IX. Appendix
A. Product design specifications

Specimen Retrieval Bag

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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
- Sterile, 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 sterile 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*: Sterile, 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 ruler

C. Markey Products and other bags used for hand-assisted laparoscopic radical nephrectomy

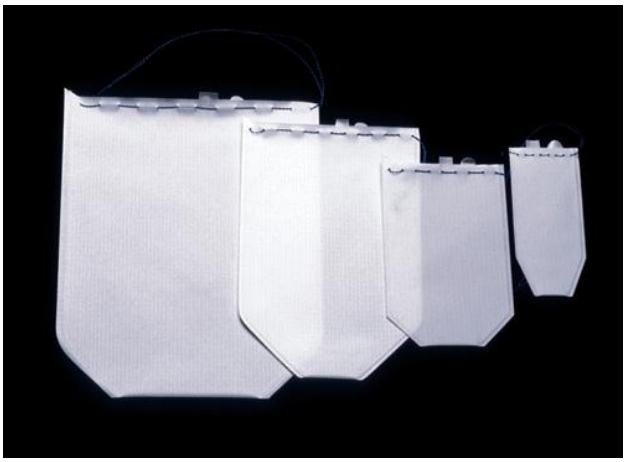

Figure 4: LabSac Surgical Tissue Pouches by Cook

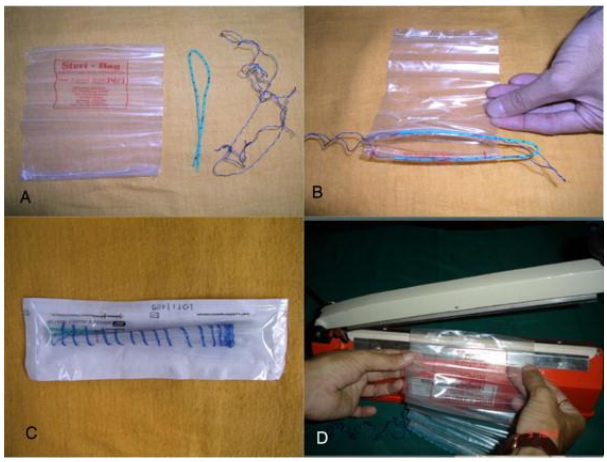

Figure 5: Homemade Nadiad Bag (Ganpule et. Al., 2010)

Figure 6: EndoCatch by Tyco

D. Alternative Designs

i. Bag Form

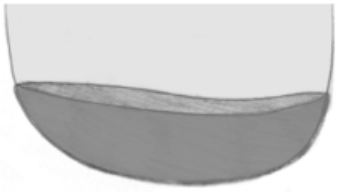

Figure 7: Firm bottom

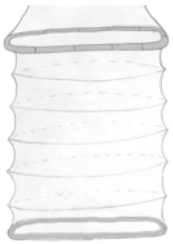

Figure 8: Accordion bag

Figure 9: Finger ports

ii. Bag Closure

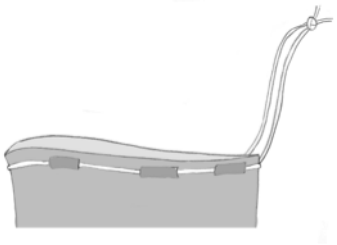

Figure 10: Draw string

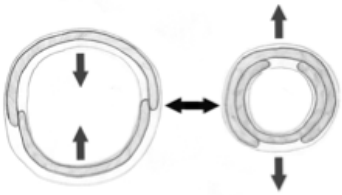

Figure 11: Concentric rings

Figure 12: Tabs

iii. Surround the abdomen

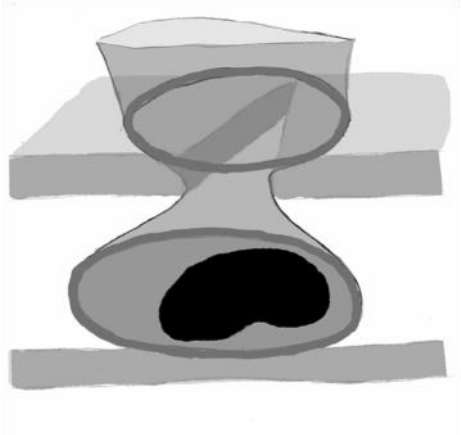

Figure 13: Bag used to protect the abdominal cavity from cancerous kidney

E. Construction

i. Heat Sealer

Figure 14: Impulse heat sealer creating seal on edge of accordion ring

Figure 15: Impulse heat sealer creating seal on inside of accordion ring

ii. Moldable Silicon

Figure 16: Clay mold used to mold EcoFlex bag

Figure 17: Un-stretched cured Ecoflex

Figure 18: Stretched cured Ecoflex

F. Final prototypes

i. Finger Port Bag

Figure 19: Finger port bag – side view

Figure 20: Finger port bag – bottom view

ii. Accordion Bag

Figure 21: Accordion bag – side view

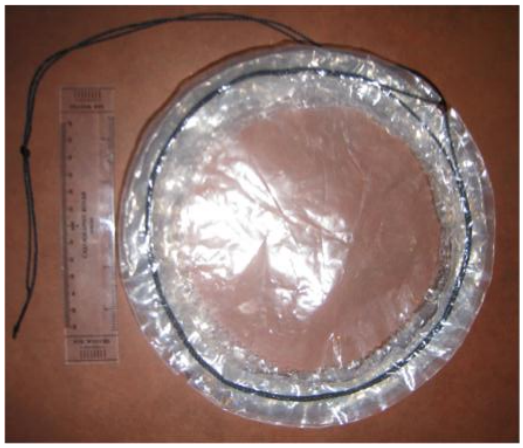

Figure 22: Accordion bag – top view

G. Testing

i. Kidney Removal Timing

1. Model Kidney

Figure 23: Metal added to clay

Figure 24: Metal wrapped in clay

Figure 25: (Top) Cancerous and (bottom) normal kidney models

2. Environment

Figure 26: Josh handling a pair of graspers and using a hand to remove kidney from model abdomen while using web cam as laparoscopic element

ii. Weight Capacity

Figure 27: Testing strength of seal by incrementally adding weight in the form of metal

iii. Watertight Seal

Figure 28: Seal on bag is watertight