

Product Design Specification Report Silicone Oil Applicator for Medical Devices

Date: 14 October 2011

Team:

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Problem Statement

Our clients, Drs. Richard Galgon and George Arndt, of the UW-Madison School of Medicine and Public Health, Department of Anesthesiology, work as anesthesiologists at the UW-Hospital. Currently, surgeons and doctors (anesthesiologists, pulmonologists, critical care medicine physicians, and emergency room physicians) use an aerosolized medical grade silicone spray to lubricate certain upper airway tubes, catheters, and bronchoscopes in the operating room, pulmonary suite, intensive care unit, and emergency room, to allow the devices to slide over one another. The devices include, but are not limited to: fiberoptic bronchoscopes, single and double lumen endotracheal tubes, airway exchange catheters, Aintree intubation catheters, laryngeal mask airways and other supraglottic airway devices, bronchoscope and airway circuit adapters, and bronchial blockers. Although the aerosolized silicone oil sufficiently lubricates these medical devices, the current application technique poses three main problems: (1) creates a slippery work environment, presenting a risk of injury to personnel and patients, (2) poses a risk for cryogenic burns (frostbite), and (3) releases particles into the air that can be inhaled. A different effective method of applying the silicone oil lubricant to these devices that eliminates these problems is sought.

Client requirements

Alternate method of applying the silicone oil must:

- Make use of current aerosol spray-Rusch Silkospray
- Not allow lubricant into external environment
- Prevent hazardous work conditions
 - Eliminate slippery surfaces outside of intended device
 - Protect users from cold effects
 - Protect users from inhalation of particles
- Be able to deliver lubricant inside various tubular medical devices
 - Internal diameter of tubes from 2.5mm to 9mm
- Lubricate the outside cylindrical medical devices:
 - External diameter of tubes up to 13.7mm
 - Length of device up to 35cm long
- Allow for fast application of lubricant
- Coat target area of device evenly
- Not interfere with other hospital equipment
- Be portable within the hospital
- Have a low cost

- Be mass producible
- Be disposable for each patient
- Take up a minimum amount of space
 - Less than 10cm x10cm x 10 cm

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements:* The device will be used to lubricate the inside of medical tubes and the outside of cylindrical tubes and equipment. The device must allow the lubricant to reach all areas of the surface of the equipment to which it is being applied.

b. *Safety:* This device must not endanger the user and others in the area. There must not be toxic materials or sharp edges within the device. The device must protect the user from cold effects of the spray and particles that may be inhaled. The device should restrict the lubricant to the intended medical device and should not allow the lubricant to get onto other surfaces, such as floors, where it may cause occupational hazards.

c. *Accuracy and Reliability:* The method and device that applies the silicone oil must coat the entire surface of the intended piece of equipment. The lubricant should ideally be evenly applied to the surface.

d. *Life in Service:* The device for applying the silicone oil must be disposable. The device will be used for a single patient surgery and will be replaced after each surgery. The total life in service shall not exceed 6 hours under normal surgical conditions.

e. *Shelf Life:* The materials of the device should not degrade over time that it would be stored until needed. The devices would be required by the hospital for usage approximately 15 times per week.

f. *Operating Environment:* The device will be used to lubricate multiple pieces of medical equipment per use. The device will be restricted to use with a single patient so there will not be cross contamination. The device will be disposable to avoid sanitation issues. The device will be used in the operating and emergency rooms.

g. *Ergonomics:* Lubrication device must be user friendly. The device must take less than 30 seconds to assemble. The lubricant must be able to be applied in less than 30 sec.

h. *Size:* The device should not exceed a size of 15 cm x 15 cm x 15 cm.

i. *Weight:* The device should weigh no more than 3 kg.

j. *Materials:* Materials must be safe for use with humans. Any material used should not pose a health risk. Non-radioactive, non-flammable, and non-corrosive materials should be used.

k. *Aesthetics, Appearance, and Finish*: The device should be pleasing to the eye. The finish should be smooth and clean looking.

2. Production Characteristics

a. *Quantity*: One device is required at this time; however, since the device may be used commercially, the device should be mass producible.

b. *Target Product Cost*: The budget for the entire project is \$1000. Once a device is mass produced it should cost less than \$5.00.

3. Miscellaneous

a. *Standards and Specifications*: This device may require approval by the FDA if this device is mass produced for market use. Currently, the device falls under Class I classification and does not require any premarket notification to the FDA regarding the device.

b. *Customer*: The device would be used by doctors that are trained to properly use the device.

c. *Patient-related concerns*: The device must not promote bacterial growth. The device should be disposable; however, since the lubricated medical devices will be used in a patient's upper airways, which are not sterile, the device does not have to be sterile. The device will not come into direct contact with patients.

d. *Competition*: Currently there are no products on the market that are used to avoid the above mentioned problems with the aerosol spray.