

Project Title: Medical Instrument Cleaning Indicator

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Function: To develop a universal indicator that displays the state of cleanliness of a medical instrument. This device must not pose any biological hazards and must be capable of being permanently affixed.

Client Requirements

- Doesn't interfere with functionality of equipment.
- Capable of withstanding autoclave environments of 250° F and 20-30 psi.
- Biologically friendly.
- Capable of withstanding cleaning from quaternary amines and CaviWipes.
- Permanently attached with an adjustable cleaning indicator.

Design Requirements:

1.) Physical and Operational Characteristics

- a. *Performance Requirements:* The cleaning indicator must be able to be permanently attached and remain affixed through physical impact and cleaning operations. The indicator must be capable of bonding to multiple surfaces to fit multiple machines. Each machine must have its own cleaning indicator. The indicator must be capable of withstanding sterilization through heat, gas, and chemical mechanisms.

- b. *Safety*: The cleaning indicator must not introduce nor harbor any biological contaminants. For the given method of sterilization, both machine and indicator must be completely exposed to sterilizing agents.
- c. *Accuracy and Reliability*: Device must accurately and reliably display the desired state of cleanliness. Device must also remain permanently affixed.
- d. *Life in Service*: The cleaning indicator should last as long as the medical device it is permanently attached to.
- e. *Operating Environment*: Must be able to withstand harsh sterilization environments and exposure to bodily fluids, primarily blood, saliva and vomit.
- f. *Ergonomics*: Indicators must be compact enough to simply affix and must be quick and easy to adjust. The indicator should be capable of being manipulated with a single, glove-covered hand.
- g. *Size*: Indicator cannot interfere with functionality of the equipment but must be easy to handle and affix. Indicator should have a depth no deeper than 2-3 cm. and length and width no greater than 8 cm. by 6 cm. The indicator should be non-obstructing but also easily visible.
- h. *Weight*: Device should be easy to handle and manipulate for technicians. Device should weigh around 5 ounces.
- i. *Materials*: Must not be composed to corrosive or biologically abrasive elements.
- j. *Aesthetics, Appearance, and Finish*: Method of indication must be bold enough to be easily discerned. Any mechanical functions must be capable of being performed with minimal user precision.

2.) Production Characteristics

- a. *Quantity:* 35-40.
- b. *Target Production Cost:* \$100

3.) Miscellaneous

- a. *Standards and Specifications:* Due to presence inside of operating room, FDA approval may be required. Medical equipment warranty considerations must also be considered.
- b. *Competition:* The carts in the hospital all have RFID tags to monitor their position in the hospital and allow the staff to quickly retrieve them. The company that the UW Hospital uses is AeroScout. In the models the Hospital is currently using there is no indication for the cleanliness of the machine included in the RFID signal. Through research we discovered that AeroScout, and multiple similar companies, offer other models that have individually programmable functions capable of indicating any variables the user desires. This technology can of course be used to monitor cleanliness. The RFIDs of this variety have multiple indicators and buttons built into the device which allow the medical instrument user to signal the status of the machine.