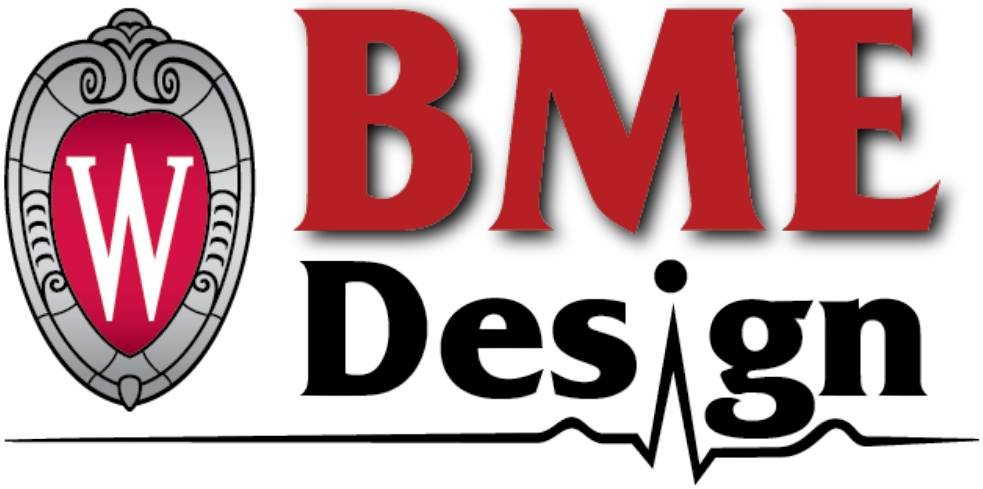

Device for Precise Radiologic Pathologic Correlation in Renal Cell Carcinoma

Preliminary Product Design Specifications

BME 400

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October 1st, 2023

Function :

The goal of this project is to develop a blade for a tumor resection coring device. The blade should be able to effectively resect a cross-section from an ex-vivo kidney tumor without causing damage to the overall tissue sample. Currently, the resection device used is too blunt and thick to effectively extract tissue without causing surrounding areas to be damaged and un-imageable on CT. By creating a new blade design, the pathologist can preserve the extracted tumor during the coring process. In maintaining the integrity of the tumor, the pathologist will be able to accurately correlate CT image markings and findings with their location in the patient sample.

Client requirements:

- Timeline: All final deliverables must be completed by December 16th, 2023
- A device is needed to allow for radiologic-pathologic correlation of resected renal cell carcinoma
- The device must accommodate ex vivo tumors of large size, approximately 20 x 7 x 7 cm
- Tissue samples should be cleanly cored without damaging the integrity of the tissue
- The device should be easily sterilized and cleaned between uses
- The device should be reusable and long-lasting
- The blade must be easily detachable from the cylindrical corer
- The team has a budget of $500 for one device

Design requirements:

1. Physical and Operational Characteristics

    a. *Performance requirement*s: The coring blade must be able to resect a single tissue sample from the kidney, roughly 7-10mm in size in order to fit on a microscope slide. The cut must be sharp enough to minimize the trauma to the surrounding tissue. The blade must be reusable and therefore must be able to withstand sterilization in an autoclave. The blade must be easily detachable in order to be removed before imaging.

    b. *Safety*: To ensure the safety of the pathologist, the blade should be round and smooth on the sides while remaining sharp at the point of incision. A cover will be made to cover the blade when not in use to protect the pathologist.

    c. *Accuracy and Reliability*: The device must be effective enough so that it takes only one cut to insert into the tumor. The extent of trauma to the surrounding tissue should be no more than 3mm in diameter.

d. *Life in Service*: The blade portion of the coring device should be reusable and able to perform at least 50 resections of tissue samples without becoming dull. Therefore, it should compare to the hardness of sterile surgical blades which are outlined in BS 2982:1992 and BS EN ISO 7153 Part 1 [1].

e. *Shelf Life*: The blade must have a minimum shelf life of 3 weeks due to the timeline of the entire procedure according to Dr. Jason Abel. When not being used, the device should be stored in sealed packaging in dry, room-temperature conditions (<50% humidity, 27 ℃) [2].

f. *Operating Environment*: The coring device should only be used in a clinical pathology lab. This laboratory should be compliant with the ISO 15189 standard [3].

g. *Ergonomics*: The blade should be comfortable and easy for the pathologist to use. Therefore, it will be lightweight (< 1 lb), have no rough edges, and be balanced so that it only takes one attempt to successfully collect a sample in less than 5 minutes [4].

h. *Size*: The coring device must produce samples that can be comfortably observed on microscope slides. Therefore, the diameter of the circular blade must be between 7 to 10 mm according to Dr. Jason Abel. The core blade must also be less than 30 mm in height in order to not interfere with the CT imaging.

i. *Weight*: The design should be as simple as possible, minimizing unnecessary bulkiness. The coring aspect of the device should be less than 1lb to not put any strain on the pathologist's hands when collecting a sample.

j. *Materials*: The blade of the coring aspect should be made of surgical-grade stainless steel that is hardened to the Rockwell C hardness of about 46-53 [5]. The material of the blade must be able to withstand high temperatures in order to be sterilized in an autoclave.

k. *Aesthetics, Appearance, and Finish*: The device should be smooth and simple. There are no appearance or finish specifications required by the client.

2. Production Characteristics

a. *Quantity*: There is only a requirement for one device, however considering the possibility of mass production, the number of devices may need to meet market demands.

b. *Target Product Cost*: The target product cost for this device is $500. It will be paid for via UW Health research funds.

3. Miscellaneous

a. *Standards and Specifications*: The device would need to adhere to the ISO 13485:2016 regulation which outlines requirements for regulatory purposes of medical devices. Regarding the blade for a tumor resection coring device, this standard specifies that a technical support device must consistently meet customer and applicable regulatory requirements [5]. In addition, the device must follow ISO 15189:2022 so that it meets the quality and competence requirements to be used in a medical laboratory [6]. Because the blade may need to be detachable, the device should also adhere to ISO 7740:2018 which states the dimensions and features needed to be a detachable blade used in a laboratory [6]. Lastly, the model would also need to follow the FDA's Code of Federal Regulations Title 21, Volume 8 which outlines the requirements for medical devices [7].

b. *Customer*: Dr. Meg Lubner is a professor (CHS) in the Abdominal Imaging Section at the University of Wisconsin School of Medicine and Public Health. She is asking for a blade that would be compatible with the tumor resection coring device that was fabricated by the previous group. Dr. Daniel Shapiro and Dr. Jason Aebl will act as alternate contacts for this project as well. Both doctors have specialties in minimally invasive surgery and urologic oncology, giving the team specialized knowledge about RCC.

c. *Patient-related concerns*: Our device will not interact directly with the patient, only with the kidney tumor after it has been fully surgically removed. However, it is crucial that the coring device takes an accurate and interpretable biopsy of the tumor. Minimizing the tissue trauma caused to the kidney tumor when taking a core biopsy is critical to conclude an accurate diagnosis and to collect data from the procedure.

d. *Competition:* Currently, there is a lack of available devices in the market designed for core biopsies of kidney tumors. The existing method involves excising square sections around markers within the tumor. However, this approach falls short of providing comprehensive insights into the depth of specific areas of interest. A device sharing a similar underlying principle already present in the market is the punch

biopsy tool employed for skin graft procedures. In a punch biopsy, a circular-tipped cutting instrument is utilized to extract deeper layers of skin for diagnostic purposes [10]. This tool is rotated into the skin and then withdrawn to generate a columnar biopsy of the skin's deeper layers. However, these devices cannot be used to create a core biopsy of a kidney tumor because they do not cut deep enough.

References:

[1] “ISO 7153-1:2016 - Surgical instruments - Materials - Part 1: Metals.” https://webstore.ansi.org/standards/iso/iso71532016?gad_source=1&gclid=CjwKCAjwyNSoBhA9EiwA5aYlb6QOZJk1WsQh60pnvlbu12DcnrgfUrEscKmUyMdjTL5-pCZ6FudwEhoCH7gQAvD_BwE (accessed Sep. 28, 2023).

[2] "Humidity control of steel for world's largest independent steel trader." Munters. https://www.munters.com/en/munters/cases/stemcor-steel-storage/. [Accessed on: September 20, 2023].

[3] 14:00-17:00, “ISO 15189:2012,” ISO, Jan. 26, 2021. https://www.iso.org/standard/56115.html (accessed Sep. 27, 2023)

[4] C. C. for O. H. and S. Government of Canada, “CCOHS: Hand Tool Ergonomics - Tool Design,” Jun. 13, 2023. https://www.ccohs.ca/oshanswers/ergonomics/handtools/tooldesign.html (accessed Sep. 28, 2023).

[5] N. K. Meckel, “Scalpel blade having high sharpness and toughness,” Sep. 20, 2001

[6] 14:00-17:00, “ISO 15189:2012,” ISO, Jan. 26, 2021. https://www.iso.org/standard/56115.html (accessed Sep. 27, 2023).

[7] “CFR - Code of Federal Regulations Title 21.” https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPartFrom=800&CFRPartTo=1299 (accessed Sep. 21, 2023).

[8] “Punch biopsy,” Mayo Clinic, https://www.mayoclinic.org/tests-procedures/skin-biopsy/multimedia/punch-biopsy/img-20005764 (accessed Sep. 27, 2023).