A ONE-HANDED KNEE ASPIRATOR MEDICAL DEVICE TO AID IN ARTHROCENTESIS

THE SOCIAL CONTEXT OF MEDICAL DEVICES

A Thesis Prospectus
In STS 4500
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University of Virginia
In Partial Fulfillment of the Requirements for the Degree
Bachelor of Science in Biomedical Engineering

By
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Technical Project Team Members
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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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A knee effusion, more colloquially known as "water on the knee," is the buildup of synovial fluid in the knee joint (Mayo Clinic, 2018). Arthrocentesis is a procedure performed to aspirate the fluid buildup from the knee and to alleviate patient discomfort. This procedure requires one hand to hold a syringe, another to pull the fluid out into the syringe, and an additional set of hands to secure the knee in place. Ideally this procedure could be performed by a single doctor using only one hand to extract the fluid with the other hand used to apply pressure to the knee. To accomplish this goal, the technical research of this prospectus will outline a potential model for a more ergonomic single-use knee aspirator device. A timeline of the project aims is rendered in Figure 1 on page 2. The device will be created by undergraduate University of Virginia (U.Va.) Biomedical Engineering (BME) students Julia Donlon, Patrick Murphy, and Sarah Zagorin. The technical project advisor is orthopedic surgeon Dr. Mark Miller from the U.Va. hospital, with additional advising from U.Va. School of Medicine resident Dr. Ian Backlund. The technical prospectus advisor is Professor Timothy Allen of the U.Va. Department of BME.

The Science, Technology and Society (STS) portion of this research will outline the tightly-coupled topic of medical waste produced from single-use devices. Due to ease-of-use and sanitation concerns, single-use medical devices are frequently used in medical practices. Because arthrocentesis can be performed as a quick outpatient procedure, physicians desire a single-use aspirator for the procedure. While the demand for single-use devices is vast, so is the amount of waste produced from them. This portion of the research will analyze the different influencers contributing to massive waste produced by the medical community, framed using Pinch and Bijker's theory of the Social Construction of Technology (SCOT) (Pinch & Bijker, 1984). The

STS portion of this prospectus will be advised by Professor Catherine Baritaud of the U.Va Department of STS.

The topics detailed in this prospectus are part of the two semester-long capstone and STS 4500 and 4600 courses at the U.Va. School of Engineering and Applied Science (SEAS). The technical capstone project will begin with research of prior art and initial brainstorming and prototyping to be done by the end of the first semester. A project proposal will be due November 13, 2019 and a semester update will be due by December 13, 2019. Throughout the second semester, product testing and manufacturing of the knee aspirator will be completed. The STS research will begin with the collection of background statistics on medical waste and initial outlines of SCOT frameworks. The next semester will focus on the ethical implications relevant to medical device creation and associated waste produced. Both projects will culminate in a bound thesis to be completed in May, 2020.

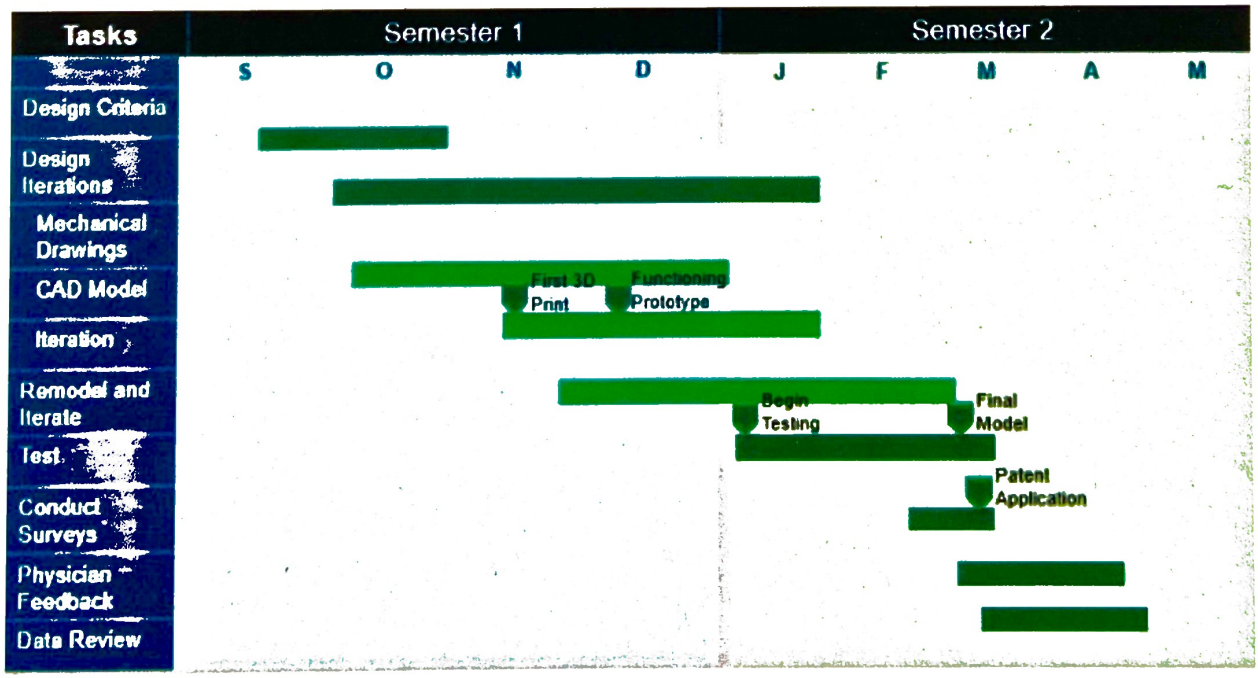

Figure 1. A Gantt chart outlining the major goals and milestones of the technical topic. Created by Patrick Murphy (October, 2019).

A ONE-HANDED KNEE ASPIRATOR MEDICAL DEVICE TO AID IN ARTHROCENTESIS

Osteoarthritis (OA) is the degradation of cartilage within a joint and currently affects more than 30 million adults in the U.S. (Centers for Disease Control and Prevention, 2019). As OA wears away cartilage, discomfort generally arises for the patient due to the increased contact between bones at joint sites, such as the joint within the knee. The contact creates a "scraping sensation" that can be incredibly uncomfortable for a patient suffering with OA (Arthritis Foundation, n.d.). In addition to feelings of scraping, a reported 90% of patients experiencing pain associated with knee OA also have knee effusions (Maricar et al., 2016). A knee effusion is an abnormal buildup of synovial fluid in in the joint of the knee. Synovial fluid is the natural lubricant that reduces friction between joints. In addition to OA-associated knee effusions, fluid buildup, also known as "water on the knee," can also result from trauma or other chronic diseases (Mayo Clinic, 2018). Limited mobility often accompanies the pain and inflammation associated with knee effusions (Gupte & St Mart, 2013).

ARTHROCENTESIS TODAY

To alleviate the swelling and pain associated with knee effusions, fluid can be aspirated from the knee. The knee aspiration procedure is medically referred to as arthrocentesis, an example of which is displayed in Figure 2 on page 4. Arthrocentesis is to be performed to relieve patient pain, as well as to understand potential effusion causes such as infection. The procedure should be executed by first applying a numbing solution to the knee, such as lidocaine 1%, then sterilizing the incision area, inserting a 60 cc syringe with an 18 g needle, and extracting the fluid from the knee into the syringe (Akbarnia & Zahn, 2019). Following extraction, fluid samples are collected and used for diagnostic testing.

Knee aspiration currently requires both of the doctor's hands to be dedicated to either pulling back the syringe plunger or holding the syringe in place. There are several concerns with this manually-limiting procedure. First, the force required to pull back the plunger on a syringe logarithmically increases as the size of the syringe increases, with the force linearly increasing for each syringe size as the plunger is pulled farther back (Haseler et al., 2011). Arthrocentesis is primarily accomplished using a 60 cc syringe, which is one of the larger syringes used in outpatient medical procedures. A larger syringe means that there is more force required to pull the plunger back compared to smaller syringe sizes, as well as worsened control over the needle movement (Haseler et al., 2011).

The precise location of synovial fluid within a knee effusion is not obvious, nor is it necessarily localized to a specific section of the knee. Resultantly, doctors must constantly move around the fluid in the knee, or "milk" the fluid, in order to accurately insert the needle into the fluid sac (Backlund, 2019). The milking is to be done in conjunction with the needle insertion and fluid extraction. The lack of distinct fluid location, coupled with poor needle control, inevitably results in inaccurate determination of the effusion. Given the current protocol, accomplishing all tasks for arthrocentesis requires three hands and is thus not conducive to an individual physician conducting the procedure. These issues mean that doctors are not executing arthrocentesis most

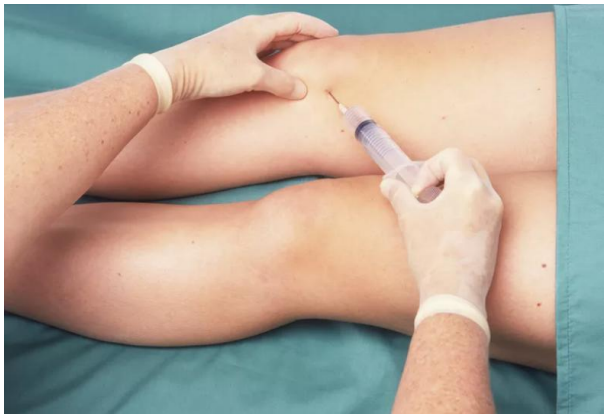

Figure 2. An example of the general method for performing knee arthrocentesis. From Eustice (2019).

efficiently nor comfortably, and patients experience extended discomfort from increased time spent in a procedure.

IMPROVING ARTHROCENTESIS

Arthrocentesis should be performed by a single-set of hands: one for extracting fluid and the other for locating fluid within the knee. In order to establish a protocol for accomplishing these goals, a medical device will be created to aid in a single-handed fluid extraction from a knee effusion. The device will be a fluid-extracting knee aspirator.

Previous capstone students, S. Kesting, D. Lindsey, and W. Hamlin, attempted to produce a working model of a knee aspirator. Their aspirator is a gun-shaped device containing a ratcheting mechanism inside, connected to a trigger pull (Lindsey, 2018). The trigger pull is manipulated by the doctor and is used to interact with a replaceable syringe attached on top of the aspirator. With each click of the trigger, the ratcheting mechanism is moved incrementally along a set of ridges, corresponding to incremental movement of the syringe plunger. This device failed to meet the design criteria outlined by Dr. Miller. Ergonomic considerations were not made for comfort nor manual stability while holding the device. The handle is too wide and bulky, with no finger groves to provide for a comfortable grip. The ratcheting mechanism is too rigid to smoothly extract fluid in a single motion. As a result, the physician must constantly press the trigger pull which can produce extraneous movement of the device during the procedure. Extra movement can lead to even further patient discomfort as the needle moves inside the patient's knee. Additionally, the device is too thick to easily perform arthrocentesis at a desired angle in relation to the distance from the doctor to the patient on the exam table.

A NEW DEVICE

To improve upon the previous knee aspirator, a new device will be designed to incorporate the basic ratcheting mechanism, while also considering mechanisms of everyday mechanical devices. There are many examples of medical devices that use syringes, however they primarily function to insert fluid rather than extract it, as depicted in Figure 3 below (Innomed, n.d.). Also, many common construction tools, such as a clamp spreader or calking gun, use similar trigger pull-ratcheting designs to incrementally push or pull something (Autodesk, 2014).

Following the mechanics of the previously listed devices, the components of the knee aspirator will be modeled using computer-aided design (CAD) softwares. The model will be 3D-printed using high-density plastic. Besides the mechanics of the device, design considerations will include a more ergonomically-shaped handle, mimicking that of a handgun. The aspirator must have space for a 60 cc syringe to be easily attached and removed. Functionality of the prototyped device will be tested using a similar shear-thinning solution to

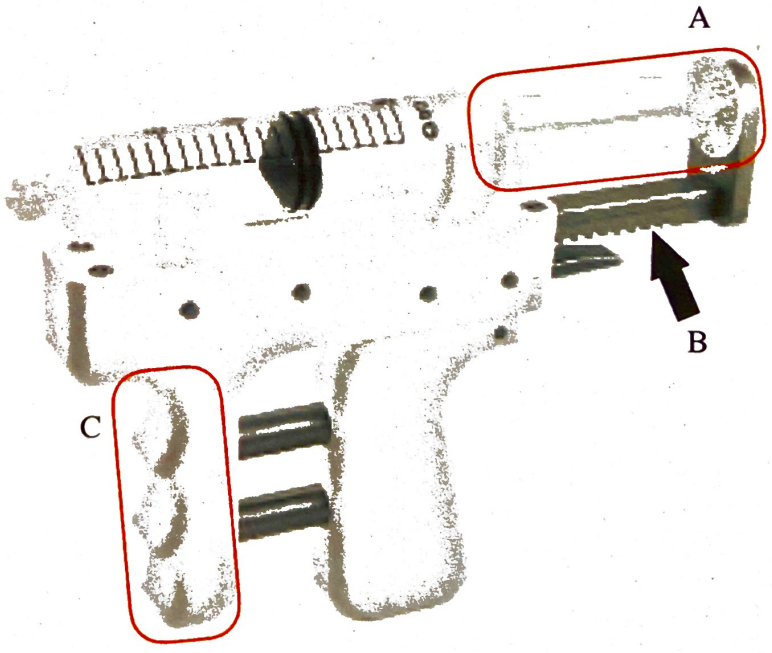

Figure 3. A current medical device that inserts fluid from a syringe. The device parts: (A) The plunger of the syringe, (B) ratcheting line, (C) ergonomic, finger-shaped handle. Adapted by Julia Donlon from Innomed (October, 2019).

synovial fluid, such as a water and corn starch mixture. Considerable ergonomic design input will be given by Dr. Miller and Dr. Backlund.

To present the findings of the technical portion of this prospectus, a journal article will be written to outline a framework for creating a fluid aspirator device to be used during knee arthrocentesis. If a workable aspirator model is produced within the two semester-long project, a provisional patent will also be written for the model. Additionally, if the device does improve arthrocentesis, potential alterations will be made to mass-produce the aspirator. Such alterations may include a different material type other than 3D-printed plastics with specific considerations made in reference to cost. Finally, considerations are to be made for making the device single-use.

THE SOCIAL CONTEXT OF MEDICAL DEVICES

Biomedical research involves the practice of maintaining sterility during experimentation or procedures. Extensive measures are necessary to eliminate the introduction of outside pathogens or microbials. Throughout such practices a significant amount of waste is created as many tools have only a few or even one use before they are considered contaminated and have to be disposed; examples of which are shown in Figure 4. There is an obvious need for single-use tools, but to what extent?

SINGLE-USE, MULTIPLE HARMS

Staggering statistics predict that prescribed at-home needle injections account for "over 13 million needles and syringes" in landfills every day (Gold, 2011). Additionally, the World Health Organization estimates that overall, approximately "16 billion injections are administered worldwide" by physicians annually (World Health Organization, 2018). Needles and syringes contribute a large amount in landfills, exacerbating problems of waste produced from plastics. An estimated twenty-five percent of waste generated from healthcare facilities is made of plastic (Gibbens, 2019). These statistics largely challenge the validity of producing a single-use knee aspirator; comprised of plastic, needles, and syringes, because of the massive waste associated with such materials.

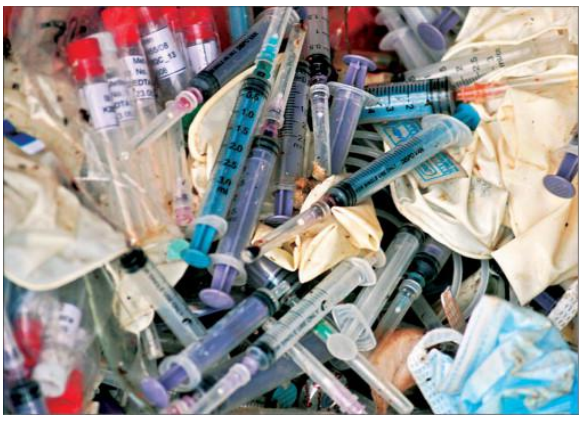

Figure 4. Common medical waste, such as needles and syringes. From Solberg (2009).

WHOSE FAULT IS IT?

Reasonable concern exists regarding the re-use of medical devices due to the risk of potential infection and spread of disease. However, there have been sufficient efforts to prove that non-plastic multi-use medical devices can safely replace plastic single-use devices (SUDs). So the question must be asked: why have more replacements not been made? To understand why SUDs still exist, an analysis must be done to identify the decision-makers and influencers in medical device creation. For the context of this prospectus, the major social groups of medical device creation will be broken down into the creators and users of the device, as well as the regulations and boundaries in between these social groups, as rendered in Figure 5.

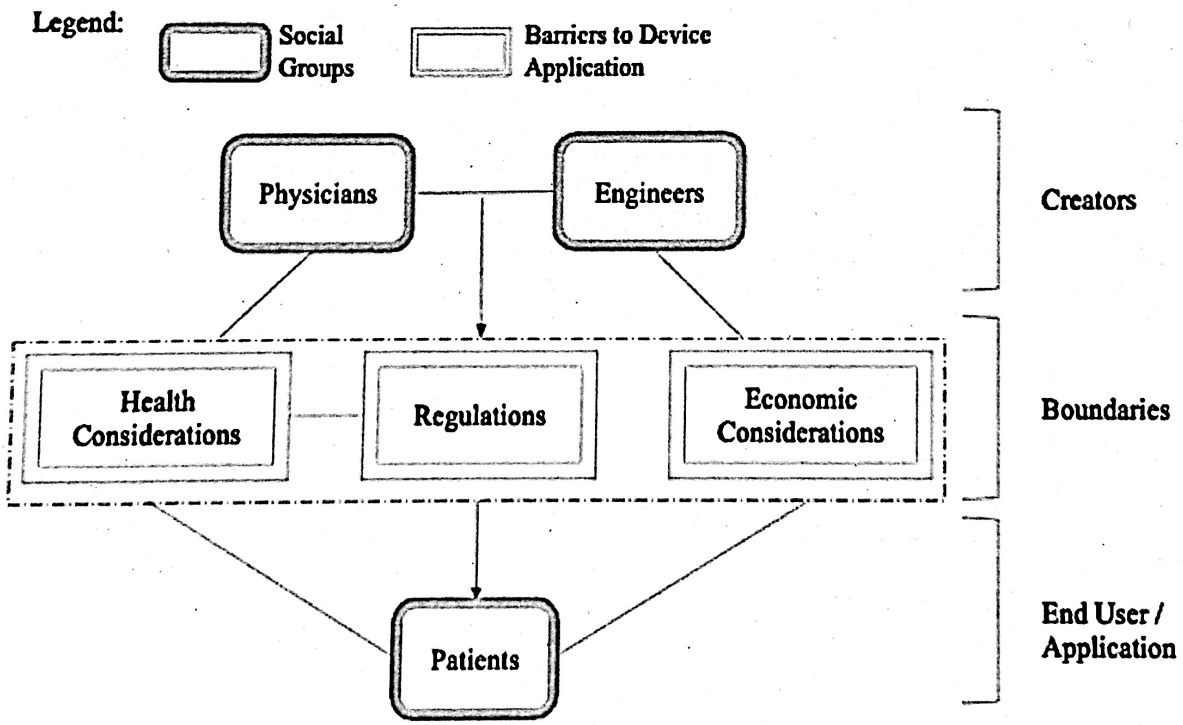

Figure 5. A flow chart depicting the overall diffusion of medical devices from the creators of the devices to the end goal of patient application. The diffusion process also includes the barriers to technological application, expressed by the social context of the device creation. Created by Julia Donlon (November 2019).

Excluding the Environment

Looking away from the environmental impacts of producing single-use devices, other societal influences must be considered. For the physicians and doctors creating the devices, the most important concern is to have a product that is easy to use, marketable, and reduces contamination risks. In a diffusion-only model, expressed in Figure 5 on page 9, patients do not influence design because they are applications of the healthcare system, and not direct users. In other words, patients are on the receiving end of these products, whereas doctors are on the applying end. Although the technology is still diffusing to the patient, he or she does not determine the functionality of the device. The differing experiences with technology for patients and physicians is mirrored in the modeling of a knee aspirator device. While the patient is the one hoping to have pain relieved, the device is designed to the specifications of the doctor's comfort. Once again, the device is designer and doctor-centric. This diffusion model does not accurately depict the influence of all social groups involved in how and why medical devices are produced.

A more inclusive rendering of technological diffusion requires a broader social context. Pinch and Bijker's theory of the Social Construction of Technology (SCOT) will be used to analyze the cause of massive diffusion of single-use medical devices (Pinch & Bijker, 1984). The SCOT theory identifies the development of an innovation in terms of economic, regulatory, and cultural influences, with particular emphasis on the human involvement in technological creation (Johnson, n.d., p. 1793-94). To understand why a technology or "artefact" interacts with its environment using SCOT, "we have to specify first the relevant social groups and second, the problem(s), each group experiences with respect to that artefact" (Bijker et al., 1984, p. 43). The relevant social groups in medical device design can be identified as the engineers, patients,

physicians and regulators, as shown in Figure 6. While each social group has varied concerns and problems regarding the technology at hand, there are still overlaps amongst these groups. The importance of a SCOT framework is to identify the many individuals and ideas that shape a technology. There is no single path of diffusion in the development of a technology, and thus no single issue to address during technological creation.

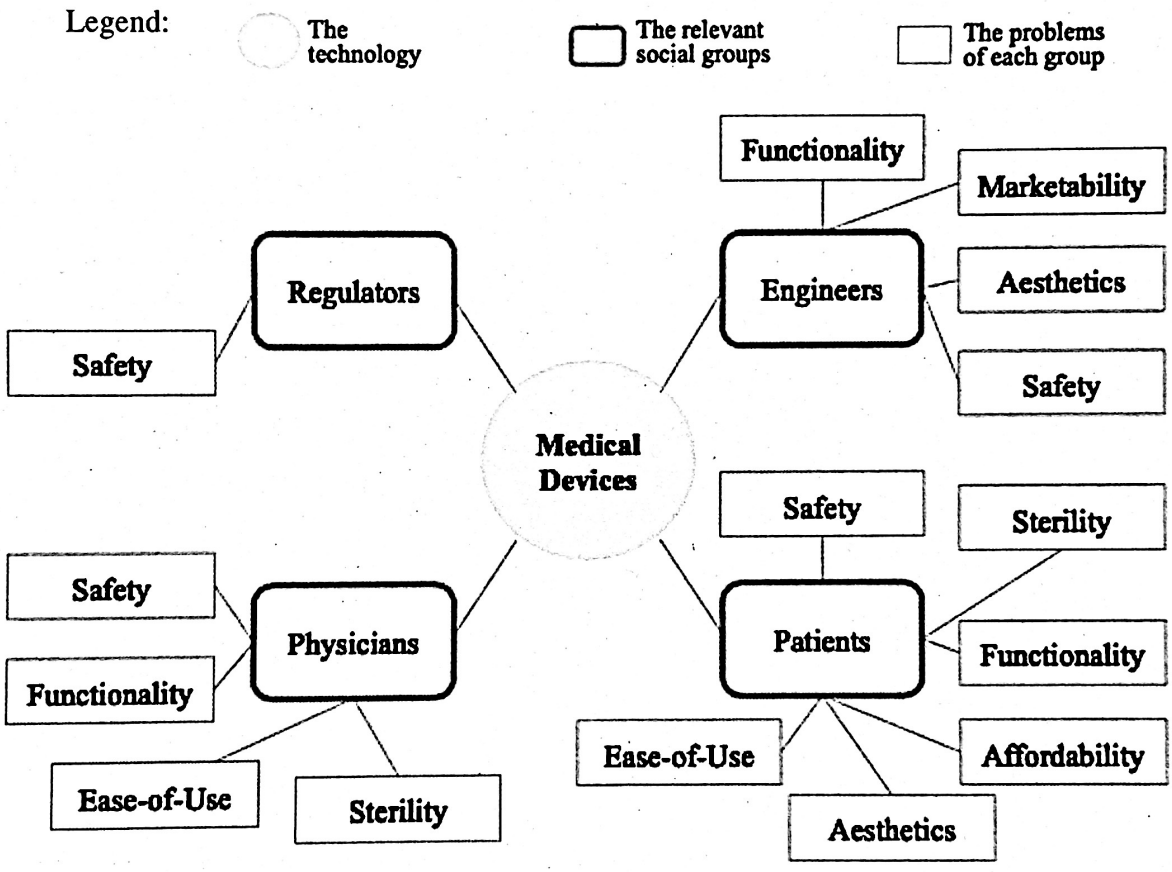

Figure 6. An application of a SCOT framework, depicting the technology at the center, with the relevant social groups and their concerns with the technology branching outwards. Created by Julia Donlon (November, 2019).

Despite studies proving single-use medical equipment costs are actually higher than sterilization efforts for reusable tools, user preference still dictates use of non-reusable medical devices (Demoulin, 1996). And even though the U.S. Food and Drug Administration (FDA) has

approved the reprocessing of properly sterilized single-use devices, SUDs are still produced and regularly used (U.S. Food and Drug Administration, 2018). These differing perceptions of SUDs among individual groups expresses the underlying importance of SCOT: the social context, construction, and relevance of a technology by all those who use it.

THE ALTERNATIVES

While biologically-contaminated waste must be disposed, there are other ways through which medical and research tools can be recycled. In most biological labs, pipettes are used constantly. Much like needles and syringes, the pipette tips become contaminated and thus must be disposed after each use. Recognizing the environmental harm created by the medical industry, the National Cancer Institute at Frederick (NCI-Frederick) has begun to gather and recycle plastic pipette tip boxes for polymer repurposing (Ragan, 2007). Pipette tips cannot be recycled, but the boxes can. An example of a pipette tip box is shown in Figure 7. Other clinical innovations designed to alleviate the copious amounts of plastic products are already being implemented in hospitals. The EnviroPouch, depicted in Figure 8 on page 13, provides a fabric substitute for plastic medical tool wrapping and has been proven safe and sterile for clinical applications (Gibbens, 2019). This type of initiative shows how improvements can be made to eliminate disposable medical products where possible, or use them for a secondary purpose.

Figure 7. An example of a common pipette tip box with pipette tips. From AliExpress (n.d.).

THE NEXT STEPS

Regardless of evidence proving cheaper means of production, encouragement from federal regulation, and increasing environmental devastation, single-use medical devices are used every day. Further research on the societal influences of medical device design should provide a greater understanding for the seemingly contradictory decisions made by device creators. Improved research can influence changes in the medical device community amongst both consumers and producers, such as device companies and physicians. This prospectus can also provide information for those outside of the medical community. The measures taken by the medical community should be done in a thoughtful, necessary manner for patients. By understanding the faults and failures of the healthcare system, all stakeholders can influence and improve the system and its impacts.

Figure 8. Several models of the EnviroPouch, showing storage of surgical tools for sterilization. From Practicon (n.d.).

An analysis of these stakeholders and their associations with medical devices will be presented in the form of a scholarly article for the Science, Technology and Society portion of this prospectus. The article will explore the influences and decisions made by social groups that lead to the creation of single-use plastic medical devices, and resulting medical waste. These influences are organized using a Social Construction of Technology framework, to express the many social groups and individual preferences of everyone involved in the production of medical devices.

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