occur. These complications can happen due to improper application of the ureteroscope.

When treating stones in the ureter, ureteral wall perforation can result in the stone migrating into the defect and can lead to formation of a stone granuloma and/or ureteral wall stricture. Particularly with extracting large stones, it is possible that the ureter can become perforated or avulsed (broken off from the kidney). To reduce this risk, large stones are reduced in size before extraction. If a distal ureteral avulsion is noted, ureteroneocystostomy repair can be performed at the time of injury or in a staged fashion.

Minor risks include urinary tract infection, fever, pyelonephritis (infection of the kidney), and false-passage creation.

As part of this research study, there is risk that may involve the risk of loss or breach of confidentiality, psychological stress, or inconvenience.

Additionally, this research study may involve unforeseeable risk.

	Mild	Moderate	Severe
Likely **1.5%**	• Fever	• Urinary tract infection • False passage creation • Kidney infection	
Less Likely **0.5%**	• Ureteral stricture	• Ureteral stricture • Stone granuloma • Ureteral perforation • Ureteral avulsion	
Rare **Less than 0.05%**			• Ureteral avulsion requiring percutaneous (through the skin) renal drainage

Unforeseeable risks:
There may be risks or side effects related to the study drug/device that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

Pregnant women, fertile females/males:
There may be unforeseen risks to an unborn child associated with your undergoing ureteroscopy. Therefore, if you are capable of giving birth to or fathering a child, you and your sexual partner should use adequate birth control measures while you are in the study. These measures may include

abstinence, oral contraceptives (birth control pills), IUD, diaphragm, approved hormone injections, condoms, or documentation of medical sterilization. If you are unwilling to do this, we ask that you not participate in this study.

Pregnancy tests will be performed on all women of child-bearing potential before beginning the study and during the study before the procedure. If you or your spouse become pregnant while taking part in this study you must notify the study doctor immediately. If birth control methods must continue after the study drug is discontinued, this time period should be provided to subjects.

Radiation:

One of the risks associated with radiation exposure is cancer. The natural incidence of fatal cancer is the U.S. is about 1 chance in 5 (18%). In this research study, you will receive 1 x-ray. The amount of radiation is too low to accurately estimate your additional cancer risk

Radiation and Skin Injury:
In addition to cancer, you may be at risk for a skin injury at the site where the radiation enters your body. This injury may be mild and include skin reddening and temporary hair loss. Prolonged exposure may lead to severe injury, including permanent hair loss at the site and skin ulceration which may require surgical repair.

3. BENEFITS
Are There Benefits To Taking Part In The Study?

Participation in this study may help to improve your condition, but it is also possible that your condition may worsen. There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study may provide information that may help other people who have a similar medical problem in the future.

4. ALTERNATIVES
What Other Options Are There?

You may talk with your physician about which ureteral access sheath during the ureteroscopy instead of having one assigned to you.

Additionally there is the alternative of no treatment and not having the ureteroscopy or use of ureteral access sheath.

5. PRIVACY AND CONFIDENTIALITY

The medical and research information recorded about you for this research will be used within the Cleveland Clinic and/or disclosed outside the Cleveland Clinic. Tests and procedures done solely for this research study may be placed in your medical record to indicate your participation in this study.

The information recorded about you as part of this research will be maintained in a confidential manner.

Upon completion of the study, you may have access to the research information if contained in the medical record. During the study, your access to research information about you will be limited. Preventing this access during the study keeps the knowledge of study results from affecting the reliability of the study. This information will be available should an emergency arise that would require your treating physician to know this information to assist in treating you.

Federal regulations require that you authorize the release of any health information that may reveal your identity. The persons and entities that you are authorizing to use or disclose your individually identifiable health information may include the study doctor, the study staff, Cleveland Clinic monitors/auditors and IRB, the U.S. Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS), and other governmental agencies from foreign countries. Because of the need to release information to these parties absolute confidentiality cannot be guaranteed. The Cleveland Clinic also may use and disclose this information for treatment and payment reasons. The Cleveland Clinic must comply with legal requirements that mandate disclosure in unusual situations. Once your personal health information is released it may be re-disclosed and no longer protected by federal privacy laws. The results of this research may be presented at meetings or in publications; however, your identity will not be disclosed in those presentation.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing Dr. Manoj Monga at The Cleveland Clinic, 9500 Euclid Avenue, Cleveland, Ohio 44195. If you do so, your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of the research. Also, information already disclosed outside the Cleveland Clinic cannot be retrieved. Even if you ask us to stop outside disclosures, information collected about you will be disclosed as required by state and federal law.

The Cleveland Clinic will not use or disclose the information collected in this study for another research purpose without your written permission, unless the Cleveland Clinic Institutional Review Board gives permission after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are authorizing such access to your medical records. If you choose not to sign this consent form, you will not be permitted to participate in this research study.

6. RESEARCH RELATED INJURIES
What Happens If An Injury Occurs?

In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by

signing this form. Further information about research related injury is available by contacting the Institutional Review Board at 216-444-2924.

7. COSTS
What Are The Costs?

There are no additional costs to you for participation in this research study. The cost for routine tests and services that would normally be performed even if you don't participate in the study will be billed to you or your insurance provider.

8. VOLUNTARY PARTICIPATION
What Are Your Rights As A Participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

9. QUESTIONS
Whom Do You Call With Questions Or Problems?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact Dr. Monga at 216-445-8678. After business hours, please call 216-444-5600. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. SIGNATURE

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date