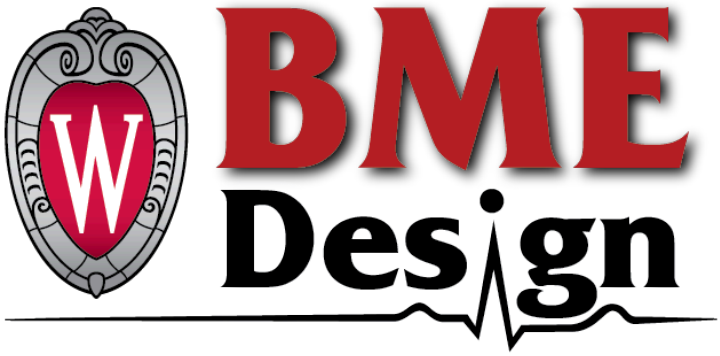

GVI: Straw Stamp and Slicer - BME 200/300

Product Design Specifications

BME 200/300 Design

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Function

Currently, Genetic Visions-ST sequences semen from artificial insemination straws, ensuring that the DNA detected matches the bull that is listed on the straw [1]. This quality control program is intensive, as it takes about an hour to cut and push 96 semen straws per 96-well plate. The clients have requested two devices: a slicer and a stamp. The slicer must uniformly cut the ends of 12 straws without cross-contamination. The components of the slicer must be removable, and a blade guard must be incorporated for safety. The stamp must accurately push bull semen out of 96 straws at once without any punctures or deformation to them.

Client requirements

- A device capable of cutting the ends of 12 insemination straws at a time.
- A mechanism to push the contents of the straws in bulk to a 96-well plate.
- Both devices must have removable components for cleaning.
- Both devices should minimize user error and eliminate any chances of contamination between the straws.
- Reduce the procedure time from 1 hour to a final time of 30 minutes.

Design requirements:

1. **Physical and Operational Characteristics**
    a. **Performance requirements**: The device must consist of a cutting component to cut 12 straws at a time, as well as a stamping component that holds 96 straws and pushes the cotton and semen out of each straw into a well plate. The device is intended to be used 8-10 times per week, and the estimated loading for the device is 0.32 N [2] per use. Design should allow for minimization of cross-contamination, and each component of the device must be able to be disassembled for sterilization [3].

    b. **Safety**: Blade guards must be included to cover blades when the device is not in use to prevent any injury to the user. A warning label may be used to bring awareness to the danger of the blade. Disease transmission during straw slicing

and stamping is rare due to lab safety procedures, cattle vaccination, and antibiotic treatment for samples, however a small risk is still posed. If safe practices are not followed, diseases such as Foot-and-Mouth disease or Leptospirosis could infect the user if they were cut by the blade [4]. Utilizing blade guards, wearing gloves, and carefully operating the device are all effective ways to reduce the risk of infection.

c. **Accuracy and Reliability**: The slicing component must cut off at least 0.20 inch and at most 0.50 inch of each straw, and the stamping component should push the entire sample into the well plate to maintain consistency in collection. To maintain precision for slicing and stamping, the straws must be held in place to prevent movement or bending [3].

d. **Life in Service**: This device must function accurately and consistently for a minimum of one year, performing 8-10 procedures per week. The straw cutter will be used 8 times per procedure for about 1 minute per use, while the straw stamp will be used once per procedure for about 10 minutes per use [3].

e. **Shelf Life**: All of the components of the device must have a shelf-life of at least one year. They will be replaced if they show signs of corrosion or decreased functionality. However, since there will be removable components, replacing specific components could increase the device's overall longevity. This device will be used multiple times during the week. When not in use, it will be stored within the Genetic Visions-ST wet laboratory.

f. **Operating Environmen**t: This device will be used in the Genetic Visions-ST wet laboratory and operated by one of the clients. The Food and Drug Administration's regulatory guidelines show that the optimal temperature for wet labs is 68 °F and 77 °F (20°C and 25 °C) with humidity levels between 30% and 50% [5]. The device will come in contact with the filled insemination straws, which are stored in the fridge at ideal temperatures of 4-18 °C to prevent bacteria growth [6].

g. **Ergonomics**: The device should be easily operable by one of the Genetic Visions-ST's employees. For efficiency and user comfort, the device should also be ergonomically optimized to support operators performing this task repeatedly through the week. The main force needed will be the one to overcome the straw's vacuum seal and push the semen into the well plate. Using the pressure equation P = F/A, the force needed to push the contents of a 0.002 meter diameter straw is 0.32 N [2].

h. **Size**: The client supplied prototypes to display the functional requirements of the tool. The first prototype, a slicer, measured 11 inches in length and 5 inches in width. It featured a hinge mechanism originating from the base plate and extending upwards approximately 7 inches. The second prototype was a rectangular stamp measuring 5 inches by 4 inches, equipped with spring-loaded pins of 2-inch length. This stamp was designed to interface with straws positioned within a transparent base plate of similar size. When not in operation, both tools are intended to be stored on a personal workbench measuring 3 feet by 2 feet. As the workbench is shared with other tasks, it is essential that the slicing and stamping tools do not obstruct or interfere with daily activities [3].

i. **Weight**: The client has not specified an optimal weight range for the device. If the equipment is placed in a holder, the holder should not exceed more than 20 kg [7]. This is to ensure safe and efficient transport of the holder between floor level to work bench height. The device itself will be placed on a workbench when not in use. It must be sufficiently lightweight to allow operation using the forearms and shoulders without physical strain. For a repetitive task at this height, the maximum weight of the tool should be between 11kg and 14kg [7].

j. **Materials**: The tool must be disinfected after each use, either by immersion in a bleach or alcohol-based solution and through surface wiping. Additionally, the material must be capable of withstanding repeated exposure to these harmful chemical agents. As the client requested, it should be a non-porous material. Various grades of steel exist, including carbon steel, which is susceptible to corrosion when exposed to moisture or oxygen. By applying a chromium oxide

coating to the surface, the chances of corrosion can be greatly reduced. Stainless steels in the 300 and 500 series exhibit enhanced corrosion resistance, while those in the 300 series are noted for weldability [8]. The material must withstand harsh conditions, maintain functionality, and prevent cross contamination.

k. **Aesthetics, Appearance, and Finish**: There are no preferences for the appearance of the device, however, the aesthetics of the device should not impede on the function of the device [3].

2. **Production Characteristics**
    a. **Quantity**: The client is aiming to have one straw stamper device and one straw slicer device to work with. The client does not have a preference on whether or not both devices are combined into a singular as long as the devices can be easily disassembled for cleaning [3].

    b. **Target Product Cost**: The overall budget is $1000. The average cost of the jagged tooth blades is around $20 but will need to be modified based on size [9]. Fine pins to push the cotton cost around $5 for a pack of 250 [10]. Currently, there does not seem to be other similar products for the straw stamper. The straw slicers have other similar products at an average cost of $10. ABS Global is selling their straw slicer at a cost of $6.38 [11]. Valley Vet is selling their straw slicer for $13.29 [12]. However, the current straw slicer products only cut one straw at a time.

3. **Miscellaneous**
    a. **Standards and Specifications**: The straw slicer and stamp must follow international standards that correspond to laboratory devices. Since the bull semen goes through a DNA sequencing process, the components that will contact the bull semen should not cause DNA damage and must exhibit biocompatibility. ISO 10993 defines this as “the ability of a medical device or material to perform with an appropriate host response in a specific application” [13].

In addition to biocompatibility of the device materials, each material’s

resistance to corrosion relates to the longevity and accuracy of the device. If corrosion tests are performed on the device materials, they must follow the guidelines set by ASTM F1089, outlining the boil and copper sulfate test, which assess corrosion and copper plating respectively [14].

The safety of the straw slicer and stamp is also a major factor of the design process. ISO 12100, a standard that covers the safety precautions, risk assessment, and risk reductions, must be taken into account when designing the blade and stamp [15]. This will help identify the risks of each design and implement safety components such as a blade guard, better grip material, etc.

b. **Customer**: The main priorities of the client are to reduce the procedure time from 1 hour to < 30 minutes, while maintaining precision of the devices. For the straw slicer, the clients are partial to their proposed jagged-tooth blade to reduce cross contamination between the 12 straws during each cut. The presence of a blade guard with 12 opening holes for the straws and a "straw stopper" to ensure equal cut length (~¼ inch) is favored. They strongly prefer the straw slicer to have removable components, allowing for easier and more thorough sterilization. No preferences were given for the straw stamp other than a light-weight design [3].

c. **Patient-related concerns**: As there is much concern about the risk of cross contamination, the device will need to be sterilized after each use. Because of this, the client would like the device to be easily disassembled for easy cleaning. The product would also need to be able to withstand a cleaning solution, such as bleach after each use. Additionally, the clients value precision the most, over other attributes such as cost and materials [3].

d. **Competition**: Currently the clients are using straws to cut each individual straw, and a paperclip to stamp each straw. There are other competing products on the market. For example, Agtech Inc has a straw cutter also available. To use this product, the straw is inserted and then a button is pushed which turns a disk inside the mechanism to cut the straw. This product can be taken apart to be cleaned, which the clients specified the product needs However, their straw cutter is only

for ¼ cc, while the clients requested the product to work for both ¼ cc and ½ cc straws. Also, this straw cutter can only cut one straw at a time, but the client needs to be able to cut 12 straws at the same time [16]. There are many similar products to this plastic semen cutter on the market.

Another product on the market is the MiniCutter for Semen Straws by Nasco Education. This product is lightweight and has an ergonomic handle for easy grip. Similar to the Agtech cutter, this product also has a notch that is pushed for the straw to be cut. However, unlike the Agtech cutter, this product is able to cut both ¼ cc and ½ cc straws. The disadvantage to this straw cutter is that it can also only cut one straw at a time, thus it would not work for the clients needs [17].

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