6-2020

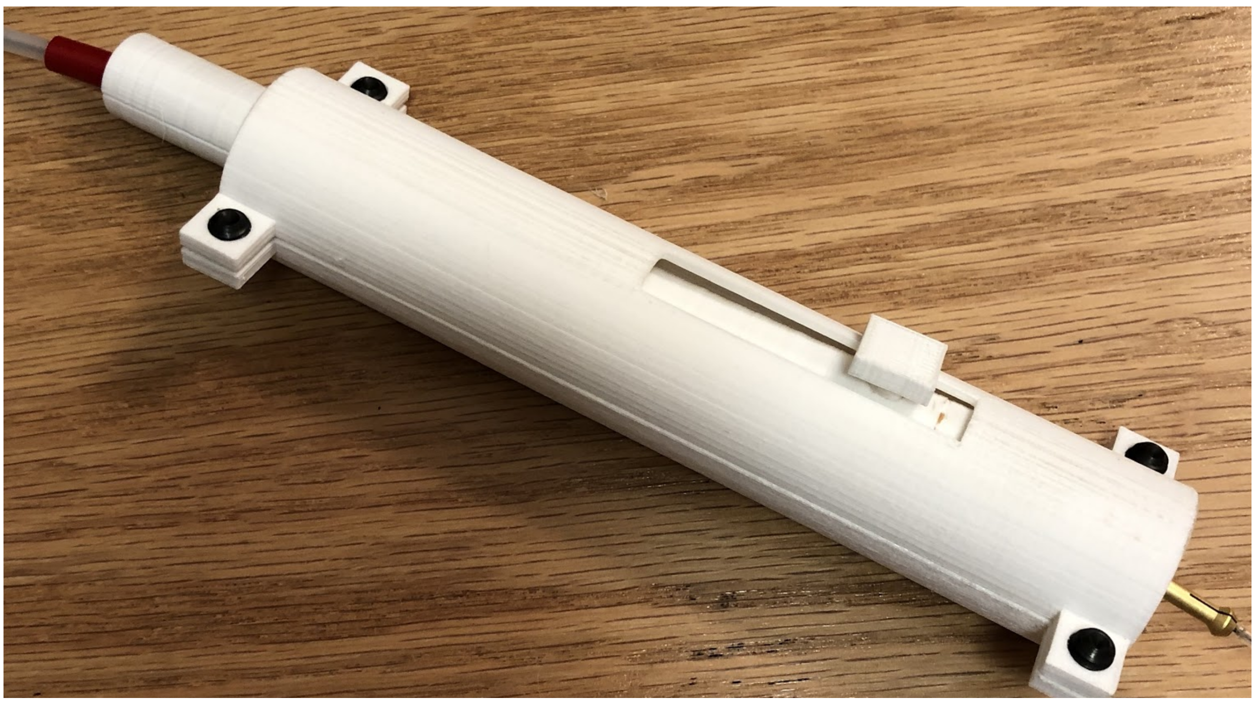
A Novel Device to Remove Kidney Stone Fragments from the Ureter

Madeline Feinberg
Union College - Schenectady, NY

Christina Pavlovsky
Union College - Schenectady, NY

John Kasel
Union College - Schenectady, NY

A Novel Device to Remove Kidney Stone Fragments from the Ureter



Authors: Madeline Feinberg, John Kasel, Christina Pavlovsky
March 26th, 2020

1. Background

1.1 The urinary tract

Food is the main source of energy and nutrients for the human body. When cells consume the nutrients, they also produce waste that must be removed. The system in the body that removes waste is called the urinary tract system. This system works by filtering blood and turning it into urine [1]. Within the urinary tract are the kidneys, which are two fist sized organs located on each side of the spine. The kidneys receive a high volume of blood everyday, approximately 120-150 quarts [1]. Using specialized blood vessels, the kidneys filter the blood by turning waste and toxins into urine. The kidneys typically produce 1-2 quarts of urine everyday [1]. Once the urine is produced, it travels down the ureters, which are thin tubes of muscle approximately 4 mm in diameter. [1]. There are two ureters that connect each kidney to both sides of the bladder. The bladder is a hollow, muscular organ that can hold up to 1.5 to 2 cups of urine [1]. As the bladder fills, signals are sent to the brain to notify the individual to empty their bladder [1]. The urine, consisting of toxins and waste, gets emptied through the urethra located at the bottom of the bladder. A figure representing the urinary tract system is located below in Figure 1.

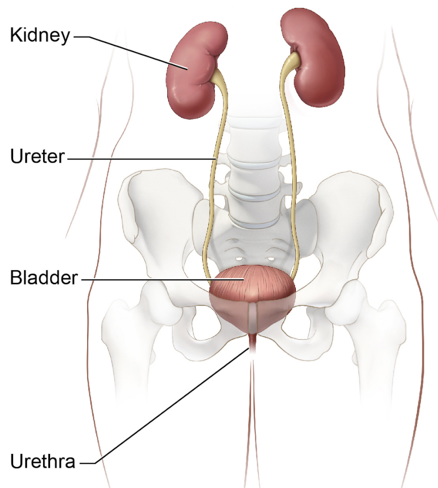


Figure 1: The urinary tract including the kidneys, the ureters, the bladder, and the urethra [2].

1.2 Kidney Stones

There is a risk of developing kidney stones when the urine has high volumes of minerals and salts, the most common being calcium. These substances can harden and form into clumps which become lodged in the kidney and/or ureters. There are many factors that put an individual at risk for developing kidney stones including urine volume, diet, obesity, or certain medical conditions. One of the more common risk factors is a low urine volume which means an individual produces less urine than normal. Low urine volume can result from dehydration, exercise, or not drinking enough fluids. As a result, there is not enough fluid to keep minerals and salts dissolved in the urine, which can lead to developing kidney stones. [3] Another risk factor is a high salt volume diet. If there is an excess amount of salt in the urine, calcium cannot be reabsorbed by the urine [3]. This causes increased levels of calcium in the urine resulting in a higher chance of developing calcium kidney stones [3]. In addition to calcium stones, there are

uric acid stones, struvite stones, and cystine stones [3]. In general, kidney stones are more common in men than women and also in obese versus normal-weight indivuals [4].

The size of the kidney stone determines whether the stone can be passed naturally or whether surgical treatment is required. It has been found that 95% of ureteral stones ranging from 1.5-4 mm can be passed naturally [5]. The chances of the stones passing naturally drop to about 50% when they are greater than 5 mm [5]. For stones that are greater than 7 mm, surgical intervention is required [5, 6]. In the cases where surgery is required, the large stone is fragmented into smaller fragments that range from 1.5-4 mm.

1.3 Types of procedures

There are numerous procedures that are used to fragment a large kidney stone into smaller fragments. These include extracorporeal shock wave lithotripsy (ESWL), percutaneous nephrolithotomy, and ureteroscopic holmium laser lithotripsy [7, 8]. An ESWL procedure can be performed on stones located in either the kidney or the ureter. During an ESWL procedure high energy shock waves, typically ultrasound waves or X-rays, are used to break up the large stone into smaller fragments, which are then left to be passed naturally [1].

A percutaneous nephrolithotomy is performed on stones located only in the kidney. During this procedure a nephroscope is inserted into a small incision in the patient's back [1]. The nephroscope then locates the stone in the kidney and removes it via an extraction device [1]. In some cases when a stone is too large to be extracted, it will be fragmented by a laser.

The final procedure is the ureteroscopic holmium laser lithotripsy, which is the procedure our group has focused on in developing a new device. The ureteroscopic holmium laser lithotripsy is performed on kidney stones greater than 4 mm located only in the ureter [9].

Approximately 25% of all kidney stone removal procedures are performed using the holmium laser lithotripsy technique [10]. This procedure uses an instrument called a ureteroscope, which is a long thin tube consisting of an eyepiece on one end and a tiny light and lens on the other end, shown Figure 2a [10]. The diameter of the ureteroscope ranges from 4.5Fr - 8.5Fr, where 1Fr = ⅓ mm, depending on the rigidity of the scope [5]. The ureteroscope also has multiple ports, of diameter 3.6Fr, in which a laser and extraction device can be inserted independently of one another, shown in Figure 2b [5].

(a) (b)

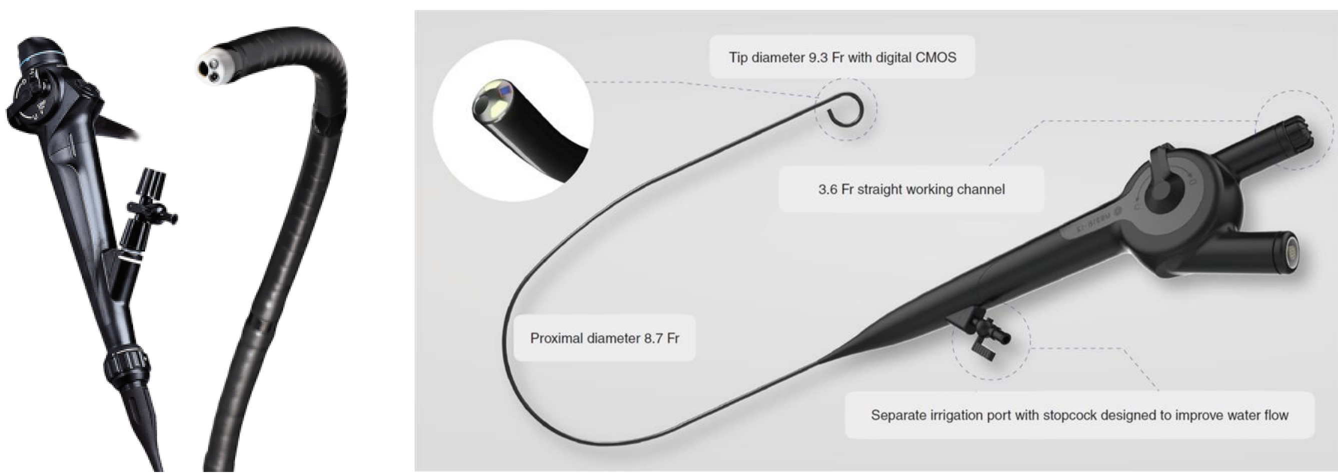


Figure 2: a) The common ureteroscope with eyepiece on one end and light and lens on the other end [11]. b) The common ureteroscope with dimensions and working channels [12].

During the procedure, the ureteroscope is inserted through the urethra of the patient and travels up through the bladder until it reaches the location of the stone in the ureter. Once the stone is located, the flexible holmium laser is inserted through a port on the ureteroscope and aims laser beams at the stone at a frequency of 10MHz and energy settings ranging from 30-140 mJoules

[13]. This ruptures the large stone into smaller fragments which can then be extracted via an extraction tool. The current extraction tools that are used with the laser produce further complications, such as reinsertion of the device into the patient multiple times and the loss of stones when the tool has reached the bladder. These complications will be addressed with our improved device. An overview image of a holmium laser lithotripsy is shown below in Figure 3.

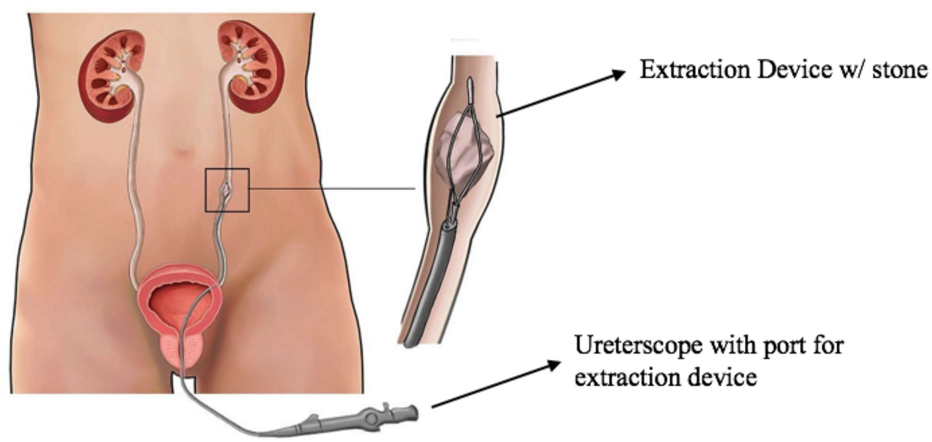


Figure 3: Holmium laser lithotripsy using a ureteroscope with a working channel for an extraction device to capture the kidney stone [14].

1.4 Current Technology

The most common extraction device used with the laser is the wire basket that can be shown below in Figure 4. The basket is composed of intertwined wires that form into a helical shape. These wires can expand and contract using a sliding button which determines the size of the basket. Once the laser has finished rupturing the large stone into tiny fragments, the basket device is inserted through the scope port. While in the scope, the wire basket tip is contained inside an outer sheath. When the basket has reached the fragments, the basket gets deployed out

of the sheath by pushing a slider button down into its open position. When the slider button is pushed up into the closed position, the basket can collapse and fit back into the sheath. The adjustable size of the basket also allows different sized stones to be collected. The drawback with the basket device is that it can only capture one stone at a time. Since the procedure produces multiple stone fragments, the surgeon must repeatedly insert the device into the ureter to gather each stone fragment. This technique can be time consuming, thus prolonging the surgery. A figure of the basket device inside of the scope port is shown below in Figure 4.

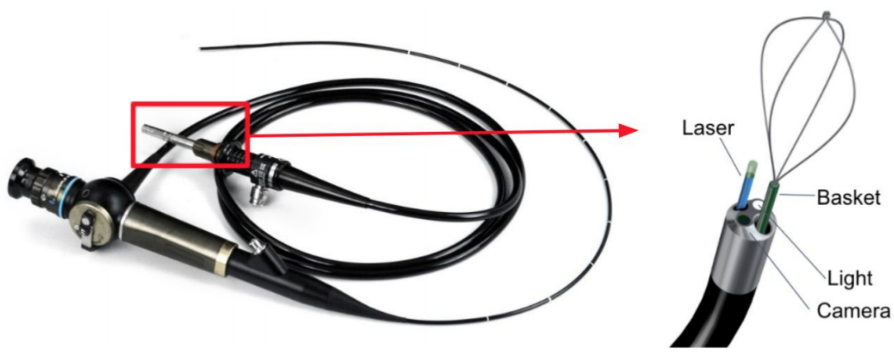


Figure 4: Ureteroscope with zoomed-in image of the ports with the laser and the currently used basket device [15].

Another type of extraction device used during the procedure is called the NTrap which is shown below in Figure 5 [16]. The NTrap is a flexible half spherical net composed of intertwined wires. The NTrap is different from the basket in that it is placed in the ureter before fragmentation. While the NTrap is in the scope port, it is contained in an outer sheath, similar to the basket. When the NTrap reaches the fragments, the NTrap can deploy out of the sheath and take on its full shape. The reason the NTrap is placed before fragmentation is that it blocks the upstream of the ureter so no fragments travel past their initial location during fragmentation. Once the stone is ruptured, the NTrap device gets pulled out through the ureter while collecting

all of the fragments simultaneously. The drawback of the NTrap is that once the device reaches the bladder, the fragments disperse and are lost in the bladder. This results in the patient having to pass the fragments naturally. Our group decided to focus on innovating the NTrap for this reason. If the NTrap had some mechanism that prevented the fragments from dispersing in the bladder, it would efficiently collect all fragments with only one insertion, which addresses the issue of the basket. Additionally, the innovated NTrap would decrease the duration of the procedure since the removal of all fragments would be done with only one insertion. An image of the NTrap device is shown below in Figure 5.

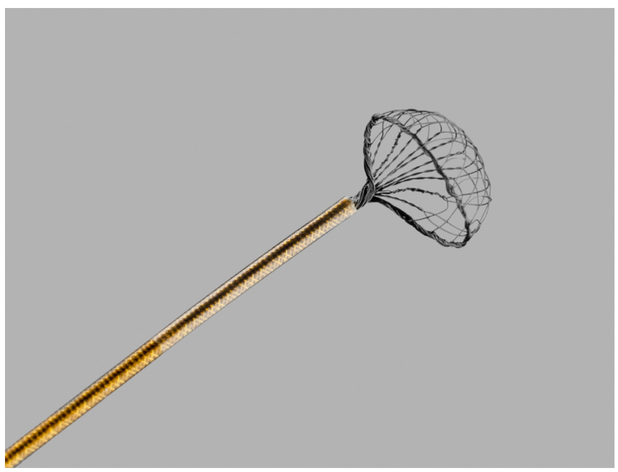


Figure 5: The NTrap extraction device [16].

2. Problem Statement

Every year kidney stones affect 654,000 Americans and 25% of these cases require a ureteroscopy, which is performed on patients with kidney stones greater than 4 mm in the ureter [4, 6]. A holmium laser is used to rupture the kidney stone resulting in fragmentation of the stone. If not removed, these residual fragments can cause pain and may require a secondary

procedure to remove them. The most common method for removing stone fragments is inserting a basket device through a port on the ureteroscope, encapsulating individual stone fragments, and manually removing the device. This device requires multiple insertions to remove the stone fragments, as it is only capable of removing one or two fragments at a time, resulting in a longer procedure time. **There is a need for a kidney stone extraction device that removes residual kidney stone fragments of sizes 1.5 - 4mm in patients who undergo laser ureteroscopies with only one insertion of the device. This device would increase productivity by allowing for more procedures and thereby increasing hospital revenue.**

3. Objectives

A list of design objectives were created such that any device fulfilling these objectives could accomplish our goal of increased productivity. The objectives were created to allow us to be free of form and function when coming up with ideas for our device. The most important objectives are that the device is easy to use, efficient, and safe for the patient. The objective tree is shown in Appendix 1.

<u>Efficient</u>

Since our device mainly focuses on increasing the efficiency of removing secondary kidney stone fragments, our device would be unmarketable if it were less efficient than the commonly used device. This objective mandates that our device remove the majority of secondary kidney stone fragments in the ureter with only one insertion of the device, ultimately reducing the

duration of the procedure. The reduction in procedure duration would allow for greater patient throughput and more revenue for the hospital.

Safe

Patient safety is the most important thing. Therefore, we had to ensure that our device will not cause any harm to the patient, and more specifically, to their ureter. We have to ensure that our device is just as safe, if not safer, than the currently used device. Safety is a determinant of how successful a hospital is and is often quantified by fast patient recovery time and a low readmittance rate [27].

Easy to Use

It is crucial that our device is easy to use. Clinicians would not want to learn how to use a new and very complicated device when the commonly used device is simple and works well enough. Thus, our device would not be marketable. Likewise, increased complexity could cascade into the other elements of our project. These problems include a drop in efficiency, due to the learning curve associated with the device, and a decrease in safety, since the procedure would last longer allowing for increased contact between the ureter and device.

4. Device Functions & Specifications

The functions and specifications for our device are based off of the overall goals we want our device to accomplish and how the device will achieve these goals. A complete overview of the functions and specifications associated with our device can be found in Appendix 2.

The result of performing a ureteroscopic holmium laser lithotripsy on a single kidney stone located in the ureter is the generation of more, but smaller, secondary kidney stone fragments. These secondary stone fragments can migrate while the main kidney stone is being fragmented, causing the fragments to move either upstream or downstream of the ureter and also potentially entering the bladder.

The main goal of our device is to remove and securely hold onto the majority of secondary kidney stone fragments in the ureter. Securing the stone fragments would reduce their chances of escaping from the device and entering the bladder, which could cause postoperative pain and/or complications. Thus, the main function of our device is to gather, ideally, all of the stone fragments, ranging from 1.5 mm - 4 mm in size, arising from the fragmentation of a kidney stone in the ureter.

The limitation of commonly used extraction devices is that they are only capable of removing a single kidney stone fragment at a time, requiring multiple insertions of the device. Alternatively, our device will be capable of removing multiple kidney stone fragments with only one insertion of the device. This will increase the efficiency of the procedure while also reducing its duration. A reduced procedure time could potentially increase the amount of procedures occurring in the hospital, therefore increasing hospital revenue. Additionally, the capability of

removing multiple stone fragments with only one insertion of the device makes the procedure safer. Since the device is only inserted once, this decreases the interaction between the device and the ureter, reducing the possibility of damage to the ureter.

Lastly, our device will also be able to fit inside the working channel of the ureteroscope, which is approximately 3.6 Fr [5]. The ureteroscope provides clinicians visualization of the ureter and kidney stone so that they can accurately locate and rupture the stone.

5. Design Requirements

There are three design requirements that drove our solution to the problem. The first requirement is that the device must contain the stone fragments throughout the entirety of the removal process. This means that once the device has encapsulated the fragments in the ureter, they must remain within the device while the device is pulled through the ureter and out of the bladder. If our device is unable to accomplish this task, then it does not solve the problem of the current devices.

The second design requirement is that the two baskets must be placed on two separate wires within the same sheath. This requirement ensures that the two NTrap nets can deploy independently of each other. Using the handle with this mechanism, each wire can be manipulated to deploy each net into or out of the single sheath without affecting the movement of the other net. Therefore, the distance between the nets is adjustable which allows the fragments to become entrapped within the two nets.

The final design requirement is that the basket must have more room to contain the fragments. In the current basket, the wires get compressed around the fragments, but it is only

capable of gathering one or two stones at time as the majority of the stones fall through the gaps between the wires. In order to prevent this issue, our device must have baskets that can hold multiple fragments which would allow more fragments to be collected and removed at once. This design requirement works in tangent with the first requirement since the shape of the nets determine the ability of the device to capture all of the fragments.

6. Documentation of the Proposed Design

6.1 Simplified Overview

The overview of the purpose of our device is outlined in the objectives and design requirements sections.

Our device is an innovation on the currently used handle and utilizes two NTraps [16]. While the nets of our device are constrained within the sheath, i.e. in their 'off' position, the sheath is able to be pushed around the unfragmented kidney stone located in the ureter, shown below in Figure 6.

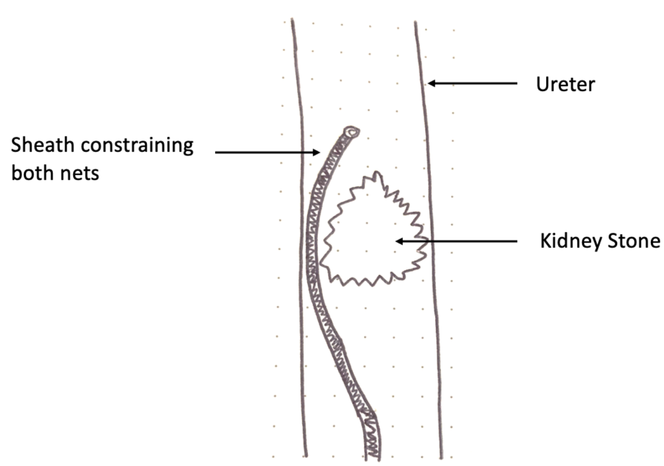
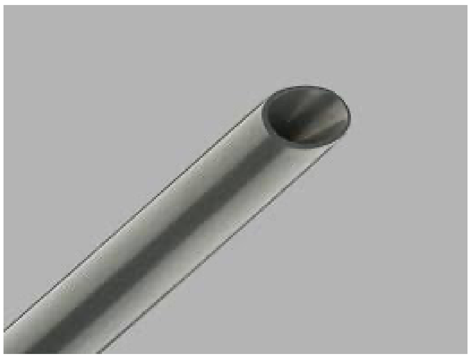


Figure 6: Our device in its 'off' position, i.e. both nets are constrained within in the sheath, and is pushed around a kidney stone located in the ureter.

Then, the first net will be deployed. The two positions, being the 'off' position of the device and the deployment of the first net, are shown below in Figure 7.

(a)



(b)

Figure 7: a) The two NTrap nets are constrained within the sheath and the device is in its 'off' position [17]. b) The top NTrap net (concave down) deployed from sheath [18].

A holmium laser will then be used to rupture the main kidney stone into smaller fragments. The deployed net will prevent these fragments from traveling upstream in the ureter, as shown below in Figure 8.

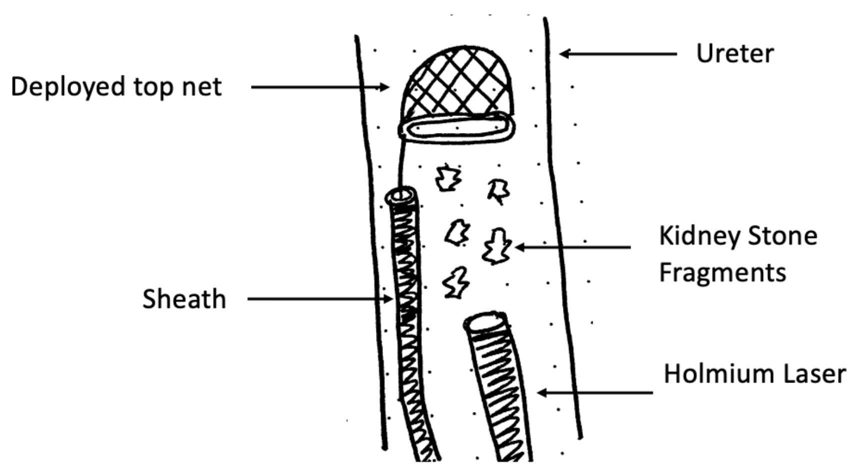


Figure 8: Top net is deployed right before the holmium laser ruptures the main kidney stone into smaller fragments. Deployed top net is used to prevent upstream migration of kidney stone fragments in the ureter.

After the kidney stone has been completely fragmented, the laser is removed and the second net is deployed to encapsulate all of the stone fragments, shown below in Figure 9.

Figure 9: Second NTrap net (concave up) deployed from the sheath. Both nets are now deployed and the device is in its 'on' position.

We had to incorporate two NTrap nets with opposite orientations in order for our device to securely encapsulate the stone fragments. Combining these opposite orientations creates a capsule that is capable of holding all the fragments at once.

These two nets move independently of each other so that the user can manually control the distance between them. This is achieved by having two separate nets on two separate wires that are controlled by two buttons, shown below in Figure 10.

(a) (b)

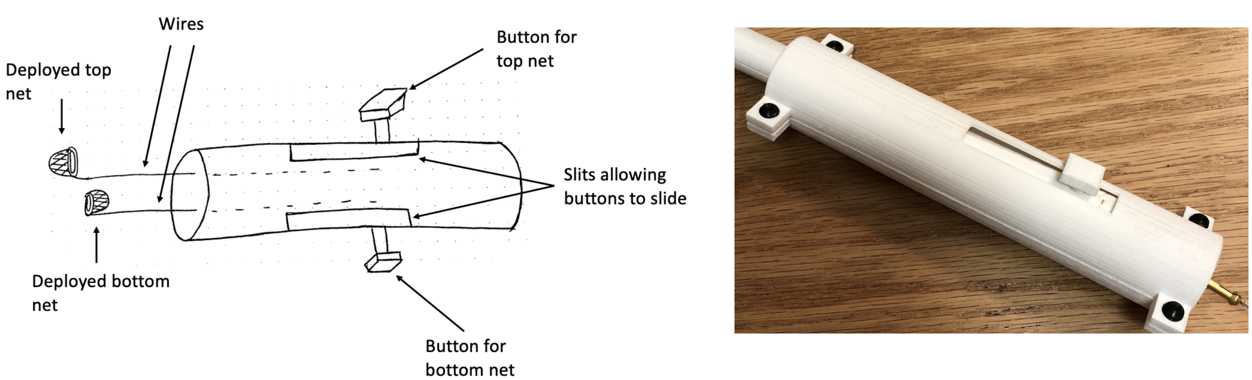


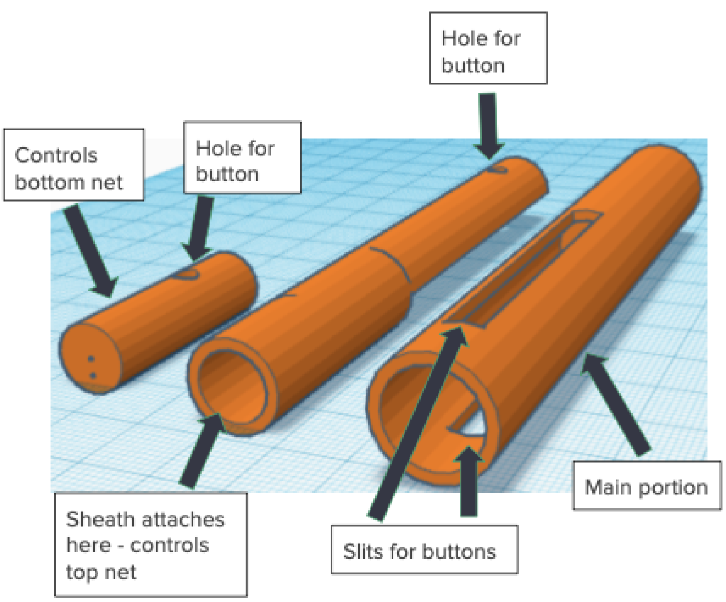
Figure 10: (a) Sketch of our handle showing the connection between the buttons and the nets. (b) Image of the top side of our actual handle.

After the second net has been deployed, it is pushed as close to the first net as possible, securely gathering all of the fragments. Once all of the fragments are collected, the nets stay pushed together and the entire device is pulled out of the ureter, moving through the bladder, and is removed from the body bringing all of the fragments along with it. A patent that inspired our design solution can be found in Appendix 3.

6.2 Design Description

Our handle consists of four parts: a long half cylindrical tube with a full cylinder at the end, a short cylindrical tube, the main body of the handle, and two triangular-shaped buttons. The four parts of the handle are shown below in Figure 11.

(a)



(b)

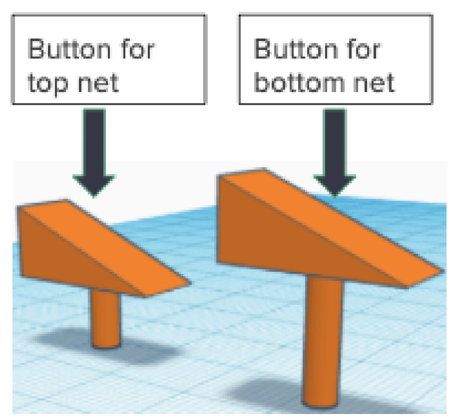


Figure 11: a) From left to right: Short cylindrical tube, long half cylindrical tube with a full cylinder at the end, and the main body of the handle. b) Triangular shaped buttons that go into the short cylindrical tube and the long half cylindrical tube.

The long, half cylindrical tube is used to control the deployment of the first NTrap, which is concave down. On the commonly used basket device, there is a sheath that slides back and forth over the basket, controlling its deployment, shown below in Figure 12.

Figure 12: Sheath slides back and forth over the basket, controlling its deployment [15].

The same type of sheath is used within our device and is attached to this long, half cylindrical tube, shown below in Figure 13.

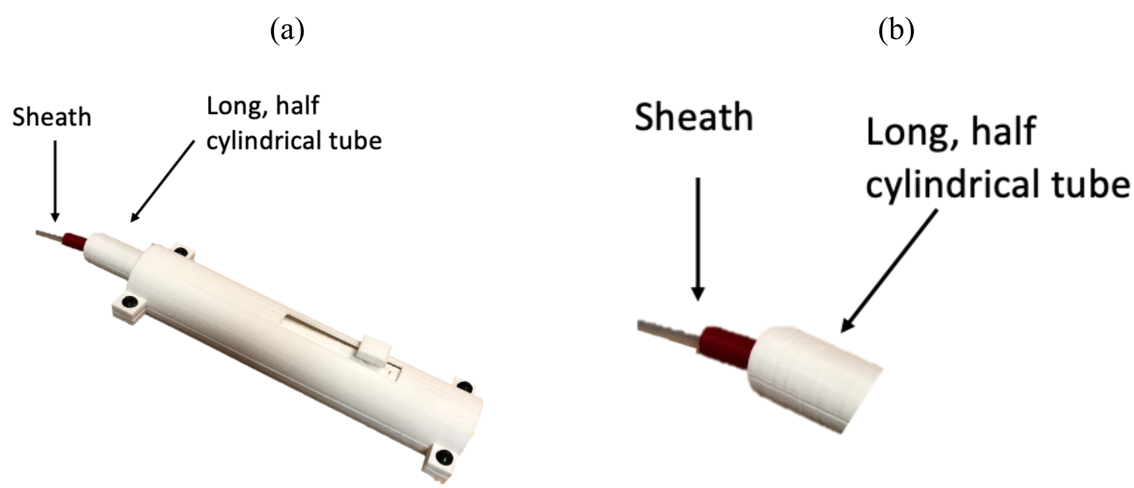


Figure 13: (a) Sheath attached to the end of the long, half cylindrical tube on our device. (b) Zoomed-in version of (a).

The sheath is inserted into the part of the tube that is a full cylinder. The half cylindrical portion of this tube is located inside the main body of the handle and the full cylindrical portion is outside the main body of the handle, shown above in Figure 13. There is also a button on top of this internal tube so that when the user holds the handle they can slide the button with their thumb, sliding the tube and moving the sheath, shown below in Figure 14.

(a) (b)

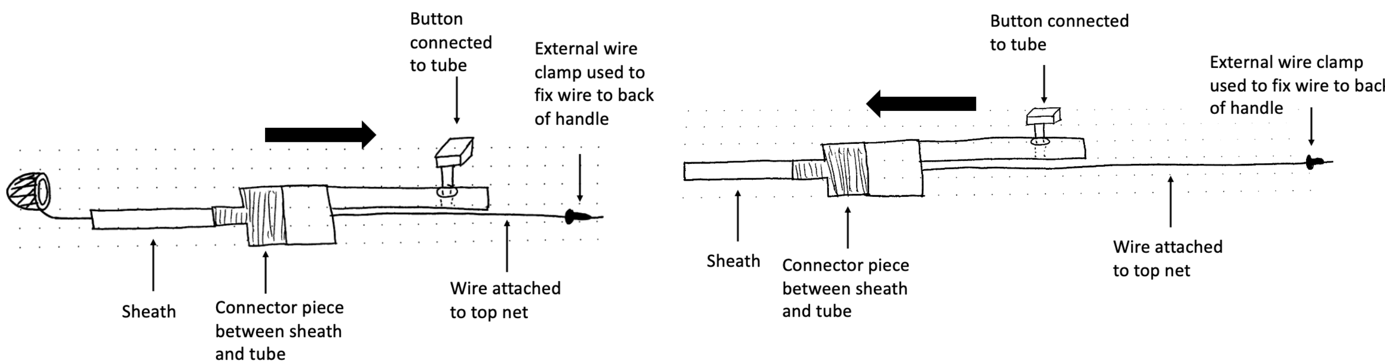


Figure 14: Mechanism behind deployment of top net. (a) Top net is deployed by sliding the button back, retracting the sheath and allowing the net to deploy. (b) Top net is constrained by sliding the button forward, pushing the sheath over the net, causing it to become constricted within the sheath.

The short cylindrical tube is used to control the deployment of the second NTrap, which is concave up, shown below in Figure 15. The second NTrap is also located within the sheath but alternatively is moved in and out of the sheath by the short cylindrical tube.

(a) (b)

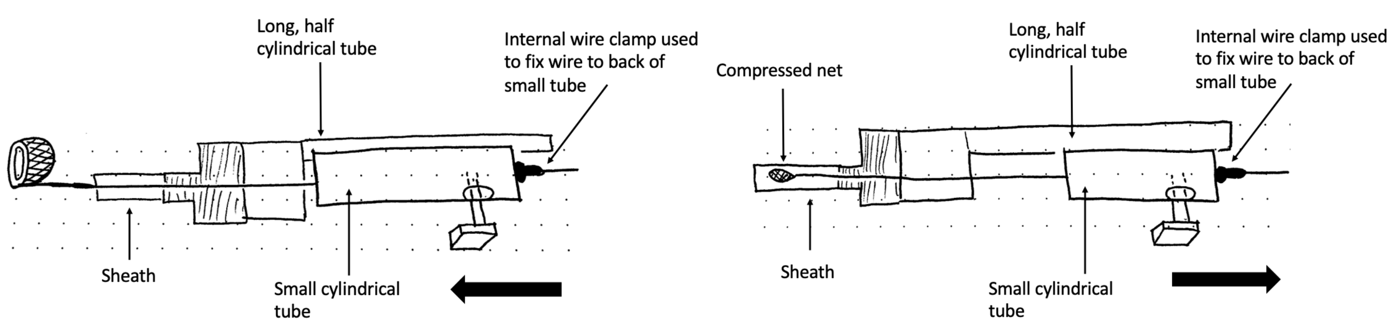


Figure 15: Mechanism behind deployment of bottom net. (a) Bottom net is deployed by sliding the button forward, pushing the net out of the sheath, allowing it to expand and deploy. (b) Bottom net is constrained by sliding the button back, pulling the net into the sheath, causing it to become constricted.

The wire that the top NTrap is attached to is fixed to the back of the main part of the handle and the wire that the bottom NTrap is attached to is fixed to the back of the short cylindrical tube. An overview of how both wires are fixed within the handle is shown below in Figure 16.

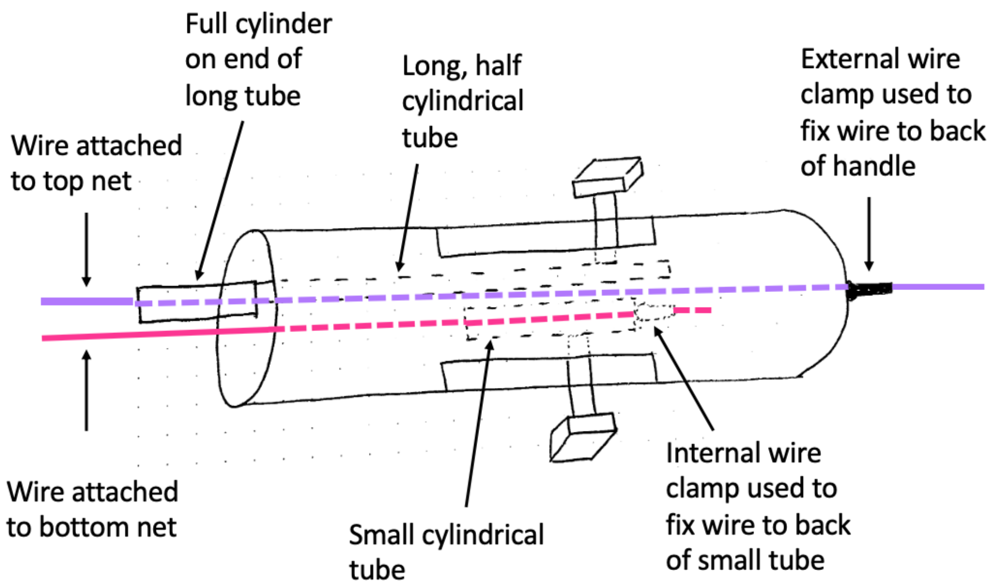


Figure 16: Sketch of the locations of both wires in the handle. The wire connected to the top net, shown in purple, is inside of the end of the long, half cylindrical tube and is fixed externally on the back of the handle. The wire connected to the bottom net, shown in pink, is inside of the small cylindrical tube and is fixed to the back of this small tube, which is located inside the handle. Wire clamps are used to securely hold the wires in place.

The short cylindrical tube has two small holes that run through the entire tube. One hole is used to provide a path for the wire of the top NTrap to be fixed at the end of the main body. The second hole is used to fix the wire of the bottom NTrap to the small tube. This tube is also

located within the main body of the handle and lies right below the half cylindrical tube. An overview of these small holes is shown below in Figure 17.

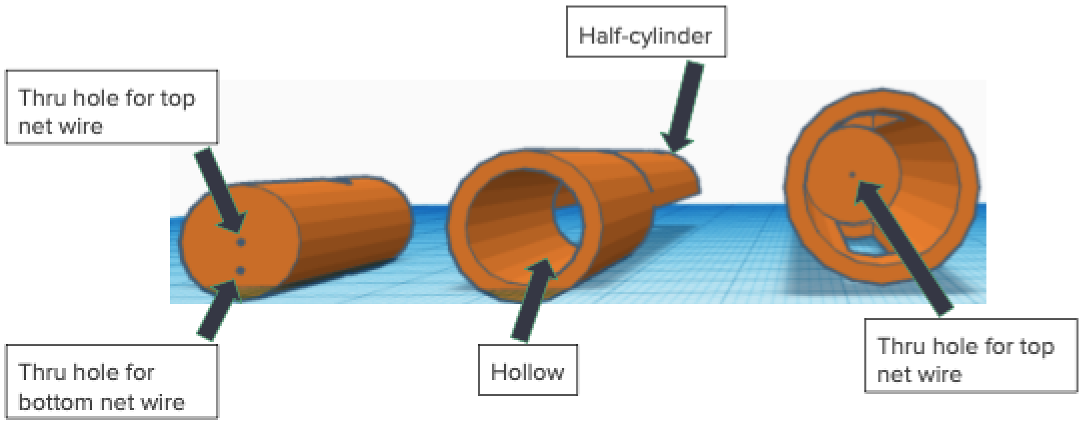


Figure 17: Location of small holes that allow the two wires, which are connected to the top and bottom nets, to be fixed to the back of the main body of the handle and the short cylindrical tube, respectively.

6.3 Procedure

First, while both nets are constrained within the sheath, the sheath will be inserted through a port on the ureteroscope and pushed around the unfragmented kidney stone located in the ureter, shown above in Figure 6.

Secondly, using the handle, the first net is deployed by pulling the top button back towards your body, shown above in Figure 14 (a). This retracts the sheath, allowing the first net to move out of the sheath and expand to its original shape. Once the first net is deployed, a holmium laser is inserted through a secondary port on the ureteroscope and is activated to rupture the kidney stone, shown above in Figures 4 & 8. Since the first net is blocking the upstream portion of the ureter, this prevents upstream migration of the secondary fragments, also

shown above in Figure 8. Once the kidney stone has been completely fragmented, the laser is removed from the ureteroscope.

Thirdly, using the handle, the second net is deployed by pushing the bottom button away from you, shown above in Figure 15 (a). This directly pushes the second net out of the sheath, allowing it to expand to its original shape. The same button is pushed further to bring the second net as close to the first net as possible, encompassing the fragments.

Lastly, once the two nets have securely gathered the majority of the fragments, the device, along with the fragments, are removed from the ureter, traveling through the bladder, and eventually removed from the body.

7. Validation of Design

7.1 Testing requirements

The purpose of testing our device was to show that we successfully met our objectives and functions. The most important objective we wanted to test was efficiency, therefore we created a test that would compare the efficiency of our device versus the basket device versus the NTrap. We will test the efficiency of these devices by calculating the percent of beads removed from a tube with one insertion of each device. By completing this test, we were hoping to see our device perform better than its competitors, and ideally capture and remove every bead from the testing apparatus.

7.2 Testing procedure

Our testing apparatus consisted of a plastic tube, 7mm in diameter, to mimic the ureter and a tennis ball to mimic the bladder, shown in Figure 18. Beads of sizes 2 mm, 3 mm and 4 mm were used to mimic varying sizes of kidney stone fragments. We performed tests with five beads of each size and one group of five randomly selected sizes. Each test was performed three times using each device by two different operators. The basket, NTrap, and our device were each inserted into the apparatus through the tennis ball. They were then navigated to the beads, and when in position they were deployed from the sheath. The operator then collected as many beads as possible and attempted to remove them from the apparatus. Once the device was removed, the number of beads that remained in the apparatus was collected. This data was then recorded in Excel to calculate the percent of stones collected for each device. There were no reinsertions of the device on any test to maintain consistency. A table representing the data collection is shown in Appendix 4.

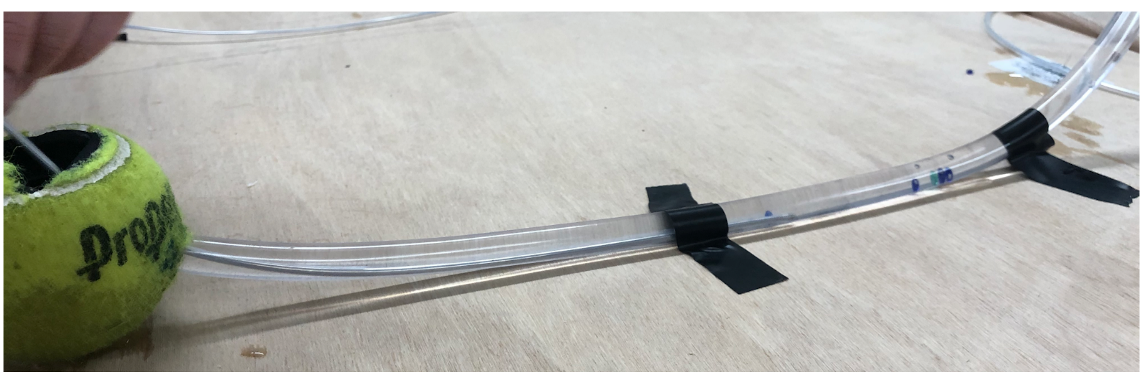


Figure 18: The testing apparatus consists of the 7mm diameter tube to mimic the ureter, the tennis ball to mimic the bladder, and the beads to mimic the fragments.

7.3 Data analysis

Our data analysis consisted of comparing the number of stones collected by each device and recording that as a percentage. The percentages were then averaged for each test group and were organized into a bar graph, shown in Figure 19.

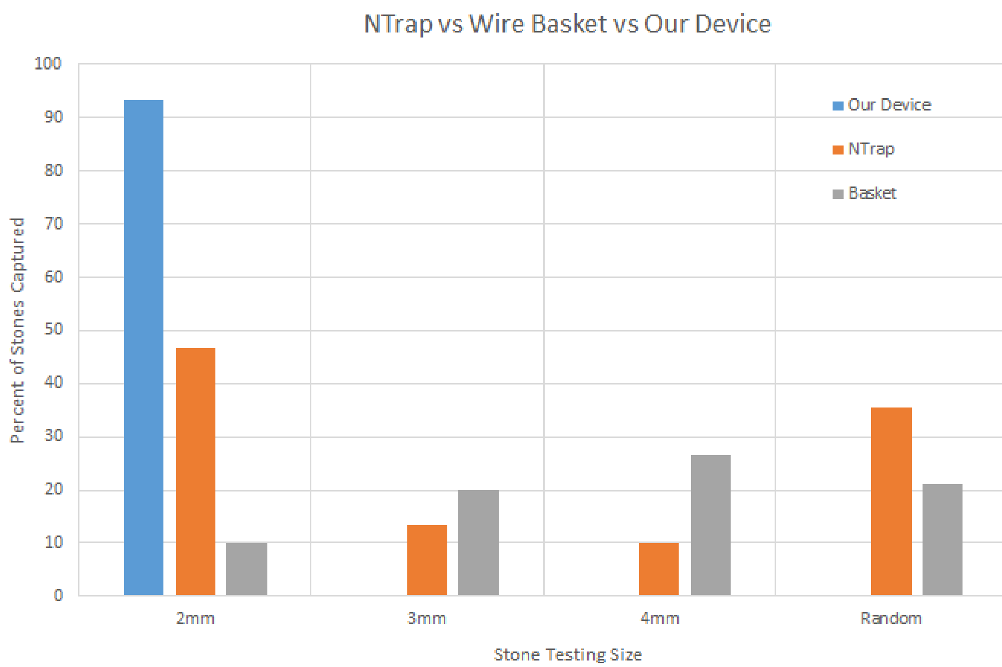


Figure 19: A bar graph representing the ability of the three different devices to remove kidney stones. The size of the stones tested is shown on the x-axis, and the average percentage of stones collected across all tests is shown on the y-axis. It can be seen that the basket device operated better at larger sizes than the NTrap. There is limited data for our device due to mechanical complications that limited our testing capabilities.

The graph shows that the NTrap and wire basket devices both have a collection rate below 50%, while our device had a collection rate of 93% when tested, therefore our basket device was more efficient in removing multiple beads. It should be noted that testing data for our device was incomplete due to mechanical issues with the baskets during testing. This was a result of relying on modified existing baskets that would get tangled up with each other. A future task that should

be pursued is to manufacture the bottom net the way we oriented it in the prototype in order to prevent these complications.

Another important observation we gathered from the test is the location of where each device left stone fragments within the apparatus. We found that the NTrap left beads behind in the tennis ball whereas the wire basket left beads behind in the tube. This suggests that the NTrap is efficient at removing multiple stones from the ureter whereas the basket device struggles with removing multiple stones from the ureter. It also suggests the NTrap struggles with containing the fragments in the bladder whereas the basket device is able to contain the fragments in the bladder. This observation is important because with the basket of the NTrap allowing for efficient removal from the ureter and the inclusion of the second inverse basket helping to contain fragments in the bladder, our device managed to solve the challenges with the two current devices. Therefore, the test provides substantial evidence that our device is the most efficient in removing multiple stone fragments out of the three devices that were tested.

8. Anticipated Regulatory Pathway

8.1 Device Classification

Under FDA classifications, a class 2 device is any device that interacts within the body but is not at high risk for causing severe health issues if malfunction occurs [21]. Since our device enters the body but is not life preserving, it meets Class 2 device regulation. Thus, for FDA approval, our device would have to go through the 510(k) review process [21].

8.2 Types of 510(k)'s

There are three main types of 510(k) processes. These include the traditional, abbreviated, and special 510(k) [26]. Each one differs in the required testing and time needed to get approval.

The traditional 510(k) is the oldest version of the 510(k) process [26]. The most important requirements for the traditional 510(k) include the cover letter, device description, and the discussion of substantial equivalence which includes the intended use of the device [19]. The traditional 510(k) has a review time of 90 days after submission [19].

The abbreviated 510(k) is similar to the traditional 510(k) since it also has a 90 day review time but was created in an attempt to streamline the process by reducing the amount of testing required for the manufacturer [19]. One would submit an abbreviated 510(k) when they are relying on FDA guidance documents, compliance with special device controls in guidance documents, or voluntary consensus standards [19]. The abbreviated 510(k) allows a company to show that they have met a set of standards that is already in place by the FDA or an outside standards regulator.

Lastly, the special 510(k) has a shorter review period of 30 days since it is used when there are proposed changes to an existing device [24].

8.3 Deciding on the 510(k) and Premarket Notification

Deciding to use the correct type of 510(k) can be extremely important in saving time and gaining approval. To help with this process, the manufacturer can send a 513(g) request, which

asks the FDA to help determine the class of the device and the appropriate 510(k) to use [25]. After choosing the appropriate 510(k) path, a premarket notification can be sent in to the FDA 90 days before the device's intended market date, starting the review process [19, 24, 26]. For our device, there does not appear to be a clear set of standards on the testing of kidney stone removal devices. Thus, the traditional 510(k) process is the desired pathway for our device.

8.4 Testing

A common form of premarket testing for kidney stone removal devices is the use of the porcine urinary tract [20]. By testing the device in a porcine urinary tract, relevant data pertaining to stone collection capability and capacity, time of use, and damage to the tissue can be observed. With this data, a company or testing facility would know if they could confidently enter human testing as well as the FDA approval process.

8.5 Substantial Equivalence

Substantial equivalence is required for the 510(k) process, which is the ability to show that a new device is similar to a device that has already been FDA approved [22]. Our device meets substantial equivalence since it incorporates modifications of two different devices.

The first modification is the handle. This modification is simple and adds no new risk to the procedure. If the handle modification was the only modification that was made, our device would have an increased chance at passing a special 510(k).

The second modification is the basket. Although the two baskets are already FDA approved devices, the addition of the second basket could result in unforeseen complications.

Providing data that shows the addition of a second NTrap will not cause harm to the patient, alongside already approved devices such as the NTrap and commonly used basket, our device would be substantially equivalent to pre-existing kidney stone removal devices [16, 23].

9. References

[1] "The Urinary Tract and How it Works." The National Institute of Diabetes and Digestive and Kidney Diseases. 2019. [Online] Available: https://www.niddk.nih.gov/health-information/urologic-diseases/urinary-tract-how-it-works.

[2] "The Urinary Tract." *The National Institute of Diabetes and Digestive and Kidney Disease* , www.niddk.nih.gov/health-information/urologic-diseases/urinary-tract-how-it-works.

[3] "What are Kidney Stones?" *Urology Care Foundation.* 2019. [Online] Available: https://www.urologyhealth.org/urologic-conditions/kidney-stones

[4] Scales, Charles D Jr et al. "Prevalence of kidney stones in the United States." *European urology* vol. 62,1 (2012): 160-5. doi:10.1016/j.eururo.2012.03.052

[5] Ordon, Michael et al. "CUA Guideline: Management of ureteral calculi." *Canadian Urological Association Journal.* Vol. 9,11-12 (2015): E837-51. doi:10.5489/cuaj.3483

[6] Coe, Fredric L et al. "Kidney stone disease." *The Journal of clinical investigation.* Vol. 115,10 (2005): 2598-608. doi:10.1172/JCI26662

[7] Fankhauser, Christian D et al. "Extracorporeal shock wave lithotripsy versus flexible ureterorenoscopy in the treatment of untreated renal calculi." *Clinical kidney journal* vol. 11,3 (2018): 364-369. doi:10.1093/ckj/sfx151

[8] Vicentini, Fabio C et al. "Percutaneous nephrolithotomy: Current concepts." *Indian journal of urology : IJU : journal of the Urological Society of India* vol. 25,1 (2009): 4-10. doi:10.4103/0970-1591.44281

[9] Takazawa, Ryoji et al. "Appropriate kidney stone size for ureteroscopic lithotripsy: When to switch to a percutaneous approach." *World Journal of Nephrology*. Vol. 4, 1. pg. 111-117. Feb. 2015.

[10] “Ureteroscopy and Laser Lithotripsy.” UF Health Department of Urology. Available: https://urology.ufl.edu/patient-care/stone-disease/procedures/ureteroscopy-and-laser-lithotripsy/.

[11] “Ureteroscopes - Urology .” *Olympus Medical Systems*, www.olympus-europa.com/medical/en/Products-and-Solutions/Products/Urology/Ureteroscopes.html.

[12] “Innovex Single-Use Ureteroscope.” *Endotherapeutics*, www.endotherapeutics.com.au/product/innovex-single-use-ureteroscope/.

[13] J D Kelly, P F Keane, S R Johnston, R M Kernohan, “Laser lithotripsy for ureteric calculi: Results in 250 patients,” *The Ulster Medical Journal*, Volume 64, No. 2, pg. 126 - 130, October 1995.

[14] “Ureteroscopy (Stone Removal)” *Health Travellers Worldwide* , www.healthtravellersworldwide.com/treatments/ureteroscopy/.

[15] “Dual uniqueness meets digital vision”, Richard Wolf USA, 2010.

[16] “Minimize Retrograde Stone Migration during Lithotripsy.” *NTrap: Stone Entrapment and Extraction Device*, Cook Medical, Feb. 2016. [Online] Available: www.cookmedical.com/data/resources/URO-D15882-EN-F_M3_2016-02-24_140318_1457555184699.pdf.

[17] “Cook® Amplatz Sheath - Opaque.” *Obex*, Cook Medical, 2020, www.obex.co.nz/product/cook-amplatz-sheath-opaque/.

[18] Barakat, Tamer S., et al. “Ureteroscopy for Upper Ureteral Stones: Overcoming the Difficulties of the Rigid Approach.” *Difficult Cases in Endourology*, 1st ed., Springer, 2013, pp. 211–222, www.researchgate.net/publication/259266871_Difficult_Cases_in_Endourology.

[19] Center for Devices and Radiological Health, “Format for Traditional and Abbreviated 510(k)s - Guidance,” *U.S. Food and Drug Administration*. [Online]. Available: Format for Traditional and Abbreviated 510(k)s - Guidance.

[20] R. Massoudi, T. J. et al., “Preclinical Testing of a Combination Stone Basket and Ureteral Balloon to Extract Ureteral Stones,” *Mary Ann Liebert, Inc., publishers*, 01-Feb-2018. [Online]. Available: https://www.liebertpub.com/doi/full/10.1089/end.2017.0626.

[21] “What Are the Differences in the FDA Medical Device Classes?,” *Qualio*. [Online]. Available: https://www.qualio.com/blog/fda-medical-device-classes-differences.

[22] Center for Devices and Radiological Health, “Evaluating Substantial Equivalence in Premarket Notifications [510(k)],” *U.S. Food and Drug Administration*. [Online]. Available: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)].

[23] “Product Classification,” *accessdata.fda.gov*. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=NQU.

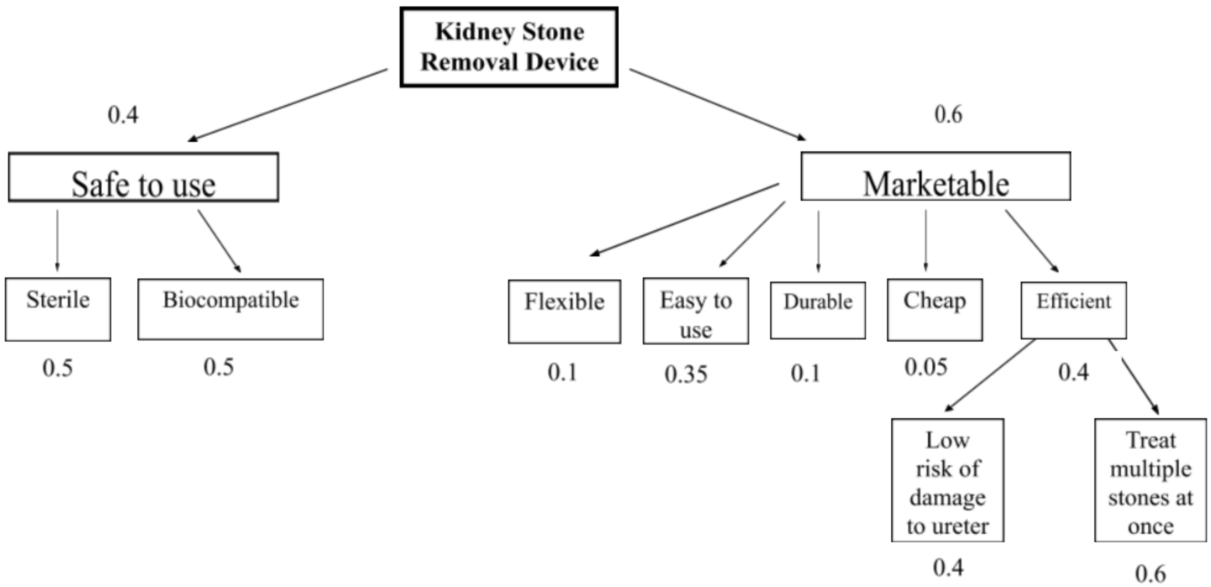
[24] Center for Devices and Radiological Health, “The Special 510(k) Program,” *U.S. Food and Drug Administration*. [Online]. Available: The Special 510(k) Program.

[25] Center for Devices and Radiological Health, “Procedures for Section 513(g) Requests for Information - Guidance,” *U.S. Food and Drug Administration*. [Online]. Available: FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act.

[26] Center for Devices and Radiological Health, “510(k) Submission Programs,” *U.S. Food and Drug Administration*. [Online]. Available: 510(k) Submission Programs.

[27] “Hospital Readmissions Reduction Program (HRRP),” *CMS*. [Online]. Available: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.

Appendix 1: Objective Tree



Shown in Appendix 1 is our weighted objective tree. It outlines all of the objectives that we considered most important and how we weighted each one. The tree is split into the categories of safe and marketable. Since safety is always required when designing a medical device we focused more heavily on the marketability side when brainstorming design solutions. Under marketable we identified five main categories. When weighting the categories, efficient and easy to use were weighted heavier than the others as we figured they were the most important in creating a successful and marketable device. Efficient is split up into two more categories involving low patient risk and treatment of multiple stones. Both are weighted heavily as they are both essential to our devices proper operation.

Appendix 2: Functions and Specifications

TABLE 1:

Required functions of the kidney stone removal device with its corresponding marginal and ideal values.

Function	**Metric**	**Unit**	**Marginal Value**	**Ideal Value**
Gathers stone fragments	Size of stone	Millimeters (mm)	4 mm [4]	1.5 mm [13]
Holds stone fragments	Percent of fragments removed	Percentage (%)	80%	100%
Safe	Damage of tissue	Binary: yes or no		
Operates efficiently	Amount of times entering/exiting ureter	Number	2 times	1 time
Collapses into ureteroscope		Binary: yes or no		
Fits in ureteroscope	Size of port on ureteroscope	Fr (French Gauge)	3.6 Fr	3 Fr

Appendix 3: Patent

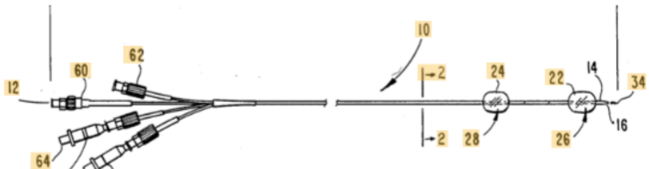


Fig. 1

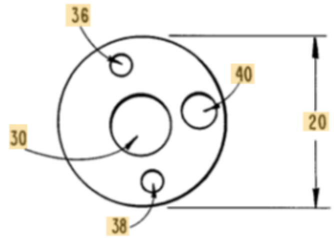


Fig. 2

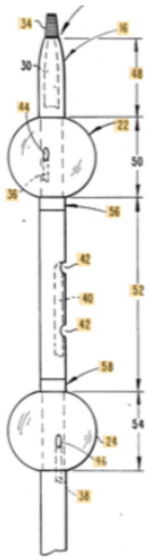


Fig. 3

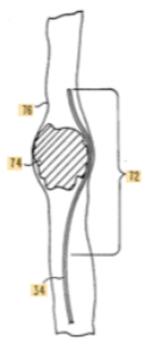


Fig. 4

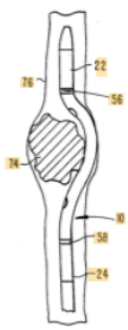


Fig. 5

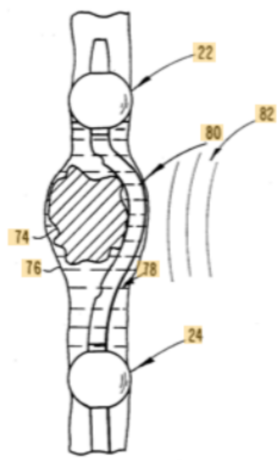


Fig. 6

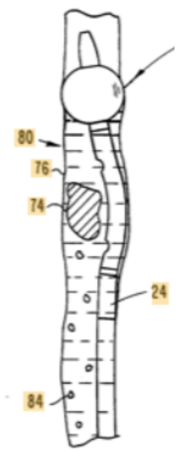


Fig. 7

Shown in Appendix 3 is a relevant patent that we found, which inspired our current design solution. This device was made to be used during a non-invasive kidney stone removal procedure. This device incorporates two balloons, which are shown by 26 and 28 in figure 1, and has a port for a guide wire and for each balloon, which are shown by 30, 36 and 38 in figure 2, respectively. During the procedure, a guide wire would be pushed around a kidney stone located within the ureter, shown in figure 4. Then, while the balloons are deflated, the device would be pushed over the guide wire so that the balloons are on either side of the stone, shown in figure 5. The balloons would then be inflated using the ports. This is to block the up and downstream parts of the ureter. Ultrasonic waves would then be used externally to rupture the stone, shown in figure 6. Once the stone has been ruptured, the bottom balloon would be deflated and irrigation would be used to flush out the stones. However, the top balloon stays inflated to prevent any fragments from traveling farther up the ureter, shown in figure 7. Once this is finished, the top balloon would be deflated and the device would be removed from the body.

Appendix 4: Testing Table

TABLE 2:
A table representing how the trials were performed and how the data was organized. Each test is performed three times per user. Five beads were used for each trial and then the final amount of beads corresponds to the number of beads left in either the tube or the tennis ball. The average percent was calculated

		Test 4: 2 mm			**Test 5: 3 mm**			**Test 6: 4 mm**		
Device	**User**	Initial Amount	Final Amount	Percent Collected	Initial Amount	Final Amount	Percent Collected	Initial Amount	Final Amount	Percent Collected
NTrap	Maddie	5	2	60	5	4	20	5	5	0
		5	3	40	5	4	20	5	5	0
		5	4	20	5	5	0	5	4	20
	John	5	2	60	5	4	20	5	5	0
		5	3	40	5	5	0	5	4	20
		5	2	60	5	4	20	5	4	20
Average				**46.7**			**13.3**			**10**