1. Cover Page

STUDY TITLE: **Initial Experience of the Treatment of Kidney Stones with the MONARCH™ Platform, Urology**

PROTOCOL NUMBER: 2021-URO-0001

VERSION: C

DATE: October 18, 2022

Revision History

Version	Description of Change
A	Original Document
B	Amendment #1
C	Amendment #2

Clinical Investigation Plan (CIP) and Protocol

Identification of Responsibility Page

Initial Experience of the Treatment of Kidney Stones with the MONARCH™ Platform, Urology

The Study will be performed in accordance with the relevant parts of Title 21 CFR Parts 50, 54, 56 and ISO 14155-1 / 14155-2.1; the ICH Guidelines for Good Clinical Practices (E6), the Declaration of Helsinki, and any regional and/or national regulations

Sponsor:	Auris Health, Inc. 150 Shoreline Dr Redwood City, CA 94065	Sponsor Contact: Nancy Sehgel, PhD Email: nsehgel@its.jnj.com
Principal Investigators / Study Center:	Principal Investigator: [redacted] Co-Investigator: [redacted] Study Center: [redacted]	
Date of Issue:	October 18, 2022	

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Initial Experience of the Treatment of Kidney Stones with the MONARCH™ Platform, Urology

Approval Page

STUDY TITLE:	**Initial Experience of the Treatment of Kidney Stones with the MONARCH™ Platform, Urology**
PROTOCOL NUMBER:	2021-URO-0001
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DATE:	October 18, 2022

We, the undersigned, have read and approve the protocol specified above and agree on its content.

[redacted] Date

[redacted] Date

[redacted] Date

[redacted] Date

[redacted] Date

Investigator's Signature Page

STUDY TITLE: **Initial Experience of the Treatment of Kidney Stones with the MONARCH™ Platform, Urology**

STUDY CENTER: [redacted]

I, the undersigned, have read and understand the protocol specified above and agree on its content. I agree to perform and conduct the study as described in the protocol. In addition, when applicable, I agree to enlist sub-investigators who also agree to perform and conduct the study as described in the protocol.

_____

Principal Investigator – Print Name

_____

Principal Investigator – Signature Date

_____

Co-Investigator – Print Name

_____

Co-Investigator – Signature Date

1.1 Table of Contents

Contents

1.2 Amendment Change History

Amendment #1- The purpose of the amendment was to: clarify the inclusion criteria, update device naming, modify the description of additional (non-endpoint) data collected, modify the schedule of assessments, modify the classification of adverse events, specify additional safety-related reason for study termination, and clarify the presence of robotic system data collection, and video and image recording of the procedures. Additionally, administrative changes were made to the protocol.

Amendment #2 - The purpose of this amendment is to: modify the classification of adverse events, specify the inclusion of interim analyses, update device naming, and reference engineering data collection from a Case Observer survey. Additionally, administrative changes were made to the protocol.

1.3 Synopsis of Trial

Initial Experience of the Treatment of Kidney Stones with the MONARCH™ Platform, Urology

Primary Objective	The aim of the study is to collect descriptive performance data on the use of the MONARCH™ Platform, Urology for robotic mini-Percutaneous Nephrolithotomy (PCNL) procedures. Data gathered from this study will be used to optimize the robotic platform and inform training and education material for the future users.
Test Device	The MONARCH™ Platform, Urology and its accessories are intended to access and visualize anatomical locations within the urinary tract and interior of the kidney of adolescents and adults, age 12 and up, for diagnostic and therapeutic procedures with transurethral or transurethral access in conjunction with percutaneous access routes.
Control Device	None
Indication for Use **510K #:**	The MONARCH™ Platform, Urology, ureteroscope, and endourology accessories are indicated to provide endoscopic visualization and access of organs, cavities, and canals in the urinary tract (urethra, bladder, ureter, calyces, and renal papillae) with transurethral access or transurethral access in conjunction with percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.
Hypotheses	No formal statistical hypotheses are defined.
Study Design	A single-center, prospective, single arm study to collect descriptive data on the robotic-assisted mini-PCNL removal of kidney stones using the MONARCH™ Platform, Urology system.
Number of Patients	The study will enroll up to 20 patients.
Site	[redacted]
Duration of Study	The total duration of the study is expected to be up to 22 weeks. The enrollment is expected to take up to 16 weeks and includes a 30-day follow-up visit for each enrolled participant.
Primary Endpoint	The primary endpoint is the completion of the robotic-assisted mini-PCNL kidney stone removal procedure including: • Gaining safe concomitant (i.e., retrograde and antegrade) access to the upper urinary tract • Locating and visualizing kidney stones • Enabling fragmentation of stones by standard of care method • Evacuating stone fragments and dust
Safety Endpoints	The following will be considered secondary endpoints: • Adverse events through 30-days post-operative, scored on the Clavien-Dindo scale • Conversion to conventional treatment methods
Follow-Up Schedule	Each enrolled subject will be followed up to 30 days ±7 days post procedure.

Pre-Operative Inclusion Criteria	1. Age ≥ 22 years 2. Simple renal caliceal and/or pyelo stone(s), ≥ 10 mm in size identified on CT scan, and appropriate for PCNL treatment according to AUA guidelines 3. Normal upper tract anatomy, amenable to PCNL and ureteroscopy 4. BMI < 40 kg/m2 5. Patients with a percutaneous tract length < 15cm as measured by the estimation of the skin to stone or skin to appropriate calyx for treatment through a CT scan 6. Patient is an appropriate candidate for a mini-PCNL based on the clinical guidelines and investigator assessment.
Pre-Operative Exclusion Criteria	Subjects will be excluded from participating in this study if they meet any of the following criteria prior to initiation of the procedure: 1. Any medical or physical condition/limitation that would contra-indicate a conventional ureteroscopy or PCNL (e.g., atypical interposition of visceral organs (bowel, spleen, or liver)) in the supine position. This assessment will be made by the investigator team. 2. Participation in any other clinical trial 30-days before and throughout the duration of the study that might impact the results 3. A solitary functioning kidney 4. Female subjects who are pregnant or nursing or those of child-bearing potential refusing a pregnancy test 5. Presence of ureteral impacted stones 6. Presence of ureteral obstruction 7. Presence of untreated urinary tract infection, urosepsis 8. Inability to give consent 9. Presence of a renal mass which has not been investigated 10. Staghorn stone 11. Patient has an electrically or magnetically activated implanted medical device 12. Significant pharmacological anticoagulant therapy or uncorrected bleeding diathesis 13. Tumor in the probable access tract area and potential malignant renal tumor
Intra-Procedure Exclusion Criteria	Any presenting condition discovered intra-procedurally that in the opinion of the investigator would make participating in this study not in the patient's best interest. For example, patients no longer considered good candidates for a mini-PCNL procedure for the removal of the kidney stones.
Study Sponsorship	
Sponsor	Auris Health, Inc. 150 Shoreline Drive Redwood City, CA 94065

2. Introduction

The current standards of care for kidney stones include Extracorporeal delivery of Shock Waves for Lithotripsy (commonly referred to as ESWL, which is trademark of Dornier MedTech), Ureteroscopy (URS), and Percutaneous Nephrolithotomy (PCNL). Each of these approaches present challenges for achieving a stone free state in the kidney, especially for patients with mild to moderate stone burden. The fragmentation of stone by ESWL has a high retreatment rate due to prevalence of residual stones. Achieving complete removal of stones with ureteroscopy is feasible but may require multiple procedures. For kidney stones larger than 20 mm, PCNL has been found to be both clinically effective and time efficient. However, the PCNL procedure often requires clinicians with specialized training in obtaining percutaneous access to the kidney, and is more invasive (requiring the creation of up to 30 Fr percutaneous tract).

The aim of the study is intended to collect descriptive performance data on the use of the MONARCH™ Platform, Urology for robotic mini-PCNL procedures. Data gathered from this study will be used to optimize the robotic platform setup and inform training and education material for the future users. The MONARCH™ Platform, Urology system will facilitate a minimally invasive, robotically-enabled hybrid procedure called the MONARCH™ Mini-PCNL to be performed by a single qualified professional. The MONARCH™ Mini-PCNL will allow the clinician to obtain retrograde and percutaneous access to patient's kidney under continuous visualization for therapeutic applications (i.e., stone removal). Additional details on the procedure are included in section 4.2.

2.1 Background

The MONARCH™ Platform, Urology system facilitates the mini- Percutaneous Nephrolithotomy (mini-PCNL) hybrid approach using the robotically assisted tools to improve procedural efficiency for removing kidney stones. The first step of the mini-PCNL is gaining both retrograde and percutaneous access to the kidney. The retrograde access is established through conventional methods and maintained with a third-party ureteral access sheath. The antegrade access is achieved percutaneously with a robotically assisted needle guidance tool. The tool targets the tip of the ureteroscope, which is placed at a location inside the kidney chosen by the surgeon. The second step is a comprehensive exploration of the renal calyceal system identifying all stones with precise robotically assisted maneuvers directed by the physician with the ergonomics advantages of a joystick controller. While visualized through the ureteroscope, the stone(s) are fragmented using standard methods (i.e., the most common being laser energy from a laser fiber inserted through a working channel in the ureteroscope). The evacuation/extraction of stone fragments and dust generated by lithotripsy is made possible by the robotically controlled suction catheter and the fluid management system. This combination maintains clear visualization of the collecting system and adequate distension, without over-pressurization of the kidney throughout the procedure. Additional details on the procedure are included in section 4.2.

As noted above, various options are available to treat patients with kidney stones. Clinicians decide the treatment approach based upon the patient characteristics and stone size. The American Urological Association (AUA) guidelines provide the following guidance to clinicians regarding patient selection for the different procedures. In symptomatic patients with a total non-lower pole renal stone burden ≤ 20 mm, clinicians may offer ESWL or URS. In symptomatic patients with a total renal stone burden >20 mm, clinicians should offer PCNL as first-line therapy. Extracorporeal shock wave lithotripsy (ESWL) is the least invasive procedure but often requires multiple treatments and is not recommended for patients with moderate to larger stone burdens. Flexible Ureterorenoscopy (URS) is the most common retrograde procedure and is routinely used in a variety of diagnostic and therapeutic indications such as ureteric and kidney stones, urothelial tumors and the treatment of strictures.[1-3] Technological improvements in ureteroscopes and

accessories such as miniature baskets or graspers and effective energy delivery through the Holmium YAG laser have contributed to its wide adoption. A limitation in ureteroscopy is the extraction of all residual stone fragments due to their retropulsion by irrigation, impaired visualization during lasering, and tedious in-out basketing maneuvers which many require repeated treatment episodes.[4-5] Another challenge associated with the procedure is controlling the fluid balance with extravasation of irrigation fluid in the retroperitoneum following hyper pressure in the urinary tract.

Percutaneous Nephrolithotomy (PCNL) is generally a more effective treatment but is more invasive as it requires making an incision through the patient's flank to directly access the kidney. This direct antegrade access to the kidney allows the clinician to use larger devices, such as pneumatic or ultrasonic lithotripters with suction mechanisms, to fragment and extract the stone fragments more efficiently. Limitations of the PCNL procedure include the difficulty in obtaining access to the kidney, placement and rigidity of the lithotrite tools and the large hole size (24 to 30 Fr), which contributes to complications such as bleeding.[6-7] Obtaining percutaneous access to the kidney, often requires specialized skills of an interventional radiologist to initiate the procedure. Additionally, PCNL access is often performed with the patient in the prone position which can increase risks related to anesthesia depending on co-morbid conditions and BMI.[8]

Standard PCNL is done with sheath size of 24 to 30 F. Mini-PCNL is done with sheath sizes ranging from 14 to 20 F.[9] Mini-PCNL is less invasive, and is associated with lower complications rates and blood loss, but may be less effective or more time consuming due to the smaller tract size requiring smaller, less efficient lithotrites.[9,10] Retrograde access with ureteroscope and laser may be used to supplement PCNL (either standard or mini) so that the percutaneous access tract can be entirely dedicated to suction (thereby maximizing the size of fragments evacuated and potentially reducing required lasing time). However, this requires two urologists to synchronize their actions between retrograde and antegrade instruments to fragment and evacuate the stone.[10]

List of Abbreviations and Definition of Terms

- Extracorporeal shock wave lithotripsy (ESWL)
- Ureterorenoscopy (URS)
- Percutaneous Nephrolithotomy (PCNL)
- Mini-Percutaneous Nephrolithotomy (mini-PCNL)

Summary of Findings from Preclinical and Prior Clinical Trials

Performance of mini-PCNL by the MONARCH™ Platform, Urology has previously been evaluated in porcine models demonstrating safety and efficiency in stone treatment procedure.

Summary of Known and Potential Risk and Benefits

Anesthesia Risk

There is a potential risk of developing side effects associated with the use of anesthesia. The risks of anesthesia depend on the agents and/or gases used. The risks of anesthesia include postoperative pain, nausea and vomiting, dizziness, drowsiness, shivering, liver toxicity and/or cardiovascular events and death. Trained professionals with extensive experience and expertise who routinely administer local anesthesia with conscious sedation to patients requiring multiple procedures will

be responsible for the induction and associate monitoring required for this study.

Patients will be in a modified supine position during the procedure rather than the conventional prone position typically used to obtain antegrade PCNL access. The modified supine position will enable access to the patient's flank for the mini-PCNL and the ureteroscope while reducing potential risks associated with anesthesia, and to improve the fluidics support.

In addition, study patients will undergo extensive monitoring throughout the recovery period prior to discharge.

Failure to Remove the Stone

There is a risk that that the procedure may not be able to successfully remove all stones, because of either size, location, or physicochemical parameters of the stone within the collecting system. Additional treatment may be required.

Infection

Bacteria can at times grow within stones and therefore cause a urinary infection and rarely sepsis during stone surgery. As a result, urinary infections should be treated before surgery and broad-spectrum antibiotics are administered at the start of the operation to minimize the risk of a urinary infection.

Radiation

The procedure will require multiple forms of radiation exposure in the forms of pre- and post-operative CT scan, as well as intraoperative fluoroscopy, which are being performed per standard of care. One of the risks associated with radiation exposure is cancer. The natural incidence of fatal cancer in the U.S. is about a 1 in 5 chance. Everyday radiation exposure from natural occurring background radiation (sun, radon exposure in the home) is approximately 3 mSv per year[11]. This radiation exposure risk from CT scan commonly used for stone detection is approximately 3 mSv[12] and is equal to an additional year of natural background radiation. The radiation exposure risk from intraoperative fluoroscopy is during a PCNL is estimated between 1.7-56 µSv[13], which is equal to an additional 0.21-6.81 days of natural background radiation.

Ureteroscopy-specific risks:

Risks associated with ureteroscopy are sepsis, urinary tract infection, fever, stricture, mucosal injury, bleeding, ureteral perforation, ureteral avulsion, ureteral intussusception, thermal injury to tissue, colic, extravasation, urinoma, extrusion of calculi.

Percutaneous Nephrolithotomy (PCNL)-specific risks:

The risks associated with percutaneous access are sepsis, bleeding, injury to the renal collecting system, colonic injury, pleural injury, liver injury, splenic injury, and death. Although rare, potential risks associated with this therapeutic approach includes but are not limited to the following:

Adjacent Tissue and Organ Injury: Rarely organs surrounding the kidney such as bowel, colon, blood vessels, spleen, and liver may be injured during surgery requiring emergent open surgery or further surgery. The chest cavity is in close proximity to the upper pole of the kidney and can be accidentally entered when accessing an upper pole kidney stone resulting in a pneumothorax (or air surrounding the lung). This may require that a small

chest tube be placed temporarily to drain air and fluid from around the lung. Permanent damage to the kidney during kidney puncture resulting in loss of the kidney is extremely rare. Damage and perforation to the ureter draining the kidney may result in scarring and obstruction requiring further surgery.

Excess Fluid in Retroperitoneal Space: In the absence of obstruction, the urinary collecting system is a virtual cavity that needs to be distended by a fluid to allow for an endoscopic working space. A saline irrigation fluid is commonly used to expand the lumen of the ureter, pelvis and reno-calyceal system. In the absence of a fluid management device there is a risk of over-pressure and extravasation of fluid in the retroperitoneal space, with possible ileus, hemodilution by reabsorption, fluid overload with cardiac and metabolic changes.[14]

The MONARCH™ Platform, Urology offers a fluid management system maintaining the working space throughout, without collapse risk, evacuating the fragments in real time and preventing the risk of rupture or reabsorption related to hyper-pressure from the fluid media.

Bleeding: Blood loss during PCNL using a single tract is generally low to moderate, and risk of blood transfusion ranges from 2-12%, depending on stone size, location, and number of tracts dilated.[15,16]

Additional: Additional procedural risks relate to the creation of the percutaneous tract and control of fluid turn-over within the kidney. The occurrence of these risks is extremely low. Prior to the procedure, all patients will be questioned about tendency to bleed prior to procedure as per standard care. Additionally, anticoagulation with antiplatelet agents will be held according to guideline recommendations for that drug. If bleeding occurs, patients will be treated with direct pressure, local instillation of epinephrine or electrocautery.

Mechanical or Thermal Injuries

Some potential risks may exist related to mechanical or thermal injuries resulting from physical maneuvers or various energy sources (e.g., shock, suction, electricity, ultrasound, laser). While these risks are small, they include:

Upper urinary system risks, including: Various grades ureteral injury leading to perforation, avulsion, intussusception and long-term stricture due to retrograde access. Uretero-iliac fistula. Perforation of renal pelvis. Extra-renal stone migration after ureteric or pelvic perforation. Renal pseudo-aneurysm. Arterio-venous fistula. Renal Fracture. Post-operative upper-tract obstruction.

Lower urinary tract risks including: Urethral false passage and long-term urethral stricture. Vesicoureteral reflux. Urinary Infection or sepsis can result from endoscopic and percutaneous maneuvers or in the presence of a stent or catheter left in situ.

Trauma to neighboring retro-peritoneal and intra-peritoneal organs including: Visceral injury due to percutaneous or retrograde access that may require secondary intervention. Retro-peritoneal or perirenal fluid collection: urinoma, hematoma, and major bleeding.

Other non-traumatic complications including: Ureteral stent migration, forgotten stent. Post de-obstruction hyper-diuresis

Risk Mitigation

The study protocol was developed with investigators that are well-known in the area of endo-urology. The site was chosen because of proven expertise in the field of endo-urology. All investigators performing the procedure using the MONARCH™ Platform, Urology system under the clinical protocol will undergo a Training Program, which includes elements of both a didactic and hands-on training program. Proficiency must be demonstrated prior to use in humans. Pre-clinical and benchtop testing have been performed in order to optimize the device safety and function.

To mitigate risks during the procedure, patients' ECG, heart rate, blood pressure, and blood oxygen are continuously monitored by a nurse, respiratory therapist, and physician during the procedure. If there is any sign of a worsening in status, such as elevated heart rate, low oxygen, or ECG changes, the procedure will be aborted. In the event that any of these were to occur, the study subject will be treated for the condition.

Postoperative oversight: Patient discharge criteria and post-operative instructions will follow local policies and scientific guidelines for standard of care following a kidney stone removal procedure. Additionally, patients will be evaluated for fluid balance by comparing the patient's pre- and post-operative weight and fluids used during the procedure.

Research-only risks

Every effort will be made to protect the privacy of the research subjects. All information and data related to this study will be maintained in secured, protected space, and access will be restricted to study personnel only. In addition to this, additional procedure time may be encountered due to the set up for robot-assisted kidney stone removal procedure or for managing potential periprocedural adverse events.

Benefits

There are several potential benefits of using the MONARCH™ Platform, Urology to perform the mini-PCNL procedure. The robotically enabled tools included in the platform will facilitate safe and efficient access to the kidneys, enhance visualization during the procedure and reduce potential risks to patients through fluid controls and patient position. The MONARCH™ Platform, Urology will also make it possible for the procedure to be completed by a single user and improve clinician experience through the ergonomic joystick controller compared to manipulating a flexible ureteroscope and positioning laser fiber at the same time.

2.2 Purpose

The aim of the study is to collect descriptive performance data on the use of the MONARCH™ Platform, Urology for robotic mini- PCNL procedures. Data gathered from this study will be used to optimize the robotic platform and inform training and education material for the future users. To be included in the study, patients must: (1) be at least 22 years old, (2) have simple renal caliceal stone(s) that are ≥ 10 mm in size identified on CT scan, and appropriate for PCNL treatment according to AUA guidelines, (3) have a normal upper tract anatomy, amenable to PCNL and ureteroscopy, (4) a BMI under 40 kg/m2, (5) have a percutaneous tract length < 15cm (as measured by the estimation of the skin to stone or skin to appropriate

calyx for treatment through a CT scan), and (6) be an appropriate candidate for a mini-PCNL based on the clinical guidelines and investigator assessment.

The Study will be performed in accordance with the relevant parts of Title 21 CFR Parts 50, 54, 56 and ISO 14155-1 / 14155-2.1; the current versions of the ICH Guidelines for Good Clinical Practices, the Declaration of Helsinki, and any regional and/or national regulation.

3. Trial Objectives

The aim of the study is to collect descriptive performance data on the use of the MONARCH™ Platform – Urology for robotic mini- PCNL procedures. The study will collect data on the ability of robotic platform and its components to complete mini-PCNL procedures by enabling:

- a single operator to gain retrograde ureteroscopic and antegrade percutaneous access to the kidney for purposes of renal stone treatment;
- the ureteroscope to navigate through the kidney to locate and visualize stone(s), and the ureteroscope to act as a target for gaining accurate percutaneous access into the kidney;
- fragmentation of stones by standard of care method; and
- removal of all visible stone debris using suction and balanced fluidics via mini-percutaneous access.

Data gathered from this study will be used to optimize the robotic platform to inform training and education material for the future users.

4. Investigational Plan

4.1 Trial Endpoints

Primary Endpoint

The primary endpoint is the completion of the robotic-assisted mini-PCNL kidney stone removal procedure including:

- Gaining safe concomitant (i.e., retrograde and antegrade) access to the upper urinary tract
- Locating and visualizing kidney stones
- Enabling fragmentation of stones by standard of care method
- Evacuating stone fragments and dust

Safety Endpoints

The following will be considered safety endpoints:

- Adverse events through 30-days post-operative, scored on the Clavien-Dindo scale (See Appendix IV)
- Conversion to Conventional Treatment Methods

Additional Data Collection, includes, but is not limited to:

Pre-Operative CT: parameters of kidney stone number, size, density and location; locations of Randall's plaques

Pre-Procedure: date and time patient admitted to hospital; manufacturer and model of operating room equipment; cystoscopy phase timestamps and equipment parameters; patient positioning parameters

Procedure: timestamps and additional parameters during procedure phases of device setup, ureteroscopy, percutaneous access, mini-PCNL setup, mini-PCNL procedure, and device teardown; assessments of stone free rate, stone removal efficiency, intraoperative visualization, intraoperative bleeding, physician qualitative experience, post-case debrief

Discharge and Follow-up: any placement of a ureteral stent or nephrostomy tube, date and time patient discharged from hospital; any additional retreatment during follow-up; assessment of any residual stones and stone free rate

4.2 Trial Design

A single-center, prospective, single arm study of the robotic-assisted removal of kidney stones using the MONARCH™ Platform, Urology system. Twenty subjects presenting with kidney stones determined to be appropriate candidate for a mini-PCNL procedure per standard medical care and meet study inclusion and exclusion criteria will be invited to participate. The site Principal Investigator will determine eligibility and will explain the study to qualified subjects prior to obtaining consent. The subject will also be given an opportunity to review and sign documentation of privacy compliance and authorization according to established practice of the institutions. All subjects are required to meet the inclusion/exclusion criteria defined in the Sections 5.1 and 5.2 in order to be considered eligible for participation in this study. The study flowchart is shown in Figure 1.

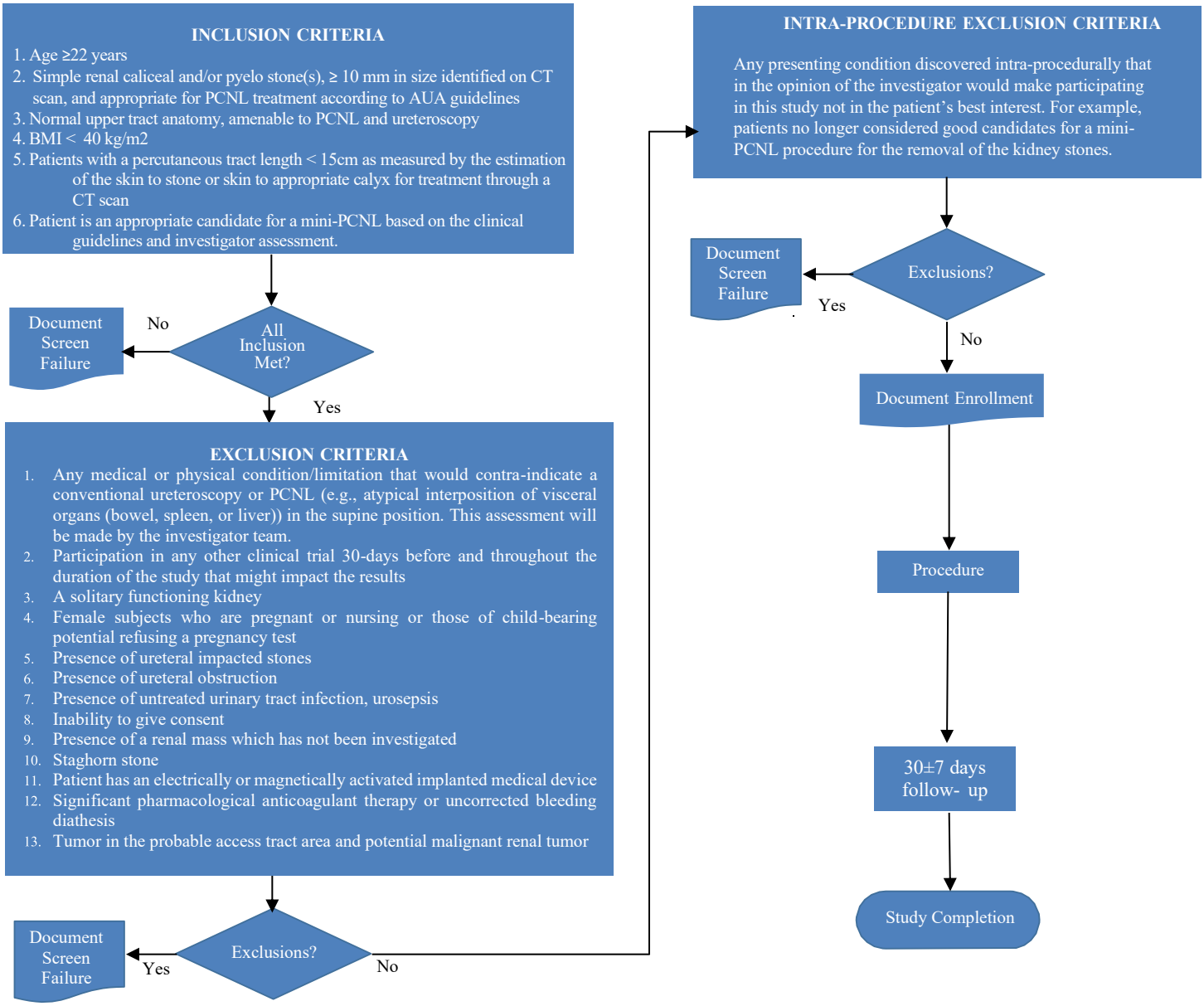

Figure 1. Schematic of Study Design

Description of the study procedure: Mini-PCNL

This robotically enabled hybrid procedure called the MONARCH™ Mini-PCNL will allow the clinician to obtain retrograde and percutaneous access to patient's kidney under continuous visualization for therapeutic applications (i.e., stone removal). The aim of the study is to evaluate clinical safety and procedural effectiveness of the robotic-assisted diagnostic and therapeutic procedures performed with the MONARCH™ Platform, Urology. The procedure includes the following components.

Retrograde Access: The user gains retrograde access to the kidney via conventional cystoscopy techniques and places a ureteral access sheath to maintain access to the kidney.

Ureteroscopic Surveillance: The user manually inserts and navigates the ureteroscope to the kidney under direct endoscopic visualization. Once the user confirms access to the kidney, the ureteroscope is docked to the arm IDM. The physician can command insertion/retraction, articulation, and roll of the ureteroscope via the MONARCH™ Controller to survey the kidney and locate the stone.

Percutaneous Access: The use of electromagnetic (EM) sensing capabilities provides a rendezvous point with the ureteroscope to guide the advancement of the needle into the kidney under direct visualization and control by the physician. The EM field generator and mount are present on the electromechanical arm by the patient's flank to create the EM field. The user determines which calyx to access and parks the ureteroscope in this calyx. the system creates a virtual target for needle alignment using the ureteroscope's location and orientation and the tower graphical user interface displays trajectory information. Upon gaining access to the kidney, the user will dilate the tract with the MONARCH™ Percutaneous Access Sheath and Dilator set.

Lithotripsy & Removal: The user will proceed with a combined percutaneous and retrograde approach. A laser fiber inserted through the working channel of the ureteroscope will be used to lase the stone, while the MONARCH™ mini-PCNL Suction Catheter uses suction from the MONARCH™ Fluidics Pump to stabilize the stone and aspirate fragments. The fluidics tower regulates irrigation and aspiration through the antegrade access, irrigating through the sheath and aspirating through the catheter. Irrigation is used to distend the kidney for visualization through the ureteroscope, while aspiration is used to stabilize the stone for lithotripsy and to extract residual stone fragments and dust. Additionally, the sheath is designed to have a second annular lumen to allow for passive outflow of fluid from the kidney to prevent over-pressurization of the kidney. Within this study, investigators will use the MONARCH™ mini-PCNL Suction Catheter as the primary method for stone and stone fragment removal, with secondary options (e.g., MONARCH™ Stone Retrieval Basket or off-the-shelf devices) available if medically necessary. When the physician believes the kidney is stone free, conventional closure techniques may be used for both antegrade and retrograde access points.

Throughout the procedure, investigators will be required to use MONARCH™ instruments and accessories. Alternative off-the-shelf devices may be used in place of the expected MONARCH™ instrument or accessory device in the event continuing with the surgical workflow is not possible without the alternative device, or it is medically deemed to be in the best interest of the patient.

Sample size

The study will enroll up to 20 patients. The enrollment is expected to take up to 16 weeks. The total duration of the study is expected to be up to 21 weeks.

Duration of subject participation

Once the subject has completed 30 (±7) days follow-up without study-related adverse events requiring further follow-up, subject will be exited from the study.

Assessment schedule

The following page outlines the required study assessments.

Table 1. Schedule of Assessments

Test/Parameter	Screening/Baseline[1]	Procedure	Follow-up 30 (±7) days
Informed Consent & Health Insurance Portability and Accountability Act (HIPPA) Authorization	X		
Pregnancy Test (if applicable)	X	X	
Preliminary Qualification (inclusion/exclusion criteria)	X		
Medical History	X		
Physical examination	X	Weight pre- & post-op	X
Urinalysis and Culture	X		X
CBC & Metabolic Panel	X	HCt and Natrium post-op	X
Renal Ultrasound[2]	(optional)		(optional)
CT-KUB non contrast All patients	X		X
ECG	X	X	
Blood test and coagulation test (PT/INR)[3]	X		
Fluoroscopy[5]		X	
Antegrade and retrograde Endoscopy[6]		X	
Concomitant medications[7]	X	X	X
Adverse Events		X	X

[1] All baseline/screening procedures should be completed approximately 30 days prior (allowing up to 60 days prior) to the procedure. [2] A renal ultrasound may be performed at 30 (±7) days follow-up.

[3] A blood test including the PT/INR coagulation test will be assessed before the procedure.

[5] Fluoroscopy will be used in conjunction to provide an additional viewing method during the procedure.

[6] Ureteroscopic endoscopic assessment will be made to evaluate residual kidney stone fragments at the end of the procedure.

[7] All medications will be recorded on a rolling log.

Informed Consent. A study specific, EC approved written informed consent must be obtained for all patients who are potential study candidates before any study-specific tests or procedures are performed.

Pregnancy Test (if applicable). If there is the potential for pregnancy, a serum pregnancy test will be conducted before entry into the study.

Preliminary qualification (Investigator/Staff). Sponsor or its designee will train the Principal Investigator and sub-investigators and research staff in the proper use of the investigational products and Protocol requirements prior to the onset of subject enrollment into the investigation or trial. The Principal Investigator is responsible for certifying that key personnel have received adequate training to ensure they are aware of the regulations governing human subjects research and understand and adhere to the Institutional Review Board- (IRB)-approved research protocol. Compliance with these standards provides assurance that the rights, safety, and well-being of human subjects are protected, and the integrity of the data collected.

Inclusion/Exclusion criteria. Potential study candidates must meet the study specific Inclusion/Exclusion criteria based on the screening assessment. For the purpose of this study, a kidney stone is defined as calculi located within the renal portion of the collecting system as opposed to ureter or bladder.

Medical history. During the screening/baseline assessment, the investigator or coordinator will record details of medical history as they relate to urologic status.

Physical examination. The investigator will perform a brief, directed physical examination, and document any preoperative abnormalities. The examination will be repeated at discharge and 30 days post-procedure.

CBC & Metabolic Panel. This involves a sample of blood drawn (1-3 cxc) to perform standard hematology and biochemistry

Urinalysis and Culture. A urine specimen will be analyzed for infection.

Renal Ultrasound Scan. Ultrasound examination of the kidneys postoperatively to detect stones obstruction and/or fluid collection.

Electrocardiogram (ECG). Stickers will be placed on each arm and leg and the chest area and a heart tracing is performed to measure electrical activity of the heart.

Blood tests including the PT/INR coagulation test. These tests may be needed before the procedure to ensure that study patients have no problems related to blood clotting. Bleeding can sometimes occur after percutaneous renal procedures. The study patients will be asked to stop anticoagulants several days prior to the procedure.

Preoperative Imaging: De-identified scans will be provided to the study Sponsor.

CT-KUB non contrast: Pre-op CT-KUB non contrast will be performed no longer than 30 days pre-procedure as part of the screening assessment.

Postoperative 30 (±7 days) days Follow-up Imaging: De-identified scans will be provided to the study Sponsor.

CT-KUB non-contrast: All patients will receive to determine remaining stone burden.

Fluoroscopy. Fluoroscopy will be used provide an additional viewing method during the procedure. De-

identified images will be provided to the study Sponsor.

Endoscopy: Endoscopic ureteroscopy will be used to evaluate the presence of residual stone fragments in the kidney at the end of the procedure. Assessment will be recorded on CRFs.

Concomitant Medications. All medications beginning from 30-days prior to screening until subject exit will be recorded on a rolling medication log on the relevant case report forms.

Follow-up

The subject will have 1 follow-up visit and have procedures completed as outlined in Table 1.

Study Exit

Once the subject has completed 30 (±7) days follow-up or has withdrawn, they should be exited from the Study provided they do not have any conditions that require continued follow-up. The date of exit and subject status will be recorded on the Study Completion Form.

Criteria for Terminating Study

Sponsor reserves the right to terminate the study but intends only to exercise this right for valid scientific or administrative reasons and reasons related to protection of patients. Investigators and associated IRB will be notified in writing in the event of termination.

Possible reasons for study termination include:

- The discovery of an unexpected, significant, or unacceptable risk to the patients enrolled in the study.
- The occurrence of any device-related death or device-related serious adverse event causing permanent injury.
- A decision on the part of Sponsor to suspend or discontinue development of the device.

Criteria for Suspending/Terminating a Study Center

Sponsor reserves the right to stop the study center at any time after the study initiation visit if no patients have been enrolled or if the center has multiple or severe protocol violations without justification or fails to follow remedial actions.

Possible reasons for suspending/terminating a study center include:

- Repeated failure to complete case report forms prior to scheduled monitoring visits.
- Failure to obtain written Informed Consent.
- Failure to report CEC Events/SAE/UADE to the study Sponsor within 24 hours of knowledge.

4.3 Investigational product

The MONARCH™ Platform, Urology includes the MONARCH™ Tower, MONARCH™ Cart and MONARCH™ Controller, MONARCH™ Fluidics Pump, and Instruments and Accessories Kits. The MONARCH™ Platform, Urology enables electro-mechanical articulation and precise control of a flexible ureteroscope and/or a flexible mini-PCNL suction catheter ("catheter") for visualization and access to the urinary tract for diagnostic and therapeutic procedures. The ureteroscope and mini-PCNL suction catheter move only under continuous and direct physician control, via the MONARCH™ Controller. See Appendix IV for additional description of the system components.

Off-the-Shelf Equipment Required for Study Procedure:

In order to complete the MONARCH™ Mini-PCNL procedure, the following off-the-shelf equipment, typically used in endourology procedures, will be required:

- Cystoscope, camera, light source, and tower
- Compatible Ureteral Access Sheath
- Laser Console and Compatible Laser Fiber
- Saline Bags
- Waste Management System
- Patient Drapes
- Ancillary disposables including but not limited to guide wires, single and dual lumen ureteral catheters, ureteral stents
- Ancillary operating room equipment including but not limited to C-arm, surgical bed, anesthesia machine, sterile drapes and tables, monitors

Device Labeling

A copy of the Instructions for Use (IFU) will be included with the devices.

Device Distribution

Device distribution for this study will be managed by Auris Health, Inc.

Device Accountability

Sponsor and Investigative Site will maintain device accountability as required for this Study.

Return of Materials Upon Study Termination

Unless other arrangements have been made, all components of the MONARCH™ Platform, Urology System will be returned to Auris Health, Inc. at the end of the study. This may include the return of all used MONARCH™ Ureteroscopy Kits and the MONARCH™ Mini-PCNL Suction Catheters for examination after every case.

5. Criteria for Subject Selection and Withdrawal

Patients may withdraw from the study at any time, with or without reason and without prejudice to further treatment. In all cases of withdrawal, the reason(s) for withdrawal (if given) will be recorded upon study termination.

In addition, the investigator may withdraw the subject due to any of the following situations:

- Adverse event

- Any other reason determined by the investigator to be in the best interest of the subject
- Lost to follow-up
- Site termination
- Study termination
- Death

Subjects withdrawn from the Study prior to insertion of the sheath should be converted to conventional ureteroscopy or percutaneous nephrolithotomy. Subjects withdrawn due to an adverse event should be followed until the event has been resolved or is stable, if at all possible.

5.1 Subject inclusion criteria

Pre-Procedure Inclusion Criteria	1. Age ≥ 22 years 2. Simple renal caliceal and/or pyelo stone(s), ≥ 10 mm in size identified on CT scan, and appropriate for PCNL treatment according to AUA guidelines 3. Normal upper tract anatomy, amenable to PCNL and ureteroscopy 4. BMI < 40 kg/m2 5. Patients with a percutaneous tract length < 15cm as measured by the estimation of the skin to stone or skin to appropriate calyx for treatment through a CT scan 6. Patient is an appropriate candidate for a mini-PCNL based on the clinical guidelines and investigator assessment.

5.2 Subject exclusion criteria

Pre-Procedure Exclusion Criteria	Subjects will be excluded from participating in this study if they meet any of the following criteria prior to initiation of the procedure: 1. Any medical or physical condition/limitation that would contra-indicate a conventional ureteroscopy or PCNL (e.g., atypical interposition of visceral organs (bowel, spleen, or liver)) in the supine position. This assessment will be made by the investigator team. 2. Participation in any other clinical trial 30-days before and throughout the duration of the study that might impact the results 3. A solitary functioning kidney 4. Female subjects who are pregnant or nursing or those of child-bearing potential refusing a pregnancy test 5. Presence of ureteral impacted stones 6. Presence of ureteral obstruction 7. Presence of untreated urinary tract infection, urosepsis 8. Inability to give consent 9. Presence of a renal mass which has not been investigated

	10. Staghorn stone 11. Patient has an electrically or magnetically activated implanted medical device 12. Significant pharmacological anticoagulant therapy or uncorrected bleeding diathesis 13. Tumor in the probable access tract area and potential malignant renal tumor

In addition, subjects will be excluded from participating in this Study if any of the following exclusion criteria occur during the endoscopic procedure.

Intra-Procedure Exclusion Criteria	Any presenting condition discovered intra-procedurally that in the opinion of the investigator would make participating in this study not in the patient's best interest. For example, patients no longer considered good candidates for a mini-PCNL procedure for the removal of the kidney stones.

Criteria identified intraoperatively to justify patient exclusion, will be reviewed by the Sponsor, and considered for articulation directly in the protocol for future cases to ensure consistency in exclusion.

6. Treatment of subjects

The MONARCH™ Platform, Urology and its accessories are intended to access and visualize anatomical locations within the urinary tract and interior of the kidney for diagnostic and therapeutic procedures via transurethral or transurethral in conjunction with percutaneous access routes. The use of this device to treat kidney stones is previously described in this protocol in Section 4.3.

7. Assessment of Endpoints

Primary Endpoint

The primary endpoint is the successful completion of the robotic-assisted kidney stone removal procedures including:

- Gaining safe concomitant (i.e., retrograde and antegrade) access to the upper urinary tract
- Locating and visualizing the kidney stones
- Enabling fragmentation of stones by standard of care method
- Evacuating stone fragments and dust

The above bulleted device endpoints will be assessed regardless of procedural outcome (e.g., evacuation of stone fragments and dust may still be achieved by the device even if the patient is not stone free).

Safety Endpoints

The following will be considered safety endpoints:

- Adverse events through 30-days post-operative, scored on the Clavien-Dindo scale
- Conversion to Conventional Treatment Methods

Adverse events: Adverse events that may have been caused by any component of the procedures including those related to the MONARCH™ Platform, Urology System and/or Components.

Clavien-Dindo scale: Clavien-Dindo system for grading the severity of postoperative complications.[17] See Appendix III.

Conversion to Conventional Treatment Methods: Number of procedures converted to the conventional ureteroscopy or percutaneous nephrolithotomy for any reason.

8. Assessment of safety

8.1 Adverse Events

All adverse events (AE) and serious adverse events (SAE) will be monitored once patient is enrolled through the end of follow-up.

An AE is defined as any undesirable clinical occurrence in a patient whether or not it is considered to be device related. In addition, the definition of AE applies to any event with an onset post study procedure or to any underlying diseases, present at baseline, that exacerbate in severity post study procedure. Therefore, an underlying disease that was present at the time of enrollment is not reported as an AE, but any increase in the severity of the underlying disease is to be reported as an AE. All reported AEs must be recorded in the database. A description of the event, including the start date, resolution date, action taken, and the outcome should be provided, along with the Investigator's assessment of the relationship between the AE, the study treatment, and the study procedure.

The following definitions for rating severity of adverse events will be used:

Mild: Awareness of signs or symptoms, but easily tolerated; are of minor irritant type; causing no loss of time from normal activities; symptoms would not require medication or a medical evaluation; signs or symptoms are transient.

Moderate: Interferes with the subject's usual activity and/or requires symptomatic treatment.

Severe: Symptom(s) causing severe discomfort and significant impact of the subject's usual activity and requires treatment.

A serious adverse event (SAE) is defined as an event which leads to any of the following:

- Death
- Life-threatening illness or injury
- A permanent impairment of a body structure or a body function
- Requires in-patient hospitalization or prolongation of existing hospitalization
- Resulted in medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
- Led to a fetal distress, fetal death, or a congenital abnormality or birth defect

Each AE will be evaluated on its relatedness (Not Related, Possible, Probably, Causal) to both the study device and study procedure, according to the following definitions:

- **Not related:** Relationship to the device or procedure can be excluded when:
    - the event has no temporal relationship with the use of the investigational device, or the procedures related to application of the investigational device;
    - the adverse event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible;
    - the discontinuation of medical device application or the reduction of the level of activation/exposure - when clinically feasible -
    - and reintroduction of its use (or increase of the level of activation/exposure), does not impact on the adverse event;
    - the event involves a body-site or an organ that cannot be affected by the device or procedure;
    - the adverse event can be attributed to another cause (e.g. an underlying or concurrent illness/ clinical condition, an effect of another device, drug, treatment or other risk factors);
    - Harms to the subject are not clearly due to use error; or

    In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedure and the adverse event.

- **Possible:** The relationship with the use of the investigational device or comparator, or the relationship with procedures, is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases where relatedness cannot be assessed, or no information has been obtained should also be classified as possible.

- **Probable:** The relationship with the use of the investigational device or comparator, or the relationship with procedures, seems relevant and/or the event cannot be reasonably explained by another cause.

- **Causal:** The serious adverse event is associated with the investigational device, comparator or with procedures beyond reasonable doubt when:
    - The event is a known side effect of the product category the device belongs to or of similar devices and procedures;
    - The event has a temporal relationship with the device uses/application or procedures;
    - The event involves a body-site or organ that:
        - The device or procedures are applied to or is adjacent to;
        - The device or procedures have an effect on;
    - The event follows a known response pattern to the medical device (if the response pattern is previously known);
    - The discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the event (when clinically feasible);
    - Other possible causes (e.g. an underlying or concurrent illness/clinical condition and/or

an effect of another device, drug, or treatment) have been adequately ruled out;
- Harm to the subject is due to error in use

In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious adverse event.

An adverse event is considered to be non-device-related and non-procedure-related when, in the judgment of the Investigator, it is reasonable to believe that the event is neither associated with the use of the MONARCH™ Platform, Urology nor the study procedure (other products, surgical techniques, or medications required specifically for the procedure). Examples of these non-device-related and non-procedure related Adverse Events are related to concomitant medications (e.g. bleeding associated with anticoagulation medication) or a subject's pre-existing condition. Pre-existing conditions that are aggravated or become more severe during or after the procedure should be evaluated on a case-by-case basis to determine if the event may be more appropriately classified as device-related or procedure-related.

Site PI will be responsible for identifying adverse events during the procedure and during the standard of care follow-up period. Site PI will review adverse events experienced by subjects treated at their site during the procedure standard of care follow-up period and will record them in the medical record. Site PI will review all adverse events, expected or unexpected, per standard medical care.

Site PI will classify AEs as expected or unexpected, and report AEs directly to the Sponsor and IRB per local reporting policy. The lead investigator will capture all AEs occurring at the site including unanticipated AEs, in the electronic data capture instrument. Sponsor or its designee, may assist the Investigator in determining potential reportability to the FDA and other regulatory authorities as an Unanticipated Adverse Device Effect (UADE).

The Investigator should follow all unresolved serious adverse events until the events are resolved or stabilize, the subject is lost to follow-up, the subject has withdrawn consent, or the adverse event is otherwise explained.

For purposes of this study, the following events are not likely to be device-specific adverse events, since they are known procedure/anesthesia related adverse events:
- Any pre-planned surgical procedures
- Urethral false passage and long-term urethral stricture
- Various grades ureteral injury leading to perforation, avulsion, intussusception, and long-term stricture due to retrograde access
- Vesicoureteral reflux
- Uretero-iliac fistula
- Extra-renal stone migration
- Visceral injury due to percutaneous access that may require secondary intervention
- Renal pseudo-aneurysm
- Arterio-venous fistula
- Retro-peritoneal or perirenal fluid collection: urinoma, hematoma
- Perforation of renal pelvis
- Major bleeding
- Urinary Infection or sepsis
- Ureteral stent migration, forgotten stent

- Post-operative upper-tract obstruction
- Post decompression hyper-diuresis
- Renal Fracture

This listing of events is intended to provide guidance to the investigational the site for purposes of adverse event reporting. The Investigator at the investigational site should utilize his/her own clinical judgment in evaluating adverse experiences and may decide that the above events should be reported as device-specific adverse events.

8.2 General Reporting Requirements (Serious & Non-Serious Adverse Events)

All adverse events must be recorded on the Adverse Event CRF by the Investigator (or designee). The report should include: severity, duration, action taken, treatment outcome and relationship of the adverse experience to the study device, procedure, concomitant medications, pre-existing condition, etc. (i.e., unrelated, related or relationship unknown). The investigative site will report non-serious adverse events into the electronic clinical database within 1 week after they become aware of the non-serious adverse event.

In the case of serious adverse events, procedure and/or device observations and malfunctions, de-identified medical record documentation (e.g. procedure notes, operative notes, discharge summary, relevant progress notes, imaging or lab studies) must be provided to study sponsor or its designee.

The following criteria must also be adhered to by the Investigator in the case of serious adverse events:

- The Adverse Event CRF must be signed by the Investigator or Co-Investigator.
- It is the responsibility of the Investigator to inform their IRB of serious adverse events as required by their IRB procedures and in conformance with FDA and local regulatory requirements.

All serious adverse events must be reported by the Investigator (or designee) to the Sponsor, within 24 hours of learning of the adverse event via CRF. The Sponsor contact information for questions is:

[redacted]

8.3 Device Failures and Malfunctions

Observations, malfunctions, or failures of the MONARCH™ Platform, Urology will be documented in the appropriate fields within the CRFs, and supplemented with data collected in an engineering Case Observer survey [redacted]. Device failures and malfunctions should also be documented in the patient's medical record.

NOTE: Device failures or malfunctions are NOT to be reported as adverse events. However, if there is an adverse event that results from a device failure or malfunction, that specific adverse event would be recorded in the manner noted in Section 8.2).

Device deficiencies and product complaints reported will be reported by the site to the Auris Complaint Process [redacted]

9. Statistical Methods

The Sponsor will be responsible for the analysis of data from this protocol. A detailed Statistical Analysis Plan (SAP) will be written and approved prior to final database lock. The SAP will describe all planned analyses based on the statistical design of this study and the subsequent data collected. A brief overview of key statistical analyses is provided below.

9.1 Interval Windows

Interval windows for the purpose of analysis in this study will not be defined outside of those already specified in the protocol for visit scheduling. The final visit occurs approximately 30 days after surgery, thus no interval windows need to be defined given the absence of long-term follow-up in this study. The Schedule of Assessments specifies a window of 7 days around the scheduling of the 30-day follow-up visit, and any information entered in the eCRFs at this visit will correspond to the 30-day visit. There will be no assigning of observations to time points outside of the visit to which they are recorded in the eCRFs.

9.2 Levels of Significance

No hypotheses are specified for this study and no p-values are being calculated, therefore no level of significance is specified. All estimation of endpoints will be performed using 95% confidence intervals.

9.3 Analysis Sets

The summary of all performance and safety endpoints will be performed on the set of subjects in whom the MONARCH™ Platform, Urology is utilized during the surgical procedure.

9.4 Sample Size Justification

No formal hypothesis is being tested in this study; thus, the sample size was not statistically sized, but rather is considered sufficient for an initial descriptive summary of performance and safety endpoints in a feasibility study.

9.5 Analyses to be Conducted

Categorical variables will be summarized descriptively by frequencies and associated percentages. Continuous variables will be summarized descriptively by number of subjects, mean, standard deviation, median, minimum, and maximum. Confidence intervals will also be provided for procedure-related variables.

Subject disposition will be summarized in total using counts and percentages. The number and percentage of subjects completed and discontinued will be tabulated along with the specific reasons for discontinuation. Subject demographics and surgical characteristics will be summarized.

The number and percentage of subjects achieving successful completion of the robotic-assisted kidney stone removal procedure (primary endpoint) will be summarized and an exact 95% confidence interval will be estimated. In cases where successful completion was not achieved, additional details will be listed on the specific step(s) preventing successful completion.

All AEs will be summarized. Separate summaries will be provided for device-related and procedure-related AEs. Serious AEs will be summarized in a similar manner. Separate summaries will be provided for events classified as major (Clavien-Dindo Class III or higher) and minor (Clavien-Dindo Class I or II). Separate summaries by Clavien-Dindo grade will be summarized.

Summary statistics will be provided for additional exploratory data points collected in this study. There are no plans for interim analyses in this study. All summaries will be performed only on subjects undergoing the scheduled procedure and only observed data will be summarized. There will be no imputation of data for early terminated subjects or for missing data within the database.

Interim analyses may be conducted to support business needs. Data will also be summarized upon study completion.

10. Access to Source Documentation

The Principal Investigator must maintain detailed source documents on all Study subjects who are enrolled in the Study or who undergo screening. Additionally, the investigator(s)/institution(s) will permit trial-related monitoring, audits, IRB review and regulatory inspection(s) by providing direct access to source data and documents. Potential source documents include subject medical records including: hospital charts, clinic charts, Investigator's subject Study files, as well as the results of diagnostic tests (e.g., laboratory tests).

The following minimum information should be recorded in the subject's medical records:

- The date the subject entered the Study and the subject number
- The Study protocol number and the name of the Sponsor
- The date that informed consent was obtained
- Evidence that the subject meets Study eligibility requirements (e.g., medical history, study procedures and/or evaluations)
- The dates of all study related subject visits
- Evidence that required procedures and/or evaluations were completed
- Use of any concurrent medications
- Documentation of specific device used, if any
- Occurrence and status of any Adverse Events
- The date the subject exited the Study, and a notation as to whether the subject completed the study or was discontinued, including the reason for discontinuation.

Record Retention

The Investigator will maintain all essential Study documents and source documentation, in original format, that support the data collected on the study patients in compliance with the ICH/GCP guidelines. Documents must be retained for at least 2 years after the last approval of marketing application or until at least 2 years have elapsed since the formal discontinuation of the clinical investigation of the product. These documents will be retained for a longer period of time by agreement with Sponsor or in compliance with other regulatory requirements. When these documents no longer need to be maintained, it is Sponsor 's responsibility to inform the Investigator. The Investigator will take measures to ensure that these essential documents are not accidentally damaged or destroyed. If for any reason the Investigator withdraws responsibility for maintaining these essential documents, custody must be transferred to an individual who will assume responsibility. Sponsor must receive written notification of this custodial change.

11. Quality Control and Quality Assurance

Site Training

To ensure accurate, complete, and reliable data, the Sponsor or its representatives will provide instructional material to the Study sites site as appropriate;

- Instruct the Investigators and Study personnel on the protocol, the completion of the CRFs, and Study procedures
- Communicate regularly with site personnel via mail, email, telephone, and/or fax
- Make visits to the Study site

During those visits, the sponsor's designee will monitor the subject data recorded in the CRFs against source documents at the Study site.

Physician Training

Prior to enrolling subjects in the Study, investigators will be provided didactic and hands-on training in a simulated clinical environment on the procedural steps required to use the MONARCH™ Platform, Urology.

Audits and Inspections

The Principal Investigator for the site will inform the Sponsor or the Sponsor's designee in advance if they are to be audited or inspected by any regulatory agencies. The Sponsor or the Sponsor's designee will also inform the site if they are made aware of a pending audit or inspection by a regulatory agency. No FDA inspections are expected to be associated with this Study.

Amending the Protocol

An Investigator may not make protocol changes without prior approval by Sponsor. All significant protocol changes that may affect the following must be submitted and approved by the IRB before initiating the change:

- validity of the data or information resulting from the completion of the approved protocol;
- relationship of the likely subject risk to benefit relied upon to approve the protocol;
- scientific soundness of the investigational plan, or;
- rights, safety, or welfare of the human subjects involved in the investigation.

Sponsor will submit a copy of the protocol amendment to the Investigator for his/her IRB to review. The

investigative site must send Sponsor a copy of the IRB approval letter for the protocol amendment.

Sponsor may make certain administrative changes to the protocol without prior approval of the IRB. The site IRB will be notified of these changes.

Emergency Actions

Sponsor accepts the right of the Investigator to deviate from the protocol in an emergency when necessary to safeguard the life or the physical well-being of a study patient. The Investigator must give notice of any emergency deviations and justification for the deviation to Sponsor and the IRB as quickly as possible after the episode, in any event no later than 24 hours after the emergency.

Protocol Deviations

A protocol deviation is defined as an event where the Clinical Investigator or site personnel did not conduct the study according to the protocol.

Investigators shall be required to obtain prior approval from Sponsor before initiating deviations from the protocol, except where necessary to protect the life or physical well-being of a subject in an emergency. Such approval shall be documented in writing and maintained in clinical study management and Investigator files. Prior approval is generally not expected in situations where unforeseen circumstances are beyond the Investigator's control, (e.g., subject was not available for scheduled follow-up office visit, blood sample lost by laboratory, etc.); however, the event is still considered a deviation and will be reported via the appropriate CRF.

Deviations must be reported to Sponsor regardless of whether medically justifiable, pre-approved by Sponsor or taken to protect the subject in an emergency. Subject specific deviations will be reported on the Protocol Deviation case report form. Non-subject specific deviations, (e.g., unauthorized use of an, MONARCH™ Platform, Urology device outside the study, unauthorized use of a MONARCH™ Platform, Urology device by a physician who has not signed an Investigator agreement or not been trained in the use of the device, etc.), will be reported to Sponsor reported via the appropriate CRF. Investigators will also adhere to procedures for reporting study deviations to their IRB in accordance with their specific IRB reporting policies and procedures.

Regulations require that Investigators maintain accurate, complete, and current records, including documents showing the dates of and reasons for each deviation from the protocol. For reporting purposes, Sponsor classifies study deviations as major and minor:

Major deviation (at a minimum)**:** Any deviation from subject inclusion and exclusion criteria, subject informed consent procedures, unauthorized device use, or which impacts the analysis of the primary endpoint or scientific integrity of the study.

*Minor deviation***:** Deviation from a protocol requirement such as incomplete/inadequate subject testing procedures, follow-ups performed outside specified time windows, etc. Minor Deviations that continue to occur at an investigational site may be classified as Major Deviations if corrective action is not taken to secure future compliance to the protocol.

Confidentiality

Confidentiality of subjects will be maintained throughout the Study. A unique identification code will be assigned to each subject participating in this Study. Any data that may be published in abstracts,

scientific journals, or presented at medical meetings will reference a unique subject code and will not reveal the subject's identity. The Sponsor will make every reasonable effort to protect the confidentiality of the subjects participating in the Study.

12. Ethics

Study Conduct & the Declaration of Helsinki

The Study will be performed in accordance with the relevant parts of Title 21 CFR Parts 50, 54, 56 and ISO 14155-1 / 14155-2.1; the ICH Guidelines for Good Clinical Practices (E6), the Declaration of Helsinki, and any regional and/or national regulations.

Institutional Review Board

A copy of the protocol proposed Informed Consent form, HIPPA authorization (to the extent not included in the informed consent form), other written patient information and any proposed advertising material must be submitted to the IRB for written approval. A copy of the written IRB approval of the protocol and Informed Consent form must be received by Sponsor before recruitment of patients into the study.

The Investigator must submit and, where necessary, obtain approval from the IRB for all subsequent significant protocol amendments and significant changes to the Informed Consent form. The Investigator should notify the IRB of deviations from the protocol or SAEs and UADEs occurring at the site and other SAE/UADE reports received from Sponsor in accordance with local procedures.

The Investigator will be responsible for obtaining annual IRB approval and renewal throughout the duration of the study. Copies of the Investigator's reports and the IRB continuance of approval must be sent to Sponsor.

Informed Consent Form

Written Informed Consent must be obtained for all patients who are potential study candidates before any study-specific tests or procedures are performed.

Patients who meet general entry criteria will be asked to sign the study-specific, IRB approved Informed Consent form and HIPPA authorization document before any study-specific tests or procedures are performed. Study personnel should explain that even if a patient agrees to participate in the study and signs the Informed Consent Form and the HIPPA authorization document, the screening observations may demonstrate that the patient is not a suitable candidate for the study.

Informed consent will take place in a private environment (e.g., patient exam room), free from distractions. The PI will approach the subject at their standard of care clinic appointment or prior to their scheduled study procedures and will explain the study to qualified subjects prior to obtaining consent. Interviews to obtain consent will not follow any stressful situation (e.g., patient being informed he/she may have cancer) and will not be conducted if the patient has received any mind-altering medications or anesthesia. Patients will be assessed for their capacity to consent by the ability to show comprehension of the procedure, ask appropriate questions, and appear properly oriented. Written Informed Consent must be recorded appropriately by means of the patient's, or their legal representative's dated signature. A signed copy of all consents and the HIPAA authorization document will also be given to consenting subjects.

A Screening/Enrollment Log will be maintained to document select information about candidates who fail to meet the entry criteria.

The written Informed Consent documents should be prepared in the language(s) of the potential patient population.

The reviewing IRB and the Sponsor must first approve the Informed Consent Form and HIPPA authorization documents that are used. The Informed Consent forms that are used should be in accordance with the current guidelines as outlined by the Good Clinical Practices (GCP) guidelines, Declaration of Helsinki, and the International Conference on Harmonization (ICH).

Prior to participation in the clinical Study, each patient must give written Informed Consent after the context of the study has been fully explained to the patient in language that is easily understood by the patient. The patients must also be given the opportunity to ask questions and have those questions answered to their satisfaction.

The patient will receive a copy of the Informed Consent form.

Investigator Responsibilities

- Sign and adhere to the Investigator Agreement
- Participate in Investigator meetings as scheduled by Sponsor
- Provide required assessments for analysis
- Perform and be capable of performing treatment procedures as outlined in this protocol
- Comply with all required elements of this protocol (e.g., perform testing and follow-up as specified, especially during personnel transitions) and supply material suitable for quantitative analysis
- Obtain written Informed Consent before any study specific procedures are performed in accordance with GCP
- Complete all Case Report Forms (CRFs) prior to scheduled monitoring visits
- Change hospital routine if required by protocol (as long as patient safety and well-being is not compromised)

13. Data Handling and Recordkeeping

Standardized electronic CRFs will be utilized by the participating site using a standardized database. Electronic data capture system will be used in this study. Investigator is responsible for the accurate completion and timely submission of the data collected during the Study. Incoming data will be monitored by the Sponsor or designee to identify inconsistent or missing data and any adverse events. Any data issues are to be promptly addressed with the investigator. Quality assurance procedures will be established to ensure that complete, accurate and timely data are submitted, that protocol requirements are followed, and that complications, adverse events and adverse device effects are correctly reported and investigated, as appropriate. Investigator is to maintain all source documents as required by the protocol, including laboratory results, supporting medical records, and signed Informed Consent Forms and HIPPA authorization forms. The source documents will be used during the regular monitoring visits to verify information from the database against data contained on the completed CRFs.

The Principal Investigator must maintain detailed records on all subjects who sign the Informed Consent and begin the pre-procedure evaluation. Data for enrolled subjects will be entered into CRFs provided by the Sponsor. All data should be entered completely, promptly, and legibly. For source documents, corrections should be made in a manner that does not obscure or eliminate the original error, by striking through the original data with one line, and initialing and dating the change, along with the reason for the change (if not obvious).

Study Exit CRFs are completed for all enrolled subjects, regardless of if they did or did not complete the Study (e.g., subject discontinuation, Study termination).

The PI will review the results, and the results will become part of the subject's medical record and research record. Any clinical follow-up or repeat procedures will be dictated by the patient's physician based on clinically relevant data and will not be influenced by enrollment into this study. All patient information will be de-identified. All information and data related to this study will be stored in a secured, locked cabinet in a secure office accessible only by the PI.

Robotics System Data Collection

By nature of design, the MONARCH™ Platform robotic system will also collect data throughout the procedure on its local hard drive. These robotic system data include procedural events and video (see section below). These robotic system data will be stored in a secured database. Robotic system data that is de-identified may also be input into the MONARCH™ Gateway portal. These robotic system data may be used in an exploratory analysis to validate the utility of robotic system data to assess several study variables. These data may also be used to support training education, and continued research and development outside of this study, including the development of software, as well as quality and operational improvement. There may be additional data collection and analysis of other variables from these data besides those described in this section. The purposes for these analyses may include, but are not limited to, scientific research beyond the scope of this study, including epidemiology studies research, and the development of future study protocols.

These robotic system data may be shared with and used by Auris Health, Inc., C-STATS, Inc., or other affiliates or subcontractors of Auris Health, Inc. Auris Health, Inc. will solely own the rights to robotic system data that will be collected during the study and any derivatives of such data. These data may be transferred to affiliates of Auris Health, Inc., including their employees, contractors, processors, and agents working on their behalf for the purposes stated above.

The robotic system data will be stored securely by the study Sponsor. These data might be stored on hard drives, CDs, DVDs, or directly uploading the data into secured databases.

The collection, use, and disclosure of all personal data included in the robotic system data will be maintained in compliance with applicable personal data protection and security laws, and regulations that govern protected health information. Appropriate measures will be taken to maintain the confidentiality of the video and to prevent unauthorized access.

For this study, the data collected by the site on the CRFs will be used for study endpoint assessment, as the robotic system data is not considered source documentation for purposes of study data collection.

Video and Image (Recording and Analysis)

Videos (including audio) and still images will be captured during the surgical procedure. Videos and still images of the surgical procedure viewed from the endoscope will be recorded by the MONARCH™ Platform, Urology device system. The videos will be stored within a secured database. In addition, videos from the operating room-perspective may be captured, and stored in a secured database. Care will be taken to avoid the videos and still images capturing the patient's face, patient's name, or the name of operating urologists. The investigative site will try to only the anatomical area

where the specific medical procedure is performed will be recorded. A subject may not participate in this study if they do not agree to allow video recordings and still images to be captured during their procedure.

Video may be used in an exploratory analysis to validate the utility of video analysis to assess several study variables. Video and captured images may also be used to support training education, and continued research and development related to surgical procedures and human diseases and conditions, including development of devices, software or algorithms, as well as quality and operational improvement. Video and images may be edited (cropped so that only the information we require for these purposes is seen) and analyzed in whole or in part. There may be additional data collection and analysis of other variables from the video and images besides those described in this section. The purposes for these analyses may include, but are not limited to, scientific research outside of the scope of this study, including epidemiology studies research, and the development of future study protocols. Video and images may be used to support scientific presentations and publications, as well as content for commercial or marketing use.

The videos and images may be shared with and used by Auris Health, Inc., C-STATS, Inc., or other affiliates and subcontractors of Auris Health, Inc. Auris Health, Inc. will solely own the rights to the video and image data that will be collected during the study and any derivatives of such data. Video and image data may be transferred to affiliates of Auris Health, Inc., including their employees, contractors, processors, and agents working on their behalf for the purposes stated above.

The video and images will be stored securely by the study sponsor. The videos and images might be stored on hard drives, CDs, DVDs, or directly uploading of the data into secured databases.

The collection, use, and disclosure of all personal data included in the video will be maintained in compliance with applicable personal data protection and security laws, and regulations that govern protected health information. Appropriate measures will be taken to maintain the confidentiality of the video and to prevent unauthorized access.

For this study, the data collected by the site on the CRFs will be used for study endpoint assessment, as the video and image data are not considered source documentation for purposes of study data collection.

Engineering Case Observers

Engineers from the Sponsor institution may also record technical observations on the device (e.g., recovery pathway from a fault message). These data do not encompass any PHI or PII. These data are intended to support root-cause assessments of product complaints, and future product improvement. These observations are not readily recorded by the investigative site staff, but rather technical subject-matter-experts on the study device. These data are detailed in a memo for this engineering Case Observer survey ([redacted]). The site will not be required to transfer this information to the CRF, and this information is not considered source documentation for purposes of study data collection.

Data Safety Monitoring Plan

All subjects enrolled in the trial will undergo the procedure that may be considered medically necessary by their physicians. Prior to the procedure, PIs will explain the risks associated with ureteroscopy and percutaneous nephrolithotomy and verify that the research only risks have been explained, and that the subject has signed an informed consent form. There are no anticipated risks, outside of the risk for the standard of care procedures for this clinical trial. All subjects are required to read, understand, and sign the informed consent form associated with the research study. Each subject will be informed of post

procedure symptoms of which to be aware that may represent adverse reactions to the procedure.

The patient will be given oral and written instruction to pay attention to the following.

Upon return to home, the patient will be aware he/her may experience or observe
- mild burning feeling when urinating
- light red stained urine in relation to moderate amounts of blood in the urine
- mild discomfort in the lower abdominal area or flank area when urinating
- the need to urinate more frequently or urgently
- mild discomfort, minimal oozing, or discrete wet feeling at the flank wound site

These problems should settle within one or two days. The patient should call the contact number given by the investigator if bleeding, pain, or discomfort is severe or if problems last more than two days.

The patient should monitor his temperature and reach out the investigator should he/her present with signs of infection:
- Fever above 100 F
- Chills
- Severe burning feeling during urination

The patient should reach out the investigator should he/her present with severe lower urinary signs or symptoms:
- Impossibility to pass urine
- Heavy bleeding in the urine or evacuating clots in the urine
- Heavily blood stained or fluid leakage at the flank wound site

The patient should reach out the investigator should he present with abdominal signs such as:
- Prolonged dizziness, nausea, vomiting
- Feeling bloated and/or does not pass wind for more than 24 hours
- Severe abdominal pain or flank pain

The patient should reach out the investigator should he present with signs that could suggest a deep vein thrombosis:
- Leg pain
- Shortness of breath
- Tachycardia
- Anxiety

If the subject notes any of these symptoms, he/she is instructed to contact his/her physician, who will determine the course of action. All events are to be reported within 48 hours of occurrence to the coordinating site. All adverse events (AEs) will be reviewed by the medical monitor within one month of their occurrence and summarized for review. The PI will be responsible for submitting this report to the IRB at his/her institution as required. AEs and other reportable events are defined above in Section 8.

14. Monitoring

Monitoring visits to the clinical site will be made periodically during the study by the Sponsor's designee to ensure that all aspects of the current, approved protocol/amendment(s) are followed. Original source documents will be reviewed for verification of data in the database. The Investigator/institution guarantees direct access to original source documents by Sponsor, Sponsor's designees, and appropriate regulatory authorities. In the event that the original medical records cannot be obtained for a patient that is seen by a non-study physician at a non-study institution, photocopies of the original source documents must be made available for review.

It is important that the Investigator and relevant study personnel are available during the monitoring visits and that sufficient time is devoted to the process.

Phone contacts and site visits will be conducted to ensure that the protocol is being followed and that any protocol deviations are properly documented. Clinical monitoring will include a verification that Informed Consent was properly obtained for all enrolled study participants, a review of clinical records for accuracy and completeness, resolution of missing or inconsistent results and a review of source documents. The clinical monitor will verify that the CRFs are in agreement with the source documentation and other records. The investigator will make available to the clinical monitor for review all Informed Consent documents, source documentation, original laboratory data and other relevant records for all enrolled subjects at the site. It is important that the investigator and other relevant site personnel are available for consultation with the clinical monitors during the monitoring visits and that sufficient time is devoted at the site to the monitoring process.

Additionally, telephone and/or e-mail contact will be conducted on a regular basis with the investigator and the site staff to ensure that the protocol is being followed and to address any issues that may occur during the course of the Study.

If a deficiency is noted during an on-site visit (or at any other time during the course of the Study), the clinical monitor is required to discuss the situation with the investigator and the Sponsor (if required) to secure compliance.

15. Compensation, Insurance, and Indemnity

The financial agreement, insurance and indemnity between sponsor and investigators are provided in separate agreements.

16. Publication Policy

The existence of this clinical study is confidential, and it should not be discussed with persons outside of the study. Additionally, the information in this document and regarding this Study contains trade secrets and commercially sensitive information that is confidential and may not be disclosed unless such disclosure is required by regional or national law or regulations. Subject to the foregoing, this information may be disclosed only to those persons involved in the study who have a need to know, but all such persons must be instructed not to further disseminate this information to others. These restrictions of disclosure will apply equally to all future information provided that is indicated as confidential.

The data generated by this clinical study are the property of the Sponsor. These data may be used by the Sponsor now and in the future for presentation or publication at Sponsor's discretion or for submission to governmental regulatory agencies. The Principal Investigator(s) may publish or present the Study results with prior consent of the Sponsor but will not disclose confidential information.

Prior to submission by a Principal Investigator for publication or presentation, the Sponsor will be provided with the opportunity to review the submission for confidential information and accuracy.

17. Appendices

17.1 Appendix I

References:

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17.2 Appendix II

Regulatory Considerations

Sponsor, in cooperation with the Investigator, will make necessary efforts to ensure that this study is conducted in compliance with GCPs and all applicable regulatory requirements.

Pre-Study Documentation Requirements

Prior to shipment of product, the following documents must be provided to Sponsor:

- Signed and dated Investigator Agreement
- A copy of the written IRB approval of the protocol
- A copy of the written IRB approval of the Informed Consent Form and HIPPA authorization document
- A copy of the curriculum vitae of the Principal Investigator and Co-Principal Investigator (if applicable)

General Duties [21 CFR 812. 40]

No IDE application to FDA is required for this Study. The Sponsor and the Investigator are responsible for obtaining IRB approval prior to start of the study. Sponsor will be responsible for providing quality data that satisfies publication requirements and informing of serious unanticipated adverse events and deviations from the protocol.

Monitoring [21 CFR 812. 46]

Sponsor or its designee will conduct investigational site monitoring to ensure that all Investigators are in compliance with the protocol and the Investigators' agreements. The sponsor and/or designee will monitor the site to ensure that the completed Case Report Forms match the medical records, and resolve any differences. The sponsor will retain the right to remove either the Investigator or the investigational site from the study.

The sponsor will review significant new information, including unanticipated serious adverse events and ensure that such information is provided to the Investigators and to all reviewing IRB.

Supplemental Applications [21 CFR 812. 335 (A) and (B)]

As appropriate, the sponsor will submit changes in the Investigational Plan to the Investigators to obtain IRB re-approval. No FDA submissions are required.

Maintaining Records [21 CFR 812. 140 (B)]

The sponsor will maintain copies of correspondence, data, shipment of devices, serious adverse device effects and other records related to the clinical Study. The sponsor will maintain records related to the signed Investigator Agreements.

Submitting Reports [21 CFR 812. 150 (B)]

No FDA submissions are required for the Study.

Site Record Retention Policy [21 CFR 812. 140 (D)]

The sponsor and clinical site will maintain all records pertaining to this study for a period of two

years following: the date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a pre-market approval application. Record retention dates will be provided to all concerned by the sponsor.

Informed Consent & Institutional Review Board/Ethic Committee [21 CFR Parts 50 & 56]

All subjects must provide written informed consent in accordance with the local clinical site's IRB. A copy of the consent form from each center must be forwarded to the Sponsor for review and approval prior to submitting it to the IRB. The site must provide the Sponsor with a copy of the clinical site's IRB approval letter and the informed consent. Yearly approvals for the continuation of the Study at each clinical site must also be forwarded to the Sponsor.

All Protected Health Information (PHI) to be collected in the study will be described in the informed consent form, and all study data will be managed in accordance with the Privacy Law (HIPAA).

17.3 Appendix III

Clavien-Dindo Classification

For classification of adverse events

Adverse events will be graded using the Clavien-Dindo Classification system. First described in 2004, it is widely used throughout surgery for grading adverse events (i.e. complications), which occur as a result of surgical procedures.[a]

Clavien-Dindo consists of 7 grades (I, II, IIIa, IIIb, IVa, IVb and V). The introduction of the subclasses a and b allows a contraction of the classification into 5 grades (I, II, III, IV and V) depending on the size of the population observed or the of the focus of a study.

Complications that have the potential for long-lasting disability after patient's discharge (e.g.: paralysis of a voice cord after thyroid surgery) are highlighted in the present classification by a suffix ("d" for disability). This suffix indicates that a follow-up is required to comprehensively evaluate the outcome and related long-term quality of life.

Grades	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Grade III	Requiring surgical, endoscopic, or radiological intervention
- IIIa	Intervention not under general anesthesia
- IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU-management
- IVa	single organ dysfunction (including dialysis)
- IVb	Multiorgan dysfunction
Grade V	Death of a patient

**brain hemorrhage, ischemic stroke, subarrachnoidal bleeding, but excluding transient ischemic attacks (TIA); IC: Intermediate care; ICU: Intensive care unit.*

[a] Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg. 2004;240:205–213.

17.5 Appendix IV

Refer to Figure 2 for MONARCH™ Platform, Urology capital equipment setup. Table 2 provides an overview description of MONARCH™ Platform, Urology's capital components and MONARCH™ Platform, Urology instruments and accessories kits that will be provided by the manufacturer, Auris Health, Inc.

Figure 2: MONARCH™ Platform, Urology Capital Equipment Setup

An overview of major capital components and instruments and accessories kits of the MONARCH™ Platform, Urology provided by Auris Health, Inc. are described in **Table 2.**

Capital Components	
MONARCH™ Tower	Main Tower that connects with the major components (Cart, Fluid Management Tower, Controller, Ureteroscope, Compact Field Generator, Percutaneous Needle) of the platform to enable use of the Urology indication. The Tower has a user interface touch screen and houses the necessary hardware and software to operate the system.
MONARCH™ Cart	Mobile Cart that is comprised of three robotic arms and a user interface touch screen. All three arms can be utilized throughout any of the Urology platform procedures.
MONARCH™ Fluidics Pump	Fluidics Pump developed by Thermedx, LLC in partnership with Auris. The system is packaged into a tower enclosure specifically for integration into the MONARCH™ Platform for Urology applications.
MONARCH™ Controller	Single Controller with buttons and joysticks used to control robotic instrumentation and adjust system settings and preferences. User holds controller with two hands.
Percutaneous Sheath Mount	A re-usable mount required to secure and position the Percutaneous Outer Sheath for the MONARCH™ Mini-PCNL procedure.
Compact Field Generator	A re-usable, commercially available electromagnetic field generator that can be positioned near the surgical site. The field generator will be sized appropriately for Guided Percutaneous Access. It requires a mount to be secured to a robotic arm.

Table 2: MONARCH™ Platform, Urology

Instruments & Accessories Kits		
Drape Kit	**Item**	**Purpose/Use**
MONARCH™ Platform Drape Kit	***Controller Drape***	Provides a sterile barrier for the MONARCH™ Controller.
	Cart Drape	Provides a sterile barrier for the MONARCH™ Cart. Sterile adapters are attached to the Cart Drape. Devices are docked to the sterile adapter which are attached to the MONARCH™ Cart.
MONARCH™ Ureteroscopy		
MONARCH™ Ureteroscopy Kit	***MONARCH™ Ureteroscope***	A single use Ureteroscope that can be used both robotically and manually. The Ureteroscope will have 2-way, single plane articulation when manually controlled and 4-way, steerable articulation when robotically controlled. The Ureteroscope will also have robotic shaft roll and integrated electromagnetic sensors.
	Ureteroscope Driver	Component that mounts to a robotic arm. Main function is to quickly and safely insert and retract the Ureteroscope into patient and to stabilize the ureteral access sheath. It will be designed to interface with various off the shelf (OTS) ureteral access sheaths.
	Laser Driver	Working channel accessory that mounts to a robotic arm intended to actuate an OTS laser fiber with the MONARCH™ platform. This accessory will be designed to be compatible with various OTS laser fibers to give users control of insertion/retraction

			actions. Users will still rely on external laser consoles and foot pedals to activate the laser.
	Ureteroscope Valve		Commodity valve and tubing used to connect fluidics to the MONARCH™ Ureteroscope. One will be included with the kit, and also sold separately in case of sterile contamination.
Urology Irrigation Cartridge	***Urology Irrigation Cartridge***		Cartridge and tubing used to connect with the Fluidic Pump. Transfers irrigation from the saline bag to the Ureteroscope or other instruments.
Stone Retrieval Basket	***Stone Retrieval Basket***		Working channel instrument comprised of a blunt tip basket and handle that mounts to a robotic arm similar to laser driver. User can have full control of the basket to perform insert, retract, open, and close actions. The basket design also allows the user the perform those same actions with the basket non-robotically.
MONARCH™ Guided Percutaneous Access			
Guided Percutaneous Access Kit	***Compact Field Generator Drape***		Provides a sterile barrier for the Compact Field Generator.
	Compact Field Generator Mount		To hold the Compact Field Generator in place and allow for generation of EM field required for Guided Percutaneous Access
	Guided Percutaneous Access Needle		A needle capable of continuously tracking the 3D location and trajectory of the needle tip using EM sensors to gain precise access into the kidney while minimizing use of fluoroscopy.
MONARCH™ Mini-PCNL			
MONARCH™ Mini-PCNL Kit	***MONARCH™ Mini-PCNL Suction Catheter***		Instrument that is a robotically 4-way steerable catheter used for suction and removal of stones during the MONARCH™ Mini-PCNL procedure.
	Percutaneous Sheath	*Percutaneous Outer Sheath*	Sheath that interfaces with patient and the percutaneous inner sheath. This sheath provides inflow of fluid from the Fluidics Pump and is stabilized by the Sheath Mount.
		Percutaneous Inner Sheath	Inner sheath that provides a protected channel for the Suction Catheter to enter the patient. The annular space between this inner sheath and the Suction Catheter provides passive outflow of fluid.
	Dilation Set	*8Fr Dilator*	Standard 8Fr dilator used to dilate the percutaneous tract.
		10Fr Catheter	10Fr catheter used to increase the dilation size from 8Fr. Typically used for the placement of a safety guidewire.
		Percutaneous Sheath Dilator	Sheath dilator used to dilate the tract to the final size for the insertion of the Percutaneous Outer Sheath.

	Alignment Set	*Alignment Plug*	Rigid plug that interfaces with percutaneous sheaths, utilized during an alignment process for positioning the arm used for docking the Suction Catheter.
		Alignment Tool	Tool that interfaces with the Alignment Plug and is used to orientate and precisely position the robotic arm for docking of the Suction Catheter.
	Suction Set	*Suction Cartridge*	A suction cartridge needed to connect the suction catheter to standard OR suction equipment.
		Suction Tubing	Suction tubing needed to connect the suction catheter to the Suction Cartridge.
	Sheath Mount Drape		Drape for the Sheath Mount to maintain sterility.