Managing Steam Sterilization Process By Patricia H. Nothum, RN, BSN, CRCST, CHL						
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### Introduction

In 1880's Charles Chamberland developed the first steam sterilizer. It resembled a modern day food pressure cooker and was used to sterilize dressings. A small amount of water was placed in the bottom of the sterilizer and the items were suspended on a rack. The lid was placed on the sterilizer and when heat was applied, the water became steam, the pressure in the container rose and sterilization occurred. (Fraser, R. 2008)

# **Charles Chamberland's Steam Sterilizer**



Picture courtesy of blog.mcientifica.com.

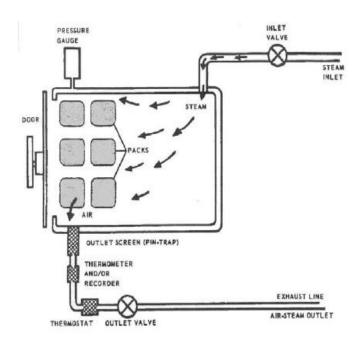
Steam sterilizer technology continued to evolve starting with gravity displacement sterilizer, prevacuum sterilizer and finally steam -flush-pressure pulse sterilizer. All steam sterilizers function of the premise set by Charles Chamberland. Water is heated in a pressure vessel and penetrates items located inside the vessel resulting in sterilization.

Steam sterilization is the preferred process used in Sterile Processing Departments. An unofficial survey of several colleagues revealed over 75% of sterilizer loads processed in their departments was processed using steam. Hospital venues represented included trauma centers, tertiary facilities and small local facilities. Quality monitors performed to monitor steam sterilization efficacy are reviewed by

sterile processing technicians and managers to ensure items being processed meet the sterility requirements for safe patient care however, these quality monitors may not alert technicians and managers when subtle changes are occurring which will in time negatively affect the steam sterilization process which requires intense investigation of all aspects of the steam sterilization process. Factors which affect the steam sterilization process include steam quality, water quality, inadequate cleaning, incorrect assembly of instrument trays, incorrect use of packaging, or incorrect loading of sterilization carriers. These factors become evident when wet packs, discoloration of instruments and stains on sterilizer packaging are identified when steam sterilized.

For those of us who have been managing sterile processing departments for a number of years, identification of wet packs, discoloration of instruments or stains on sterilizer packaging are events we may have experienced and never want to experience again. Resolution of any of these issues is not easy. It requires looking at all aspects of the steam sterilization process. More importantly it involves a assembling a team to identify and correct the cause of the negative event(s) identified. This collaborative team should include the Sterile Processing Manager, Surgery, Facility Maintenance and the sterilizer manufacturer. (Brown & Bliley, 2008, p. 50) Because each area represented is focused on their areas of responsibility and providing their required services they may not understand how each of their areas affects the other areas. As the team begins to work together to solve the sterilization negative effects educational materials may need to be provided to raise the understanding of each areas needs. Members of this team must work together to provide a positive outcome. The purpose of this paper is to identify factors which may affect the steam sterilization process and to assist sterile processing managers in the development of a quality management plan to reduce the occurrence of negative events in the steam sterilization process including wet packs, discoloration of instruments or stains on sterilizing packaging.

#### Steam Sterilization



Picture courtesy of Infection Prevention Guidelines

Gravity Displacement Sterilizers operate by allowing steam to enter the top of the sterilizer chamber. Steam, which is lighter than air, rises to the top of the chamber. During the conditioning phase the chamber fills with steam and the cooler air is forced out of the chamber through the drain near the bottom of the chamber. When the cool air has been replaced by the steam, steam will enter the drain and trigger the thermally (heat) regulated valve to close. The closing of the valve allows the pressure to build inside the chamber until the required operating temperature is reached. The timer on the sterilizer is activated and the sterilization phase begins. (Tiejen, Cronin, MacIntosh, 1992, p. G-1 and G-2) When the sterilization time has elapsed, the evacuation phase allows steam to evacuate through the drain and the drying phase begins. At the end of the dry cycle, items are considered sterile and ready to use.

Prevacuum Sterilizers have the four phases of the gravity displacement sterilizer, conditioning, sterilization, evacuation and dry. The difference is a vacuum pump system to remove the cool air which shortens the conditioning phase allowing the temperature and pressure to rise more quickly.(Tiejen, Cronin, MacIntosh, 1992, p. G-2) Removal of the cool air in a prevacuum sterilizers results in a below atmospheric pressure. Prevacuum cycles are susceptible to leaks items are processed below atmospheric pressure.

Steam-Flush Pressure-Pulse Sterilizer uses a repeated sequence of steam flush and pressure pulse which removes air from the sterilizer chamber. Items are processed above atmospheric pressure. Like the prevacuum sterilizer, air is rapidly removed from the chamber and wrapped items. Steam-Flush-Pressure-Pulse cycles are not susceptible to air leaks because the pressure in the chamber is above atmospheric pressure. (Autoclave Testing Services)

It is important to know the type of steam cycle being used because each cycle has different working mechanisms which can affect the outcome of the sterilization cycle.

## **Steam Supply**

Steam supply for steam sterilizers is made up of two major components. These components include the steam generator or boiler system and the steam delivery system. Each of the components has a direct effect to the quality of steam delivered to the steam sterilizers.

#### **Steam Generators**

The steam source for steam sterilization is provided by two sources. Electric steam generators connected directly to the steam sterilizer is one source. The second and most common source is a facility steam generating system or boiler system which generates steam for all areas of the facility requiring steam power. These operations include the heating and air-conditioning systems, laundry, food service as well as sterile processing. Sterile Processing uses less than five percent of the steam which is generated by the facility steam generator. Nationally five percent translates into at least

500,000 sterilization cycles daily. (Moore, 2008) In a typical U.S. health care facility the steam required is often generated by one large boiler but there is often a back up boiler in the steam line sequence to provide back up steam if the main boiler must be taken out of service.

### **Steam Generator**



Picture courtesy of ttboilers.com

The process of making steam begins with drawing tap water into the boiler reservoir.

Components of the boiler are boiler feedwater system, feedwater heaters, deaerator, feed pump, economizer, superheater, attemperator, steam system, condenser, condensate pump and fuel system.

There are also controls to monitor water and steam flow, fuel flow, airflow and chemical treatment additives. (Boiler Basics, 2003) The function of these components is:

# **Feedwater System**

Feedwater is the water supplied to the boiler which is then converted to steam. One source of feed water includes condensate or condensed steam which returns to the boiler from the user areas.

The second source is called make up water which is drawn from water from an outside water source.

We know this second source as tap water. (Boiler Basics, 2003)

#### **Feedwater Heater**

Heat from the spent, or returned steam, is extracted to preheat the boiler feedwater. The heaters are comprised of shell and tube heat exchangers with the feedwater in the tube side (inside) and the steam on the shell side (outside). The feed water continues through the steam processing system while the condensed steam is returned to a condensate storage tank or condenser hot well. This system increases the efficiency of the boiler through the preheating process. (Boiler Basics, 2003)

#### **Deaerator**

Feedwater contains dissolved oxygen at levels which contaminate the steam. This occurs when there is air in-leakage from condenser, pump seals or through condensate. Deaerator mechanically removes the oxygen from the feedwater by passing a stream of steam through the feedwater as the temperature of the feedwater rises. (Boiler Basics, 2003)

#### **Economizers**

The last stage of the feedwater system is the economizer. They extract heat value from the exhaust gases to heat the steam and water which increases the efficiency of the boiler. Not all boilers have economizers. (Boiler Basics, 2003)

#### Steam Systems

## **Steam and Mud Drums**

The boiler system is made up of the steam and mud drum. The upper drum is the steam drum in a water tube boiler is where the separation of the water and steam occurs. The steam drum contains internal elements for:

- Feedwater entry which allow tap water to enter the steam drum.
- Chemical injection which adds chemicals to the steam drum to remove impurities.

- Blowdown removal which is a water removal process to control the concentration of impurities (suspended or dissolved solids) in boiler water.
- Level control which is the addition of tap water to maintain levels required to generate required steam. (HPAC Engineering)

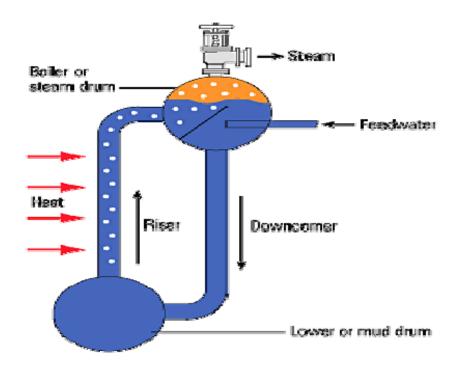


Diagram courtesy of spiraxsarco.com

The colder water sinks through the downcomer tubes and enters the mud drum along with the solids formed from the blowdown. The mud drum equalizes the water distribution to the riser tubes.

Heat is applied to the tubes to form steam which passes through the riser tubes back to the steam drum. The steam bubbles being lighter than the water in the steam drum rise above the water and enter the steam distribution system. (Boiler Basics, 2003)

### **Boiler Tubes**

High-strength carbon steel is the usually used to make boiler tubes. They are welded to form a wall of tubes. Usually more than one wall is used in the construction of the boiler. (Boiler Basics, 2003)

#### Superheaters

Superheaters remove all moisture content from the steam by raising its temperature above the saturation point. The tubes carrying the steam are suspended in a convective or radiation zone of the boiler to ensure temperatures above saturation point are reached. (Boiler Basics, 2003)

## **Attemperators**

Attemperation controls the degree of superheat in the superheater boiler. The process controls the degree of superheat by injecting a stream of high purity water into the superheated steam. (Boiler Basics, 2003)

### **Condensate Systems**

The condensate system is not an integral part of the boiler because condensate is usually returned to the boiler through feedwater. Condensate systems include heat exchangers, process equipment, flash tanks and storage tanks. The importance of the concentrate system to generating steam is to know the amount and quality of the condensate when determine the treatment parameters for the boiler. (Boiler Basics, 2003)

### **Fuel Systems**

The choice of the fuel system is an economic and resource availability of the facility. Fuel choice does not directly affect the quality of steam produced.

### **Steam Delivery System**

The function of a good steam distribution system is to get the steam from the boiler to where it is needed and return the condensate to the boiler. (Dutta & Datar, 2006) To accomplish this requires a complex system of steam circuits comprised of steam pipes, drip legs, moisture separators and pressure valves.

#### **Basic Steam Circuit**

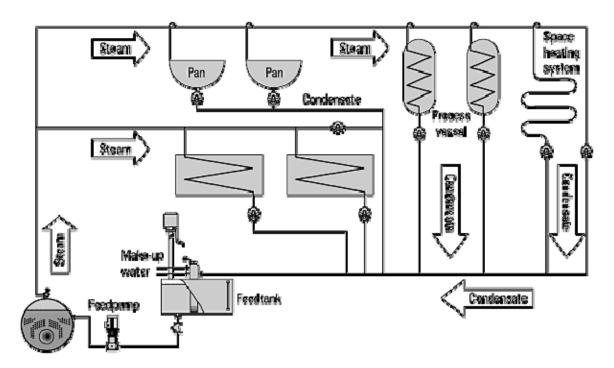


Diagram courtesy of wermac.org

Steam piping transports steam from the boiler to the end-use services. The piping system must have equipment connections to accommodate thermal reactions during end-use equipment start ups and shut downs. The piping needs to be equipped with enough drip legs to collect condensate as it moves through the piping system and cooling occurs. (Dutta & Datar, 2006)

**Drip Leg** 

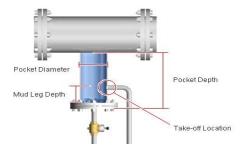
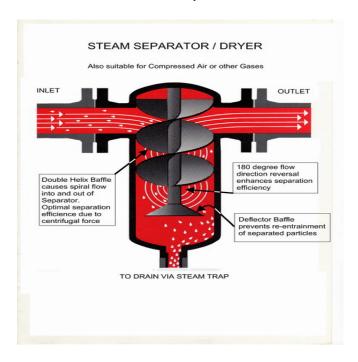


Diagram courtesy of tvlglobal.com

Mechanical moisture separators with traps need to be installed at intervals to separate the moisture particles in the steam. (Dutta & Datar, 2006)

# **Moisture Separator**



Picture courtesy of thermoguard.com

Automatic air vents are required at the dead end of steam mains to allow for removal of air and non-condensable steam which accumulates in steam space. (Dutta & Datar, 2006) Steam pipes need to be pitched away from the boiler towards the drip trap stations. The drip trap station needs to be installed ahead of any risers in the piping to prevent accumulation of condensate. (Dutta & Datar, 2006) The piping system requires insulation to reduce the amount of heat loss as the steam is delivered to the end-user. Steam traps and strainers are used throughout the system to separate condensate from the steam. (Dutta & Datar, 2006)

As the steam moves through the complex piping system of the facility, its pressure needs to be reduced depending on the end-user's needs. (Spriaxsarco) This is an example of a pressure reducing valve station:

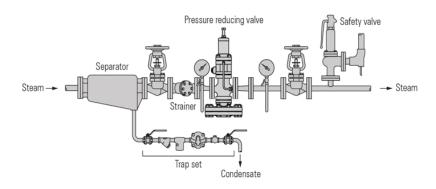


Diagram courtesy of spiraxsarco.com

# **Water Supply**

Water supply affects all aspects of processing instrumentation in sterile processing departments. Impurities in the water affect the function of the steam sterilizer from the boiler, through the steam supply into the sterilizer. Impurities affect the condition of the instruments being processed manually and automatically. It is important to ensure the water supply to all areas of sterile processing meets the criteria outlined by the manufacturer's instructions for instrumentation processing, equipment use and manufacturing of steam. Maintaining water criteria requires the input from Engineering, Infection Control and the sterile processing management staff.

Water quality is a measure of suitability of water for the particular use based on selected physical, chemical and biological characteristics. (USGS, 2001) Types of water used in sterile processing include:

• Tap water can be hard or soft depending on factors including geographic location, water source (ground, well, river, lake). Tap water naturally has salts, minerals and other chemicals dissolved in it from the source. In addition, municipal water treatment plants may add additional chemicals to provide fluoridation in the water supply and to render the water safe for consumption.

- Softened water occurs when tap water is processed through a water softening process
  which removes significant amounts of calcium using either magnesium or sodium as a
  removal agent.
- Reverse Osmosis (R/O) water is filtered by forcing the water through a thin permeable membrane which removes most of the solid contaminants and dissolved minerals. R/O filtration does not remove bacteria or viruses.
- Deionized water (DI water) is water that has had the ions removed. Removing the ions removes the majority of impurities such as dissolved salts. DI water also contains bacteria or viruses. The high purity of the water resembles that of distilled water.
- Distilled water has virtually all of impurities removed through distillation. Distillation
  involves boiling the water then condensing the steam into a clean container. Distilled
  water is high purity water which does not contain bacteria and viruses. A downside of
  distillation is a white or yellow mineral scale left on the distillation equipment.
   (Consolidated Sterilizer Systems)

Water naturally contains dissolved substances including minerals or salts reserved to as dissolved solids. Dissolved solids include calcium, sodium, bicarbonate, and chloride. Water also contains nitrogen, phosphorus and trace elements such as selenium, chromium, and arsenic which are known as plant nutrients. (USGS, 2001)

Water hardness is measured by how many minerals such as calcium and magnesium are dissolved in the water. The more minerals in the water results harder the water. Water hardness information of tap water is available from the local water treatment facility. (Consolidated Water Systems)

### **Water Purity**

Resistance to electrical current in ohms/cm or the conductivity of the water to electrical current is the methods used to measure water purity. Ohm is represented by the Greek letter omega. The higher the resistance indicates the water purity.

# **Water Purity Table**

Approximate	10,000,000 -	5,000,000 -	1,000,000 -	10,000 - 100	100 -1
Ohms/cm	5,000,000	2,000,000	100,000		
Water Type	ater Type Distilled Water		R/O	Tap or	Sea
				Softened	

Water harness is a measurement of the number of minerals such as calcium and magnesium are dissolved in the water. As the number of minerals increase in the water, the hardness level of the water increases.

#### **Water Hardness Scale**

Grains/Gal	mg/L & ppm	Classification
Less than 1	Less than 17.1	Soft
1 - 3.5	17.1 - 60	Slightly Hard
3.5 - 7	60 - 120	Moderately Hard
7 - 10	120 - 180	Hard
Over 10	Over 180	Very Hard

Numbers for the Water Purity Scale and the Water Hardness Scale are courtesy of Consolidated Sterilizer Systems.

# **Steam Quality**

Steam quality is the measureable aspects of steam used for medical sterilization. (STERICERT)

Steam vapor has a highly transferable heat content which is ideal for sterilization. It is expressed in terms of saturation. The accepted value for high-quality steam is 97% steam with 3% moisture content. (Moore, 2008) Reaching the 97% steam 3% moisture begins with water entering the boiler and ends with delivery to the sterilizer chamber. The numbers of variables which affect steam along this delivery system are many and not always easy to discern when defects in the sterilization process occur.

Water quality entering the boiler is a large factor in achieving the desired steam content.

Maintaining that water quality is a complex science and a change in one factor affects steam content.

Chemicals are added to the water to remove impurities and to protect damage to the boiler and steam delivery system. (Moore, 2008)

As mentioned earlier, blowdown, a periodic or continuous water removal is performed in addition to use of chemical treatment. (NCDENR, 2004)This function is essential to prevent:

- Boiler Waterside Fouling which is a scale buildup of solid material because of the reaction to the
  impurities in the water and tube metal. Scale acts as an insulator and reduces heat transfer
  decreasing the efficiency of the boiler.
- Oxygen Attack is the most common cause of corrosion inside the boilers causing damage the boiler and condensate piping.
- Acid Attack is another cause of corrosion which happens when the pH drops below 8.5 and can cause damage to the boiler and condensate piping. (NCDENR, 2004)

Chemicals used to reduce the impurities in the water are listed in the table below.

# **Table of Chemicals and Their Response**

Chemical	Response
Lime Softening	Cause the calcium, magnesium and some silica to precipitate from
	the water.
Soda Ash	Causes non-bicarbonate to precipitate from the water.
Chelates	Chemical compound which forms heat-stable soluble complexes of
	calcium and magnesium to control scaling.
Neutralizing Amines	High pH chemicals that neutralize the carbonic acid formed in the
	condensate.
Filming Amines	Chemicals that form a protective layer on the condensate piping to
	protect it from oxygen and acid attach.
Phosphates	Buffers the water to minimize pH fluctuation.
Polymers	Act like Chelates in controlling hardness deposits or iron deposits.
Oxygen Scavengers	Removes small amounts of oxygen that escape the deaerator which
	removes most of the oxygen before it enter the boiler.

(NCDENR, 2004)

# **Monitoring Steam Quality**

Accepted steam content for steam sterilization is 97% steam and 3% water. (Moore, 2008)

Factors which may affect the quality of steam can occur at any point in the steam delivery system and within the steam sterilizer. These factors are wet steam, superheated steam, and non-condensable gases. (Hughes, 2002)

Wet Steam occurs when packaging of instruments and creation of sterilizer loads do not follow accepted recommended practices. Packaging techniques require instruments and containers are dry before being placed in the sterilizers. When the steam makes contact with the wet instruments additional condensate and cause dripping on other instruments that may not dry. (Hughes, 2002)

Superheated Steam occurs when the temperature of the steam is higher than its saturation pressure. This usually happens when the pressure of the steam drops as it moves through the steam supply system. This dries the steam and once there is a reduction in moisture, less energy is required to raise the temperature of the steam. (Hughes, 2002)

Non-condensable gases should be removed before the steam leaves the boiler. When they are not, they modify the steam from being pure water vapor to a mixture of steam and gas. They become an unwanted contaminate which does not allow steam to make contact with the item. (Hughes, 2002)

### **Steam Quality Monitoring Tests**

Your sterilizer manufacturer or Facilities Manager can obtain steam from the steam sterilizer and from the boiler to determine the quality of the steam entering the steam sterilizer. This test will provide information to ensure steam quality is acceptable for sterilization. Results of the steam quality test will help determine if any changes need to be made to the chemical additives within the boiler.

# **Changes in Steam Sterilization Process**

Negative effects to the steam sterilization process present themselves slowly often with almost indiscernible changes which suddenly become large issues. Suddenly a Sterile Processing Technician will find a processed load contains wet packs. They or the end user may notice discoloration of the

instruments. Discolored stains on the packaging material may become evident. When these events occur the prime concern of the Sterile Processing Manager in providing good customer service becomes one of damage control. Sterilizer loads must be carefully inspected for signs of wet packs and staining. The Sterile Processing Department customers must be notified of the issues occurring in Sterile Processing to allow them to watch for potentially unsterile packages in their area. The Sterile Processing Manager must assemble an interdisciplinary team to correct whatever is causing the changes identified.

# **Interdisciplinary Team**

As stated earlier, the variables affecting the steam sterilization process involve processes managed by areas not under the umbrella of the Sterile Processing Department. It may be more than one variable which is causing the deviation. Each member brings different information and needs which must be analyzed and addressed to the interdisciplinary team. Members and their roles are:

- Sterile Processing Manager is responsible for ensuring product is sterile for provision of quality
  patient care. She/he is charged with ensuring the use of recommended practices is followed
  though all phases of the sterilization process including quality monitoring processes. The Sterile
  Processing Manager understands the need for quality steam but may not understand the
  processes required for the delivery of that steam
- Facilities Manager is responsible for ensuring all departments requiring steam for daily
  operations receives an adequate supply. The Facilities Manager will have a working knowledge
  of generating the steam supply but not understand how the process of creating steam affects
  the sterilization process.
- Surgical Service Manger is responsible for ensuring instrumentation is available for caring for the surgical patient but may not understand the processes required to furnish those instruments.
- Biomedical Engineering staff may be responsible for preventive maintenance for the steam sterilizers but may not understand the process of generating steam.

Sterilizer manufacturer service technician may be responsible for preventive maintenance. Their
expertise is the function of the sterilizer. Their experience is essential in assessing sterilizer
function. (Brown & Bliley, 2008 p. 50)

#### **Wet Packs**

Steam supply to the sterilizer accounts for about 60% of all wet packs. Sterilizer performance is responsible for 30% of wet pack incidents. Improper loading and wrapping of trays and basins is responsible for 10% of wet pack issues. (Moore,2008, p. 393) Since wet packs are not usually caused by one issue all factors of the processing cycle which need to be assessed include:

- Sterilizer Operation
- Utility supply to the sterilizer
- Pack preparation process
- Post-sterilization handling process. (Brown & Bliley, 2008, p. 50)

As deficits to the steam sterilization process are identified and repaired the incidents of wet packs may decrease or disappear. Caution must be taken by the interdisciplinary team as these assessments are made not to discontinue the process prematurely but continue to make a full assessment of the factors which create wet packs. Diligent monitoring of sterilized packages for wetness should be a part of the Sterile Processing Technician's practice.

# **Examples of Wet Pack**



Photograph: Moore, 2008

# **Sterilizer Operation**

Sterilizer operation needs to be assessed by those responsible for preventive maintenance. This could be the sterilizer manufacturer, Biomedical Engineering department or a third party sterilization company. Examples of items requiring assessment include:

- Vacuum integrity
- Vacuum performance
- Temperature/pressure calibration
- Chamber level
- Chamber/jacket trap performance
- Chamber valves (solenoid and check)
- Jacket insulation integrity
- Sterilizer exposure time
- Sterilizer dry time. (Brown & Bliley, 2008, p. 51)

# **Vacuum Integrity**

Vacuum integrity is measured using the Vacuum Leak Test. It assures air is not being admitted into the sterilizer during vacuum drawdowns. The results are recorded in mm/Hg (millimeters of

mercury). If the result of the vacuum leak test is greater than 1mm/Hg there is a problem with the sterilizer which must be addressed. (STERIS Operator Manual, 2008, p. 3-3) Sterile Processing Managers should address their sterilizer operating manual to determine specific vacuum leak test requirements.

### **Vacuum Performance**

Vacuum performance is measured using a Bowie-Dick test pack. This pack is designed to simulate product and constitute a defined challenge to the sterilization process. Test results are shown on a sheet inside the test. The sheet has a pattern of bars that should have a uniform color change. Entrapped air indicating a failure in vacuum performance will be evident by variations in the color change. Results of the Bowie-Dick test will indicate the function of the vacuum performance test. (CDC, 2008)

### **Temperature and Calibration**

Required temperature settings are calibrated when the steam sterilizer is installed. Steam sterilizers are complex machines built with parts which are subject to wear. This wear can result in temperatures not reaching required levels which directly affect the sterilization process. Periodic calibration of items such as pressure and temperature gauges are required to ensure items are properly sterilized. (Hughes, 2001)

#### **Chamber Level**

Chamber level refers to level above sea water where the sterilizer is installed. Chamber pressure and temperature and effective sterilization have been established in a scientific setting. The published results have been adjusted for the barometric pressure of that area. During installation the chamber pressure and temperature need to be adjusted for the barometric pressure depending on the location of the sterilizer above sea level.(Clement, & Bliley, 2004)

# **Chamber Jacket/Trap Performance/Jacket Insulation Integrity**

The interior walls of the sterilizer chamber are heated by steam in the metal jacket surrounding the chamber. This heating process is to minimize condensation when the steam is introduced into the sterilizer chamber.

The outside of the jacket is covered with insulation to maintain the steam temperature in the jacket. Steam enters the jacket from the steam supply system. When the sterilizer cycle starts, the steam leaves the jacket and enters the sterilizer. As the steam is drawn through the chamber, it enters the chamber drain. (IAHCSMM . 2007, p. 290)

When the steam contacts the thermostatic trap a sensor in the trap measures steam temperature and automatically controls the flow of air and condensate from the sterilizer chamber. (IAHCSMM . 2007, p. 291)

### **Sterilizer Exposure Time**

Steam exposure time is a relationship between chamber pressure and temperature.

Temperature is not reached without adequate steam pressure. Ensuring the temperature and pressure are calibrated to meet the barometric atmospheric conditions of the location of the sterilizer. (Infection Control Today, 2004)

### **Sterilizer Dry Time**

The sterilizer dry time follows the exhaust phase of the steam sterilizer cycle. During the exhaust phase, the chamber drain opens and the steam is removed through the discharge line. At the same time sterile, filtered air is introduced into the chamber. The drain line contains a chorgrill or wadded wire that causes the steam to condensate into water and discharge through the discharge line. This is to prevent water from reentering the chamber. (IAHCSMM, 2007, pp. 296-297) Malfunction in the process removes the steam and draining of the steam condensate will affect the drying time required.

## **Sterilizer Loading Car**

At the same time, the Sterile Processing Team needs to be assessing their processes for placing items on the sterilizer loading car. (Brown & Bliley, 2008, p. 50) The principles for loading a sterilizer cart are to assure removal of air from the chamber before sterilization begins and full steam contact for all items during the sterilization process. In addition, items need to be loaded to allow condensate which occurs when the hot steam makes contact with the colder metals and allow air to circulate and not pocket preventing steam from making contact with the item. (IAHCSMM, 2007, p. 305)

When reviewing loading cart procedures ensure established principals:

- Allowing for proper steam circulation by not overloading the cart. Packages must be positioned
  for efficient air removal, steam penetration and evacuation. There must be minimal resistance
  because steam vapor is passive and won't enter tightly packed places.
- Use absorbent shelf liners to cover sterilizer cart facilitate absorption of condensate and prevent dripping on items on the lower shelves.
- Rigid sterilization containers should be placed on the lower shelves to prevent dripping on packages below them on the cart.
- Solid containers should be positioned to allow air to get out and steam to get in. Solid bottom containers should be placed on their edge.
- Small items should be placed in a small basket.
- A visible space should be allowed to facilitate steam circulation and drying.
- Combined loads should be positioned with smaller items on the top rack and metal items on the bottom rack to prevent dripping on the lower packs.
- Position textile packs with the layers perpendicular to the shelf.
- Paper/plastic peel pouches must stand on edge using a basket or rack to allow steam penetration. They should be positioned paper to plastic in the basket or rack.

- It is not ideal to mix textiles and hard goods in the same load but if that occurs, textile packs are placed on the top racks and hard good items are placed on the lower rack(s).
- Packages must not touch the chamber walls.
- Items, except for lumens, must be dry before they are placed in the sterilizer. Sterilizer cycle parameters are verified using dry instruments and additional water may lead to a wet pack.
- Surgical instrument trays with perforated bottoms sit flat on the rack to maintain even
   instrument distribution and facilitate proper drainage. (IAHCSMM, 2007, pp. 306 & 307)





Pictures courtesy of Sterile Processing University

Procedures for removing sterilizer carts from the chamber must also be assessed. When the carrier is removed from the chamber, the contents must be inspected for visible liquid. Each item should be inspected without touching them. (IAHCSMM, 2007, p. 307) The sterilizer cart should be moved to an area that is free from traffic and is not near air-conditioning vents. Excessive air flow and cool air may cause condensation on the cooling instruments. (IAHCSMM, 2007, p. 308)

Some sterile processing departments have purchased infrared thermometer guns to assess the temperature of the items before removing them from the loading car. The infrared thermometer gun directs a red beam at the package and gives the temperature of the area being monitored. Each department needs to set their own temperature parameters for release. A baseline ambient

temperature of 70° - 72°F can be used as a starting point. (Sterile Processing University, 2009) Infrared Thermometer Guns are available from general merchandise stores which offer tools for sale.



# Picture courtesy of Sterile Processing University

# **Steam Supply Systems**

Brown and Bliley refer to the steam supply system as a utility supply for the steam sterilizers because the steam supply system falls under the responsibility of Facilities

Management staff. The steam supply system consists of the boiler and the steam delivery system. Steam supply systems are designed and installed when the facilities are first constructed. Over the years, as the services of the facility change various construction projects will change the original designed and requirements of the steam supply system. These changes and the aging of the steam supply system can affect steam delivery performance. The affect of these changes include:

- Rap (Water Hammer) location
- Trap performance
- Supply line slope
- Supply line dips/sags
- Supply line insulation
- Supply line size
- Steam pressure static

- Steam pressure dynamic
- Location of sterilizer relative to other equipment (requiring steam)
- Steam boiler size
- Steam boiler water level
- Steam boiler drums size. (Brown & Bliley, 2008, p. 51)

# **Rap Location**

Rap location or water hammer is a rapping noise that develops in the steam system. It is one of the most common complaints a steam system develops. It is most commonly caused by an accumulation of condensate. This accumulation of condensate or slug can enter the sterilizer which will result in wet packs. (Moore, 2008) Accumulation of condensate builds up and forms a solid mass or slug and fills the pump. Reasons for the accumulation of steam will be described later. If the problem causing the rap location isn't resolved, it can damage the vents, traps, regulators and piping of the steam system. (Dutta & Dtar, 2008)

# **Steam Traps**

Steam traps are located throughout the steam delivery system to separate condensate which occurs as the steam moves through the system and cools. Leaking in the steam trap allows steam to escape along with the condensate. (Dutta & Dtar, 2008)

#### **Steam Lines**

Steam lines are installed to slope to facilitate movement of steam through the supply system.

The steam traps and drip legs are place to remove the condensate where the slopes meet. The design of the steam supply system must address level changes which occur along the path of the delivery

system. Steam pipes are held in place with anchors to maintain the slope. If these anchors are not properly placed it will affect the alignment of the pipe joints affecting the ability to deliver the quality of steam required. (Kirsner Consulting Engineering, Inc, 2002, p. 3)

# **Example of Steam Line**

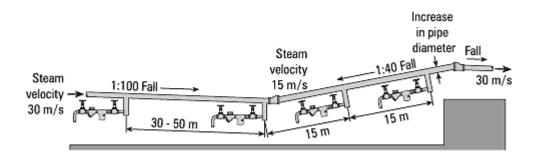
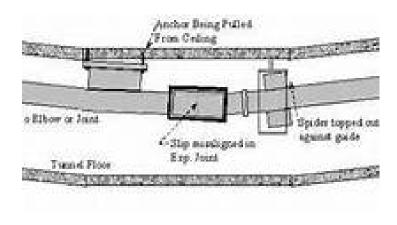


Diagram courtesy of piraxsarco.com

# **Example of Steam Pipe Anchor Failure**



Picture courtesy of Kirsner Consulting Engineering, Inc

### Insulation

Steam pipes need to be insulated to prevent heat loss as the steam moves through the system. Effective insulation may prevent up to 90% of heat loss as the steam moves through the steam delivery system which ensures steam quality. (Dutta & Dtar, 2008)

# **Example of Pour Steam Pipe Insulation**



Picture courtesy of InspectAPedia.com

### **Steam Line Size**

Steam pipes must be properly sized to allow pressure drop between the boiler and the user. Pressure drop affects the steam quality received at the sterilizer. Unused steam lines affect the pressure drop and need to be isolated or steam quality will be affected. (Dutta & Dtar, 2008)

# **Steam Pressure/Static/Dynamic**

Steam pressure need to be adjusted between the pressure being delivered and the pressure required by the user. (Duttar & Dtar, 2008) As steam flows through the system and condensate occurs, steam must continue to flow through the systems. As it bubbles through the condensate, it loses pressure. This is called static steam pressure or static pressure drop.

Dynamic steam pressure or dynamic pressure drop results as the steam flow is restricted as it passes through the system. (CSI. 2013)

# **Location of the Sterilizer Relative to Other Equipment**

The distance from boiler and the steam sterilizer should be the shortest route possible.

Steam quality delivered to the sterilizer is affected by dead end steam mains, dynamic and static pressure drops, pipe sizing and integrity of insulation. Duttar & Star, 2008)

# **Boiler Sizing/Drum Size/Water Level**

The size of the facility and steam requirements determines the size and number of boilers for effective steam production. Drum size and water levels effect the amount of steam produced. Steam producers understand steam production but not sterilizing equipment. Sterile Processing Managers understand sterilizing equipment. It is important for them have an effective working relationship to help each department meet each of their needs. This is critically true during renovation or construction projects which may affect the amount of steam required for all facility functions. (Moore, 2008)

Assessment of the efficacy of the steam supply system may require enlisting outside resources to determine the cause of wet packs. Facility Management staff are charged with the maintenance of a steam supply system but may not understand all the nuances of the proper construction of the system. This decision will need to be made by the Facility Manager.

# **Packaging of Instruments**

Sterile Processing Technicians are experts at packing instruments for sterilization. It is a process they complete many times every day. It is important to assess the current practice of instrument assembly and packaging to ensure the principles for packaging of instruments hasn't been compromised with subtle practice changes.

Members of the surgical team, while concerned for providing sterile instruments to their patients, also must contend with efficient room turn over. They may ask to reconfigure surgical trays and packaging to reduce the amount of time spent in opening sterile trays. Their requests may not meet requirements for effective steam sterilization. Collaboration between sterile processing management and the surgical team is essential to prevent such situations. Configuration of surgical trays when experiencing wet pack issues needs to be assessed to ensure they are one of the factors causing wet packs.

#### **Package Material Selection**

Techniques use to prepare instruments for set assembly and the packaging material used for packaging may have a direct effect on the sterilization process. When being faced with wet pack or staining issues, the Sterile Processing Manager must review current practices related to instrument preparation and packaging that are being use. This is part of the assessment process required to determine wet pack and staining issues. Brown & Bliley, 2008)

When selecting packaging material for steam sterilization processing, the packaging should:

- Allow for adequate air removal from the package and permit steam penetration of the package contents
- Provide an adequate barrier to microorganisms or their vehicles
- Resist tearing or puncturing
- Allow a method of sealing which provides a complete tamper proof seal
- Allow easy aseptic presentation
- Be free of toxic ingredients and nonfat dyes
- Be cost-effective. (ANSI/AAMI ST79:2010 & A1 & A2, 2010, p. 67)

### **Wrapping Material**

Before using wrapping material, it should be held at room temperature (20°C to 23°C {68°F to 73°F}) in a relative humidity of 30% to 60%.

When wrapping trays, the wrap should be kept snug to prevent low spots that could collect condensate on the outside of the package. At the same time, it should not be wrapped too tightly because strike through of moisture could occur.

Wrapping material manufacturer's instructions for use must always be followed to ensure sterilization parameters are met. (ANSI/AAMI ST79:2010 & A1 & A2, 2010, p. 67)

# **Example of Properly Wrapped Package**



Picture courtesy of fisherscl.com

### **Rigid Containers**

Rigid containers must be scientifically proven to be suitable for the selected sterilization cycle being used. Filter materials used must also be tested and have documented effectiveness for the container system used and the selected sterilization cycle. Rigid container manufacturer's instructions for use must be followed to ensure adequate sterilization. (ANSI/AAMI ST79:2010 & A1 & A2, 2010, p. 67)

# **Peel Pouches**

Paper -plastic peel pouches are used for small light weight instruments. In the event the double peel pouch is required, the inner peel pouch must not be folded and the pouches should be paper to paper and plastic to plastic to allow steam permeation. Peel pouch manufacturer's instructions must allow for using the double peel pouching techniques. Use of peel paper-plastic peel pouches inside instrument trays is an unacceptable practice in any form unless the practice has been validated by the peel pouch manufacturer. The laminate side of the peel pouch does not allow steam to permeate to the instruments below. Steam may also condensate inside the peel pouch. (ANSI/AAMI ST79:2010 & A1 & A2, 2010, p. 73)

#### Instrument Placement

Guidelines for instrument placement in trays and rigid containers to minimize the possibility of condensation in the container include:

- When using a container system, it should be large to allow containment of all instruments within the basket. Metal mass of the instruments should be evenly distributed within the basket.
- Instruments must not be held together with rubber bands.
- Items with concave surfaces or broad flat surfaces that will retain water should be placed on edge to facilitate drainage.

Use of the mesh tray, ensuring instruments are not bundled together in a large metal mass and placing items that will retain surface water will minimize pooling of condensation which can lead to moisture in the container at the end of the sterilization cycle. (ANSI/AAMI ST79:2010 & A1 & A2, 2010, p. 76 & 77)

## **Weight and Density**

Weight and density of trays, besides being an ergonomic issue, can affect the ability of the tray to dry. Distribution of the metal mass must allow proper drainage of condensate to prevent pooling resulting in wet packs. Random sampling of trays will determine if sets are dry at the end of the sterilization cycle.

## **Discoloration Instruments**

Surgical instrument spotting, staining and corrosion are serious problems in a number of health care facilities. These issues can impair the function of the instruments. Opening of instruments becomes difficult when corrosion occurs in the box lock area. Scissors become dull and instrument breakage can occur if corrosion is too severe. (Kaiser, Schwab, Trey, 2000)

Stainless steel instruments are manufactured with a protective layer called the passive layer.

When the passive layer of the instrument is damaged when being cleaned and sterilized the areas will

begin to corrode. Possible causes of damage related to processing of instruments in sterile processing include:

- Harsh cleaners
- Soil residues left on the instruments
- Not following manufacturer instructions for dilution of detergents
- Use of reusable instrument wraps
- Hard water deposits when instruments are rinsed with water other than deionized water or softened water
- Impurities in steam. (Kaiser, Schwab, Trey, 2000)

# **Instrument Cleaning**

During cleaning of instruments care must be taken to follow instrument manufacturer's instructions for use to ensure proper debris removal. Brown stains can occur on instruments with incomplete removal of debris. A procedure to test for organic debris is:

- Use a dropper to place several drops of 3% hydrogen peroxide on the stained area of the instrument.
- Check for the formation of bubbles.

Interpretations of the results of this test are:

- Rapid foaming indicates excessive debris is present.
- Formation of small isolated bubbles indicates old debris from previous cleaning is present.
- No bubble formation indicates the stain is not a result of debris. (Lewis)

### **Brown Stains**



## Picture courtesy of www.quickmedical.com

In addition manufacturer's instructions for use for detergents, cleaners and instrument lubricators including dilution rates, required temperature and rinsing must be followed. The nearly neutral pH and low siding properties of detergents make them difficult to rinse. (Lewis)

Two common stains found on instruments processed in low impingement washers are either black or orange in color. Low impingement washers use a highly alkaline detergent followed with an acidic rinse to neutralize the alkalinity. The black color occurs when the alkaline detergent is not completely neutralized. The rust color means the alkalinity has been over neutralized. Measuring the pH of the rinse water before it is used and then checking the pH after the rinse cycle will determine the adjustments required to the washer detergent deliver system. If the pH is 0.5 units higher than the initial

result, the alkalinity is not being neutralized. If the pH is 0.5 units lower than the initial result, the amount of neutralizer needs to be reduced. (Kaiser, Schwab, Trey, 2000)

# **Problems with Wrapping Material**

For those in Sterile Processing who still use linen when processing instruments, either as wrap or tray liners, staining of instruments will occur if the linen material is not completely rinsed. Another issue is linens treated with excessive amounts of chemical, or the chemicals are not compatible with the chemicals used in steam production. A chemical reaction can also occur with the chemicals in the linen and chemicals which make up disposable wrap. (Lewis)

During the cleaning process in commercial laundries, linens are processed in s strong alkaline detergent to clean them. This process is followed by a rinse. Then the linen is processed in an acidic rinse called laundry sour is used. The purpose of the laundry sour is to neutralize the alkalinity in the detergent. If the alkaline detergent is not completely neutralized, it can react to the high temperatures in the sterilization process and leach onto the instruments. (Kaiser, Schwab, Trey, 2000)

The residues left in linen after rinsing may be alkaline or acidic in nature. A simple test for determining if the linen wrap may be a cause of the issue involves deionized water. The DI water is boiled and tested for pH level. A sample of wrap is immersed in the boiling water and boiled for a period of time. Remove the wrap and test the water for pH level. The difference between the first and final pH is more than 0.5 pH units there is residue present. If the final pH is 0.5 pH units greater than the initial pH, the residue is alkaline. The residue is acidic if the pH is 0.5 pH units less than the initial pH level. (Kaiser, Schwab, Trey, 2000)

If the water is foamy during the boiling procedure, there may be detergent residues present in the left in the linen. (Kaiser, Schwab, Trey, 2000) STERILE PROCESSING Managers need to collaborate with the Linen Department responsible for washing the linen to ensure proper rinsing occurs.

# **Poor Quality Steam**

That steam quality is important to the sterilization process has been established. When steam is carrying unnecessary chemicals, they can be deposited on the instruments during the sterilization process. (Lewis)

Ensuring the steam quality is high can be done by ensuring the boiler water and steam is routinely monitored. Inadequate maintenance of the boiler can result in boiler chemicals being carried into the steam. Steam traps and filters associated with steam sterilizers also need to be checked and cleaned regularly. Steam lines need to be flushed when major adjustments are made to the boiler. (Kaiser, Schwab, Trey, 2000)

# **Stains on Instrument Packing**

Chemicals are found in all areas of processing in sterile processing. They are in the detergents and lubricants used in decontamination of instruments. The water used in the cleaning process may contain chemicals. Disposable wrapping materials are made of chemicals. Chemicals are used in steam production.

When items are placed in the steam sterilizer and become wet, these chemicals can be released inside the chamber. Over time, these substances accumulate on the sterilizer walls. (STERIS, 2013)

Oxidation causes rust, greenish or black residue to build up. (Zimmerman) These build ups affect the efficiency of the sterilizer including the ability to dry. (Zimmerman) This residue can contaminate packages. To prevent this accumulation sterilizer chambers and loading cars must be cleaned on a routine basis. This cleaning can be done by staff in the facility or bringing a professional sterilizer cleaning service.



Pictures courtesy of zimmercontract.com

# **Quality Management Program**

Sterile Processing Managers complete a number of quality management programs routinely.

Quality management programs include but are not limited to: biological monitoring of sterilizers, BowieDick testing for prevacuum sterilizers, process monitoring for equipment used in decontamination and
so on. A comprehensive quality management which proactively identifies when deficits to processing of
instruments may occur will include water and steam programs.

# **Water Quality Assurance Program**

One quality process when may need to be instituted is water quality assurance. According to AAMI TIR34:2007, "Water quality is an important consideration at all stages of medical device reprocessing. Ensuring adequate water quality in device reprocessing requires collaboration between personnel who reprocess medical devices and the personnel who establish and maintain the water treatment system."

Water systems can be treated in a variety of ways and produce different levels of water quality.

As the chemical quality of the water improves, the microbial content may increase unless the system is closely monitored. Gram-negative bacteria and no tuberculosis mycobacterium can grow in any type of

water. It is important to prevent problems in the water delivery system through a water quality monitoring process. (AAMI TIR34-2007)

# **Wet Pack Monitoring**

The first discovery of a wet pack situation requires establishment of documentation of each instance found. One document is the Wet Pack Log:

Sterilizer	Gravity	Date	Time	Wet	Location	Comments:	Ехро-	Exposure	Dry
#	or		of	Item	in the	Nature of	sure	Tempera-	Time
	Prevacuum		Day		load	Wetness	Time	ture	
	Cycle								

(Karle & Ryan. 1983, p. 50)

Several of these columns are self explanatory: sterilizer #, gravity or prevacuum, wet items, exposure time, exposure temperature and dry time. For the others, the reasons for keeping the date are:

- Date and time are important to determine what other departments are using steam which may affect the delivery of steam to the sterilizers.
- Location in the load. Which rack of the loading car is the item on? How close to the steam entry point? How near the drain? This data is necessary to help pinpoint a cause.
- Nature of the wetness. How wet is it and where is it wet? Is it too much condensate or is the dry time inadequate for the item.
- Another item than could be documented is type of wrapping material used in the tray. Should a change in wrapping practice occur to eliminate excess linen?
- Documentation of the number of sterilizers running at the time may also be helpful information.

There may be other information the Sterile Processing Manager wants to gather during this investigation. The information provided by Karle and Ryan is a starting point that can be modified to meet the needs of the specific department.

### Conclusion

Sterile Processing Managers are charged with ensuring sterile instruments are available to care for patients in a number of areas in the healthcare facility. This is accomplished by following regulatory body requirements, recommended practices, creating standard operating procedures, educating Sterile Processing Technicians and monitoring processes involved in all aspects of Sterile Processing Department processes. The majority of the time, successful processing of instruments is achieved.

That changes when the first wet pack is discovered or the surgical department notifies the Sterile Processing Manager that instruments are discolored or corroded. This is when the Sterile Processing Manager must reach out to other department managers to determine what is happening to the sterilization process. The Sterile Processing Manager must accept that while the problem may be due to a steam quality issue or a laundry issue it also may by a sterile processing issue. It may be a combination of issues is several departments. To solve the immediate issue, the Sterile Processing Manager needs to bring an interdisciplinary team including Facilities, Linen, Surgery, Biomedical Engineering and the sterilizer manufacturer together in a cohesive team. To create this cohesive team, the team members need to accept their departments may be part of the issue.

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