Hand-Assisted Laparoscopic Radical Nephrectomy Specimen Retrieval Bag

October 20, 2010

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I. Abstract

Specimen retrieval bags are necessary during a hand-assisted laparoscopic radial nephrectomy for the safe removal of a cancerous kidney from the abdominal cavity. The aim of this project is to design and manufacture a more efficient specimen retrieval bag to decrease total operative time of the nephrectomy. Tests will be conducted using a model of the human abdominal cavity. The client will have medical students practice the nephrectomy in an animal lab on campus to test the total time and ergonomics of the final designs.

II. Background

a. Procedure – Hand-assisted laparoscopic radical nephrectomy

A hand-assisted Laparoscopic radical nephrectomy is a procedure used to remove a cancerous kidney from the abdominal cavity if a patient. This procedure uses a laparoscope or small camera to view the inside of the abdomen or pelvis during surgery (Patel). Its use reduces the size of the incisions made on the patient, thereby shortens the post-surgery recovery time (Patel). The laparoscope, a machine for the insufflations of the abdomen, and a pair of graspers, as seen in Figure 6 of Appendix d, are inserted into the abdomen through 3 incisions of 0.5 to 1.5 cm (Dhobada, Patankar, and Gorde 119-22). An extra incision, dependent on the size of the surgeon's hand, is made to allow the surgeon to use his/her hand to assist in the removal of the kidney (Patel). A hand-port with gel foam is placed in this incision to ensure easy insertion of the hand (Patel). The graspers are used to sever the kidney from the abdomen and a specimen retrieval bag is used to remove the kidney from the body (Patel). Images from the procedure can be seen in appendix b.

b. Bags in the market

The current specimen retrieval bag that the client uses, LapSac©, manufactured by Cook® Medical, is a simple plastic bag with a drawstring closure as seen in figure 4 of appendix c. There is no widely accepted design on the market. Some surgeons choose to make their own specimen bags, such as the Nadiad bag seen in figure 4 of appendix c (Ganpule, and Gotov et al. 1213-16). Other products with a similar function are the EndoCatch bags, as seen in figure 6 of appendix c. The most common features among the specimen retrieval bags on the market are the drawstring closure and their flat shape with no fixed structure.

c. Motivation

Although the abdomen is inflated with CO_2, due to the limited maneuvering space within the abdominal cavity, it is usually difficult to retrieve the kidney after it has been disconnected from the ureter and blood vessels (Patel). The kidney can be difficult to remove due to the fluids present in the cavity and the enlarged size of the cancerous organ. The bag is primarily used in the procedure to prevent metastasis, the spread of cancerous cells from one area and/or organ to another (Patel). The main areas of concern for metastasis are the abdominal cavity and the incision sites (Dhobada, Patankar, and Gorde 119-22). The bag also assists the surgeon in removing the enlarged kidney through as small of an incision as possible.

III. Design Criteria

The design must decrease the time required to place the kidney in the bag while protecting the abdominal cavity from metastasis. The bag should be non-permeable and water-tight to prevent tumor spillage. It must also be sterile before use. The bag should support the weight of the organ, up to ten pounds, while held from the closure apparatus. The bag must fit through the hand port while containing the kidney. With all of the above features, the surgeon must be able to properly maneuver the bag with one hand and the graspers. For more detailed specifications of the final product, see the product design specifications in Appendix a.

IV. Design

Due to the nature of this project, multiple designs for specific aspects of the current bag were developed, which can be mixed and matched. The following features will improve the ease of inserting the kidney into the bag and the total operative time.

a. Surround the kidney

The bag's purpose in this procedure is to enclose the entire kidney with a secure closure. It will be maneuvered over the kidney with the help of a single hand and a pair of graspers.

i. Bag Form

1. Accordion

The bag would be shaped as a cylinder in its inflated form and would be able to stack down like an accordion into a thin disk, allowing it to be inserted into the abdomen as seen in figure 9 appendix e. The bag would be made from a low-density polyethylene.

2. Finger ports

For this design, the surgeon would need to remove his hand from the abdomen and reenter with the bag. This bag would have four finger holds and two thumb holds, one for right-handed surgeons and one for left-handed surgeons as seen in figure 10 appendix e. This bag would also be constructed from low-density polyethylene.

3. Rigid bottom plate

Regardless of the form or material of the bag, a rigid piece of curved plastic could be adhered to the bottom of the bag as seen in figure 8 appendix e. This material would allow the bag to keep its structure. The bag would be made from low-density polyethylene and the ridged bottom from moldable silicone.

ii. Closure Features

1. Drawstring

A simple drawstring could be affixed to the opening of the bag to allow proper closure of the bag, as well as to provide a material that can be easily grasped and pulled on this can be seen in figure 11 appendix e.

2. Telescoping ring

A flexible set of plastic rings could be added to the opening of the bag to create a telescoping closure. This set of plastic rings would overlap allowing the mouth of the bag to be opened or closed. The surgeon only needs to exert a minimal amount of pressure to open or close the set of rings, which would remain in position until acted on by the surgeon as seen in figure 12 appendix e.

3. Tabs

The addition of a 1 inch by 1 inch tab on both sides of the bag's opening could be helpful when using the graspers to get an adequate hold on the bag as seen in figure 13 appendix e.

b. Surround the abdomen

Based on the research done on the current designs present on the market, as well as the information provided by the client, the design of the bags used in this procedure have been focusing on enclosing the kidney within a fitted bag just large enough to hold the cancerous organ.

Hence, in an attempt to think out of the box, a design that allows the protection of the abdomen from the kidney was developed. The bag would be inserted into the abdomen at the beginning of the procedure and rest on the floor of the cavity. Once the organ has been detached from the body and placed in the bag, the edge of the bag would be lifted over the kidney and through the hand port. This action would be simple due to the relatively large size of the bag, which should line the entire abdomen. To remove the organ, the edges of the bag, exposed from the incision, would be pulled seen in figure 14 appendix e.

The bag would be shaped as a cylinder in its inflated form with a 20 cm diameter and 40 cm height. The bag would be made from a low-density polyethylene. Attached to the bottom and 10 cm from the top of the bag would be two flexible plastic rings with a 20 cm diameter to keep the shape of the bag.

c. Materials and Sterilization

The material of the specimen bag must be flexible, smooth, strong, and also be able to withstand a weight of ten pounds while being held by its closing device. It must not corrode when briefly subjected to the internal human environment. Based on these factors, low density polyethylene was selected as the primary material to form the body of the bag. According to a manufacturer of low density polyethylene, Dynalab Corporation, their product can withstand temperatures between -50^{o}C to 80^{o}C, and can be exposed to temperatures as high as 95^{o}C for a short period of time (Dynalab Corporation). It can be translucent to opaque in color, has a tensile strength of 1700 psi, and is not reactive at room temperature (Dynalab Corporation). The drawstring and the harder rings of the accordion design will be made of nylon and silicone gel respectively.

The threat of contamination continues to be a concern during the manufacturing process; however, many steps can be taken to reduce the amount of contamination and ensure a sterile product. The specimen will be manufactured and packaged in a sterile environment, and will be removed from its packaging in the sterile operating room. The polyethylene material cannot be autoclaved and cannot undergo chemical sterilization. To further ensure a sterile product gamma radiation can be used. This is the most accepted method currently used to sterilize polyethylene. Although exposing polyethylene to radiation has shown to slightly decrease the wear of the material *in vivo*(Crowninshield, and Muratoglu S80-85). This process has deep penetration power, which allows for the sterilization of densely packed and pre-packed products (Sharma). There are no toxic residues and no quarantine periods required (Sharma). Gamma radiation appears to be an effective additional form of sterilization for the retrieval bag.

V. Design Matrix

In order to compare all of the different aspects of the above designs, a design matrix (Table X) was constructed. First, the different designs were grouped based on whether they focused on protecting the abdominal cavity or the organ. For the designs that involved protecting the organ, they were further subdivided based on their overall form, the types of closures they could have, and whether tabs could be added to the openings. Each category was weighed based on its importance to the overall design, with all of the categories adding to 100 points. From these comparisons, it was decided that the fingers design and the accordion design are to be the final designs for this project.

Protection	Sub	Options	Client Preference (40)	Practicality (40)	Ease of Construction (20)	Total (100)
Kidney	Form	Accordion	23	37	10	70
		Finger Ports	35	20	15	70
		Rigid Bottom	25	25	10	60
	Lid	Drawstring	30	20	15	65
		Telescoping	35	20	10	65
		Tabs	20	35	10	65
Abdomen	Cylinder		20	10	10	50

Table 1. To determine the final design, the features were evaluated with a design matrix.

a. Client Preference

Because the client has an intimate knowledge of the procedure, he can take an educated guess on which designs might give the surgeon better maneuverability. Hence, his opinion was taken into consideration when comparing designs.

b. Practicality

Practicality is important because it considers the possibility of each design being successful, while taking into account how it will reduce the time it takes to get the kidney into the bag.

c. Ease of Construction

Ease of construction was considered because it is important for the bag to be easily constructed in order to keep the cost of manufacturing low.

VI. Final Designs

Keeping in mind that each hand-assisted laparoscopic nephrectomy procedure differs from another due to various factors, such as the size of the kidney, the degree of cancerous growth, and the preferences of the surgeon, two final designs were selected. The specimen bag with finger ports and a drawstring closure is the first design and the accordion-style collapsible bag was combined with the telescoping closure to make an equally competitive second design.

a. Finger ports

One of the main issues urologists have with the current specimen bags on the market is it is extremely difficult to transfer the kidney into the specimen bag since the mouth of the bag tends to conform back to its flat shape. This main area of concern is what is primarily addressed in the finger port design. The six finger ports around the middle of the bag – two thumb ports on one side (one for right-handed surgeons and one for left-handed surgeons) and four finger ports on the opposite side – allow the surgeon to essentially hold the mouth of the bag open, making it much easier to guide the kidney through the mouth and into the bag. With all fingers in their respective ports and the bag resting in the palm of the hand, the mouth of the bag is brought around the kidney, and once the kidney is entirely through the mouth of the bag, the finger ports are used to bring the rest of the bag over the remaining portion of the kidney. The surgical graspers used in the operation can also be used to pull the mouth around the kidney. Above the finger ports is a drawstring, much like the one used in the LapSac® Surgical Tissue Pouches, which will be pulled after the kidney is entirely closed within the bag. The drawstring not only ensures the complete enclosure of the kidney in the bag but also makes for a simple, easy removal of the bag and kidney through the hand port. Our main concern with this design is that this design might not effectively reduce the time it takes to get the kidney into the bag. To determine if this is a legitimate concern, further testing must be conducted.

b. Accordion bag with telescoping ring

The second final design incorporates the accordion bag design and the telescoping ring design into one concept. The accordion bag will be able to collapse into a flat position and also expand into a full size bag, much like how an accordion expands and contracts. The bag will be molded from polyethylene in such a way that gives the side of the bag the general accordion shape and function. The bag will be inserted into the abdominal cavity in its flat formation and placed at the bottom of the cavity. The telescoping ring, stitched close to the mouth of the bag, is in its largest form at this point, providing a firm opening to the bag and a large passageway for the entire kidney. When the kidney is ready for extraction, the kidney is maneuvered on top of the bag and the sides of the bag are pulled upward. The telescoping ring closes off the bag by collapsing in on itself and creating a tight seal. Once the telescoping ring is secured shut, the bag can be removed through the hand port. This design leaves open the option of adding a drawstring around the rim of the mouth, further sealing off the bag and making the bag much easier to remove. The main concern with this design is whether the diameter of the bag will be large enough to accommodate the kidney size.

VII. Future Work

Currently, the team has decided to go ahead with two designs. This decision was made after explaining the designs to the client. He really liked the finger port design and thought that it was a very simple and easy way that could solve the problem of efficiency when getting the diseased kidney into the bag. He also believed that the accordion design could work and it is unlike anything currently on the market. For this reason, the team chose to pursue both designs.

It was decided that the most feasible way to create the finger port design is to use polyethylene tubing (sold in rolls) as the plastic for the bag. To actually create the bag, a tabletop poly bag sealer will be used. These sealers work by heating the plastic and "melting" it to the other side of the bag. Based on the research conducted, these seals are air and water-tight and the only drawback is the excess plastic it can leave on the seal (Cleaveland Equipment & Machinery Company). This slight drawback will be avoided by cutting off most of the excess and making the bag inside out so when it is done the seals and extra plastic will be inside of the bag. This will protect the inside of the abdominal cavity and other organs from the sharp plastic sealed edge.

To create the accordion design, moldable polyethylene will be used to make the different levels of the accordion. To make the connecting pieces of the accordion, polyethylene will either be sealed to or sewn onto the each other. Once again, if a sealer is to be used, any extra plastic could be cut off or folded inside of the bag. If sewn together a way to seal the stiches will have to be designed and implemented

Once prototypes for each of the bags have been created, a model of the abdominal cavity will be made to test the designs. In order to do this, the current plan is to use a small cardboard box (slightly larger than a shoe box) as the abdominal cavity. To make this prototype as realistic as possible, holes will be made on the box to place the graspers and a web camera, hooked to a laptop, inside the box to replicate the laparoscope. If a hand port cannot be obtained from the client due to expenses, a rubber glove will be used to cover the replicated incision. For a prototype of the kidney, a kidney-shaped model will be made out of foam and filled with coins to get the correct weight. This will be our initial testing with actual animal testing by medical students to be conducted in the spring of 2011.

VIII. References

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Sharma, Abhaya. "Radiation Sterilization of Healthcare Products at ISOMED."*National Association for Applications of Radioisotopes & Radiation in Industry*.N.p., 01 Jan 2007. Web. 10 Oct 2010. <www.naarri.com/presentations/abhaya_final.pdf >.

IX. Appendix
a. Product design specifications

Specimen Retrieval Bag

October 20, 2010

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Definition and Purpose: Hand assisted Laparoscopic Radical Nephrectomy is a delicate procedure that requires a specimen retrieval bag for the removal of the kidney from the abdominal cavity. The current models are bulky and inefficient. The purpose of this project is to decrease total operative time, improve ease of use, and reduce tumor spillage while protecting the abdominal cavity.

Client requirements:

- Decrease time required to place kidney in bag
- Protect abdominal cavity
- Sterilizable, non-permeable, water-tight
- Should not increase the chance of Metastasis or cause trauma to the surrounding environment
- Bag should support the weight of a removed organ when held by the closure apparatus
- Must fit through hand port in deflated state
- Must fit through the incision when containing the kidney
- Sealable to prevent tumor spillage
- Able to use with one hand and a grasping instrument

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: This one-time use bag should require 5 minutes or less to retrieve the organ. It should also be strong enough to withstand insertion and extraction from the abdominal cavity without leakage. It should be able to withstand up to 10 pounds of load when held by the closure apparatus.

b. *Safety*: The bag should be made of a material that is able to be sterilized or the bag should be able to be created and packaged in a sterile environment so it can be used right out of the package. The material should be soft and flexible enough to ensure that the surrounding tissue is not harmed in any manner at any stage throughout the operation. The bag should be water-tight and non-permeable to prevent tumor leakage.

c. *Accuracy and Reliability*: The bag material should be sterilazable before packaging. The bag should be able to be combined with the other disposable medical equipment and hazardous material collected during the procedure in the biohazard waste.

Life in Service: The bag should be able to withstand the abdominal cavity conditions for 2 hours and 1 hour outside the body with organ contained post-surgery.

e. *Shelf Life*: The bag should be confined to medical storage environment.

f. *Operating Environment*: The surgeon should be able to deform the bag to fit into a hand port with an opening of size 6 to 10 centimeters. It should be able to withstand a temperature range of 60 to 130 degrees Fahrenheit. The bag should be sterile and not corrode in normal body fluids. It should be able to withstand 10 pounds of force within the bag when being held by the closure apparatus.

g. *Ergonomics*: The surgeon should be able to handle the kidney and place it into the bag using a single hand and pair graspers.

h. *Size*: The required internal dimensions of bag are 8 by 10 inches with a tolerance of plus or minus 0.25 inches and 1500 milliliters in volume.

i. *Weight*: The bag should not exceed 100 grams.

j. *Materials*: Sterilizable, non-corrosive and water-resistant material should be used.

k. *Aesthetics*, *Appearance, and Finish*: The bag should be lubricated.

2. Production Characteristics

a. *Quantity*: One per surgery.
b. *Target Product Cost*: The price range for the current models is from $2 to $150 per bag. The budget for this project is set at $300.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is required and should meet the requirements of the procedure.
b. *Customer*: The client specified that the design for the rim of the bag should be the focus of improvement. When the bag is under no stress, it should not lay flat.
c. *Patient-related concerns*: The bag needs to be sterile and be able to effectively contain tumor cells.
d. *Competition*: Many devices exist on market. The client uses LapSac Surgical Tissue Pouches manufactured by Cook. There is no standard design among available models. Some physicians manufacture their own specimen bags.

b. Images from procedure

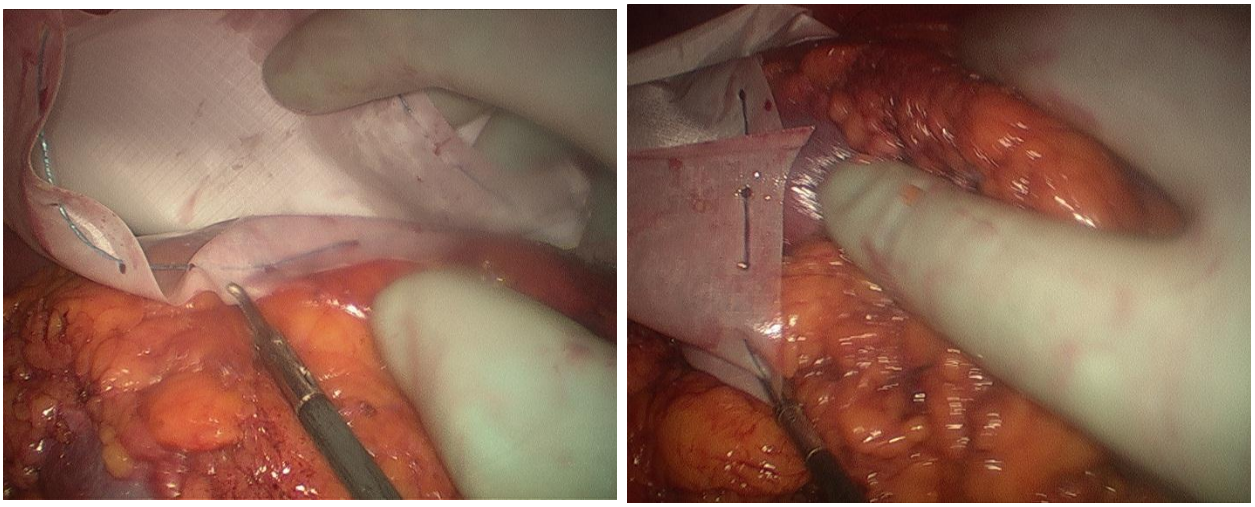

Figure 1 Using a pair of graspers and one hand to open the LapSac Specimen Retrieval Bag and place the kidney inside

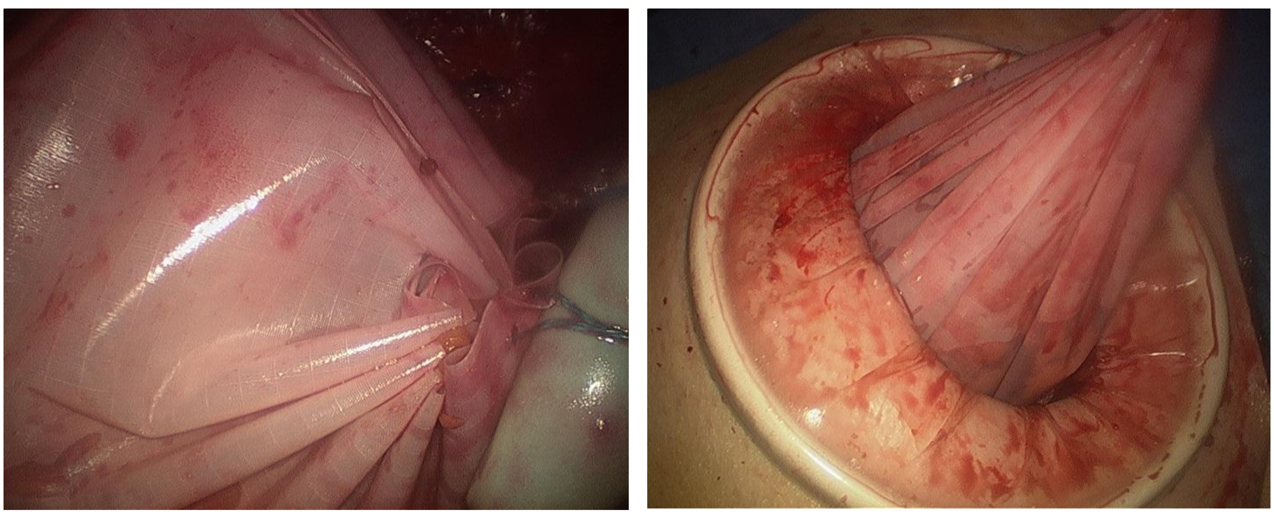

Figure 2 Closing the LapSac Specimen Retrieval Bag and pulling the bag with kidney our the incision

Figure 3 Removed cancerous kidney next to a ruler

c. Market products and other bags used

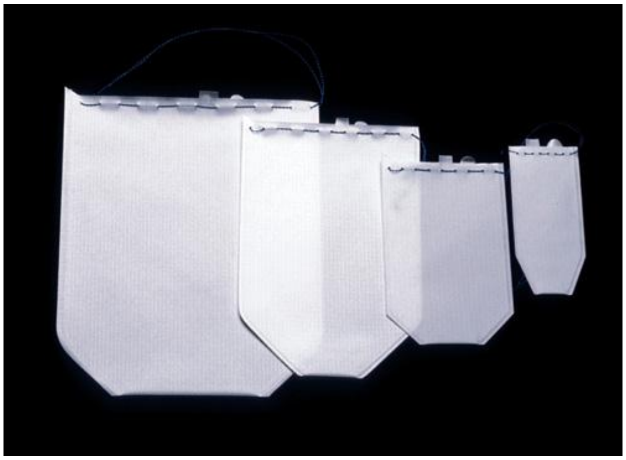

Figure 4 LapSac Surgical Tissue Pouches by Cook

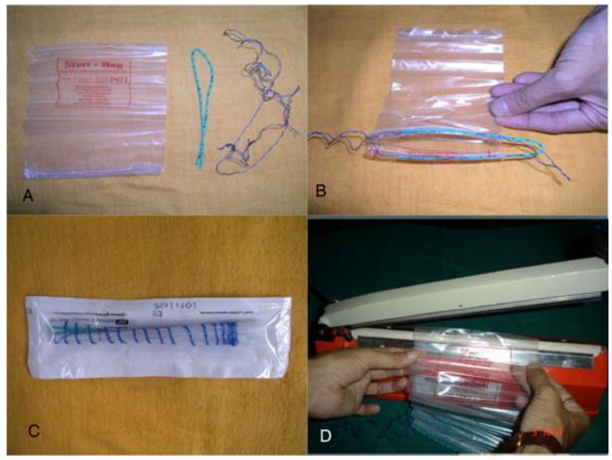

Figure 5 Homemade Nadiad Bag (Ganpule et. al, 2010)

Figure 6 EndoCatch by Tyco

d. Other tools used during procedure

Figure 7 Standard pair of graspers

e. Alternative Designs

i. Bag form

Figure 8 Firm bottom

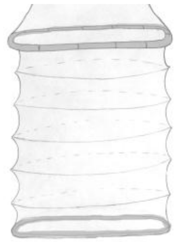

Figure 9 Accordion bag

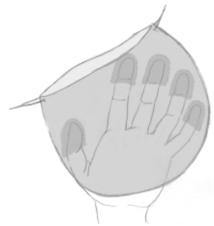

Figure 10 Finger ports

ii. Bag closure

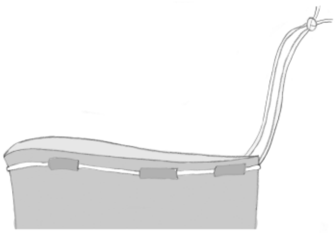

Figure 11 Drawstring

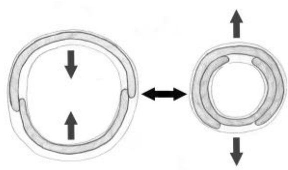

Figure 12 Telescoping ring

Figure 13 Tabs

iii. Surround the abdomen

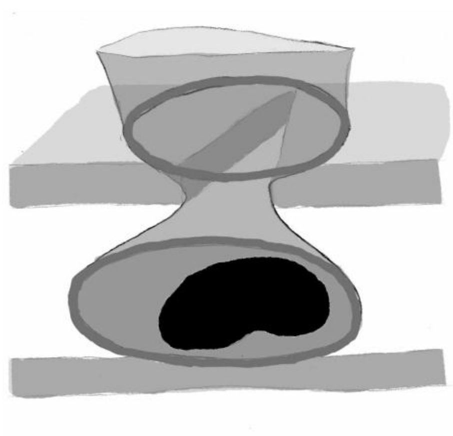

Figure 13 Bag used to protect abdominal cavity from kidney