# EFFECTIVENESS OF HOSPITAL CENTRAL STERILIZATION PROCESSING VS. CLINIC-BASED STERILIZATION PROTOCOLS: A NON-INFERIORITY TRIAL

by

Peter Stefanuto

Submitted in partial fulfillment of the requirements
for the degree of Master of Science

at

Dalhousie University
Halifax, Nova Scotia
September 2014

# DEDICATION

This work is entirely dedicated to my family and loving wife, Alison: whom without, the countless hours in the laboratory, library, and hospital would have been impossible. Thank you for all of your positivity, love and support.

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## ABSTRACT

**Purpose**: .The purpose of the study was to determine if clinic-based sterilization is non-inferior to hospital-based central sterilization.

**Methods:** This study was a blinded and standardized, direct comparison of commonly used sterilization methods. Clinic-based sterilization was compared with hospital-based central sterilization for usage with non-complex surgical instruments. Instruments (n=1264) were randomly assigned to 1 of 5 groups as either test groups (Groups A, B, C) or negative control groups (Groups D, E). Groups A, B and C were artificially inoculated using vital strain of *E. faecalis* and *S. aureus*, Groups D and E were non-inoculated negative controls. Test Groups B and C (n=593 and n=584) were sterilized using either a clinic based sterilization protocol or hospital-based central sterilization protocol, whereas Group A was used to determine the viability of methods used. All groups were then incubated at 37 degrees Celsius in a validated culture medium (Tryptic-soy broth) for 72 hours and checked for bacterial growth (turbidity) by a single blinded observer.

**Results:** Group B (clinic-based sterilization) the rate of successful sterilization was 99.8314% (592/593) and for Group C (hospital-based sterilization) the rate was 100% (584/584). Groups A, D, and E were used to determine the validity of the results. Statistical analyses of all variables failed to identify significant differences between test Groups B and C at a 95% confidence interval.

**Conclusion:** From this study we can conclude that for non-complex surgical instruments, centrally-based sterilization protocols and clinic based sterilization protocols are equivalent in sterilization. Thus, other factors should be considered when determining which sterilization method is appropriate for each specific department within a hospital setting.

## LIST OF ABBREVIATIONS USED

| | |
|---|---|
| SPD | Sterile Processing Department |
| CBS | Clinic Based Sterilization |
| SSIs | Surgical Site Infections |
| BBP | Blood Born Pathogens |
| CDC | Centers for Disease Control |
| Cfu | Colony forming Units |
| CDHA | Capital District Health Authority |
| IFU | Instructions for Use |
| ETO | Ethylene Oxide |
| SAL | Sterility Assurance Level |
| BSI | Blood Stream Infections |
| BI | Biological Indicators |
| MDRT | Medical Device Reprocessing Technician |
| CSA | Canadian Standard Association |
| FDA | Food and Drug Administration |
| MCID | Minimal Clinically Important Difference |

## ACKNOWLEDGEMENTS

I would like to thank Dr. Archie Morrison for the initial idea and inspiration, Dr. Song Lee for the guidance and expertise provided in development of the scientific methodology, Nabil Moussa for his countless hours in the laboratory, and Dr. Colleen O'Connell for her assistance with the statistics to make the project possible.

Many thanks to my thesis committee members: Drs. Jean-Charles Doucet, Curtis Gregoire, and external reviewer Dr. Walter Schlech for providing invaluable input for the manuscript.

# CHAPTER 1 INTRODUCTION

## 1.1 Preamble

Infection control in medicine has become a highly regulated and regimented part of modern day health care. Failure to adequately ensure the cleanliness of medical devices may lead to the introduction of pathogens and possible resultant patient infections: an unnecessary risk to public health. Health care-associated infections are an important source of morbidity and mortality with an estimated 1.7 million infections and 99,000 deaths annually in the United States.(1) While hand-washing remains the most efficacious way to prevent hospital acquired infection, contaminated instrumentation and the possibility of spread of infectious disease is highly scrutinized in the public eye. It is imperative that health care personnel are stewards of infection control while being mindful of budget constraints that the Canadian health care system must function within.

Outbreaks continue to occur due to improper adherence to current disinfection guidelines. This is primarily due to failure of health care facilities to have policies and procedures in keeping with current guidelines.(2) Patient safety is dependent on instruments that are appropriately cared for and adequately reprocessed (i.e. cleaned, disinfected and sterilized).(3)

Instruments that are considered “resusable” must receive clearance from the American Food and Drug Administration and Health Canada, which includes instructions for use and sterilization provided by the manufacturer, prior to use.(3) The clearance process is dependent on the complexity of the instrument in question (e.g. the number of components, different surfaces, or lumened vs. non-lumened instruments).

Within a given hospital environment, there are two main areas for sterilization of surgical instruments: a centrally based hospital-wide sterilization processing department (SPD), and a clinic based sterilization (CBS) area which utilizes smaller scale protocols to ensure instrument sterility.

Infections that may be transmitted via contaminated surgical instruments include surgical site wound infections (SSIs) and systemic infections/blood borne pathogens (BBP). Post operative infections may be a potentially devastating complication depending on the type of surgery performed. Ophthalmologic and orthopaedic procedures are highly susceptible to post-operative wound infections and also infer the highest morbidity and cost expenditures associated with SSIs.(4) While most SSIs can be attributed to the patient's own flora,(1) there are also elements of human and system error (e.g. poor handling practices) which may lead to SSIs.(4) Transmission of blood born pathogens, including Hepatitis B, C and HIV, is a potential risk for any patient undergoing surgery.(5) These potentially devastating nosocomial infections have been the source of public scrutiny of infection control practices in the recent past, and current guidelines and practices continue to evolve to best eliminate the chance of transmission.(5) Failure to properly disinfect or sterilize equipment has been shown to be, in large part, due to lack of compliance with established scientifically-based guidelines (i.e. human error).(6)

## 1.2 Sterilization and Disinfection in Health Care

### *1.2.1 Definitions*

Much of the terminology used in the infection control literature is attributed to Earle H. Spaulding who in 1968 published a paper defining and describing the terms currently used by the known authorities on infection control, including the CDC.(7) Definitions include:

*Sterilization*: a process that destroys or eliminates all forms of microbial life and is carried out in healthcare facilities by physical or chemical methods.(6)

*Disinfection*: a process that eliminates many or all pathogenic microorganisms (with the exception of bacterial spores) on inanimate objects.(6)

*Cleaning*: the removal of visible soil, both organic and inorganic material, from surfaces via manually or mechanically using water with detergent or enzymatic products(6)

*Decontamination*: removal of pathogenic microorganisms from objects so they are safe to handle, use or discard.(6)

### *1.2.2 Sterilization Practices*

Within any given health care institution, there are many individuals involved with the appropriate handling, sterilization, disinfection, cleaning and decontamination of instruments used in surgical procedures. These individuals must perform well orchestrated tasks and follow protocol set forth by the institution that are based largely on standards dictated by the Centres for disease Control (CDC), Food and Drug Administration (FDA) and Health Canada. These

governmental organizations are tasked with protecting the public and ensuring the transmission of disease is at the lowest possible level. The delivery of sterile products for use has many steps including: decontamination, disassembling, packaging, loading of the sterilizer, monitoring sterilant quality and quantity and selecting the appropriate cycle for the load contents.(6)

### *1.2.3 Instrument Processing Guidelines*

There are various professional organizations and legislative bodies that publish guidelines for the processing of instruments including the Association of Perioperative Registered Nurses (AORN) and Association of Advancement of Medical Instrumentation (AAMI); however, most guidelines are similar and are based on the CDC recommendations. The four main steps to successful decontamination are: pre-sterilization cleaning and decontamination, packaging, sterilization, and storage. Each individual step has criteria, which must be adhered to, to ensure quality and safety of sterilization processes.

Cleaning and decontamination are the first steps and begin in the operating room proper by keeping instruments free of gross soil during procedures.(8) The decontamination area must be separated from direct patient care areas by a physical barrier and should have negative air pressure with a minimum of 10 air exchanges per hour. Temperature should be regulated to remain between 16-18 degrees Celsius.(8)

Packaging is completed for terminal sterilization next and is largely based on manufacturers recommendations for packaging materials and sterilization modality used. Sterilization modalities will be discussed at length below.

Lastly, sterile items are to be stored under a specified list of environmental conditions including temperature less than 24 degrees Celsius, a minimum of four air exchanges per hour, humidity

not exceeding 70%, items should be at least 10 inches off of the floor, 18 inches below fire sprinklers, and 2 inches from outside wall, and within a controlled traffic area.(8)

*1.2.4 Efficacy of Hospital Based Sterilization Protocols*

Although it is recommended that most cleaning, disinfection, and sterilizing of patient-care supplies be carried out in a central processing department to maintain quality control, there is a paucity of literature with regards to how well instruments are being processed in centrally based Sterile Processing Departments (SPD). The risk of patient to patient transmission due to contaminated instruments is exceedingly low when sterilization protocols are properly followed although the risk is not zero. Failure to properly sterilize instruments can be attributed to human error (eg. incorrect temperature setting on a steam sterilizer, failure to clean properly prior to disinfection), equipment or product failure, or system failures (organizational, procedural, or environmental).(9) Recent data suggest that instrument reprocessing remains a concern for infection control experts. In a joint FDA/AAMI commission report 36% of accredited hospitals surveyed failed to comply with standards to reduce the risk of infection associated with medical devices, equipment and supplies.(10)

*1.2.5 Sterile Processing Department*

The Sterile processing Department at our institution (CDHA) consists of many personnel:

One manager and two supervisors

Twenty-two full time staff plus ten casuals (Victoria General site).

Fifty-seven full time staff and seven casuals (Halifax Infirmary site).

Dartmouth General Hospitalf and seven casuals (Halifax Infirmary

One manager and one supervisor.

Dartmouth General Hospital has 10.5 technicians and 3.5 utility workers.

Hants Community Hospital Hants Community Hospital has 10.5 technicians.(11)

At the CDHA the Sterile Processing Departments (SPD) are typically divided into four main areas: the decontamination area, assembly and packaging area, sterile storage area, and distribution area.(12) Decontamination involves sorting, soaking, washing, and inspection of instruments. Assembly and packing pertains to the assembly and packaging of instruments in the appropriate medium (textile wrap, pouch, rigid container) for sterile processing and storage. After assembly and packaging is complete the instruments are sterilized using steam, dry heat, ethylene oxide, microwaves, ionizing radiation, hydrogen peroxide plasma, ozone gas, and various other chemical solutions according to protocol dictated by individual manufacturers and the FDA. Once sterilized, the instruments must be kept in the sterile storage area for transport to the distribution area for use in the individual operating rooms as necessary.(12)

## 1.3 Sterilization Types

### *1.3.1 Steam Sterilization*

Steam sterilization functions by inactivating microorganisms via irreversible coagulation and denaturing of structural proteins and enzymes.(6, 13, 14) No living creature can survive a temperature of 120 degrees Celsius for longer than 15 minutes.(12) The four variables that affect steam sterilization are steam, pressure, temperature and time. There are various types of steam autoclaves in use including pre-vacuum and gravity displacement sterilizers. Pre-vacuum

sterilizers actively remove air from the sterilization chamber thus allowing full saturation of steam. The Statim 2000 used in this study is a pre-vacuum type autoclave unit. Steam sterilization, although effective, is known to have deleterious effects on certain instruments.(1) However, studies investigating the effects of steam on the sharpness of simple instrumentation, such as dental instruments (periodontal scalers and endodontic files), reported that there were no changes after sterilization.(28, 29) Furthermore, no changes in fatigue and mechanical properties were found in endodontic files after a series of sterilization cycles.(30) These studies show that for small, fine instruments there is minimal effect caused by the use of steam sterilization and it would be plausible to suggest that for larger, more durable instruments the effect would be considerably less.

### *1.3.2 Gravity displacement Sterilization*

Gravity displacement sterilizers function by injecting steam into the upper part of a sterilization chamber. Consequently due to differences in densities between the steam and the air, steam displaces the air contained in the chamber downwards. The displaced air is then evacuated via a temperature sensitive valve ensuring that only steam remains in the chamber. Gravity displacement sterilizers are used for nonporous articles where direct steam contact can be achieved. Porous items trap air, thus are not ideal for gravity displacement sterilization units.(6)

### *1.3.3 Flash Sterilization*

Flash sterilization involves the processing of an unwrapped object at a minimum of 132 degrees Celsius for 3 minutes. The time is dependent on the type of instrument sterilized (porous

vs. nonporous). Flash sterilization was developed to provide rapid sterilization at the point of use but is not recommended for routine sterilization processing due to the lack of timely biological indicators (although recently developed are indicators that are available to read in 1 hour).(15) There has been some question of the efficacy of flash sterilization of implantable devices in the literature due to an increase in neurosurgical infections in craniotomy plate implants as described by Hood et al.(16)

## 1.4 Low-Temperature Sterilization

### *1.4.1 Ethylene Oxide Gas Sterilization*

Ethylene oxide (ETO) has been used as an alternative to steam sterilization for heat labile or heat sensitive instruments and devices. The advent of low temperature sterilization methods has become of increasing importance due to the increasing use of polymers in medical devices.(17) Traditionally, ETO uses a stabilizing agent, chlorofluorocarbon, which, due to the Clean Air Act, had been phased out.(6) [1] Ethylene oxide is either used at 100% concentration or is now stabilized by the addition of carbon dioxide or hydrochlorofluorocarbon.(6, 18, 19) ETO acts as an alkylating agent on components essential for microbial life, such as nucleic acids, functional proteins and enzymes.(6, 18) Although advantageous in the sterilization of heat labile materials, ETO is known to have deleterious effects. As an occupational hazard it has carcinogenic properties, and is highly flammable in nature. ETO also requires a protracted sterilization cycle of up to 15 hours. (6, 7, 20)

*1.4.2 Hydrogen Peroxide Gas Plasma*

Hydrogen peroxide gas plasma relies on the production of cellular-machinery-destroying free radicals by the active agent. Gas plasmas are the fourth state of matter (along with liquid, gas, and solids) and are created by the production of charged particles with radio frequency or microwaves in a vacuum. When the hydrogen peroxide gas is exposed to radiofrequency waves in the deep vacuum an atom with an unpaired electron (free radical) destroys microbiological enzymes and nucleic acids essentially rendering them useless. (6, 7, 20) Typical sterilization cycles take 75 minutes and the process functions in the range of 37-44 degrees Celsius. The process is efficacious for a broad range of microorganisms including bacterial spores, vegetative bacteria, viruses, and fungi. Most medical devices (>95%) are able to be sterilized in this manner, with current limitations being lumened instruments with an inside diameter of greater than 1mm and length of less than 125 mm. (7) One advantage of this system is that the by-products of the process are non-toxic (water and oxygen).

*1.4.3 Peracetic Acid*

Peracetic (Paroxyacetic acid, $CH_3CO_3H$) acid is an organic peroxide that is biocidal. Its use is primarily in removal of surface contaminants from endoscopic tubing. Due to its highly corrosive nature, it is supplied with an anticorrosive agent. Its single-use containers are a concentrated form diluted to 0.2% with filtered water by the paracetic acid sterilization unit at the time of use. The benefit to peracetic acid is the short processing time, approximately 12 minutes at 50-56 degrees Celsius.(1, 6)

There is a paucity of information available regarding the details of the mode of action of peracetic acid. It is postulated that it denatures proteins, alters cell wall permeability and acts as an oxidation agent against gram positive and gram negative bacteria, fungi, and viruses. (7) Peracetic acid sterilization, like other methods, is limited by the necessity to contact the organisms in question and its efficacy is diminished by soil challenges and thick biofilm.(7)

### *1.4.4 Ozone*

Ozone sterilization of surgical instruments has recently been approved by the FDA (August 2003). Ozone (O3) results from the splitting of O2 and the collision of monatomic O with O2. The O3 molecule is highly unstable and is a potent oxidizer when it contacts other molecules. It functions by oxidizing microorganism proteins.(7, 21)

The sterilization units create their own O3 internally and produce non-toxic byproducts (oxygen and water) thus aeration is not required. However, due to its relatively short time in use there is little published data on penetrability of ozone and efficacy.(7) The sterilization process lasts 4.5 hours and occurs at 30-35 degrees Celsius.(7, 22)

## 1.5 Classification of Instruments

### *1.5.1 Spaulding Classification*

In addition to the aforementioned definitions, Spaulding is also attributed with categorizing instruments and items used for patient care. He classified them hierarchically as critical, semi-critical, and non-critical.

Critical instruments can be defined as items that confer a high risk of infection if they are contaminated with any microorganism. This includes any object entering sterile tissue or coming into contact with the vascular system. Surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities are included here. Items in this category should be purchased as sterile or have the ability to undergo steam sterilization. Heat labile instrumentation should be sterilized by liquid chemical sterilants, ETO, or hydrogen peroxide gas plasma.(7)

Semi-critical instruments may be in contact with mucous membranes, or non-intact skin. These instruments must be free from all microorganisms, but small numbers of bacterial spores may be permissible. Examples of semi-critical items are respiratory therapy and anesthesia equipment, endoscopes, laryngoscope blades, and manometry probes.(6) The protocol for semi-critical instrumentation is to undergo high-level disinfection using dependable chemical disinfectants. The FDA definition of high-level disinfection is a 6-$\log_{10}$ kill of an appropriate *Mycobacterium* species.(6)

Non-critical instruments are those that come into contact with intact skin but not mucous membranes and can include patient care items (i.e. bedpans, sphygmomanometer cuffs, crutches) and environmental surfaces (i.e. bed rails, food utensils, bedside tables). There is minimal risk of infectious disease transmission via non-critical item contact.(23)

## 1.6 Resistant Microorganisms

The goal of sterilization is the elimination of flora and contaminants from the surface of instruments. As such, there are multiple species that deserve designation due to their unique ability to resist sterilization processes, including bacteria, viruses, protozoa, and prions. Together, prions and bacterial spores possess the highest level of innate immunity against steam sterilization.

### *1.6.1 Bacteria*

Intrinsic and acquired bacterial resistance to disinfection have been well documented. Intrinsic resistance is defined as any natural property of bacteria, including bacterial cell wall structure (particularly the mycobacterial cell wall), biofilm development and sporulation (with *Bacillus, Geobacillus and Clostridium*).(24) Acquired resistance is defined as resistance due to mutations (developed environmentally and under laboratory conditions) and/or acquisitions of plasmids/transposons. Resistance manifests as increased minimum inhibitory concentration (MIC) levels to biocides such as chlorhexidine, triclosan and quaternary ammonium compounds.(24) Different groups of bacteria vary in their susceptibility to biocides, with bacterial spores being the most resistant, followed by mycobacteria, then Gram- negative organisms, with cocci generally being the most sensitive.(25)

Sporulation is an intrinsic bacterial defence; it renders bacteria highly resistant to inactivation via chemical or biological means. Pathogenic spore forming bacteria include

*Clostridium difficile*, the *Bacillus* species, and the *Clostridium* species. These organisms are known to cause serious infections in hospitalized patients.(26)

It is widely accepted that successful elimination of bacterial spores would ensure inactivation of microorganisms that are more susceptible (i.e.. fungi and viruses), hence their usage in sterility assurance testing.(26-28)

Mycobacteria provide a unique challenge to sterilization in that they, although are non-spore forming, are intrinsically resistant to disinfectants (such as those used in the prewash cycle) via their impermeable mycobacterial cell wall. They must be wholly inactivated by steam/heat sterilization. In addition, due to their slow growing nature they are difficult to study in vitro.(25)

### *1.6.2 Viruses*

Viruses are infectious agents that are dependent on infected host cell machinery for replication. Virion structure consists of genetic material and a protein coat known as a capsid. Animal viruses consist of two types, enveloped and non-enveloped. Enveloped viruses, such as HIV, HBV, HSV, have a phospholipid layer covering their capsids derived from host cell plasma membranes.(29) Non-enveloped viruses include rotavirus, poliovirus and parvovirus among others.(29) The effectiveness of sterilization practices is not as well studied for viruses as for bacteria. Enveloped viruses are very sensitive to disinfectants. Large non-enveloped viruses have intermediate resistance to disinfectants, whereas small non-enveloped viruses have the highest resistance to disinfectants.(24)

*1.6.3 Prion Proteins*

Creutzfeldt-Jakob disease (CJD) and other transmissible spongiform encephalopathies are a group of lethal degenerative neurological disorders. These degenerative encephalopathies are transmitted by infectious agents called prions (protein particles without nucleic acid) and are characterized by accumulation and distribution of the specific prion protein in the human body. (29, 30) The pathogenesis of transmissible spongiform encephalopathies remains unclear, however it is known that the prion protein induces a conformational change of normal cellular protein to an abnormal isoform.(29) It also remains unclear whether it is solely an infective agent responsible or a combination of allelic variation in the host gene and infective agent that renders one susceptible to spongiform encephalopathy.(31) There are three forms of CJD: iatrogenic, sporadic and familial, with 90 % of cases being sporadic. The incidence is approximately one case per 1,000,000 in the USA.(32) Because of the unique nature of the infective agent, the inactivation of the protein via standard sterilization methods has been studied and has been deemed ineffective. Despite this, over the past few decades, no known cases of CJD have been transmitted via surgical instrumentation.(30) Transmission can occur by peripheral routes of inoculation, but peripheral routes require larger doses than does intracerebral inoculation. Oral transmission has been demonstrated with even larger doses. (32)

*1.6.4 Protozoa*

Protozoa are a group of microorganisms that include pathogens such as, *Giardia lamblia, Acanthamoeba castellanii, Plasmodium falciparum and Cryptosporidium parvum*.(24) They are a particular challenge to inactivate via conventional sterilization methods as they have both vegetative and dormant (cyst or oocyst) forms during their life cycles. Protozoal cysts/oocysts

are known to present greater resistance to environmental factors (such as drying and, to a limited extent, elevated temperatures compared with bacterial endospores) and chemical disinfection.(24, 33) Interestingly, notable bacterial pathogens (*Campylobacter, Escherichia, Helicobacter, Legionella, Listeria, Mycobacterium, Pseudomonas and Staphylococcus*) are known to replicate and survive in certain forms of protozoan amoebae. It has been proposed that these bacterial pathogens may escape traditional sterilization methods by being protected intracellularly by their host protozoa.(24)

*1.6.5 Hierarchy of Resistance*

Microorganisms have achieved various levels of resistance to disinfection and sterilization and knowledge of the spectrum of resistance aids in determining the best sterilization practices for health care providers to institute. The levels of resistance are summarized in Figure 1.

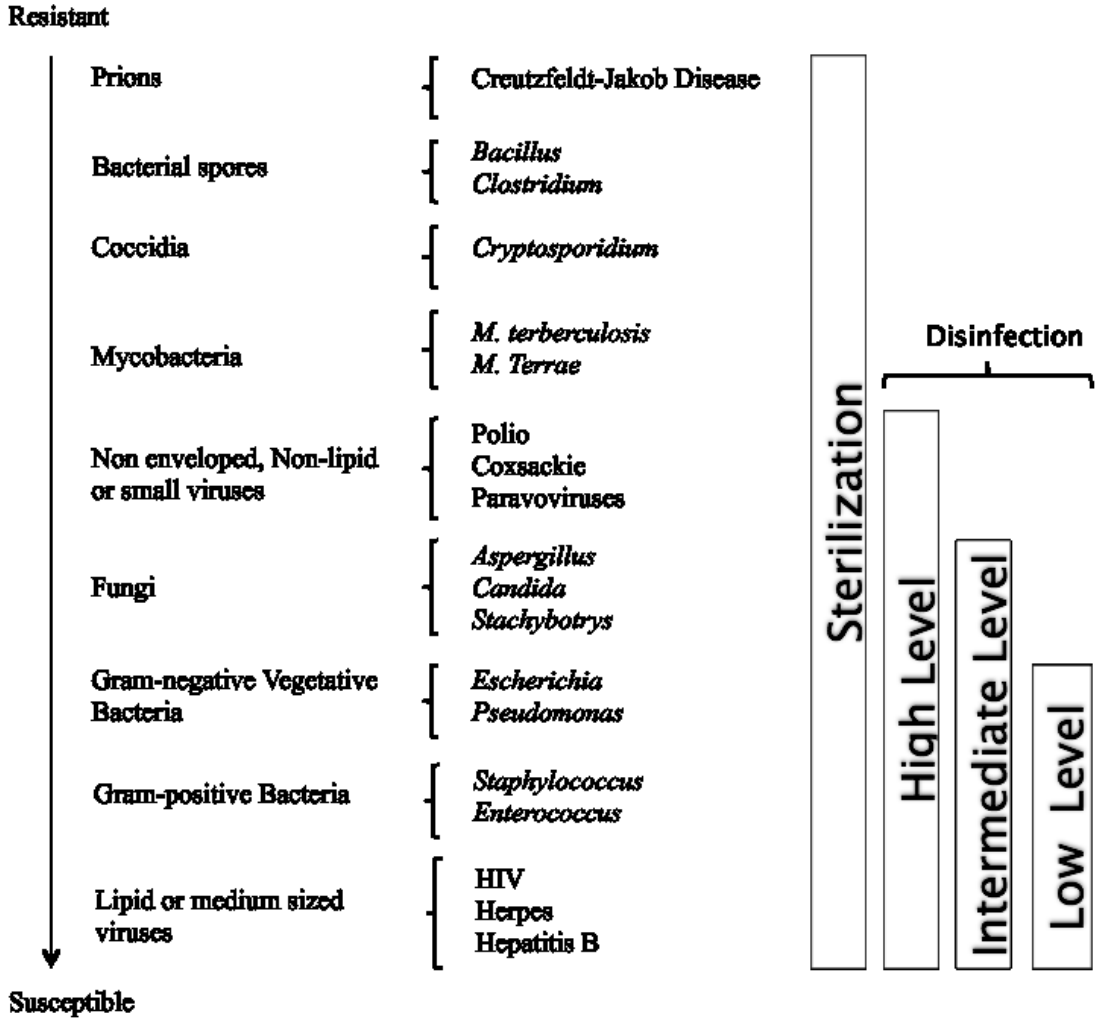



Figure 1 Hierarchy of Resistance (adapted from Moussa et al)(34)

## 1.7 Bioburden

### *1.7.1 Effect of Bioburden on Sterilization Efficacy*

Bioburden is defined as the accumulation of biologic material (i.e. blood, mucus, bone, microorganisms, biofilm) on a used instrument. The effect of bioburden varies according to the instrument design, body cavity breached and level of soil on the instrument. Areas of the body that have a high level of indigenous microorganisms (e.g. the colon or the oral cavity) can contain a bioburden in the range of $10^5$ to $10^9$ post use, while sterile body cavities should have a relatively low bioburden.(35)

The precleaning/washing of instruments prior to sterilization is paramount to the efficacy of the sterilization method being used and the importance of precleaning/washing is recognized by organizations worldwide.(36) Washing clearly reduces the bioburden associated with the clinical procedure itself; however, the washing process may also introduce environmental microbial flora, which present minimal challenge to sterilization and disinfection systems.(35) The scientific data demonstrate that vegetative bacteria levels can be reduced by at least 8 log10 cfu with cleaning followed by chemical disinfection for 20 min.(37)

## 1.8 Sterility Assurance

Instruments used in health care can present unique challenges in achieving appropriate sterility assurance levels (SAL). Complex instruments with hollow cavities and deep recesses are particularly challenging as they harbour bioburden and potential infectious contaminants. Endoscopes and surgical drills/saws/hand pieces have deep recesses and cavities, which are

known to trap bacteria and contaminated fluid.(14, 38) It has been shown that for complex instruments sterility assurance can only be achieved through vigorous washing prior to autoclaving to remove bioburden/biofilm. It is further recommended that automated washing methods be used preferably over conventional manual washing methods.(39, 40) The instruments used in this study are of the simple variety (metal, without lumen). Instruments such as surgical burs are often reused in the dental practice. Hogg *et al.* investigated the bacterial contamination on bone burs after gross cleaning (ultrasonic bath) and hospital sterilization (ETO). Evidence suggested that sterilization was not effective in sufficiently reducing bacterial loads on bone burs. The study suggested that reuse of disposable or single use instruments should not be encouraged unless sterility assurance can be guaranteed.(41)

Regular monitoring and validation of sterilization systems and their cycles is essential and mandated by Health Canada. Manufacturers must provide an evidence-based monitoring schedule to Health Canada prior to the sale of equipment in Canada. Each load sterilized must have a physical indicator that monitors physical parameters (temperature, pressure) achieved during a given cycle. Sterilizers must be validated weekly using chemical and/or biological indicators as per manufacturer instructions. The CDC further recommends validation after installment, major repair, sterilization failure and relocation.(42)

### *1.8.1 Sterility Assurance Levels*

Currently, a sterility assurance level (SAL) of $10^{-6}$ is generally accepted for medical sterilization procedures. This means the probability of not more than one viable microorganism in one million sterilized items of the final product.(43) A theoretical overall performance of the procedure of at least 12 log increments (overkill conditions) is demanded to verify an SAL of $10^{-}$

$^{6}$. This is a theoretical parameter since it is inherently problematic to evaluate the success of such sterilization by means of a final inspection, because contamination rates on the order of an SAL of $10^{-6}$ cannot be recorded experimentally. (43)

*1.8.2 Physical indicators*

Physical or mechanical indicators (time and temperature) are monitored by operator observation and recorded for each load. These indicators change colour under a given parameter of heat, moisture and time. There are two main types: visual markings incorporated into the paper pouches used to wrap instruments or paper indicator strips placed inside pouches.(44)

*1.8.3 Chemical Indicators*

Chemical indicators are regularly attached to or included in the sterilization pack and monitor both temperature and time of the sterilization cycle. Chemical indicators are convenient and inexpensive, but do not provide adequate sterility assurance. They are used to detect failures in packing and loading techniques. In large institutions where sterilization errors are not a rarity, they can provide quick information regarding processing errors.(44)

*1.8.4 Biological Indicators*

Biological indicators typically contain bacterial spores and are the most widely accepted method of monitoring efficacy of sterilization due to the spores' inherent resistance to sterilization procedures.(45) There are multiple spores that are used as biological indicators, *Bacillus atrophaus* (formally known as *subtillis*) and *Geobacillus stearothermophilus* are considered to possess the most resistant characteristics.(46)

### *1.8.5 Supervision of Sterility Work Practices*

It is essential that work practices with respect to sterile processing be closely supervised and monitored. Personnel must be responsible and accountable for adherence to written policies and procedures.(43) There are non-profit organizations that concern themselves with the standards of practice and qualification maintenance of employees working in sterile processing, such as the Association for PeriOperative Registered Nurses (AORN) and the Association for the Advancement of Medical Instrumentation (AAMI).(8) At the Capital District Health Authority (CDHA), the Medical Device Reprocessing Technicians (MDRT) are graduates of a community college certificate programme, which is typically 11.5 weeks in length.(47)

## 1.9 Hospital Central Processing Departments

### *1.9.1 Organization*

The ultimate goal of central processing departments is to regulate processing practices of medical and surgical instruments to ensure patients are protected from infection while minimizing risks to staff and preserving the value of the items being reprocessed.(42) Consistency of sterilization practices requires adherence to a comprehensive program that ensures operator/staff competence and appropriate methods of cleaning, sterilizing and monitoring of the entire process. Furthermore, the CDC recommends that care must be consistent from an infection prevention standpoint in all patient-care settings including hospital and outpatient facilities.(42) The organization of hospital based central sterile processing departments varies from institution to institution. Regardless of the institution most SPDs have

similar systems, which include Cleaning, Sterilizing, Inspection, Validation and Monitoring, Packaging, Loading, and Storage. The department on the whole functions as an "assembly line" where an instrument (product) is passed from one stage to the next down the line from cleaning to sterilizing to inspection and so on until storage. At each step there is a change of hands from one employee to the next, which ends with the delivery of the instrument to the clinic or operating room.

### *1.9.2 Capital District Health Authority Sterile Processing Department*

Capital District Health Authority (CDHA) is the largest tertiary care academic health district in Atlantic Canada. Capital Health consists of nine facilities with 11,000 employees, physicians, learners and volunteers.(48) There are 38 operating rooms across the district, performing approximately 33,845 operations per year. CDHA has an annual operating budget of almost $800 million.(48) The Capital District Health Authority (CDHA) maintains a SPD staff of 22 full time plus ten part time staff at the Victoria General, 57 full time staff and seven part time staff at the Halifax Infirmary, including one manager and two supervisors per site. The SPD departments are located centrally, within the confines of the restricted operating room environment. All instruments used for patient contact that are to be re-used are transported from various outpatient clinics or procedure areas to the central location and processed according to manufacturer instructions by certified technicians.

The processes instituted by the CDHA SPD are in keeping with the recommendations of the CDC and Health Canada.

## 2.0 Clinic Based Sterilization Units

There are a number of clinic based commercially available sterilization units in use today. These include (but are not limited to): steam autoclave, dry heat sterilizing oven, and sterilization in chemical vapor. Each method has its advantages and disadvantages. Steam sterilization is both effective and safe for use on both packaged and unpackaged items due to the penetrating ability of the steam itself. However, it cannot be used on instruments that cannot tolerate heat and moisture. Dry heat sterilization ovens are applicable to items that are intolerant of moisture but require a lengthy sterilization cycle and cannot be used on heat labile items. Finally, chemical vapour can be used on heat labile items but requires the appropriate disposal of chemical waste products.

Manufacturers of individual sterilization units have maintenance schedules and quality assurance indicators that are unit specific and must be adhered to by the technicians responsible for sterilization. Prior to allowing a sterilizer to be taken to market, the manufacturer must demonstrate to the FDA that the sterilizer is capable of achieving a sterilization assurance level (SAL) of $10^{-6}$.(8)

The CDC recommends identical steps for instrument processing for both clinic based sterilization units and centrally based units. These include cleaning (pre-scrub to decrease bioburden), decontamination using physical or chemical means, appropriate packaging, sterilization, and storage.

### *2.0.1 Statim 2000®*

The clinic based sterilization unit used in the current study was the Statim 2000m 2Scican) (Appendix A). The unit is classified as a counter-top cassette autoclave. The Statim 2000m 2Scican) has three sterilization cycles for different types of instruments: unwrapped, wrapped, and rubber and plastics. The differences between cycles is represented graphically below. The unit itself costs approximately $4700 CAD.

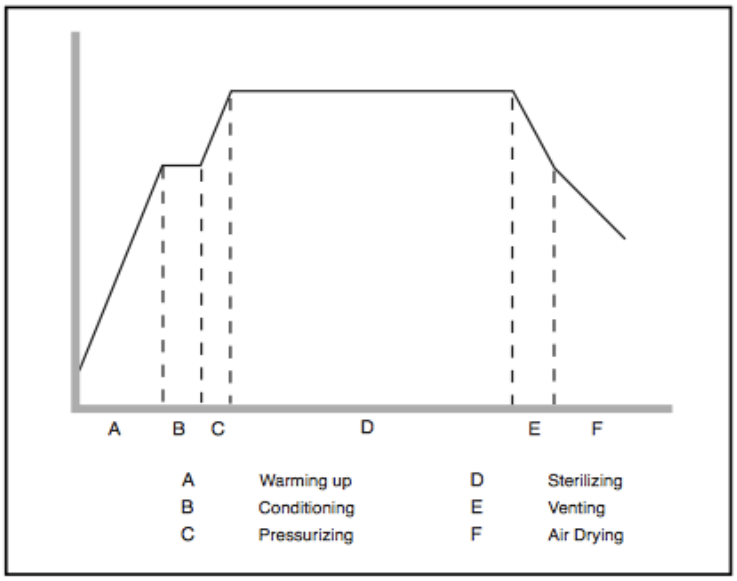



Figure 2a The unwrapped cycle is a general purpose sterilization cycle used to sterilize up to 1.0 kg of solid metal instruments, with a sterilization temperature (y axis) of 135 degrees Celsius and a holding time of 3.5 minutes.(49)

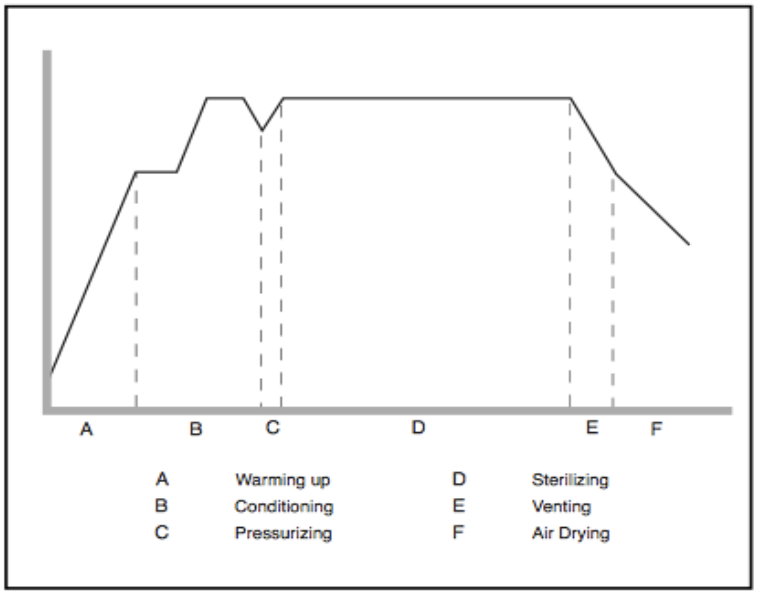



Figure 2b The Wrapped cycle is used for up to 1.0 kg of solid or hollow metal instruments which have been sealed in an autoclave bag. The sterilization temperature (y axis) is 135 degrees Celsius and holding time is 10 minutes. (49) The Wrapped cycle was used in the current study.

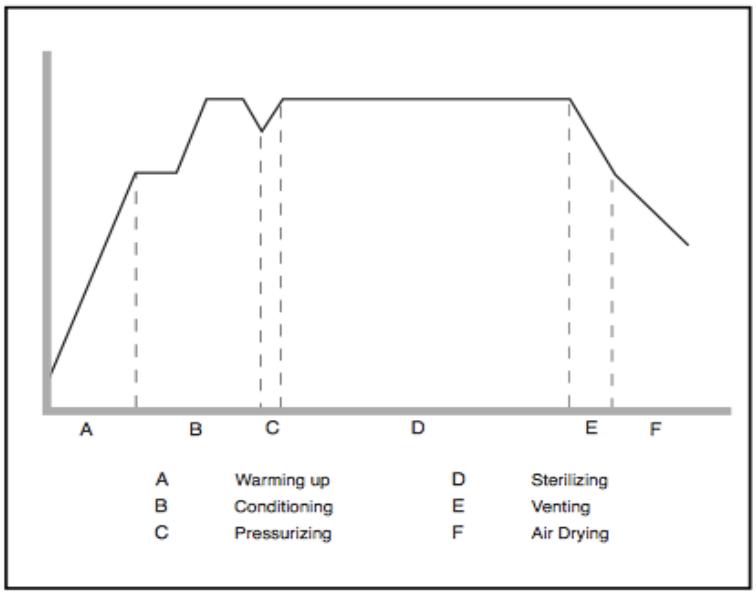



Figure 2c The plastics and rubber cycle is used to sterilize up to 0.4 kg of solid unwrapped non-metal instruments. The sterilization temperature (y axis) is 121 degrees Celsius and holding time is 15 minutes.(49)

## 3.0 Challenges in Sterile Processing

The top challenges in sterile processing are mostly due to the improper following of manufacturers instructions for use (IFU), and/or the recommended practices from the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Registered Nurses (AORN).(50) These challenges are compounded by the inherent assembly-line design of the system.

### *3.0.1 Assembly Line Error*

When systematic processes are examined, it is a common view that the assembly line process heavily affects a product's final quality. Monitoring assembly line quality is one of the

most demanding problems in systems design and quality monitoring comes with many challenges.(51) There are four main categories of assembly-line error: improper design, defective parts, variance in the assembly system and operator error. (51) Many studies show that human/operator error has a significant influence on assembly system performance, more so than technological error.(52) Some studies show that between 20-25% of the total errors in an assembly line are produced by human mistakes(51) There are multiple mathematical models used to predict the probability of errors expected in the assembly line process such as the Hinckley model. (50) The probability for error increases with the number of people/workstations involved in the process, the complexity of the process, and the amount of variability in the process.(50)

### *3.0.2 Magnitude of Error in Sterile Processing*

Due to the nature of a Sterile Processing Department, errors can and do happen on a daily basis. Thankfully, critical errors that place patients at risk are few and those that occur are mostly caught at the *unpacking for use* stage, where a licensed perioperative registered nurse identifies and ensures sterility by checking indicators and close inspection of instrumentation. However, errors that are less critical, (i.e. missing or lost instruments) are common and very costly to the institution. They cause delays in operating rooms and operations, as well as necessitate the need for locating or replacing the misplaced instrument. This study will examine missing or misplaced instruments as a secondary outcome measure.

# CHAPTER 2 HYPOTHESIS AND PURPOSE

## Purpose

To determine if clinic-based sterilization using a standard commercial autoclave unit (Statim 2000m  Scican) is as effective as hospital-based central sterilization (SPD-Sterile Processing Department) for non-complex surgical instrumentation.

## Hypothesis

A commercial clinic-based sterilization unit is non-inferior to hospital-based central sterilization for surgical instrumentation.

# CHAPTER 3 METHODS AND MATERIALS

## 3.1 Primary Outcome Measures

### *3.1.1 Test Instrumentation and Test Groups*

This prospective randomized controlled trial was completed using 2 groups of artificially inoculated instruments (# 9 Molt periosteal elevators, 77R dental elevators, implant healing abutments and cover screws) prepared in a standardized and identical fashion for sterilization analysis. A positive control group was also inoculated (but not sterilized) to confirm viability of methods and organisms. Two groups were used as negative controls (non-inoculated and sterilized).

Table 1 Summary of Trial Groups

| Group | A | B | C | D | E |
|---|---|---|---|---|---|
| Test Group | Inoculated Instrument | Inoculated Instrument | Inoculated Instrument | Non-inoculated Instrument | Non-inoculated Instrument |
| Sterilization Method | no sterilization | Statim 2000m | SPD protocol | Statim 2000m | SPD protocol |
| Group type | + control | Test group | Test group | - control | - control |

Instruments in the A, B, and C group were inoculated and randomly assigned to test or control groups. Non-inoculated sterile instruments (groups D and E) were withheld as negative controls. The groups were then processed for sterilization utilizing either standard operating procedure for the Statim 2000m steam sterilization unit or sent through a standard SPD protocol. The sterile processing employees were blinded as the instruments being tested (Group C) were sent for sterilization with regular instrumentation (as separate allotments) and were not labeled as "test". The instruments destined for sterilization in the Statim 2000 (Group B) were processed by the Department of Oral and Maxillofacial Surgery clinic staff. Groups B, C, D and E were soaked, scrubbed and processed in accordance to CDHA sterile processing protocol and as per manufacturer's instructions. All instruments in Groups B though E were presoaked in Endozime AW at a dilution of 15 ml to 4 L tap water for a minimum of 10 minutes (See Appendix for Endozime SPS sheet). The instruments were then rinsed with tap water and packaged for either SPD sterilization or Statim 2000 "Wrapped cycle" sterilization. Implant healing abutments and cover screws were used in this study as analogues for other metallic surgical instrumentation due to their ease of use, complex and variable shape, and relatively high surface area (due to threads and wells).

### *3.1.2 Control Groups*

Positive controls (Group A) consisted of inoculated instruments that were not sterilized. The purpose of these controls was to monitor the viability of the methods used to recover live microorganisms. Growth was expected from the positive controls. Whereas, growth was not expected from the negative control groups (Groups D and E). Negative controls consisted of

non-inoculated instruments that were processed as per protocol. The purpose of these groups was to monitor the asepsis of the methods used.

### 3.2 Test Microorganisms

The surgical instruments were artificially inoculated by incubation in Tryptic Soy broth with a vital clinical strain of *Enterococcus faecalis* and *Staphylococcus aureus* for 1 hour at 37 degrees Celsius. One hour was chosen as the approximate length of time for a minor outpatient procedure completed in the Oral and Maxillofacial Surgery clinic. A single colony stock of *E. faecalis* (DG1RF) and *S. aureus* (6538D) isolated via plate streaking on sheep's blood agar plate was used.

The broth colonization was standardized and tested with an optical density mass spectrophotometer (OD600) to ensure that the minimum number of bacteria per inoculate was at a standardized minimal level for all trials. The OD600 was used to determinate the absorbance of light at 600 nm. Bacterial cell cultures are grown until the absorbance at OD600 reaches a minimum of 0.2 absorbance units prior to use. A linear relationship exists between bacterial cell number (density) and OD600 up to approximately 0.8 (the range must be between 0.2-1.4).

*Enterococcus faecalis (E. faecalis)* is a typical gram positive facultative anaerobic pathogen.(53) It is considered a "gold standard" pathogen for study due to its ability to survive extreme challenges and its inherent antibiotic resistance. Enterococci inhabit the gastrointestinal tract, the oral cavity, and the vagina in humans as normal commensals. They can cause a wide variety of diseases in humans, infecting the urinary tract, bloodstream, endocardium, abdomen, biliary tract, burn wounds, and indwelling foreign devices and are responsible for many nosocomial infections. (53) For a bacterium to be pathogenic, it must be able to adhere to, grow

on, and invade the host. It must then survive host defense mechanisms, compete with other bacteria, and produce pathological changes.

An estimated 90% of enterococcal infections are caused by *E. faecalis*, which has shown increasing antimicrobial resistance secondary to a number of virulence factors summarized by Kayaoglu et al. These include: aggregation substance, sex pheromones, surface adhesins, lipoteichoic acid, extracellular superoxide production, lytic enzymes gelatinase and hyaluronidase, cytolysin toxin production.(53)

*S. aureus* is normal bacterial flora of the upper respiratory tract. It is also the commonest cause of surgical site infection (SSI) and is a major cause of bloodstream infection (BSI). It is a Gram positive cocci with the ability to endure dry environments (such as skin). It is known to produce biofilm allowing it to colonize indwelling catheters.(54) It is used in the present study due to its virulence and propensity for causing SSIs. There are many virulence factors described for *S. aureus* including: Panton Valentine Leukocidin toxin, mec A coded Penicillin Binding Protein.(54) The elimination of *S. aureus* from surgical instrumentation is necessary and has become more important recently with the emergence of Methicillin Resistant *S. aureus* (MRSA).

### 3.3 Culture Medium

Tryptic soy broth is a general purpose medium that was developed for use without blood. The final pH of the mixture is 7.3 +/- 0.2 at 25 degrees Celsius, the constituents per liter of which are in table below. (55) Tryptic-soy broth (7164) from Acumedia was prepared from dehydrated medium and sterilized according to manufacturer's instructions. Thirty grams of dehydrated medium/1L distilled H2O were mixed in a 1 L Erlenmeyer flask . The mixture was then autoclaved for 15 mins at 121 degrees Celsius. The mixture was placed in sterile resealable flasks and used for no longer than 2 weeks.(55) See Appendix C for preparation algorithm.

Table 2 Tryptic Soy Broth Constituents

| Formula/1 L | Grams |
|---|---|
| Enzymatic Digest of Casein | 17 |
| Enzymatic Digest of Soybean meal | 3 |
| Sodium Chloride | 5 |
| Dipotassium Phosphate | 2.5 |
| Dextrose | 2.5 |

The medium has "Good to Excellent" expected cultural response via growth promotion testing for *Escherichia coli* and *Staphylococcus aureus* species for an incubation period of 18-72 hours.(55)

*3.3.1 Validation of Culture Medium*

The culture medium was viable and this was confirmed for each trial by the use of positive controls in Group A. Valid medium is defined as medium that shows no growth when not inoculated but incubated under study conditions and does show growth after inoculation with test microorganisms under study conditions.(56)

*3.3.2 Preparation of Culture Medium for Trials*

Once mixed, the culture medium was prepared and micro pipetted into test tubes labeled 1-109 in a sterile fashion using a Class II biological safety cabinet. Each tube was then covered

with a plastic cap and autoclaved in preparation for the test groups to ensure a sterile medium for each trial.

### 3.4 Preparation of Inoculum

The inoculum "batch culture" was prepared using single colony strains (DG1RF, 6538D) contained in a -80 degree Celsius freezer. Single colony strains were obtained by plate streaking both the *E. faecalis* and *S. aureus* on sheep's blood agar plates. A single 10 mL inoculate was created for each strain and incubated at 37 degrees Celsius for 12-24 hours. The CFU/ml were confirmed using the Mandel spectrophotometer (OD600) for each. The batch culture was then used to either inoculate instruments (healing abutments and cover screws) or to create 20 ml of inoculum in 250 ml Erlenmeyer flasks (for larger instrument trials) and incubated at 37 degrees Celsius for 12 hours (see Appendix C for preparation algorithm). The OD600 reading was again confirmed and, if adequate, the inoculum was ready for use. The OD 600 reading for each trial is listed in Appendix D.

### 3.5 Inoculation of Instruments

Once the inoculum batch culture was prepared, the two strains were mixed into one flask and the instruments to be tested were submerged in mixture. The inoculate was then incubated at 37 degrees Celsius for a minimum of one hour.

The instruments were then removed from the culture medium and transferred in a sterile fashion via air-tight container for sterile processing. The instruments were then assigned randomly (via a random number generator) to either Group A, B, or C.

### 3.6 Sterilization of Instruments

Groups B, C, D and E were sterilized according to set protocols. The groups were grossly debrided by clinic staff using Endozime AW. Once adequate debridement was completed, Groups B and D were sterilized in a Statim 2000m 2Scican) following manufacturersturers was completed, Groups B and D were sterilized in a grossly debrided by clinic staffstaff were blinded to the instruments being part of a study to decrease bias and extra levels of vigilance. In SPD the instruments were again further debrided using an ultrasonic cleaner for 3 minutes to remove gross contaminants. They were then washed with water heated to 98 degrees Celsius and dried. Upon completion of the wash and dry cycle, the instruments were packed into standard plastic gas sterilization packets. Gas vapour sterilization with 10% ethylene oxide and 90% CO2 mixture was completed in 4 stages including: 1 hour conditioning cycle, 3 hour sterilization cycle, 20 minute exhaust cycle, and a 12 hour aeration cycle. The appropriate physical, chemical and biological sterilization monitors were instituted throughout.

Prior to the commencement of the study, the Statim 2000m 2Scican) was installed and validated by a licensed technician. The protocol set forth by the manufacturer (Scican) was adhered to for Groups B and D. This included being grossly debrided using Endozime AW and rinsed with water. The instruments were sterilized wrapped in autoclave bags and ”Wrapped cycle was used. Post cycle autoclave bags were confirmed dry and bags were stored in an airtight container. Chemical process indicator tape was included on each package. Weekly monitoring was completed via the use of Ensure (SciCan) biological indicators and incubators.

### 3.7 Testing of Instruments

Upon completion of the sterilization protocol for Groups B through E. The instruments were transferred in a sterile fashion (using sterile forceps in a Class II biological safety cabinet)

into previously prepared and sterilized test tubes containing the validated culture medium. Once transfer was complete and the test tubes capped with plastic stoppers, the instruments were incubated at 37 degrees Celsius. All instruments (n=1177) were then checked by a single blinded observer at 24, 48 and 72 hours respectively. The test tube numbers were covered until the end of the trial and the observer marked the tubes that were considered turbid without knowledge of what group they were assigned to. Instruments that were dropped or compromised upon transfer were considered "contaminate" and excluded from the study. Turbidity (haziness created by particulate matter or bacterial growth) of the medium of each test tube was then recorded for each test tube in both a lab manual and via spreadsheet as either positive of negative. Upon completion of the trial, the tubes marked as turbid were confirmed via spectroscopy and their OD 600 values recorded. Intra-rater reliability and repeatability of observation was established by using the same measurement conditions for all trials (visual observation under identical light conditions), a single observer, multiple repetitions over a relatively short period of time, and confirmation of turbidity at the completion of each trial. However, the inherent limitation of using a human observer (i.e. human error) for the identification of positives vs. negatives was accounted for by the lead investigator checking all trials upon completion to determine if any positive results were missed by the single blinded observer.

## 3.8 Statistics

### *3.81 Sample Size Calculation*

A sample size calculation for this study was based on the predicted difference in the proportion of success (no turbidity seen) between the two test groups (Group B and C) being less that 1%. The margin of non-inferiority (Δ) was therefore 0.01. *A priori* power analysis and sample size estimates were completed using the formula found in Table 2.

The sample size to achieve appropriate power for the study was n= 172 per Test Group B and C.

$H_0$:$\Theta_1$-$\Theta_2 \leq \delta$ versus $H_a$:$\Theta_1$-$\Theta_2 > \delta$

***Data Input***

$\alpha$=0.05
$\beta$=0.1
$\Theta_1$=.999
$\Theta_2$=.999
$\delta$=0.01
r=1

***Calculated Sample Size***

n1= 172
n2= 172
N=344

*Variables*

$\alpha$= one-sided significance level
1-$\beta$= Power of test
$\Theta_1$= expected success proportions of sample one
$\Theta_2$= expected proportions of sample two
$\delta$= true difference of mean response rates, $\delta > 0$, the superiority margin or value of $\delta < 0$, the non-inferiority margin
r= ratio of sample size of group two to group one
n1= sample size of each sample one
n2= sample size of each sample two
N= Total sample size

Table 3 Power Calculation for Non-inferiority Trial

*3.82 Statistic Analyses*

The results were analyzed using the IBM SPSS Statistics 14.0 software (version 14.0.0, SPSS Inc, Chicago, Il). All variables were categorical variables and dichotomous (binary). Groups B and C were compared for each of these variables. The Fischer's exact test was used to analyze the two dichotomous variables. For all statistical tests, a 95% confidence interval (CI) was used, and a *P* value less than .05 was considered statistically significant.

**3.9 Secondary Outcome Measures**

Instruments that were used in regular rotation in the operating room setting (i.e. not study instruments) and processed by central SPD and either deemed non-sterile, lost, missing or misplaced within a given sterile reprocessed set were recorded on a spreadsheet by a member of the perioperative nursing team. A record was kept of all days over a 33 day time period between November 1st 2013 to December 20, 2013 during regularly scheduled operating room days. Evenings and weekends (on call) were not recorded. The number of operations taking place during a regularly scheduled operating room day varied between one and four, thus a minimum of one surgical set was required from SPD. Errors were divided into two categories: errors in sterility or packaging, and misplacement or loss of instruments.

As a comparison, the number of instruments lost or irreversibly damaged in the process of sterilization by SPD in the Department of Oral and Maxillofacial Surgery outpatient clinic were recorded by a single clinical staff over a six month period (June 2009-January 2010).

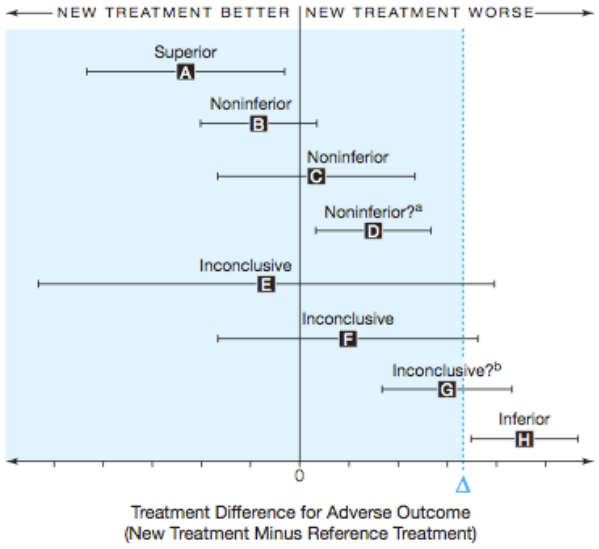
# CHAPTER 4 RESULTS

*4.1 Primary Outcome Measures*

There were 13 individual trials run in total to achieve an appropriate sample size and adequate power for the study. By treating each instrument as a "eatin there were a total of 1264 instruments (cases) completed. In the test groups B and C there were 1 of 596 (0.002%) and 0 of 587 (0.000%) instruments, respectively, that showed evidence of bacterial growth after 72 hours (Table 4). The first 3 cases in each group were considered to be pilot samples and were not included in further analyses. The sample size (n) for Groups B and C was therefore 593 and 584 respectively. For Group B, the rate of successful sterilization (non-turbidity) was 99.8314% (592/593); for Group C, the rate of success was 100% (584/584). The Risk Difference (Group B risk minus Group C risk) was therefore 0.1686%. The 95% Confidence Interval around this Risk Difference is (-0.1616% to 0.4989%) or (-0.001616 to 0.004989). This Confidence Interval lies to the left of (i.e. is less than) the margin of non-inferiority and crosses 0. This indicates that Group B is non-inferior and is not shown to be superior to Group C as in the table below (See Figure 3).

Figure 3 Treatment Differences in Non-inferiority Trials

Adapted from Piaggio et al.(68)




Error bars indicate 2-sided 95% CIs. The dashed line at x = Δ indicates the margin of non-inferiority; the shaded region to the left of x= Δ indicates the zone of inferiority.

**A**: if the CI lies wholly to the left of zero, the new treatment is superior.

**B** and **C**: if the CI lies to the left of Δ and includes zero, the new treatment is non-inferior but not shown to be superior.

**D**: if the CI lies wholly to the left of Δ and wholly to the right of zero, the new treatment is non-inferior in the sense already defined but also inferior in the sense that a null treatment difference is excluded.(68)

Positive control Group A showed positive bacterial growth in 36 of 39 instruments after 24 hours (Appendix E). Group D demonstrated evidence of bacterial growth in 1 of 39 (0.025%) instruments while Group E demonstrated growth in 0 of 39. The turbidity results were confirmed for Group A with an average OD 600 of 1.557 (+/-0.802). The turbidity of Instrument # 16 in Trial # 11 (Group B) was 0.964 and the turbidity of Instrument # 60 in Trial # 9 (Group D) was 1.260. See Table 4 for Results Summary and raw data can be found in Appendix G.

Table 4 Results Summary

| Test Groups | | | clean after sterilization | | |
|---|---|---|---|---|---|
| | | | no | yes | Total |
| Group number | B - Statim | Count | 1 | 592 | 593 |
| | | % within Group number | .2% | **99.8%** | 100.0% |
| | | % within clean after sterilization | 100.0% | 50.3% | 50.4% |
| | C- SPD | Count | 0 | 584 | 584 |
| | | % within Group number | .0% | **100.0%** | 100.0% |
| | | % within clean after sterilization | .0% | 49.7% | 49.6% |
| Total | | Count | 1 | 1176 | 1177 |
| | | % within Group number | .1% | 99.9% | 100.0% |
| | | % within clean after sterilization | 100.0% | 100.0% | 100.0% |

The bacterial growth found on the instrument in Group D was examined and the Gram stain and colony structure were consistent with the growth of both *S. aureus* (clusters) and *E. faecalis* (clusters and short chains) *(*Appendix F).

Statistical analyses of all variables failed to identify significant differences between the groups B and C at a 95% confidence interval. The p-value for the comparison of proportions is 1.0. The Asymptotic Significance (Asymp. Sig. 2-sided) for the Pearson Chi-squared test is greater than 0.05, indicating no relationship between the test Groups. Additionally, Fisher's Exact Test of independence Exact Significance (2-sided) p value is 1.000 and Exact Sig. (1-

sided) is 0.504, again indicating that there is no significant difference between test groups. The data are summarized in Table 5 below.

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) |
|---|---|---|---|---|---|
| Pearson Chi-Square | .986(b) | 1 | .321 | | |
| Continuity Correction(a) | .000 | 1 | 1.000 | | |
| Likelihood Ratio | 1.372 | 1 | .241 | | |
| **Fisher's Exact Test** | | | | **1.000** | .504 |
| Linear-by-Linear Association | .985 | 1 | .321 | | |
| N of Valid Cases | 1177 | | | | |

Table 5 Statistical Analyses
(a)=computed for a 2x2 table
(b)= 2 cells (50.0%) have expected count less than 5. The minimum expected count is .50.
df= degrees of freedom

*4.2 Secondary Outcome Measures*

A central SPD error in sterilization (non-sterile instrument trays) occurred in 12 of 33 days recorded (36%), while lost, missing or misplaced instrumentation were recorded in 13 of 33 days (39%) in the operating room setting (Appendix H)

The number of lost or damaged instruments delivered to the Oral and Maxillofacial Out-Patient Clinic by SPD over the specified 6 month period totaled 23 (See Appendix I). There is

no comparable outcome measure for the Statim 2000 as the sterilization unit is currently not being used for clinical purposes, solely for completion of this study

# CHAPTER 5 DISCUSSION

The intent of this study was to determine if clinic-based sterilization using a standard commercial autoclave unit (Statim 2000, SciCan) is as effective as hospital-based central sterilization (SPD-Sterile Processing Department) for non-complex surgical instrumentation.

The results of this study show that the clinic based sterilization (CBS) unit is not inferior to centrally based sterilization processes (SPD). Both methods produced consistent results when challenged with standardized pathogens. This is in keeping with other studies in the field.(57) Clinic based sterilization units are considered medical devices, and therefore fall under the regulatory purview of the United States Food and Drug Administration and Health Canada. Manufacturers must submit adequate data to show that the sterilization equipment is efficacious before the unit is to be marketed.(58, 59) There are a number of manufacturers that produce sterilization units such as the one used in this study (Statim 2000, SciCan).(60) To our best knowledge this is the first direct comparison between a clinic based sterilization (CBS) unit and a centrally based hospital sterilization department (SPD).

The differences in effectiveness of sterilization between Test Groups B and C based on a 95% confidence interval was statistically insignificant (0.1686%). The addition of the Control Group A showed that the microorganisms used were viable and the trials valid. Groups D and E were used as negative controls to ensure that the sterilization process as well as the transfer of instruments in itself did not render the instruments non-sterile.

There are a number of potential causes of sterilization failure. Sterilization is a complex process; and a deficiency in any of the variables necessary to effect sterilization can result in

non-sterile product. These variables include: sterilizer performance, sterilant quality and quantity, choice of packaging materials, packaging technique, sterilizer loading techniques, and inappropriate cycle parameters for the items being processed. (61, 62)

The parameters needed for steam sterilization, as was used in this study, are time, temperature and saturated steam. A steam sterilization process failure can be caused by poor steam quality and/or inadequate steam quantity, equipment malfunction and human error (See Appendix J). (50)

Poor steam quality and/or inadequate steam quantity, equipment malfunction can be monitored via usage of appropriate biologic indicators. However adherence to the manufacturers recommendations with respect to maintenance and usage limitations of each sterilization device is wholly dependent on operator vigilance and is susceptible to human error.

Human error consists of a complex set of variables which are difficult to define, let alone test for and correct. Human error includes: inadequately cleaned items preventing steam penetration, packaging materials impermeable to steam, packs too large or too dense for the cycle parameters, poor loading techniques that entrap air and prevent steam penetration, incorrect operation of sterilizer, and finally the possibility of an entire load inadvertently not being processed.(63, 64)

The rate of SPD error was unacceptably high for both the operating room setting and the outpatient clinic setting. Errors in processing in 12 of 33 days and missing or misplaced instruments in 13 of 33 days recorded was unexpected and may illustrate some deficiencies in the protocol established by the CDHA. There is no "accepted" level of error when sterile processing of surgical instruments is concerned, as any error may have devastating consequences. Additionally, there were 23 lost or damaged instruments in instrumentation trays

delivered to the outpatient clinic setting during a 6 month period by SPD. Costs of missing instruments ranged from $39.60 (CAD) for a Bishops cheek retractor to $275 (CAD) for a bone Rongeur. However, a direct comparison to instruments lost or damaged via usage of an in-clinic sterilization unit was not completed. It is presumably a function of sheer volume of instruments through SPD that is responsible for the errors seen. Smaller instruments may be lost or misplaced due to the magnitude of the instruments that are sterilized each day in any given hospital. SPD staff have catalogues of instruments that can be referenced in setting up trays for sterilization, but with multiple departments using thousands of different types of instruments it is impossible for a sterilization technician to truly know each instrument and process. Conversely, if an SPD technician is dedicated to a department solely, they will develop an inherent familiarity with each instrument and the intricacies of sterilization and tray set-up.

The current model in use for centrally based SPD is an assembly line type process. At CDHA SPD an instrument changes operator hands a minimum of five times. This includes: personnel to initiate the sterile processing protocol, one in decontamination, one to inspect the instruments for gross debris, one to package for sterilization, one to verify sterilization is complete and valid, and finally one to deliver the instrument to respective storage areas. This entire process can be completed in a minimum of 4 hours, however, depending on the number of instruments requiring processing at a given time, it normally takes longer than 4 hours. It is a common view in the systems design engineering literature that the assembly line process heavily affects a productoductation, one to vecost.(51) Many investigations disclose that human errors have a significant influence on assembly system performance, often more than the technological ones.(51) Most of the literature in assembly line error comes from the private manufacturing sector, where in U.S. manufacturing plants human failures caused by improper human action on

the average accounted for 40% of all error.(51) Based on defect data of semiconductor products, Hinckley (1993) found that defect per unit (error) was correlated with number of assembly operations (See Appendix K)(51); meaning that errors increased in frequency with the number of steps/persons in an assembly line. Young (2012) points out the top 10 challenges to sterile processing and 7 of 10 are based upon human error including incorrectly loaded containers into a washer, improper following of a manufacturers IFU, usage of incorrect Biological Indicators (BI), incomplete verification of mechanical cleaning efficacy, uncertainty about what instruments require extended cycles, and alteration of instrument packaging for sterilization.(50)

There are many challenges to sterile processing and infection control in the hospital environment including (but not limited to): difficult to kill microorganisms, poorly trained technicians, complex medical devices, lack of resources allocated to central processing and immediate use steam sterilization (65)

Processing devices for immediate use steam sterilization can be safe and efficacious only if all appropriate steps are followed, including proper cleaning, decontamination, and aseptic transfer to the point of use.(65) With the limited resources of the Canadian health care system, there are fewer health care dollars available to hire and train technicians for sterile processing purposes.(50) Allowing a technician to fully and effectively utilize their technical skill set by taking advantage of immediate use steam sterilization units of immediate use steam sterilization units (i.e. Statim 2000) at the point of care (outpatient clinics) for simple instruments would decrease the number of hands that an instrument goes through in order to become sterilized. Thus, using the Hinckley model, would decrease the number of errors in sterility and lost or damaged instruments resulting in the more complete utilization of each health care dollar.(51)

The limitations of clinic based sterilization are that it would be increasingly complex to monitor appropriate adherence to protocols by an individual technician without having the watchful eye of a supervisor in close proximity (as is the case with a centrally based SPD), and it could only be limited to simple (non-complex) instrumentation where disassembly and reassembly and specialized techniques are not necessary. Appropriately trained individuals, as MDRTs, are necessary at the point of sterilization to ensure standards are maintained.

Health Canada leaves it to the individual health care institutions to determine the policies and procedures for sterilization staff qualification and training, competency assessment and occupational health and safety as outlined by the Canadian Standards Association in Section 6.1, document Z314.8-08.(66) In order to maintain accreditation a health care facility must demonstrate that the standard of care is at or above the minimum standard of care nationwide.

There are multiple factors which must be weighed in determining what sterilization method is acceptable for each individual department. Each method, SPD and in-clinic based sterilization (Statim) has both positives and negatives. One could argue that SPD may be more regulated and supervised, as there is a manager overseeing the entire process from point of entry of an instrument to completion of the sterilization cycle. However, it also comes with negatives including: cost, lost, damaged, or misplaced instruments, assembly line type error, and increased turn over time. Additionally, in-clinic sterilization has negatives which include: a lack of supervision at the point of sterilization, and a limited number of sterilization modalities available on a smaller scale. But positives such as, cost, less assembly line type error, fewer lost, damaged or misplaced instruments and rapid turn over time may outweigh the negatives.

Limitations of this study include the lack of bioburden introduced during inoculation of the instruments. Bioburden clinically comes in many forms including mucus, blood, and bone. To

accurately control levels of bioburden would have been a challenge in the context of the rigid parameters in the current study methodology. Additionally, one might argue that the usage of spore forming species (*Geobacilus stearothermophilus*) would have proven to be a more rigorous test of the sterilization protocols. The lead investigator decided to use common pathogenic bacteria instead as they may provide more clinical relevance to the reader, whereas *G. stearothermophilus* is not known to be the causative microbe for SSI's or other nosocomial infections. Furthermore, the protocol used by SPD consisted of more steps prior to sterilization than the clinic based protocol in addition to using a different sterilization method (ethylene oxide vs. steam). The intent was to allow SPD the autonomy to use whichever sterilization method they saw fit to employ as a routine protocol for the test instruments. The intent of the author was to compare in-clinic protocol vs. central- sterilization protocol as opposed to individual sterilization methods.

There may have been a source of bias introduced by the inability to blind the one technician responsible for the initial debridement, which began the Statim sterilization processes. The instruments were only handled by one of two people and were necessarily segregated based on the inclusion in the study. Also, the blinded observer may have introduced error as the initial reading of the results may be inherently subjected to human error; however, all trials were checked by the lead investigator upon completion to minimize positives missed and the positives were confirmed via OD600 spectrophotometry. Test tubes visually deemed non-turbid (negatives) were not checked via OD600 as the positives were clearly positive and due to lab constraints it would not have been feasible to test all tubes following trial completion.
With respect to the secondary outcome measures, there may have been inherent inaccuracies in the counting of the number of instruments lost or damaged in the outpatient clinic setting due to

the reliance on one observer's records. Furthermore, there may have been error introduced by the perioperative nursing staff during the recording of instruments deemed non-sterile, lost, missing or misplaced.

There is also the matter of clinical significance when one considers sterility of surgical instruments. The question must be addressed regarding the positive instrument in Trial # 11 (Statim) and while not statistically significant, may in fact be clinically significant. In sterilization research, the acceptable level of error (non-sterility) is zero. While the results of this study showed a statistically insignificant difference between the test groups (99.8314% vs. 100% sterility) is that difference large enough to claim clinical significance? In the view of the patient, one would assume that the preference is for 100% sterility and therefore the difference between to two test groups is *clinically* significant. The minimal clinically important difference (MCID) is the smallest treatment efficacy that would lead to a change in management.(69) However, the MCID is not entirely applicable in our study simply due to the fact that a single non-sterile instrument (proven to be non-sterile in the laboratory environment) does not confer a 100% infection rate in a patient as there are multiple other factors that affect infection rates such as host immunity, instrument contact time with host tissue and pathogenicity of contaminating microorganisms. Studies have shown the importance of combining clinical importance with statistical significance in the context of making treatment recommendations if the MCID is clearly known, which is not the case in our study. (69)

Areas for further research include a detailed cost-benefit analysis for comparing in-clinic sterilization vs. central sterilization processes to determine the cost advantages or disadvantages of each method. This is out of the scope of the current study

# CHAPTER 6 CONCLUSION

We have shown in this study that for non-complex instruments, centrally based sterilization (SPD) and clinic-based sterilization (Statim 2000) are equivalent in terms of sterilization. Therefore, other factors should be considered when determining which sterilization method is appropriate for each specific department within a hospital setting.

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**APPENDIX A Statim 2000®**

## APPENDIX B Endozime AW SPS Sheet

# MATERIAL SAFETY DATA SHEET

### 1. Identification of the Substance and Company

Product Name: ENDOZIME® AW PLUS
Product No: 345AP
Manufactured by: RUHOF CORPORATION
Address: 393 Sagamore Avenue, Mineola, NY 11501-1919 USA
Emergency Telephone No: 1-800-424-9300 (CHEMTREC)
Emergency Telephone No: 1-800-537-8463 (RUHOF)
Date Created: April 9, 2009

*NFPA 704 HAZARD RATING:*

*HEALTH: 1*
*FIRE: 0*
*REACTIVITY: 0*
*SPECIAL NONE*

### 2. Hazardous Ingredients/Identity Information

| Hazardous Components: | OSHA PEL | CAS # | % |
|---|---|---|---|
| 2-propanol | 400ppm | 67-63-0 | 10 |

| Sara Hazard: | Fire? | NO | Pressure? | NO | Reactivity? | NO | Acute? | NO | Chronic? | NO |
|---|---|---|---|---|---|---|---|---|---|---|

### 3. Hazards Identification

Irritating to eyes and skin.

### 4. First Aid Measures

Eye Contact: Flush eyes immediately with water for at least 15 minutes. Get medical attention.
Skin Contact: Flush skin immediately with water for at least 15minutes. Get medical attention if irritation persists.
Inhalation: Remove patient to fresh air. If not breathing, give artificial respiration. Get medical attention.
Ingestion: Do not induce vomiting. Get medical attention. Do not give anything by mouth to an unconscious person. If conscious, drink a large quantity of milk or water.

### 5. Fire-Fighting Measures

Conditions of Flammability/Flash Point/Auto-ignition Temperature: Not flammable.
Upper Flammable Limit: Not Applicable
Lower Flammable Limit: Not Applicable
Special Hazards: None known
Explodability Data: Not Determined
Extinguishing Media: Use media appropriate for the primary source of fire.
Special Fire Fighting Procedures: None known.
Hazard Combustion Products: CO, CO2

### 6. Accidental Release Measures

Spills may be picked up with a mop and followed by a water rinse. Small spills may be flushed to a sanitary sewer with copious amounts of water if in accordance with National and local regulations.

### 7. Handling and Storage

Handling: Wash hands thoroughly after use.
Storage: Avoid exposure to high temperature or humidity. Keep container closed when not in use. Keep from freezing.

### 8. Exposure Control/Personal Protection

Respiratory Protection: NIOSH-approved mask if mist is likely. Normal handling and use as directed do not involve generation of mist, but respiratory protection is recommended for persons with allergies or respiratory sensitivity.
Eye Protection: Safety glasses or goggles.
Protective Gloves: Plastic or Rubber.
Other Protective Clothing and Equipment: Apron
Other Work/Hygiene Precautions: Wash contaminated clothing before reuse.

### 9. Physical and Chemical Properties

Appearance: CLEAR BLUE LIQUID
Odor: FLORAL ODOR
pH: 6.0 – 8.0
Boiling Point: 212°F
Melting Point: N/A
Evaporation Rate: 1
Evaporation Standard: WATER
Specific Gravity (Water = 1): 1.01-1.03
Vapor Pressure (mm Hg): AS WATER
Relative Vapor Density (Air = 1): N/A
Solubility in Water: COMPLETE

### 10. Stability and Reactivity

Stability: Stable
Hazardous Polymerization: Will not occur.
Incompatible Materials: Strong oxidizers.
Conditions to Avoid/ Conditions of Reactivity: Heat, Light, Freezing Temperatures
Hazardous Decomposition or Byproducts: CO and CO2 in fire situations.

### 11. Toxicological Information

| Carcinogenicity? | NO | NTP? | NO | IARC? | NO | OSHA Regulated? | NO |
|---|---|---|---|---|---|---|---|
| Mutagenicity? | NO | Reproductive Toxin? | NO | Possible Sensitizer? | NO | | |

### 12. Ecological Information: Not Determined

### 13. Disposal Considerations:

Dispose in accordance with local, state, and Federal regulations. Empty containers should be rinsed and discarded in a waste container or offered for recycling if possible. Do not use empty containers for other purposes. Follow all national or regional regulations for disposal.

### 14. Transport Information:

Ground: Non-hazardous, Sea: IMDG Class: Non-hazardous, Air: ICAO/IATA Class: Non-hazardous

### 15. Regulatory Information:

Special Health and Safety Information: None
Classification, Risk, and Safety Information for Label: R36/38 Irritating to eyes and skin. S24/25 Avoid contact with skin and eyes. S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

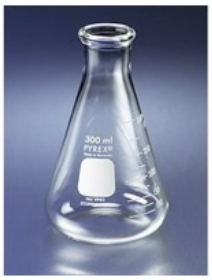
### 16. Other Information:

The information provided in this safety data sheet has been obtained from sources believed to be reliable. The manufacturer provides no warranties; either expressed or implied, and assumes no responsibility for accuracy or completeness of the data contained herein. The information is offered for your consideration and investigation. You should satisfy yourself that you have all current data relevant to your particular use. The manufacturer knows of no medical conditions other than those noted on this safety data sheet, which are generally recognized as being aggravated by exposure to this product.

## APPENDIX C Culture Medium and Inoculate Preparation Algorithm

Step 1

**Mix Tryptic Soy Broth** (BD/ Accumedia):
30 gm/1 L distilled H2O in a 1 L Erlenmeyer Flask
Autoclave 15 mins, 121 degrees Celsius



Step 2a

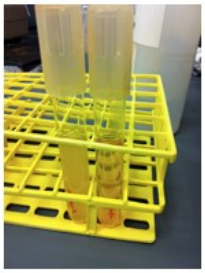
**From plated, single colony strains contained in -80 degree freezer.**

**Box marked "Stefanuto"**
Middle shelf.

Step 2

**Create 10 mL inoculate with single colony**
*E. faecalis* (DG1RF) and *S. aureus* (6538D) mixed with 10 ml sterile broth (created above) in separate sterile test tubes.
Incubate x 12 hours @ 37 degrees Celsius

Label tubes
Strain number, date, time



Step 3

**Test OD 600**
Zero spectrophotometer with sterile TS Broth.
Test both *E. faecalis* (DG1RF) and *S. aureus* (6538D)
Should be a minimum OD600=0.4=1x10$^{8}$ CFU/ml

Step 4

**20 ml Inoculum Batch culture**
If both tubes of *E. faecalis* (DG1RF) and *S. aureus* (6538D)
are a minimum OD600=0.4=1x10$^8$ CFU/ml above then mix into a sterile 250 ml Erlenmeyer flask

Label flasks with tape
Strain number, date, time

Step 5

**Final Inoculum Batch culture**
If both tubes of *E. faecalis* (DG1RF) and *S. aureus* (6538D)
are a minimum OD600=0.4=1x10$^8$ CFU/ml above then mix into 500 mL sterile beaker and incubate at 37 degrees x 12 hours
**Ready for Use**

Transfer tape from 500 ml flasks with
Strain number, date, time

**Inoculating Instruments**

Step 1

**Final Inoculum Batch culture**

Place sterile instruments into inoculate broth. Re-cover with tin foil. Incubate at 37 degrees Celsius x 1 hour

Step 2

**Transfer to VG**

Retrieve inoculated instruments from broth with sterile forceps. Place into disinfected (70% ETOH) air-tight container marked "dirty" for transport.

Step 3

**Disposing of inoculate broth**

Autoclave at 121 degrees Celsius for 15 minutes.
Once complete, drain into sink.
Rinse glassware and leave for cleaning.

Step 4

**Transfer directly to VG OMFS dirty utility room for processing.**

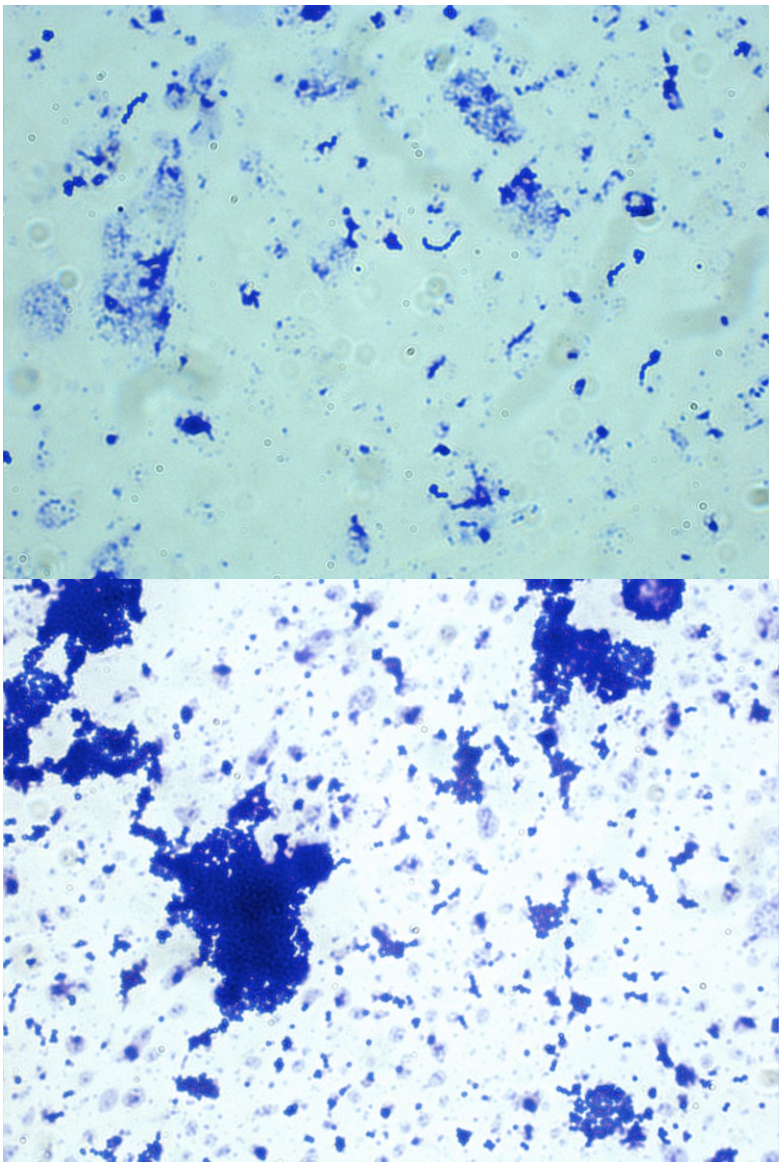
## APPENDIX D OD Values of Inoculum

| | Strain | |
|---|---|---|
| Trial | DG1RF | 6538D |
| 1 | 1.28 | 0.75 |
| | | |
| 2 | 1.39 | 0.51 |
| | | |
| 3 | 1.02 | 0.55 |
| | | |
| 4 | 0.92 | 0.96 |
| | | |
| 5 | 1.35 | 1.35 |
| | | |
| 6 | 1.09 | 1.22 |
| | | |
| 7 | 1.046 | 1.699 |
| | | |
| 8 | 1.12 | 1.519 |
| | | |
| 9 | 1.14 | 1.35 |
| | | |
| 10 | 1.531 | 1.738 |
| | | |
| 11 | 1.661 | 1.72 |
| | | |
| 12 | 1.18 | 1.522 |
| | | |
| 13 | 1.491 | 1.611 |

## APPENDIX E OD Values of Group ical Importanceontrol

| Trial | Tube # | OD600 |
|---|---|---|
| 1 | not recorded | |
| | | |
| 2 | not recorded | |
| | | |
| | | |
| | | |
| 3 | 63 | 1.165 |
| | 64 | 1.691 |
| | 65 | 1.373 |
| | | |
| 4 | 63 | 1.503 |
| | 64 | 1.691 |
| | 65 | 1.653 |
| | | |
| 5 | not recorded | |
| | | |
| | | |
| | | |
| 6 | 63 | 1.702 |
| | 64 | 1.53 |
| | 65 | 1.473 |
| | | |
| 7 | 63 | 1.12 |
| | 64 | 1.519 |
| | 65 | 1.67 |
| | | |
| 8 | 63 | 1.637 |
| | 64 | 1.528 |
| | 65 | 1.67 |
| | | |
| 9 | 63 | 1.14 |
| | 64 | 1.253 |
| | 65 | 1.132 |
| | | |
| 10 | 63 | 1.688 |
| | 64 | 1.896 |
| | 65 | 1.922 |
| | | |
| 11 | 63 | 1.726 |
| | 64 | 1.735 |
| | 65 | 1.686 |
| | | |
| 12 | 63 | 1.126 |
| | 64 | 1.431 |
| | 65 | 1.397 |
| | | |
| 13 | 63 | 1.747 |
| | 64 | 1.913 |
| | 65 | 1.799 |

## APPENDIX F Gram Stain of Positive Test Groups



## APPENDIX G Raw Data Table

| Groups | A | B | C | D | E |
|---|---|---|---|---|---|
| Trial | | | | | |
| Pilot | 3/3 | 0/3 | 0/3 | 0/3 | 0/3 |
| 1 | 3/3 | 0/18 | 0/12 | 0/3 | 0/3 |
| 2 | 0/3 | 0/28 | 0/27 | 0/3 | 0/3 |
| 3 | 3/3 | 0/51 | 0/51 | 0/3 | 0/3 |
| 4 | 3/3 | 0/51 | 0/51 | 0/3 | 0/3 |
| 5 | 3/3 | 0/51 | 0/51 | 0/3 | 0/3 |
| 6 | 3/3 | 0/51 | 0/49 | 0/3 | 0/3 |
| 7 | 3/3 | 0/51 | 0/49 | 0/3 | 0/3 |
| 8 | 3/3 | 0/49 | 0/49 | 0/3 | 0/3 |
| 9 | 3/3 | 0/49 | 0/49 | 1/3 | 0/3 |
| 10 | 3/3 | 0/49 | 0/49 | 0/3 | 0/3 |
| 11 | 3/3 | 1/49 | 0/49 | 0/3 | 0/3 |
| 12 | 3/3 | 0/49 | 0/49 | 0/3 | 0/3 |
| 13 | 3/3 | 0/49 | 0/49 | 0/3 | 0/3 |
| Totals | 36/39 | 1/596 | 0/587 | 1/39 | 0/39 |

## APPENDIX H Secondary Outcome Measures- SPD Error Operating Room

| | Error Type | Error Type |
|---|---|---|
| Date | Error in processing | Instrument lost or misplaced |
| 2013-11-01 | N | Y |
| 2013-11-04 | N | N |
| 2013-11-05 | N | N |
| 2013-11-06 | N | Y |
| 2013-11-07 | N | N |
| 2013-11-08 | N | Y |
| 2013-11-12 | N | Y |
| 2013-11-13 | N | Y |
| 2013-11-14 | Y | Y |
| 2013-11-15 | Y | N |
| 2013-11-18 | N | N |
| 2013-11-19 | N | Y |
| 2013-11-20 | N | N |
| 2013-11-21 | N | Y |
| 2013-11-22 | N | N |
| 2013-11-26 | Y | N |
| 2013-11-27 | Y | N |
| 2013-11-28 | N | N |
| 2013-11-29 | Y | N |
| 2013-12-02 | N | N |
| 2013-12-03 | N | N |
| 2013-12-04 | N | Y |
| 2013-12-05 | Y | N |
| 2013-12-06 | N | N |
| 2013-12-09 | N | N |
| 2013-12-10 | Y | N |
| 2013-12-11 | N | N |
| 2013-12-12 | Y | N |
| 2013-12-13 | N | Y |
| 2013-12-16 | Y | Y |
| 2013-12-17 | N | Y |
| 2013-12-18 | Y | Y |
| 2013-12-19 | Y | N |
| 2013-12-20 | Y | N |
| Total Days | Total Error | Total Instruments Misplaced/Lost |
| 33 | 12 | 13 |

## APPENDIX I Secondary Outcome Measures- Out-patient Clinic

| Date | Instruments Lost/ Damaged |
|---|---|
| Jun 2009-Jan 2010 | 23 |

## APPENDIX J Technical causes of Steam Sterilization Failure(45, 67)

1. Poor steam quality and/or inadequate steam quantity can be due to
    i) inadequate trap in steam line
    ii) steam contact with a cold load
    iii) steam pressure too high for the temperature

2. Superheated steam
    i) improper chamber heat up
    ii) desiccated packaging materials
    ii) steam pressure too low for the temperature

3. Variations in steam pressure due to clogged filters, poorly engineered piping or excessive demands.

4. Out-of-calibration pressure gauges and controllers.

5. Incomplete air removal
    i) plugged drain screen
    ii) clogged vent lines
    iii) faulty vacuum pump
    iv) inadequate door gasket seal  equate door gasket seal  quate door gasket seal  r excessive demands.he temperature  5, 67)</DisplayText><reco

6. Inadequate cycle temperature
    i) temperature gauge out of calibration
    ii) long heat-up time of large loads (heat lag)
    iii) variations in steam pressure due to clogged filters, poorly engineered piping or excessive demands on the steam supply

7. Insufficient time at temperature
    i) timer gauge out of calibration
    ii) inappropriate cycle parameters for the load being processed
    come up time less than 1.5 minutes

## APPENDIX K The Hinckley Model of Assembly Line Error(51)

$$\log \text{DPU} = k \cdot \log Cf - \log C$$

$$\text{DPU} = \frac{(Cf)^K}{C}$$

$$Cf = \text{TAT} - t_0 \times \text{TOP}$$

Where *C* and *K* are constants
DPU=*Defects per Unit*
*Cf*=*Complexity factor*
TAT=*total assembly time*
TOP=*total # of assembly operations*
$t_0$=*threshold assembly time*