Silicone Oil Applicator for Medical Devices

BME 400
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Department of Biomedical Engineering
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Abstract

Currently, Rusch Silkospray is used at the UW-Hospital in Madison, WI to lubricate various medical devices, such as bronchoscopes, single lumen endotracheal tubes, and catheters before they can be used in the operating room. The current spray, however, is not ideal because it can create slippery work environments, its particles can be inhaled, and it can cause cryogenic burns (i.e. frostbite). A disposable pad, clamp, and enclosed box design were created to solve these issues. After evaluating each design, it was determined that the final design is the enclosed box. Future work for this design includes making an initial prototype using a 3D printer and researching whether this device will need FDA approval.

1.0 Introduction

1.1 Problem Statement

Our clients, Dr. Richard Galgon and Dr. 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 (e.g. anesthesiologists, pulmonologists, critical care medicine physicians, and emergency room physicians) use Rusch Silkospray, an aerosolized medical grade silicone spray, to lubricate upper airway tubes, catheters, and bronchoscopes in the operating room, pulmonary suite, intensive care unit, and emergency room. The silicone spray allows 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, 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 (i.e. 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.

1.2 Background

1.2.1 Background of Silicone Oil

Silicone oil is waterproof grease produced by mixing polydimethylsiloxane with a thickener, such as, amorphous fumed silica. Silicone oil is thermally stable, fire resistant, and resists incorporation of air bubbles into the liquid. Silicone oil is manufactured in different purities including a food grade and medical grade silicone oil. It is available in both a liquid and an aerosolized form within different products, as shown in Figure 1. It is used in electrical applications requiring a lubricant as an insulator. Silicone oil is also used widely in the medical, automotive, and manufacturing industries as a lubricant to devices and machinery (Silicone and Silicon, 2006). The application that this design is focusing on is when it is applied as a lubricant to medical devices.

Figure 1: SILIK'ON 5 silicone oil aerosol spray (Novatech, 2011)

1.2.2 Aerosolized Silicone Oil Lubricant Safety

In viewing the material safety data sheet for several aerosolized silicone lubricants, it was determined that silicone is relatively safe in application if used correctly. Aerosolized silicone oil is under high pressure and uses propane and butane as propellants (LPS, 2011). These aerosol propellants make the canister of silicone oil flammable. A potentially dangerous situation when using aerosolized silicone oil can be avoided by keeping flames and heat sources away from the product (Dupont, 2011).

It is recommended that users who are spraying aerosolized silicone oil lubricant equip themselves with respiratory equipment, safety goggles, and protective gloves when coming in prolonged contact or repeated exposure to the spray (Betco, 2007). Contact with the eyes will result in irritation and repeated exposure of the skin to the silicone oil results in dryness and cracking (IMS, 2011).

1. 2.3 Cryogenic Burns

Although silicone oil itself cannot cause frostbite, propane and butane, which are used as propellants in the aerosol spray, can. Butane has a boiling point of -5^{o}C and propane has a boiling point of -41^{o}C (Sigma Aldrich, 2009). Because both propellants have low boiling points,

when the pressurized propellants are released, they quickly vaporize and absorb heat from the surrounding environment. The sub-freezing environment created by these propellants can damage skin tissues, thereby causing frostbite (Aerosol-Induced Frostbite Injury, 2011).

There have been a few documented cases of frostbite and cryogenic burns caused by aerosol propellants. In Switzerland, there was a 14 year old girl who developed first degree cryogenic burns after she used a deodorant spray containing propane and butane propellants (Aerosol-Induced Frostbite Injury, 2011). There have also been other children that received cryogenic burns after use of aerosolized products, such as toilet air fresheners, containing propane and butane as propellants (Camp, 2003) (Lacour, 1991). In all cases, the user of the aerosol had misused the product and sprayed for extended periods of time. Various factors can contribute to the severity of the cryogenic burn or frostbite. The ratio of propellant to solvents, the heat of vaporization of liquid, size of the droplets, and etc. are all possible influences to the burn severity (Moser, 1999).

1.2.4 Particle Inhalation and Irritation

The aerosol silicone oil can be easily inhaled because it suspends its particles in the air. Prolonged exposure and use of aerosolized silicone oils have been linked to respiratory problems (Conrad, 1994). Excessive inhalation can lead to irritation of the respiratory tract, nausea, dizziness, or headache. The use of such aerosols in operating rooms is currently under scrutiny by OSHA. They want to impose stricter standards on the necessity of wearing the proper respiratory masks to protect surgeons from inhaling aerosol silicone oil particles in along with other inhalants in the operating rooms (LPS, 2011).

Propane and butane within aerosolized silicone sprays have also been documented as a source of mucous membrane irritation when the spray was as a lubricant for an endoscopy procedure. Although the silicone oil was not the cause of the reaction, since the aerosolized silicone oil contains butane as its propellant, this issue is something that must be kept in mind when performing endoscopic procedures with aerosol silicone oil lubricants (Rusch Silkospray, 2011).

1.2.5 Slippery Surfaces and Floor Hazards

Aerosol and liquid silicone lubricants have the ability to create a slippery surface, the most problematic of which is the floor in workplaces. When the floor is covered by the silicone

oil, either from the aerosol or a liquid, it creates a slipping hazard for any workers in the vicinity (Valencia, 2006).

2.0 Motivation

The main concerns with the current aerosolized silicone oil spray that can create a slippery environment, has the potential to cause frostbite, and particles can be inhaled when applying the spray. To coat the inside of medical devices, doctors spray the silicone oil into the packaging of the device. To coat the outside of the medical devices, the doctors hold the medical device over a trashcan while spraying in an attempt to contain the spray. Even with these techniques, a slippery environment occurs and particles are inhaled. For these reasons, other hospitals have banned the use of aerosolized silicone oil from the operating room. Lubrication is essential to a successful operation; therefore, it is necessity to resolve the problems caused by the aerosol spray.

3.0 Design Specifications

3.1 Client Requirements

The alternate method of applying the silicone oil must adhere to the requirements set forth by the clients. Most importantly, the device must use the existing Rusch Silkospray aerosolized silicone oil. The device must prevent the spray particles from being released into the air where they can be inhaled. The device must not allow the spray particles to settle on workplace surfaces, such as the floor, because this creates hazardous working environments where employees may slip and injure themselves. A way to protect the user from the cold effects of the propellants used in the aerosol spray is also needed. The device should be able coat the inside and outside of medical tubes and devices within 30 seconds. The devices must be able to coat the both the inside and outside of the listed medical equipment with internal diameters ranging from 2.5 mm to 9 mm and external diameters up to 13. 7 mm. The longest length of medical equipment that would need to be coated is 35 cm long. The device should be portable and less than 10 cm x10 cm x 10 cm. To avoid complicated cleaning processes, the device needs to be disposable and mass producible so that it can be replaced for each patient.

3.2 Ethics

As with any engineering design, the topic of ethics must be considered while designing the device. The device that will be created must not pose any ethical issues. In order to ensure this, the device must be made from materials that are safe for humans. In addition, the device must not hinder the ability of the surgeons to perform their job. The device must pose no risk of cross contamination between patients or cause adverse health effects in the patients it is used with.

3.3 Ergonomics

In order to create the most practical and effective prototype, the device must be ergonomical. As the prototype will be used in limited space of the operating room, it must take up a maximum space of 10cm x 10cm x 10cm. Furthermore, the prototype must be user friendly and easy to intuitively use. Because the silicone oil sometimes needs to be applied in a limited time frame, the device should be able to be assembled in less than 10 seconds and the lubricant should be able to be applied in 30 seconds or less.

4.0 Existing Devices

There are several common types of existing devices that are used to apply silicone oil lubricants. There is a bottle brush applicator, a syringe applicator, and an automatic silicone oil applicator machine.

4.1 Brush Applicator

The advantage of a brush applicator (Figure 2) is that they are readily available and are cheap-around $4.00 per brush (Tool Shack, 2011). This product is able to coat the outside of medical devices; however, it is very difficult to coat the inside of small tubes. These will not work for the application of the lubricant to both the inside and the outside of medical devices.

Figure 2: Brush applicator for silicone oil lubricant (Tool Shack, 2011).

4.2 Syringe Lubricant Applicator

Another existing applicator is the syringe tool shown in Figure 3 that uses liquid silicone oil (High Island Health, 2011). The syringe works well for lubricating the inside of devices; however, it cannot lubricate the outside of medical devices. The

Figure 3: Syringe Lubricant Applicator (High Island Health, 2011).

small amount of lubricant that the syringe can dispense at once is not enough to coat the inside or the outside of the medical devices in a timely manner that is required for an operating room. Also, the syringe does not use the aerosol form of the lubricant that is currently available at the UW-Hospital.

4.3 Automatic Silicone Oil Spray Chamber

McClellan Automation makes an automatic silicone oil spray chamber (Figure 4). This chamber is especially designed for coating medical devices (McClellan Automation Systems, 2006). Although, the chamber eliminates the need for a person to apply the silicone oil directly, thus eliminating the hazards mentioned previously, the chamber is costly and to be used in an emergency situation.

Figure 4: Automatic silicone oil spray chamber (McClellan Automation Systems, 2011).

5.0 Design Proposal Overview

5.1 Design 1: Disposable Pads

The basis of the first design is to transform the aerosolized spray into disposable pads soaked in silicone oil. To accomplish this, a cyclindrical canister with a height of 8 cm and a diameter of 7 cm containing disposable cotton pads will be attached to the nozzle the Rusch Silkospray bottle via a tube (Figure 5). When the nozzle is depressed, the tube will direct the spray into the canister, thereby soaking the cotton pads in silicone oil. The canister will contain a removable lid similar in design to a coffee canister lid, which will ensure that the oil does not leak into the surrounding environment while the pads are being sprayed. The canister will contain a gasket on its side that will close once the canister is removed from the can. This ensures that cotton pads will remained soaked with the oil and not dry out. The canister can then be taken into the operating room instead of the aerosol can.

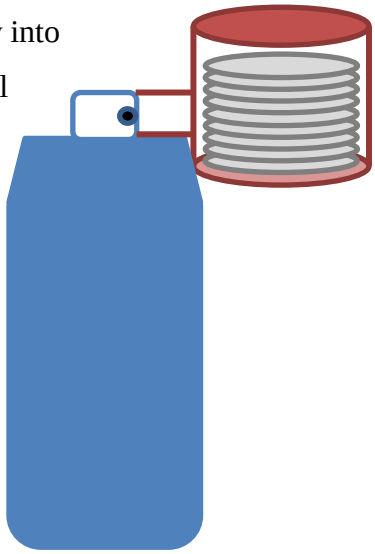

Figure 5: Disposable pad design

To coat the outside of the various medical devices, the user can remove the lid can simply rub the cotton pad over the outside of the tube. To coat the inside of the medical tubes, the fibers of the cotton pad will be looped into a hook attached to a

Figure 6: Rod to coat the inside of tubes

metal rod (Figure 6). The rod will be 42 cm long, which will ensure that it will fit through the longest tube used by the client. It will be made of metal material that will allow it fit through the curves of the tube without getting stuck or caught. This risk getting caught will further be decreased by having a loop at the opposite end of the hook. The user will string the wire through the tube and pull the wire through, which will cause the silicone oil soaked pad to be pulled through as well, thereby coating the inside of the tube.

There are several advantages to this design. The canister will contain the spray, so the spray will not be able to leak into the operating room, thus decreasing the slippery environment that the current method creates. Also, because user is not spraying directly into his/her hand, the hazards due to the cold environment created by the propellants will no longer be an issue. This design is relatively small, so it will only occupy minimal space in the operating room, and remove the need to bring the can into the operating room entirely.

Although the design does resolve the three main problems with the current method, there are several flaws associated with it. Because the user uses his/her hands to run the cotton pad on the outside of the tube, this may cause his/her hands to be coated with silicone oil as well. The smallest diameter of the tubes is 2.5 mm, so the cotton pad may be too big to pull through the inside of all the tubes to coat them with the oil. Because the canister is closed when spraying the pad, a buildup of pressure in the can due to the propellants in the aerosol may occur Also, this design has few outside applications; therefore, it is not very marketable, which will hinder its chance of mass production. Yet another issue is the risk of cross contamination. When removing a pad from the top of the canister, the user may contaminate the other pads; therefore, each canister could only be used for one patient.

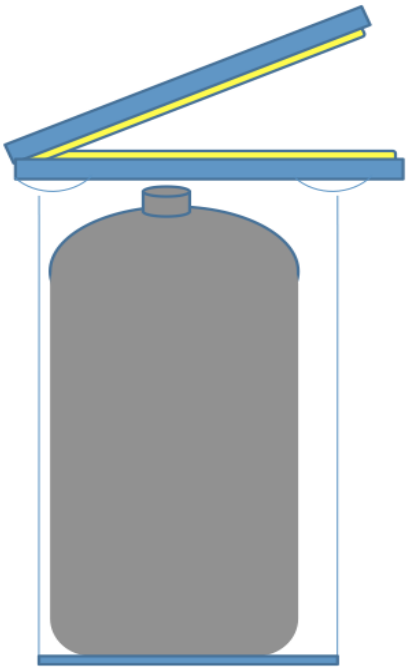

Figure 7: The clamp design mounted to the top of the aerosol spray

5.2 Design 2:Clamp

The second design option is the clamp design, which is shown in Figure 7. It attaches directly to the top of the silicone spray can and is held in place by a strap that wraps around the bottom of the can. For this design, the nozzle would have to be re-engineered so that it sprays the lubricant vertically instead of horizontally. The nozzle of the aerosol can will rest in a series of notched holes (shown in Figure 8), which enable the lubricant to be released by pressing down on the

clamp. In accordance with the design specifications, there are two main facets to this design: the mechanism to coat the outside of tubes with lubricant, and the mechanism to coat the inside of tubes

The clamp design works well in its ability to coat the outside of tubes with silicone oil. In order to do this, the user would close the clamp and apply a downward force on it. This force would depress the nozzle and cause the silicone oil to spray into the inside of the clamp. The inside of the clamp features two sponges, one on each surface. Spraying the lubricant will cause the sponges to become saturated with silicone oil. A medical device, such as an endoscope, that requires lubrication on its outer surface could then be inserted into the clamp and ran through it. The sponges would adequately cover the device's outer surface with silicone oil.

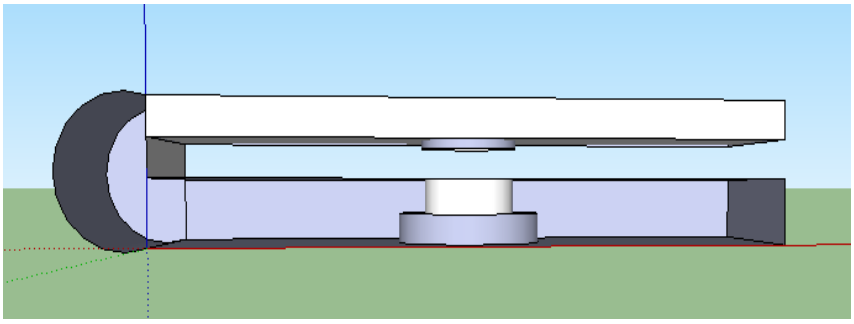

Figure 8: The notched holes that the nozzle of the aerosol can rests in are shown

In order to cover the inside of tubes, a different mechanism would be used. The user would first remove a stopper from the top of the clamp, which would expose a hole that ran through the entire clamp to the nozzle of the aerosol can (shown in figure 9). The user would place the tube such that it completely covered the mouth of the whole. The user would then close the clamp and press down on it allowing the spray be dispensed vertically. The spray would run through the entire clamp, emit from the top, and flow into the tube. Via this mechanism, the user could successfully coat the inside of tubes with silicone oil.

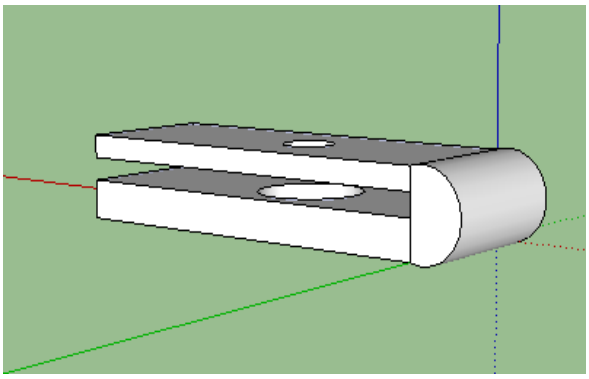

Figure 9: The vertical hole through the clamp design

As with any device, the clamp design has several pros and cons associated with it. The clamp design has the potential to work very well in its ability to coat the outside tubing of medical devices with lubricant. It would reduce the probability of overspray significantly, thus reducing workplace hazards. The clamp design would also work with the current lubricant spray

bottle, which is desirable. On the negative side, the biggest downfall of the clamp design is its complexity. As an example to this, the clamp design would require that the nozzle to the current spray can be re-engineered to spray vertically. The clamp design may also be lacking in its ability to coat the inside tubing of medical devices with lubricant. In addition to these faults, the sponges of the clamp design would need to be replaced after each patient in order to minimize risks of infection. This could be considered wasteful and tedious.

5.3 Design 3: Enclosed Box

The enclosed box design (Figure 10) features a snap on and off connection and three circular ports of entry to allow for the lubrication of the inside and outside of medical devices. The whole box will be disposable to avoid complicated cleaning procedures between patients.

The device will snap onto the top of the Rusch Silkospray bottle, which will allow the enclosed box to easily be attached and removed. The box will be 3.85cm high so that the top of the box is flush with the top of the spray nozzle, which will give the user easy access to the nozzle. The top surface of the box will have an opening of 1.8 cm in diameter (top opening in Figure 10) to allow the nozzle to be depressed to release the spray, which will be directed horizontally into the enclosure.

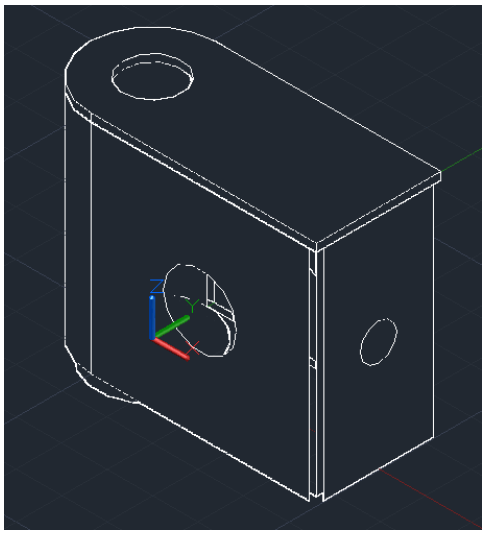

Figure 10: Enclosed box design

The three ports of entry will be placed as follows: one directly across from the spray nozzle, and two located horizontally such that the space between them is directly in the path of spray. In Figure 4, the opening directly in front of the spray nozzle is located in the far right of the drawing and one of the horizontal openings is located right behind the X-Y-Z axis marker. The second horizontal opening is located directly across the box from the other horizontal opening. Each hole will contain a gasket closure, shown in Figure 11 that will ensure a tight seal around the various medical devices while they are being sprayed. The front opening will be 0.9 cm in diameter, and the two horizontal

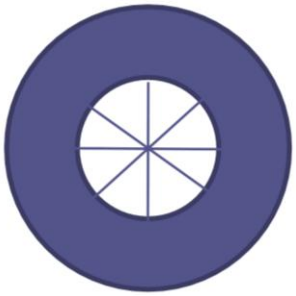

Figure 11: Gasket design for holes in box design

openings will be 1.5 cm in diameter. The total length of the box will be 11.1 cm with the width being 7.6 cm.

To spray the inside of tubes, the tube opening will be held up to the hole across from the nozzle. When the nozzle is depressed, the spray will leave horizontally from the nozzle and be directed into the inside of the tube. The tube is kept within the packaging so that the spray does not exit the other side of the tube and escape into the outside environment. To coat the outside of the medical devices, the device will be inserted horizontally into the two horizontal openings. The nozzle is depressed while the device is pulled through the box, thereby coating the entire outer surface with silicone oil.

This design has several advantages and disadvantages. This design is ideal in that it will minimize the overspray from the aerosol spray. This will reduce both the particles that are released into the air, that may be inhaled, and the hazards associated with the spray falling on the floor and becoming slippery. The enclosed box design can also coat both the inside and the outside of medical devices to suit our client's needs. Since the enclosed box is disposable, there are no contamination issues to worry about. A disadvantage of this design is the possible instability of the can caused by the use of the enclosed box atop the canister of silicone oil spray.

6.0 Design Evaluation

In order to choose the final design, a design matrix was created to examine six different aspects of each design. Each aspect was weighted differently based on client requirements with a maximum score of 100 points. The first category was compatibility with the current spray container. This examined whether the current spray would need to be remanufactured for the design. All of the designs work with the current spray; however points were deducted from the clamp design because it would require a new cap that sprays vertically instead of horizontally. The maximum score in this category was 20 points.

Criteria	Weight	Disposable Pads	Clamp	Enclosed Box
Compatibility with Container	20	19	14	**20**
Contain Spray	20	20	16	**18**
Ease of Use	10	7	7	**9**
Portability	10	7	9	**9**
Coat Inside	20	15	10	**19**
Coat Outside	20	20	20	**20**
Total	20	88	76	**95**

Table 1. The design matrix evaluating the disposable pads, clamp, and enclosed box designs. The enclosed box design received the highest score; therefore, it was chosen as the final designs.

The ability of the device to contain the spray was also examined and also had a maximum score of 20 points. Two of the three hazards the current method creates are caused by the aerosol particles not being properly contained; therefore, it was crucial that the design eliminates this problem. Although they will be covered by gaskets, the holes in the enclosed box design may leak some of the particles. The clamp design is not completely closed, so leaking may be an issue with this design as well. On the other hand, the disposable pad design contains a completely enclosed canister causing it to receive the highest score in this category.

The final design should be easy to use, so this aspect of each design was included in the matrix. Although the enclosed box design may have some balance issues, it is the simplest design, so it was given the highest score. The clamp requires the pads to be changed for each client and the hook of the disposable pad design may be hard to work with so these designs were marked down in this category. The maximum score in this category was 10 points.

Because the working space in the operating room is limited, the final design must be small and be able to be stocked in the operating room. The disposable pads' canister will occupy the most space in the operating room, so it was marked down in this category. The clamp and enclosed box designs occupy less space and can be stocked in the drawers in the operating room, so they were given a higher score.

The current spray's function is to coat the inside and outside of various medical devices; therefore the design must also be able to do this for a variety of lengths and dimensions. The disposable pad design uses the hook to coat the inside of the tubes. The complications associated with this mechanism caused points being deducted in this category for this design. Although a mechanism for the clamp design to coat the inside of the medical tubes was created, it is unclear whether or not it will be effective; therefore, half of the possible points were deducted from the clamp design. The enclosed box has the best method for coating the inside of the tubes, so it received the highest points. The maximum points available for coating the inside was 20 points. All three of the designs are able to coat the outside; therefore, all three were given the maximum score of 20 points.

The scores from each category were summed together, and the enclosed box design achieved the highest score of 94/100. The disposable pads design and clamp design achieve 89/100 and 76/100 respectively; therefore, the enclosed box design was chosen as the final design.

7.0 Final Design

The enclosed box design fulfills all of the client's needs in the most efficient manner of all three designs, so it was chosen as the final design. The design will be disposable, coat the inside and outside of medical devices, and eliminate the danger of inhaling silicone oil particles along with the hazard of a slippery work environment. The enclosed box design will be manufactured from a plastic that is to be determined at a later date, and will also be mass producible.

8.0 Future Work

In the next several weeks, details on the final design will further be refined to create an optimal design. After finalizing the dimensions of the box, a 3D printer using a CAD drawing will be used to make an initial prototype. This prototype will be used to test the device and finalize the design. The final material for the box will also be selected, and a final prototype will be developed out of this material by the end of the semester based on the testing done on the initial prototype. Also, work will be done with a FDA representative to ensure that the design will not need FDA approval to be used in the operating room. The Wisconsin Alumni Research

Foundation (WARF) will be contacted to undergo patenting/licensing of the final design. By the end of the academic year, a paper describing the end product will be submitted for publishing to scientific journals, and companies will be contacted to gain interest in manufacturing the final design.

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Appendix A:
Product Design Specification Report
Silicone Oil Applicator for Medical Devices

Date: 14 October 2011

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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 10 cm x 10 cm x 10 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.