Identification Marking of Laparoscopic Instruments for Video Recording
Preliminary Product Design Specifications
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Function: The function of the device being designed is to make laparoscopic instruments identifiable during surgery, without compromising the instruments performance ability. During laparoscopic surgeries, there is often a teaching physician accompanied by a resident, each having his or her own instrument. Currently, there is no way of identifying which instrument belongs to whom, which is reason for developing a type of marker to attach to the instrument.

Client Requirements:

1. Device must be sterile as to not cause infection in the patient.
2. Device must not compromise the functionality of the laparoscopic instrument.
3. Must be securely fastened on the device so it does not separate during surgery.
4. The device should be located at or near the tip of the instrument so that it shows up on the video.
5. Device needs to stay within a budget of less than $200.

Design Requirements:

1. **Physical and Operational Characteristics**
    a. *Performance Requirements*: The device must not deviate from its original position prior to surgery. It also must not impede the functionality of the laparoscopic device, therefore not slipping over the mechanical hinge. The color of the device must be easily distinguishable while in operation.
    b. *Safety*: The device must not fall off during operation. It also must be sterile prior to operation, whether that be opening up a new device or using one that has gone through processing. Finally, there can be no sharp corners that have the potential of snagging tissue during use.
    c. *Accuracy and Reliability*: The device must be able to remain intact during surgery, meaning its strength cannot be compromised by contact with tissue or blood. If reusable, it must be able to withstand the sterilization process.
    d. *Life in Service*: The device is expected to be reusable, but could be determined to be for one time use depending on physical integrity after several rounds of processing.
    e. *Shelf Life*: The device must remain sterile while in packaging.
    f. *Operating Environment*: The laparoscopic labeling device will be used in laparoscopic surgeries, therefore within the human body. It must also be able to withstand the processing environment, which includes several enzyme baths and a steam cleaning at 270'F for 6 minutes.
    g. *Ergonomics*: The device must be easily applicable and removable from the laparoscopic instrument.
    h. *Size*: Diameter will be ~5-6mm and total length will not exceed 3cm.
    i. *Weight*: Weight is expected to be less than 10 g.

j. *Materials*: Device will be made out of a polymer to be determined based on biocompatibility. Secondary options include various types of alloys also based on biocompatibility.
k. *Aesthetics, Appearance, and Finish:* Device needs to be visually appealing. It relies on the visual appearance for functionality, so color choice will be crucial.

2. **Production Characteristics:**
    a. *Quantity:* ~10
    b. *Target Product Cost*: $1.00 per piece
3. **Miscellaneous**
    a. *Standard and Specification*: Built to United States legal standards. Must be approved by proper hospital committees and staff to comply with HIPPA and patient disclosure or release. Needs to receive FDA approval.
    b. *Customer*: Dr. Carly Seaberg and the surgery staff of the University of Wisconsin-Madison Hospital.
    c. *Patient*-Related Concerns: The device will need to receive proper sterilization between uses as laid out in operating room protocol. If necessary, use of device during surgery may need to receive patient approval.
    d. *Competition*: N/A.