Growth Plate Measurement Device
Product Design Specifications (PDS)
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Function of Device:
The growth plate measurement device should sense the rate of growth across a single growth plate in a young, actively growing lamb by time intensive sampling. The device should be able to produce readings continuously over a four week period. It will help to answer the questions about the rate of growth in mammals. It is not known whether growth occurs continuously during development or if it comes and goes in spurts.

Client Requirements:
• Be innocuous to the lamb and its natural movements
• Capable of measuring 10 millimeters of growth over a one month period
• Have the accuracy of 10-20 micrometers per measurement
• Capable of time intensive sampling rates—measurements every 1-5 minutes
• *Device should have no element spanning the growth plate

*Current method has a transducer coil spanning the growth plate which is a major limitation. Its accuracy is compromised after a few days due to cell growth and animal movements.

1. Physical and Operational Characteristics

a. Performance requirements: There will be a few specific performance demands on this device. Initially, it is expected that each growth plate distance measurement unit that is placed in the lamb will be discarded after one use so the sterile conditions are more likely, however, this may change after more cost analysis. The device will also have to endure some loading from surrounding tissues while implanted in the lamb.

b. Safety: Safety issues are a very important part of the design process for this device. The device must be sterile to ensure it does not cause harmful reactions. Upon introducing a foreign material numerous infectious, and host response reactions are possible. A sterile device would help to lower the probability of these type of reactions.

c. Accuracy and Reliability: While measuring the change in distance in the two separating phases of the bone growth plate, the device is expected to maintain accuracy of within 10-20 micrometers per measurement.
d. *Life in Service:* The device is expected last for about three weeks which is the duration of the experiment. It is also expected that the device will be able to measure up to 1 centimeter in total length over the period of the experiment with the capability of time intensive measurement sample rates. (about 1 every 2.5 minutes)

e. *Shelf Life:* This device should not be stored in extreme temperatures because this may compromise many of the electrical components of the displacement sensor.

f. *Operating Environment:* This device will be exposed to physiological type conditions while operating. This means temperatures around 37º C, and a pH of about 7.4-7.6. Although stainless steel, a highly non-corrosive material will likely be used in this device, overtime corrosion of this material could occur due it’s implantation in the extracellular fluid of the lamb. The people who will handle this device are veterinarians who implant it into the lamb.

### 2. Production Characteristics

a. *Quantity:* Initially, one complete unit will be needed. This will include all components; The non-contact DVRT and all components necessary to fixate it to the bone. Because the fixation components will be the most replaceable pieces, a few extra could be considered.

b. *Target Product Cost:*

<table>
<thead>
<tr>
<th>Component</th>
<th>Cost</th>
<th>Purchase Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEMOP-DVRT</td>
<td>$445.00</td>
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</tr>
<tr>
<td>DEMOD1-TC</td>
<td>$445.00</td>
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<tr>
<td>DEMOD-DIN</td>
<td></td>
<td>NO</td>
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<tr>
<td>Motherboards, enclosures, and power</td>
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<td>NO</td>
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<tr>
<td>supplies</td>
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<td>NC-DVRT</td>
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<tr>
<td>Fixation Components</td>
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<td>YES</td>
</tr>
<tr>
<td><strong>Total Purchase:</strong></td>
<td><strong>$300.00</strong></td>
<td></td>
</tr>
</tbody>
</table>

### 3. Miscellaneous

a. *Standards and Specifications:* No FDA approval necessary, however specifications for the operation of the non-contact DVRT and related components are guaranteed.
b. **Customer**: Several aspects must be considered. The device should:

- Be innocuous to the lamb and its natural movements
- Capable of measuring 9 millimeters of growth over a one month period
- Have an accuracy of 10-20 micrometers/measurement
- Capable of time intensive sampling rates
- Have no element spanning the growth plate
- Take accurate measurements when the lamb is in any position
- Provide a signal that is not effected by movement of the lamb

c. **Patient-related concerns**: For each study, the device will be implanted for approximately 3 weeks. At the end of the 3 weeks the device is to be removed and then have the ability to be reused. The device must be sterilized before each implantation and thoroughly cleaned and sterilized after each extraction. In addition, because the patient is a lamb whose movements cannot be controlled, the device itself must have the ability to move with the lamb and in turn cannot be effected by the lamb’s movement.

d. **Competition**: We will be using our design in combination with components that are commercially available. For this reason, there is no competition that we see at this time.