

Product Design Specifications

A New Vascular Clamp for Robotic Partial Nephrectomy (VASCLAMP)

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Function

During laparoscopic partial nephrectomy this blood flow to the kidneys is occluded by placing clamps on the renal artery and vein. This clamping causes global ischemia to the kidney, which can cause long term damage to the patient. Our client would like us to develop a device that can occlude blood flow to the site of the tumor and not to healthy tissue.

Client Requirements

- Device must be able to provide enough strength to occlude renal blood flow.
- Device must be a laparoscopic instrument.
- Device must be reusable.
- Surgeon must be able to operate the device with one hand.
- Clamp neck must be flexible.

Design Requirements

1. Physical and Operational Characteristics

- Performance Requirements:* The product must be able to be applied during the duration of the surgery (5- 30 minutes) and must be reusable for future laparoscopic procedures.
- Safety:* The product cannot cause any harm to the operators or the kidney and the surrounding tissue.
- Accuracy and Reliability:* The device must be able to apply 8.5 lbs of force across the entire kidney for a maximum time of 30 minutes. Additionally, it must reliably provide this force after at least 100 applications.
- Life in Service:* The device must be able to operate for the duration of the surgery (approximately 5 – 30 minutes).
- Shelf Life:* The product must be able to remain in storage in a sterile package without corroding for at least 10 years.
- Operating Environment:* The expected environment for use is in an operating room in contact with living tissue.
- Ergonomics:* The device must be easily sterilized, operated with one hand, accommodate hand breadth ranging from 6.5 – 9.5 cm, and not cause discomfort to the user. In addition the device must have a flexible shaft
- Size:* The device must be able to fit through a 12 mm by 15 cm laparoscopic trocar

and the arm should be 60.96 cm in length. The clamp should be 5 cm long to occlude flow to a 4 cm tumor.

i. Weight: Weight should not exceed one pound.

j. Materials: The device should be made of materials that are sturdy and do not deteriorate or infect the tissues of the patient.

k. Aesthetics, Appearance, and Finish: For this project the client emphasized functionality over appearance and therefore this category is not applicable to our design.

2. Production Characteristics

a. Quantity: One device is required.

b. Target Product Cost: The marketable price for the device should not exceed the cost of a commercially available surgical clamp, \$10,000. Our prototype should not exceed \$500.

3. Miscellaneous

a. Standards and Specifications: The device should adhere to FDA medical device guidelines.

b. Customer: The final product is intended for use by our client; however, it has the potential to be integrated into other laparoscopic procedures that involve the kidney or similar organs.

c. Patient-related Concerns: The device is intended for use on patients needing laparoscopic partial nephrectomy. The device will need to be sterilized to be used on the next patient.

d. Competition: There are no commercially available clamps designed solely to clamp the kidney parenchyma that are also laparoscopic. The Satinsky laparoscopic clamp has been used in this manner, but it doesn't provide the flexible shaft our client desires.