

## **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 adjusted or affixed in a minimal amount of time while maintaining reliability.

### **Client Requirements**

- Easily placed and removed.
- Doesn't interfere with functionality of equipment.
- Capable of withstanding autoclave environments.
- Biologically friendly.
- Easy to clean thoroughly.
- Minimal user interaction.

### **Design Requirements:**

#### **1.) Physical and Operational Characteristics**

- a. *Performance Requirements:* The cleaning indicator must be able to be easily removed but must also be permanently attached when desired. The indicator must be capable of bonding to multiple surfaces to fit multiple machines. 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 affixed as long as desired.
- d. *Life in Service*: Device can be either disposable after single use or reusable.
- e. *Operating Environment*: Must be able to withstand harsh sterilization environments and exposure to various biological elements.
- f. *Ergonomics*: Indicators must be compact enough to simply affix and must be quick and easy to adjust.
- g. *Size*: Indicator cannot interfere with functionality of the equipment but must be easy to handle and affix.
- h. *Weight*: Device should be easy to handle and manipulate for technicians.
- 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*: If reusable: 35-40.  
If disposable/single use: 200+.
- 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:*

<http://www.bio-specialists.com/biospecialists-indicator.php.htm>

\*Spray that foams when in contact with Bio-hazardous material\*

<http://atssupplies.com/ProductDetail.aspx?PID=38>

\*Tape that is white, but changes color to black when cleaned\*