



Faculty of Engineering
Department of Textile Engineering

Thesis Paper

On

Sterilization of Medical Textile

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A thesis submitted in partial fulfillment of the requirements for the degree
of

Masters of Science in textile engineering

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DECLARATION

I hereby declare that the work which is being presented in this thesis entitled, “**Sterilization of medical textile**” is original work of my own, has not been presented for a degree of any other university and all the resource of materials uses for this thesis have been acknowledged.



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To

My

Beloved

Parents

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CONTENTS

	Page no.
Chapter-1	
Introduction	2
Chapter-2	
Literature survey / review:	
2.1 Technical textile	4
2.2 Medical textile	10
2.3 Sterilization of medical textile	20
Chapter-3	
Experimental details and survey details etc.	
3.1 Steam sterilization	46
3.2 Study about autoclave sterilization	47
3.2.1 Jahurul islam medical college and hospital, Bajitpur, Kishoregonj.	47
3.2.2 Holy Family Red Crescent Medical College, Dhaka.	50
3.2.3 Mymensingh medical college, Mymensingh.	54
3.7 A common test for sterilization	57
Chapter-4	
Discussion of results	60
Chapter-5	
Conclusion	63
References	65

LIST OF TABLES

Sl. No.	Table	Page no.
1.	Applications of different fiber in medical field	11
2.	Product application on fiber & fabric type	13
3.	Textile implants	16
4.	Non-implantable materials	18
5.	Sterilization categories	21
6.	The relationship between the pressure and temperature of steam at sea level	28
7.	The effect of container size on autoclave sterilization times for liquid solutions	30
8.	Summarizes the results	43
9.	Process details of autoclave treatment	58
10.	Summary of microbiological test	58

LIST OF FIGURES

Sl. No.	Figure	Page no.
1.	Technical textiles	4
2.	The complexity of the technical textile process chain	5
3.	Global technical textile industry outlook	9
4.	Medical textile	10
5.	Constituent element of medical textile products	10
6.	Classification of medical textiles	12
7.	Bio medical textiles	19
8.	Steam autoclave	25
9.	Steam autoclave diagram	26
10.	Graph showing relationship between temperature and pressure	27
11.	Graph showing relationship between number of living microbes with time	28
12.	Mechanism of continuous sterilization	37
13.	Process diagram of cosmetics sterilization	39
14.	Theory of operation	40
15.	preservation by sterile packaging	44
16.	Process of steam sterilization	46
17.	Operator shows the machine function.	47
18.	Shelves of autoclave room	48
19.	Front view of autoclave machine	48
20.	Auto-cleave room	48
21.	Result of micro-biological test (gauge sample taken from Jahurul islam medical college and hospital).	49
22.	Front view of autoclave machine.	50
23.	Side view of autoclave machine.	51
24.	Pressure meter of autoclave machine	51

25.	Temperature meter of autoclave machine	51
26.	Me,in front of autoclave machine.	52
27.	Different types of box for auto-clave.	52
28.	Result of micro-biological test (gauge sample taken from holy family red crescent medical college, Dhaka).	53
29.	Autoclave room of Mymensingh medical college	54
30.	Autoclave room of Mymensingh medical college	55
31.	Front view of autoclave of Mymensingh medical college	55
32.	Meters of autoclave of Mymensingh medical college	55
33.	Result of micro-biological test (gauge sample taken from Mymensingh medical college, Mymensingh)	56
34.	A sterilization indicator tape	57
35.	Before sterilization indicator tape	57
36.	After sterilization indicator tape	57

ABSTRACT

A large quantity of textile products is used by the medical personals and in the hospitals. Attempt has been made to see the aspects of sterilization of these textile products. In this regards study has been conducted in three important medical organizations e.g.

1. Jahurul islam medical college and hospital, Bajitpur, Kishoregonj
2. Holy family red crescent medical college,Dhaka &
3. Mymensingh medical college, Mymensingh.

It found that the medical personals are very well aware about the aspect of sterilization. Each of the organizations has their own autoclave facility where they sterilized their gauge and bandages. The procedure of sterilization was studied and sterilized gauze samples were collected from each of the organization and subjected to microbiological test. It was observed that all the samples were perfectly sterilized.

CHAPTER-1

INTRODUCTION

INTRODUCTION

Textile has always been a part of healthcare. Combination of textile technology and medical sciences has resulted into medical textiles. Medical textiles are one of the faster growing sectors of the global technical textile industry.

Healthcare is a serious business which is not only influenced by practicing medical professionals but also by the manufacturers of diverse medical products. In today's healthcare environment, textile products are finding innovative applications which were not imaginable just a few years ago. The importance of textile materials in the medical field is credited to their excellent physical properties, such as strength, extensibility, flexibility, suppleness, air and moisture permeability and wicking.

Describes the different sterilization methods and technologies currently available in today's medical equipment sterilization market. Each method is reviewed in detail and major differences amongst each are highlighted.

Focus is given to the more common sterilization methods used and/or available for medical equipment in hospitals and clinics today. At the end of the paper, there is a conclusion and table, which summarizes the common sterilization methods. Six sterilization methods/products were isolated and ranked based on their sterile efficacy and applicability to medical instruments.

CHAPTER-2

LITERATURE SURVEY

2.1: technical textiles



Figure1: Technical textiles

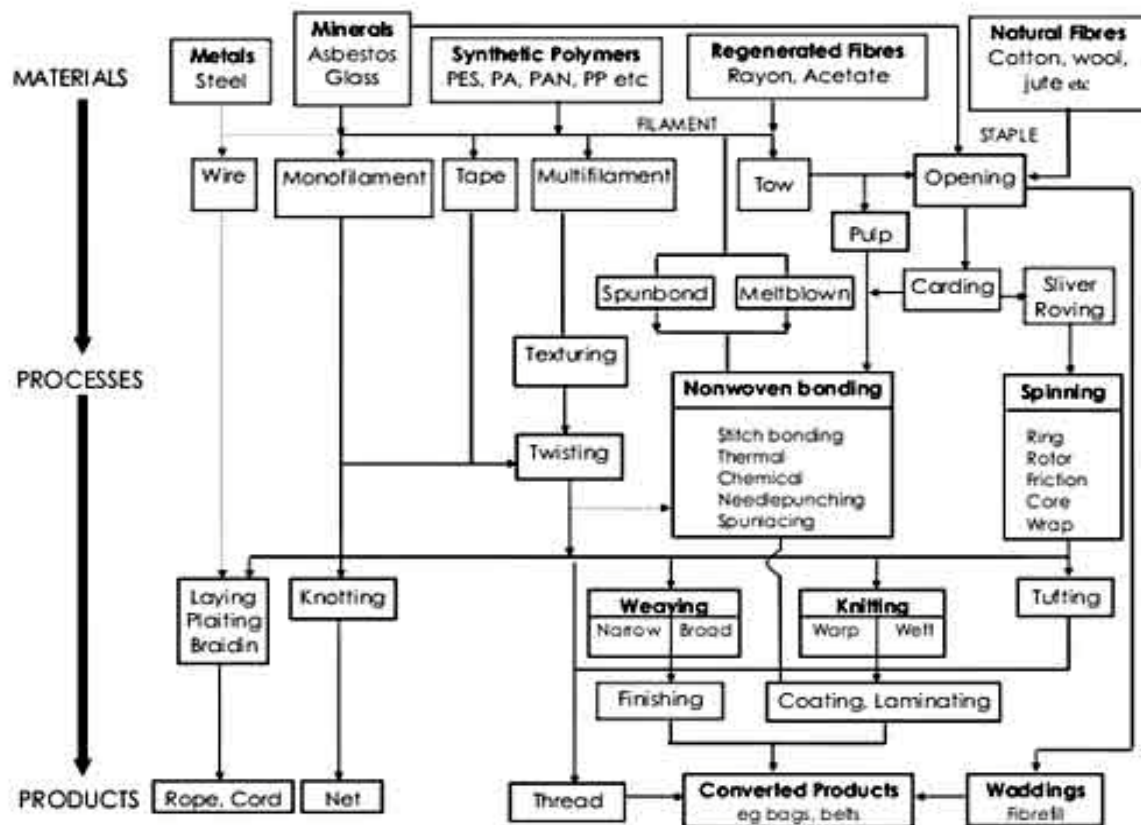
The term ‘technical textiles’ was coined in the 1980s to describe the growing variety of products and manufacturing techniques being developed primarily for their technical properties and performance rather than their appearance or other aesthetic characteristics. It largely superseded an earlier term ‘industrial textiles’ which had become too restrictive in its meaning to describe the full complexity and richness of this fast growing area.

A technical textile is a textile product manufactured for non-aesthetic purposes, where function is the primary criterion. Technical textiles include textiles for Automotive applications, Medical textiles (e.g., implants), Geotextiles (reinforcement of embankments), Agrotextiles (textiles for crop protection), and Protective clothing (e.g., heat and radiation protection for fire fighter clothing, molten metal protection for welders, stab protection and bulletproof vests, and spacesuits).

Over all, global growth rates of technical textiles are about 4% per year greater than the growth of home and apparel textiles, which are growing at a rate of 1% per year.

In present market opportunities and in free quota system the importance of technical textile materials is increasing to accommodate the needs of requirement. Now-a-days the most widely technical textile materials are used in filter clothing, furniture, hygiene medicals and construction material.

Figure 1: The complexity of the technical textile process chain



Source: David Rigby Associates

Figure 2: The complexity of the technical textile process chain

2.1.1: Classification

Technical textiles can be divided into many categories, depending on their end use. The classification developed by Tec textile, messes Frankfurt exhibition is widely used in Europe, North America and Asia. The classifications are:

2.1.1.1: Pro-tech (Protective textiles)

The main target of the technical protective fabrics is to improve people safety in their workplaces. A technical protective fabric can save a worker's life, that's why; most of them are mainly used to manufacture PPE (personal protective equipment). The demand of these fabrics is growing around the world thanks to the sensibilization of the society, requiring more safety at work. There are some organizations around the world (ASTM and ISO) which describe the requirements and regulations, to fulfill by a fabric, to be considered as a technical protective fabric. The aim of a technical protective fabric isn't fashion; they are designed to have extra values in protection, against some hazards.

Applications:

Nowadays it can be found in the market, technical fabrics which protect of:

- High temperatures (insulating, firefighters)
- Burns (flame, convective and radiant heat, firefighters, atex area)
- Electric arc flash discharge (plasma explosion, electric companies)
- Molten metal impacts (foundries)
- Metal sparks (welding)
- Acid environment (petrochemical, gas, refineries, chemical)
- Bullet impact (military, security)
- Cut resistant (gloves, glass industry)
- Astronaut's suits

These fabrics are made of different kind of fibers, because every blend apport different technical characteristics to the fabric:

- Meta-para aramides – nomex: high resistance, tear, tensile strength, expensive,
- Wool viscose's polyamide – marlan : repelency of molten metal, heat insulation, transparency.
- Glass fiber - high resistance, insulating.
- Modacrylic cotton – marko wiki: marko : electric arc flash protection, comfort, flame-resistant, multinorm, efficient, skin friendly, antistatic.
- Polyamide – Kevlar : extreme resistance, low ageing

2.1.1.2: Agro-tech (agro-textiles)

Textiles used in agriculture are termed as Agro textiles. They are used for crop protection, fertilization; the essential properties required are strength, elongation, stiffness, and bio-degradation, resistance to sunlight and resistance to toxic environment. All these properties help with the growth and harvesting of crops and other foodstuffs. There is a growing interest in using materials which gradually degrade.

Some of the examples of agro textiles are:

- Preventing erosion and paving way for a forestation in greenhouse cover and fishing nets.
- For layer separation in fields, nets for plants, rootless plants & protecting grassy areas.
- As sun screens (since they have adjustable screening) and wind shields.
- As packing material and in bags for storing grass (that has been mowed).
- Controlling stretch in knitted nets.
- Shade for basins.
- Anti-birds nets.
- Fabrics for sifting and separation, for the phases of enlargement of the larvae.
- Materials for ground and plant water management at the time of scarcity and abundance of water.

2.1.1.3: Mobil-tech (automotive and aerospace textiles)

These textiles are used in Automobiles, Ships and Aircraft. Many coated and reinforced textiles are used in materials for engines such as air ducts, timing belts, air filters, and non-woven for engine sound isolation. A number of materials are also used in the interior of cars. The most obvious are seat covers; safety belts and airbags but one can find textiles also for the sealing. Nylon gives strength and its bursting strength being high is used as air bags in cars.

Carbon composites are mostly used in the manufacture of aero plane parts while carbon fiber is used for making higher end tires. High tensile polyester is used for making air balloons.

2.1.1.4: Build-tech (construction textiles)

Textiles used in construction - concrete reinforcement, façade foundation systems, interior construction, insulations, proofing materials, air conditioning, noise prevention, visual protection, protection against the sun, building safety.

An interesting and aesthetic appealing application is the use of textile membranes for roof construction. This area is also referred to as textile architecture. PVC coated high tenacity PES, Teflon coated glass fiber fabrics or silicone coated PES are used for their low creep properties. Splendid examples of such construction are found in football stadia, airports and hotels.

2.1.1.5: Cloth-tech (clothing textiles)

Technical textiles for clothing applications. Especially in the finishing process where fabric is treated under pressure and high temperature the technical textile supports the fabric for smooth processing. This is usually the blend of Polyester, Modal, Viscose, Nylon, etc.

2.1.1.6: Lift-tech (lifting textiles)

Technical textiles for lifting applications. Used in process of lifting heavy goods. The textile produced is strongly woven with high tenacity yarns and the fabric is treated with heat and high temperature controlling its elongations. This is usually made of high tenacity polyester and nylon however hmpe yarns as dyneema are also used.

2.1.1.6: Geo-tech (geo-textiles)

These are used in reinforcement of embankments or in constructional work. The fabrics in geo textiles are permeable fabrics and are used with soils having ability to separate, filter, protect or drain. The application areas include civil engineering, earth and road construction, dam engineering, soil sealing and in drainage systems. The fabric used in it must have good strength, durability, low moisture absorption and thickness. Mostly nonwoven and woven fabrics are used in it. Synthetic fibers like glass, polypropylene and acrylic fibers are used to prevent cracking of the concrete, plastic and other building materials. Polypropylene and polyester are used in geo textiles and dry/liquid filtration due to their compatibility.

2.1.1.7: Home-tech (domestic textiles)

Textiles used in a domestic environment - interior decoration and furniture, carpeting, protection against the sun, cushion materials, fireproofing, floor and wall coverings, textile reinforced structures/fittings.

In the contract market such as for large area buildings, ships, caravans, busses, Fire retardant materials are used. Fire retardant properties are obtained either through the use of inherent fire retardant fibers such as modacryl or through the application of a coating with fire retardant additives (bromide of phosphorus compounds).

2.1.1.8: Indu-tech (industrial textiles)

Textiles used for chemical and electrical applications and textiles related to mechanical engineering. Silk-screen printing, filtration, plasma screens, propulsion technology, lifting/conveying equipment, sound-proofing elements, melting processes, roller covers, grinding technology, insulations, seals, fuel cell.

2.1.1.9: Mobil-tech (textiles used in transport)

These textiles are used in the construction of automobiles, railways, ships, aircraft and spacecraft. Examples are truck covers (PVC coated PES fabrics), car trunk coverings (often needle felts), lashing belts for cargo tie downs, seat covers (knitted materials), seat belts, non-woven's for cabin air filtration (also covered in indutech), airbags, parachutes, boats (inflatable), air balloons.

2.1.1.10: Oeko-tech or eco-tech (environmentally friendly textiles)

New applications for textiles in environmental protection applications - floor sealing, erosion protection, air cleaning, prevention of water pollution, water cleaning, waste treatment/recycling, depositing area construction, product extraction, domestic water sewerage plants.

2.1.1.11: Pack-tech (packaging textiles)

Packaging, silos, containers, bags, lashing straps, canvas covers, marquee tents.

2.1.1.12: Sport-tech (sports textiles)

Shoes, sports equipment, flying and sailing sports, climbing, angling, cycling, winter and summer sports, indoor sport it can vary from anything including sports bags.

2.1.1.13: alternative spelling

These application areas are sometimes alternatively spelled: agrotex, buildtex, clothtex, geotex, hometex, indutex, medtex, mobiltex, oekotex (ecotex), packtex, protex and sportex.^[2]

Specific areas of application:

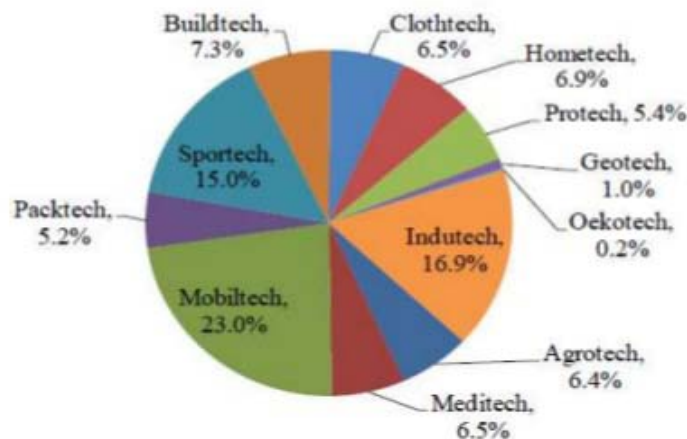
Conveyor belts

For industrial applications and in power transmission, technical textiles are used in conveyor belts. Carcass is a fabric inside the conveyor belt, which is responsible for the strength and stretch properties of the belt. This carcass is made with layers of woven fabrics bonded together.

Electronics in textiles

It has been heard that soon textiles will be merged with electronics in all areas. In future wearable computers would be launched, these will not be like advance wrist watches etc., they will contain ic s in fabric to develop fabric keyboards and other wearable computer devices. These types of products are known as interactive electronic textiles (iet). Research to support iet development is being conducted in many universities. Growing consumer interest in mobile, electronic devices will initiate the demand for iet products.

Global Technical Textile Industry outlook



Value-wise share of each segment in global technical textile market

Sources: Report of the Expert Committee on Technical Textiles (ECTT) Volume – I, 'World Market Forecasts for 2010 of technical textiles and industrial nonwovens' by David Rigby Associates

Figure 3: Global technical textile industry outlook

2.2: Medical textile



Figure 4: Medical textile

Combination of textile technology and medical sciences has resulted into a new field called medical textiles. New areas of application for medical textiles have been identified with the development of new fibers and manufacturing technologies for yarns and fabrics. Development in the field of textiles, either natural or manmade textiles, normally aimed at how they enhance the comfort to the users. Development of medical textiles can be considered as one such development, which is really meant for converting the painful days of patients into the comfortable days.

2.2.1 Constituent element of medical textile products:-

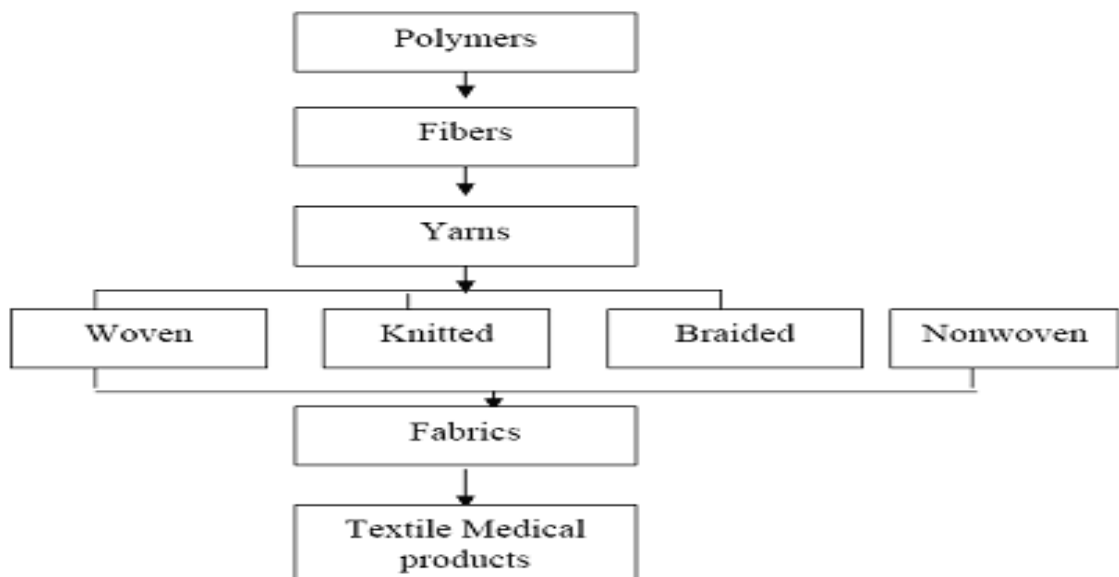


Figure 5: Constituent element of medical textile products

2.2.2. Characteristics of materials for medical use

The major requirements for biomedical polymers

- Non toxicity
- No allergenic response
- The ability to be sterilized
- Mechanical properties
- Strength
- Elasticity
- Durability
- Biocompatibility
- As biomedical materials may be contaminated with bacteria, sterilization is important for biomedical polymers. The sterilization technique can be physical or chemical.

2.2.3. Fibers used for medical and healthcare application

Textiles materials that are used in medical applications include fibers, yarns, fabrics and composites. Depending upon the application, the major requirements of medical textiles are absorbency, tenacity, flexibility, softness and at times bio ability or biodegradability.

Fibers used in medical field may vary from natural fiber such as cotton, silk, regenerated wood fluff (absorbent layer), to, manmade fibers like polyester, polyamide, polyethylene, glass etc.

The various applications of different fiber in medical field are shown as follows:

Table 1: Applications of different fiber in medical field

Fiber	Application in medical field
Cotton	Surgical clothing gowns, beddings, sheets, pillow cover, uniforms, surgical hosiery
Viscose	Caps, masks, wipes
Polyester	Gowns, masks, surgical cover drapes, blankets, cover stock
Polyamide	Surgical hosiery
Polypropylene	Protective clothing
Polyethylene	Surgical covers, drapes
Glass	Caps mask
Elastomeric	Surgical hosiery

A number of crucial issues regarding medical products in general and healthcare and hygiene products in particular have been identified and debated amongst clinicians, environmentalist, drug companies etc. For a long time. The issues such as

- Natural against chemical or manufactured fibers
- Disposable against reusable or durable fabrics

- Antibacterial or antimicrobial fibers against finishes or coatings for infection control.
- Methods of disposal of clinical waste i.e. Landfills against incineration and other forms of medical and clinical waste disposal

There is general move towards an increased use of natural polymers that are biocompatible, biodegradable and nontoxic

2.2.4 Classification of medical textiles

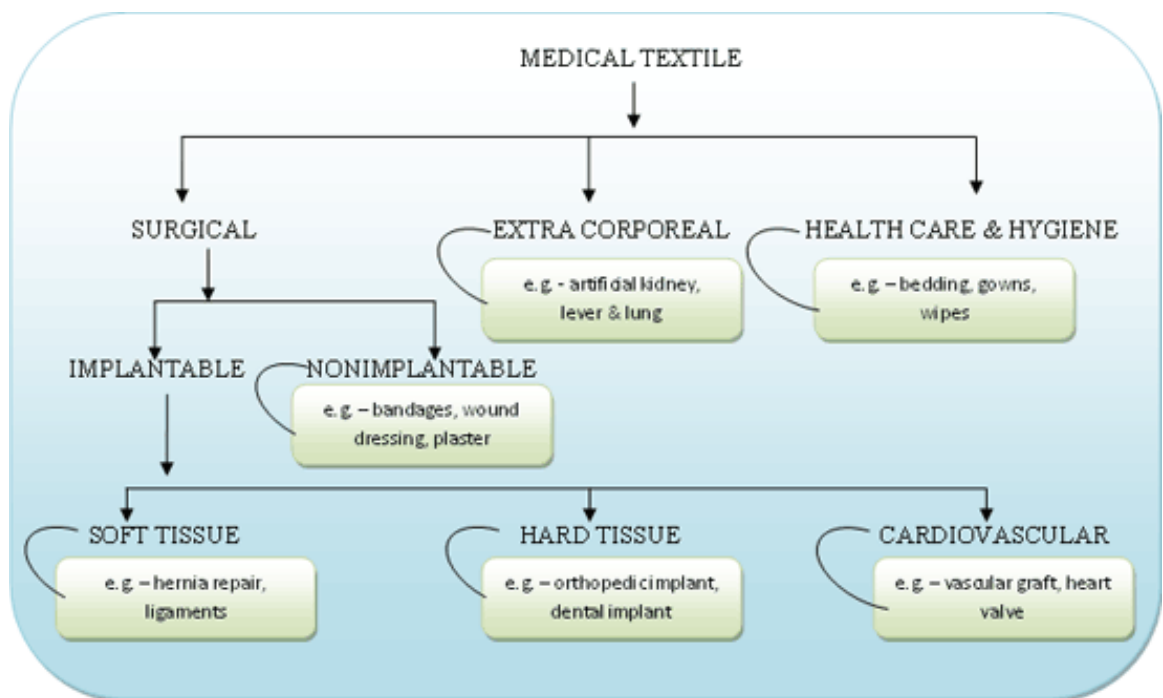


Figure 6: Classification of medical textiles

These are the textile products for medical applications include materials as fibers, yarns, woven, knitted, nonwoven, pte felts and mesh etc.

Depending upon the usage, they are classified as:

- I . Healthcare and hygiene products
- II . Extracorporeal devices
- III . Implantable materials
- IV . Non-implantable materials

I: Healthcare & hygienic products:

An important area of textile is the healthcare and hygiene sector among other medical applications. The range of products available for healthcare and hygiene is vast, but they are typically used either in the operating theatre or in the hospital wards for hygienic, care and safety of the staff and patients. They could be washable or disposable.

Operating theatre:-

This includes surgeon's gown, caps and mask, patient drapes and cover cloth of various sizes.

Surgical gown: -

It is essential that environment of operating theatre is clean and strict control of infection is maintained. A possible source of infection to the patient is the pollutant particle shed by the nursing staff, which carries bacteria. Surgical gowns should act as barrier to prevent release of pollutant particles into air. Traditional surgical gowns are woven cotton goods that not only allow the release of particles from the surgeons but also a source of contamination generating high levels of dust (lint). Disposable non woven surgical gowns have adopted to prevent these sources of contamination to patients and are often composite materials of nonwoven and polyethylene films.

Surgical masks:-

They should have higher filter capacity, high level of air permeability, lightweight and Non allergic.

Healthcare and hygiene products:

Table 2: Product application on fiber & fabric type

Product application	Fiber type	Fabric type
Surgical clothing gowns	Cotton, polyester, viscose rayon, polypropylene	Nonwoven, Woven
Caps masks	Viscose rayon, polyester, viscose, glass	Nonwoven Nonwoven
Surgical covers Drapes cloth	Polyester, polyethylene Polyester, polyethylene	Nonwoven or woven Nonwoven or woven
Beddings, Blankets, sheets Pillow covers	Cotton, polyester Cotton Cotton	Woven, knitted Woven Woven
Clothing uniforms Protective clothing	Cotton, polyester Polyester, polypropylene	Woven Nonwoven
Incontinence diaper sheet Cover stock Absorbent layer Outer layer	Polyester, polypropylene Wood fluff Super absorbents Polyethylene fiber	Nonwoven Nonwoven Nonwoven
Cloths/ wipes	Viscose rayon	Nonwoven
Surgical hosiery	Polyamide, polyester, cotton, elastomeric yarns	Nonwoven Knitted

Surgical caps: -

These are made from nonwoven materials based on cellulose.

Surgical drapes and cover cloths: -

These are used to cover patients or to cover working areas around patients. It should be completely impermeable to bacterial and also absorbent to body perspiration and secretion from wound.

Hospital ward:

This includes beddings, clothing, mattresses covers, incontinence products, clothes and wipes e.g. in hospital cross infection should be prevented and hence traditional woolen blankets replaced by cotton leno woven blankets.

Incontinence products for patients are available in both diaper and flat sheet forms with later used for bedding. Cloths and wipes are made from tissue paper or nonwoven bonded fabrics, which may be soaked with an antiseptic finish.

Super absorbent fibers for healthcare and hygiene products

They absorb up to 50 times their mass of water, whereas the conventional wood pulp and cotton linter absorbents absorb approximately 6 times their mass of water. The superabsorbent fibers offer advantage as compared to superabsorbent powders due to their physical form, or dimensions, rather than their chemical structure. Whilst they do absorb fluids to a similar level as powder, they do, however, do it faster. This is due to the small diameter of the fibers ($\approx 30\mu$), which gives a very high surface area for contact with the fluid. Typically fiber will absorb 95% of its ultimate capacity in 15 seconds.

II. Extracorporeal devices

These are extra corporeally mounted devices used to support the function of vital organs, such as kidney, liver, lung, heart pacer etc. The extracorporeal devices are mechanical organs that are used for blood purification and include the artificial kidney (dialyzer), the artificial liver, and the mechanical lung. The function and performance of these devices benefit from fiber and textile technology.

Artificial kidney:

- Tiny instrument, about the size of a two-cell flashlight.
- Made with hollow hair sized cellulose fibers or hollow polyester fibers slightly larger than capillary vessels.
- Fabric, which is used to remove waste products from patients blood.

Artificial liver:

Made of hollow viscose to separate and dispose patient's plasmas and supply fresh plasma.

Artificial heart:

- An 8-ounce plastic pump lined with decom velour to reduce damage to blood.
- Chambered apparatus about the size of human heart
- Silastic backing makes the fabric impervious to emerging gas that is not desirable in the blood.

Mechanical lung:

- made with a hollow polypropylene fiber or a hollow silicone membrane.
- used to remove carbon dioxide from patients blood and supply fresh oxygen.

III. Implantable materials:

Textile fibers, yarns, fabrics, composites and 3-d shaped fabrics from woven, knitted, nonwoven, braided and embroidery play a vital role in the manufacture of various implants, including the replacement of diseased or non-functioning blood vessels and segments of aorta or other big arteries. It is even feasible to produce vascular prosthesis as fine as 2-3mm in diameter.

These materials are used in effecting repair to the body whether it is wound closure (sutures) or replacement surgery (vascular grafts, artificial ligaments etc)

Biocompatibility is of prime importance if textile materials are to be accepted by the body and four key factors will determine how the body reacts to the implants

- The most important factor is porosity, which determines the rate at which human tissue will grow and encapsulate the implant.
- Small circular fibers are better encapsulated with human tissue than larger fibers with irregular cross sections.
- The fiber polymer must not release toxic substances, and fiber should be free from surface contaminants such as lubricants and sizing agents.
- Biodegradable

Why textile implants?

- Biocompatible materials
- Material combinations
- 2d- and 3d-structures
- Mechanical characteristic adapted to the environment
- Adjustable macroscopic structure
- Specific surface design

Table 3: Textile implants

Products		
Sutures Bio – degradable Non- Bio degradable	Collagen, polyactide, polyglycoide Polyester fiber, polyamide fiber, Polytetrafluoroethylene, polypropylene fiber, steel, polyethylene	Mono filament braided
Soft – issues Implants Artificial tendon Artificial ligament Artificial skin Eye contact lenses / Artificial lumen	Polytetra fluoro ethylene fiber polyester fiber, polyamide fiber silk Ploytetrafluoro fibre Polyester fibre, carbon fibre Natural skin equivalent (dried pig skin, collagen, chittia) silicon/ nylon, polypeptides, silicon, collagen / glycosaminoglycans/ hybrid skin equivalents) polymethyl/ metha relate fibre/ silicone collagen fiber	Woven Braided
Orthopedic implants Artificial joints /bones	Silicone, Polyacetyl fibre, polyethylene/ appetite polysulphone Carbon fibre, polyethylene terephthalete glass ceramic	
Cardio vascular implants Vascular grafts, heart valves	Polyester fibre Polytetra fluoro ethylene fiber. Polyester fibre.	Knitted woven Knitted, woven

Polyamide is most reactive material losing its overall strength after only 2 years as a result of biodegradation. e.g. Sutures, soft tissue implants, orthopedic implants, cardiovascular implants etc.

Vascular prosthesis:

The first artificial vascular graft was produced from polyamide fiber in 1956. Polytetrafluoroethylene (PTFE) fiber soon replaced polyamide and then polyester fiber was introduced. The implants are made from variety of synthetic materials. The main fibers include polyester, PTFE. Polypropylene, polyacrylonitrile. However polyester and PTFE are most common vascular prosthesis currently available.

The major requirements of a good vascular graft include

- Non-fraying
- Flexibility
- Durability
- Biocompatibility
- Stability to sterilization
- Resistance to bacteria/viruses

Knitted polyester vascular prosthesis has become the standard vascular graft for replacement of arterial vessels of 6mm and greater. However while this has many features required by a surgeon, such as ease of handling, satiability, and

conformability, it has one major disadvantage; it is not blood-tight. The knitted structure, by its nature, is porous, which is what is required for rapid incorporation by tissue in growth from the host. At the time of surgery the surgeon has to percolate the graft using some of the patients own blood, which is taken before heparinisation- a time consuming process which can be difficult to carry out satisfactorily. This prevents its use when patients are heparinised such as cardiopulmonary bypass and in emergency aneurismal surgery when percolating is not possible.

The potential for localized delivery of antibiotics from braided surgical sutures. It is an attempt to address the problem of nosocomial infections associated with braided sutures; they have proposed the incorporation of a restorable antibiotic coating. The sutures coating has been engineered to release its active ingredients locally during the first few days following surgery. Two broad spectrum antibiotics with superior gram-positive activity, moxifloxacin and clindamycin were selected and each incorporated at two levees of loading into a reasonable

Epsilon-caprolactum glycolide copolymer which was then coated onto polyester braided sutures. In vitro exposure experiment to phosphate buffered saline (pbs) were undertaken at room temperature for a period of 5 days in order to determine the duration and efficacy of the released antibiotic against a standard strain of staphylococcus aurous. The results from zone of inhibition tests demonstrated that both antibiotics provided effective prophylactic bacteripostatic properties for periods of up to 2 days.

A suture should be chosen with the following properties of importance: -

- Tensile strength
- Stiffness
- Easy handling properties
- Good knotting security

IV. Non-implantable materials:

These materials used for external applications on the body and may or may not make contact with skin. They are made from co-polymer of two α amino acids.

This includes wound care, bandages, plasters, pressure garments, orthopedic belts etc.

Table 4: Non-implantable materials

NON – IMPLANTABLE MEDICAL TEXTILES		
Wound care absorbent pad Wound contact layer base materials	Cotton, viscose silk, polyamide fiber viscose, polyethylene fiber viscose plastics film	Non – woven knitted woven, non woven.
Bandages simple inelastic/ Elastic light support Compression	Cotton viscose polyamide fiber, Elastomeric-fiber yarns, cotton, viscose, electrometric fiber, electrometric fiber yarns	Woven, knitted, Non – woven Woven, knitted woven Knitted
Orthopedic	Cotton, viscose Polyester fibre, Polypropylene fiber, polyurethane foam	Woven , non- woven
Plasters	Viscose, pasties film, polyester fibre, glass fiber, polypropylene fibre	Knitted woven Non woven
Gauze's	Cotton, viscose	Woven, non- woven
Lint	Cotton	Woven
Wadding	Viscose, cotton, linters, wood pulp	Non- woven

Surgical dressing:-

These are employed as coverings, adsorbent, protective and supports for injured or diseased part. They are different types

- Primary wound dressing
- Absorbent
- Bandages
- Protective
- Adhesive tapes

Primary wound dressing:

- placed next to the wound surface
- Nonwovens with a binder content of 60% and made of cellulose fabrics are being used.

A dressing should possess the following properties:

- Healing properties, regulated mainly with the substances which are applied to or added to the dressing.
- causing no mechanical injury of a granulating wound.
- decreased adherence surface.
- eliminating a possibility of loose fibers getting caught in the wound.
- Stable and spatial structure
- Easy penetration of wound secretion to the absorbing dressing.
- not- interrupted process of wound healing - as only the outer gauze compress is changed.
- Painless changing of the dressing.

Absorbent:

Similar to wound pads used in surgery. Manufactured from well bleached, carded and cleaned cotton fabrics. Absorbent lint is cotton of plain weave, warp nap raised on one side, by a process known as linting epi 36, ppi 32, used as an external absorbent and

protective dressing and for the applications of ointments and lotions, as antiseptic adsorbent and protective dressing in first aid treatment.

Surgical and other gauze provide absorbent materials of sufficient tensile strength for surgical dressing. They are made of cotton gauze loosely woven. Now-a-days nonwovens are used.

Bandages:

These are narrow cotton or linen, plain weave cloth of low texture, either woven or knitted. There are different types

- Cotton and rubber elastic net bandages- for sprains and strains
- Cotton rubber elastic net bandages- net fabric of lace construction.
- Plaster of Paris bandages- cotton cloth is impregnated with a mixture of calcium sulphate
- Orthopedic cushion bandages.
- Crepe bandage- elastic in nature due to special weave allows it to stretch twice its length.

The field of bio-medical textiles covers a large number of application areas. Bio-medical textiles include textile products that are used to [1]

1. Improve health and wellness – for example, hospital gowns and bed-sheets with antimicrobial treatments.
2. Maintain comfort and hygiene – for example, sportswear fabrics with improved air circulation and sweat management.
3. Treat an external injury – for example, wound dressings/bandages with improved haemostatic and wound healing properties.
4. Replace damaged tissue with implantable prosthesis – for example, artificial artery or heart valve.
5. Prevent an injury – for example, wrist, neck and back support fabrics.
6. Prevent infection – for example, face mask.
7. Surgical aids – for example, suture.
8. Deliver a drug – for example, nicotine patch.
9. Grow new tissue – for example, tissue engineering scaffold.

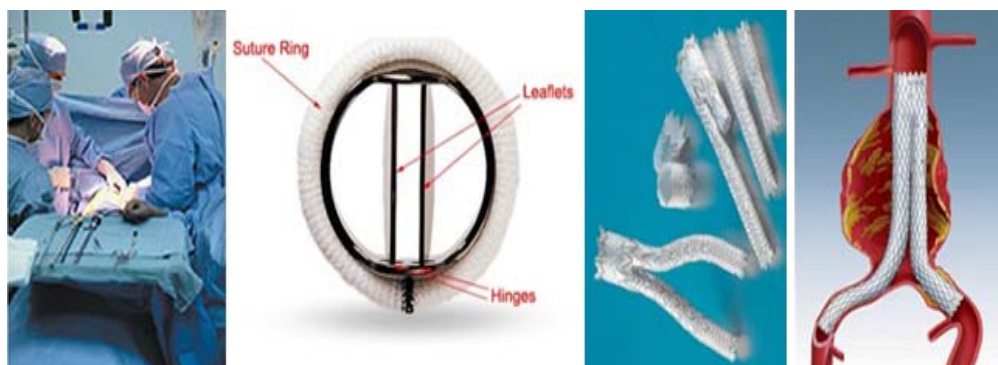


Figure 7: Bio medical textiles

2.3: Sterilization of medical textile

According to the CDC (centers for disease control and prevention), “sterilization means the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endoscopes.” Bacterial spores are the most resistant of all living organisms because their capability to withstand destructive agents.

Although the chemical or physical process used to destroy all pathogenic microorganisms including spores is not absolute, when all parameters of the sterilization process have been met, instruments, supplies and equipment are thought to be sterile. Sterilization is the process used to inactivate microbiological contaminants and thereby transform the non sterile items into sterile ones. It is essential for hospital applications that sterile products are employed, and there are various techniques by which this can be achieved. Sterilization by steam, dry heat, ethylene oxide, and irradiation process are used depending on the product type and fiber characteristics. A sterilization process can bring about changes in properties as strength, absorbency and appearance.

Many hospitals have added peroxide plasma systems, such as sterrad, to their standard steam autoclaves and ethylene oxide chambers in the central supply room. When designing fabrics for sterilization it is essential to understand the impact of sterilization procedures on fabric performance features. In the U.S., steam autoclaves generally operate at 250-2700 (121-132⁰c). In Europe, flash sterilization temperatures up to 138⁰c have been proposed in respect to concerns about jakob-cruetze disease. The polymer selection must be made with this type of temperature exposure in mind.

2.3.1. Sterilization vs. Disinfection:

While discussing this topic, it becomes important to distinguish between sterilization and disinfection. Sterilization results in destruction of all forms of microbial life, while disinfection results in destruction of specific pathogenic microorganisms.[2] because disinfection is faster and less expensive, some hospitals substitute high level disinfection for sterilization of medical instruments. An object should be disinfected or sterilized depending on its intended use. Critical objects (those that enter sterile tissues or the vascular system or through which blood flows, such as implanted medical devices) require sterilization before use. Items that touch mucous membranes or nonimpact skin, like endoscopes, respiratory therapy equipment, and diaphragms, require high-level disinfection.

Sterilization falls into the following three categories:

- High temperature/pressure sterilization (autoclave)
- Chemical sterilization
- Radiation sterilization

The following table summarizes the various sterilization methods available within each category:

Table 5: Sterilization categories [4]

Sterilization Categories		
	Common Methods	Others
High Temperature/Pressure	<ul style="list-style-type: none"> • Steam Autoclave 	<ul style="list-style-type: none"> • Dry Autoclave
Chemical	<ul style="list-style-type: none"> • Ethylene Oxide (EtO) • Sterrad[®] • Steris System 1[®] • Cidex[®] OPA Solution 	<ul style="list-style-type: none"> • Glutaraldehyde (Cidex Plus[®], Cidex[®]) • VHP[®] MD Series • Chlorine Dioxide • Ozone
Radiation	<ul style="list-style-type: none"> • Gamma 	<ul style="list-style-type: none"> • Electron Beam (E-Beam) • X-Ray

Quantification:

The aim of sterilization is the reduction of initially present microorganisms or other potential pathogens. The degree of sterilization is commonly expressed by multiples of the decimal reduction time D denoting the time needed to reduce the initial number N_0 to one tenth (10^{-1}) of its original value. Then the number of microorganisms N after sterilization time t is given by

$$\frac{N}{N_0} = 10\left(-\frac{t}{D}\right)$$

D is a function of sterilization conditions and varies with the type of microorganism, temperature, water activity, pH etc.. For steam sterilization typically the temperature (in °Celsius) is given as index. For sterilization a reduction by one million (10^{-6}) is minimally required with six times D . For transfusion or other venous injections 10^{-7} is typically required to reduce infection risks. For disinfection 10^{-5} is sufficient. Theoretically, the likelihood of survival of an individual microorganism is never zero.

2.3.2. Methods:

Reliable sterilization depends on contact of the sterilizing agent with all surfaces of the item to be sterilized. Selection of the agent to achieve sterility depends primarily upon the nature of the item to be sterilized. Time required to kill spores in the equipment available for the process then becomes critical.

Steam:

Heat destroys microorganisms, but this process is hastened by the addition of moisture. Steam in itself is inadequate for sterilization. Pressure, greater than atmospheric, is necessary to increase the temperature of steam for thermal destruction of microbial life. Death by moist heat in the form of steam under pressure is caused by the denaturation and coagulation of protein or the enzyme-protein system within the cells. These reactions are catalyzed by the presence of water. Steam is water vapor; it is saturated when it contains a maximum amount of water vapor.

Direct saturated steam contact is the basis of the steam process. Steam, for a specified time at required temperature, must penetrate every fiber and reach every surface of items to be sterilized. When steam enters the sterilizer chamber under pressure, it condenses upon contact with cold items. This condensation liberates heat, simultaneously heating and wetting all items in the load, thereby providing the two requisites: moisture and heat.

No living thing can survive direct exposure to saturated steam at 250 F (120° C) longer than 15 minutes. As temperature is increased, time may be decreased. A minimum temperature-time relationship must be maintained throughout all portions of load to accomplish effective sterilization. Exposure time depends upon size and contents of load, and temperature within the sterilizer. At the end of the cycle, re-evaporation of water condensate must effectively dry contents of the load to maintain sterility.

Ethylene oxide:

Ethylene oxide is used to sterilize items that are heat or moisture sensitive. Ethylene oxide (EO) is a chemical agent that kills microorganisms, including spores, by interfering with the normal metabolism of protein and reproductive processes, (alkylation) resulting in death of cells. Used in the gaseous state, eo gas must have direct contact with microorganisms on or in items to be sterilized. Because eo is highly flammable and explosive in air, it must be used in an explosion-proof sterilizing chamber in a controlled environment. When handled properly, eo is a reliable and safe agent for sterilization, but toxic emissions and residues of eo present hazards to personnel and patients. Also, it takes longer than steam sterilization, typically, 16-18 hrs. For a complete cycle.

EO gas sterilization is dependent upon four parameters: EO gas concentration, temperature, humidity, and exposure time. Each parameter may be varied. Consequently, EO sterilization is a complex multi-parameter process. Each parameter affects the other dependent parameters.

Dry heat:

Dry heat in the form of hot air is used primarily to sterilize anhydrous oils, petroleum products, and bulk powders that steam and ethylene oxide gas cannot penetrate. Death of microbial life by dry heat is a physical oxidation or slow burning process of coagulating the protein in cells. In the absence of moisture, higher temperatures are required than when moisture is present because microorganisms are destroyed through a very slow process of heat absorption by conduction.

Microwaves:

The non-ionizing radiation of microwaves produces hypothermic conditions that disrupt life processes. This heating action affects water molecules and interferes with cell membranes. Microwave sterilization uses low-pressure steam with the non-ionizing radiation to produce localized heat that kills microorganisms. The temperature is lower than conventional steam, and the cycle faster, as short as 30 seconds. Metal instruments can be sterilized if placed under a partial vacuum in a glass container. Small tabletop units may be useful for flash sterilizing a single or small number of instruments, when technology is developed for widespread use.

Formaldehyde gas:

Formaldehyde kills microorganisms by coagulation of protein in cells. Used as a fumigant in gaseous form, formaldehyde sterilization is complex and less efficacious than other methods of sterilization. It should only be used if steam under pressure will damage the item to be sterilized and ethylene oxide and glutaraldehyde are not available. Its use for sterilization has been almost abandoned in the United States, Canada, and Australia. The method dates back to 1820, and it is still used in Europe and Asia.

Hydrogen peroxide plasma:

Hydrogen peroxide is activated to create a reactive plasma or vapor. Plasma is a state of matter distinguishable from solid, liquid, or gas. It can be produced through the action of either a strong electric or magnetic field, somewhat like a neon light. The cloud of plasma created consists of ions, electrons, and neutral atomic particles that produce a visible glow. Free radicals of the hydrogen peroxide in the cloud interact with the cell membranes, enzymes, or nucleic acids to disrupt life functions of microorganisms. The plasma and vapor phases of hydrogen peroxide are highly sporicidal even at low concentrations and temperature.

Ozone gas:

Ozone, a form of oxygen, sterilizes by oxidation, a process that destroys organic and inorganic matter. It penetrates membrane of cells causing them to explode. Ozone is an unstable gas, but can be easily generated from oxygen. A generator converts oxygen, from a source within the hospital, to ozone. A 6 to 12 percent concentration of ozone continuously flows through the chamber. Penetration of ozone may be controlled by vacuum in the chamber, or enhanced by adding humidity. At completion

of exposure time, oxygen is allowed to flow through chamber to purge the ozone. Cycle time may be up to 60 minutes depending on the size of the chamber or load.

Chemical solutions:

Liquid chemical agents registered by the epa as sterilants provide an alternative method for sterilizing heat sensitive items if a gas or plasma sterilizer is not available, or the aeration period makes ethylene oxide sterilization impractical. To sterilize items, they must be immersed in a solution for the required time specified by the manufacturer to be sporicidal. All chemical solutions have advantages and disadvantages; each sterility has specific assets and limitations. These chemicals are: peracetic acid, glutaraldehyde, and formaldehyde.

Ionizing radiation:

Some products commercially available are sterilized by irradiation. It is the most effective sterilization method but is limited for commercial use only. Ionizing radiation produces ions by knocking electrons out of atoms. These electrons are knocked out so violently that they strike an adjacent atom and either attach themselves to it, or dislodge an electron from the second atom. The ionic energy that results becomes converted to thermal and chemical energy. This energy causes the death of microorganisms by disruption of the dna molecule, thus preventing cellular division and propagation of biologic life.

The principal sources of ionizing radiation are beta particles and gamma rays. Beta particles, free electrons, are transmitted through a high-voltage electron beam from a linear accelerator. These high-energy free electrons will penetrate into matter before being stopped by collisions with other atoms. Thus, their usefulness in sterilizing an object is limited by density and thickness of the object and by the energy of the electrons. They produce their effect by ionizing the atoms they hit, producing secondary electrons that, in turn, produce lethal effects on microorganisms.

Cobalt 60 is a radioactive isotope capable of disintegrating to produce gamma rays. Gamma rays are electromagnetic waves. They have the capability of penetrating to a much greater distance than beta rays before losing their energy from collision. Because they travel with the speed of light, they must pass through a thickness measuring several feet before making sufficient collisions to lose all of their energy. Cobalt 60 is the most commonly used source for irradiation sterilization. The product is exposed to radiation for 10 to 20 hours, depending on the strength of the source.

2.3.3. Common sterilization methods:

2.3.3.1. Common high temperature/pressure sterilization

I. Steam autoclave:



Figure 8: Steam autoclave

Steam autoclave is the oldest, safest, and most cost effective method of sterilization in the medical equipment industry. The steam reaches 121-148°C (250-300°F) in the pressure chamber at 15 p.s.i. The sterilization period is dependent on the temperature and size of load and can range from 10-60 minutes. The common types of steam sterilization cycles are gravity-displacement, which removes air from the chamber by gravity displacement as steam-entering chamber exerts pressure on air; and the pre-vacuum cycle, which removes air by a vacuum pump while steam is simultaneously injected into the chamber. The following summarizes the processing parameters for each cycle:

configuration	temperature	time
gravity-displacement	121-123° c (250-254° f)	15 - 30 minutes
	132-135° c (270-272° f)	10 - 25 minutes
pre-vacuum	132-135° c (270-272° f)	3 - 4 minutes

configurable cycles allow the user to customize the sterilization cycle for items such as hard items, wrapped items, liquids in vented containers, waste, and glassware. The fastest steam sterilization used is flash sterilization and it can be accomplished using either gravity-displacement, or pre-vacuum cycles. It is generally a high-speed steam sterilization of an unwrapped instrument or device for 3 to 10 minutes in 132°C saturated steam.[15] this type of sterilization is only intended for use in hospital operating rooms for urgently needed equipment. In the steam autoclave process, microorganisms are killed by heat, and this is accelerated by the addition of moisture. Steam by itself is not sufficient for sterilization, and pressure that is greater than atmospheric is needed to increase

the temperature of steam for thermal destruction of microbial life. Steam, for a specified time at required temperature, must penetrate every fiber and reach every surface of items to be sterilized. When steam enters the sterilization chamber under pressure.

- It condenses upon contact with cold items.

- this condensation frees heat, simultaneously heating and wetting all items in the load, thus providing heat and moisture. Any living thing will be killed when exposed to saturated steam at 120°C (250° F) longer than 15 minutes. As temperature is increased, time may be decreased. A minimum temperature-time relationship must be maintained throughout all portions of load to obtain effective sterilization. At the end of the cycle, re-evaporation of water condensate must effectively dry contents of the load to maintain sterility.

Preparation of items for autoclaving: in preparing items for autoclaving, containers should be unsealed and articles should be wrapped in materials that allow steam penetration. Large packages of dressings and large flasks of media require extra time for heat to penetrate them. Likewise, packing many articles close together in an autoclave lengthens the processing time to as much as 60 minutes to ensure sterility. It is more efficient and safer to run two separate, uncrowded loads than one crowded one. Wrapping objects in aluminum foil is not recommended because it may interfere with steam penetration. Steam circulates through an autoclave from a steam outlet to an air evacuation port

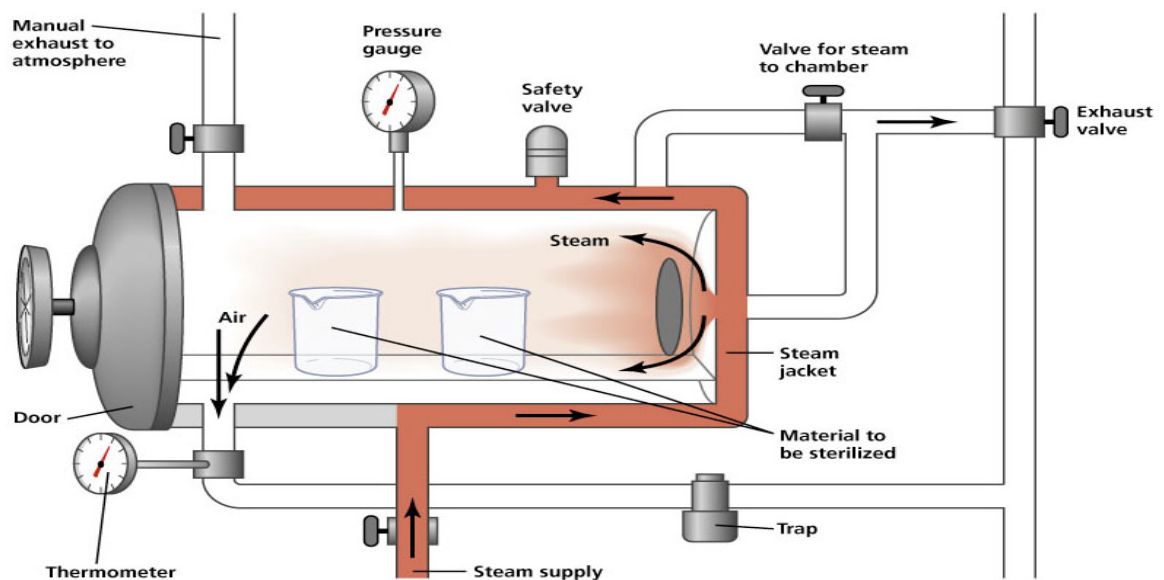


Figure 9: steam autoclave diagram

Importance:

Moist heat in the form of pressurized steam is regarded as the most dependable method for the destruction of all forms of life, including bacterial spores. This method is incorporated into a device called the autoclave. Over 100 years ago, French and

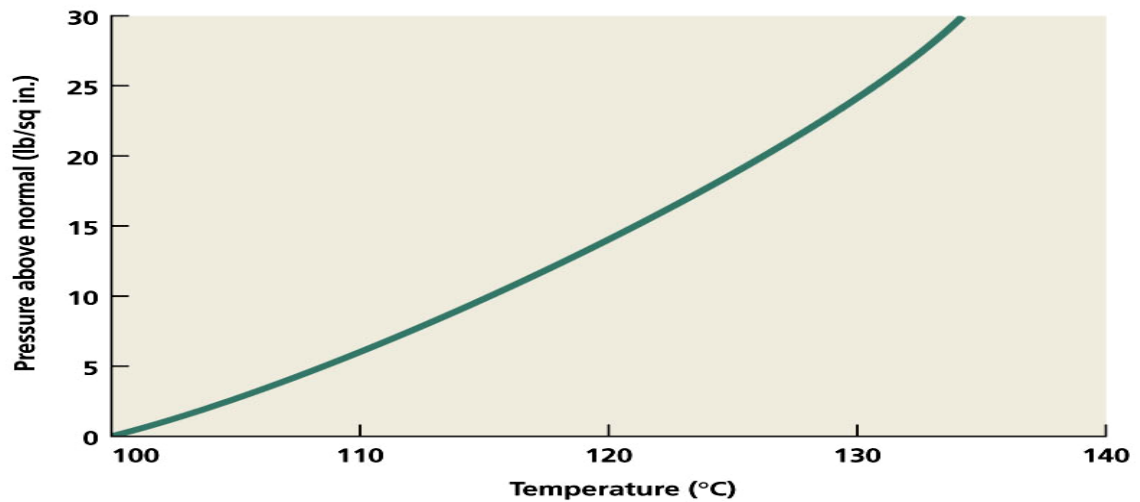
German microbiologist developed the autoclave as an essential component of their laboratories.

Need of autoclaving:

Reliable sterilization with moist heat requires temperatures above that of boiling water. These high temperatures are most commonly achieved by steam under pressure in an autoclave. Autoclaving is the preferred method of sterilization, unless the material to be sterilized can be damaged by heat or moisture.

Sterilization in an autoclave is most effective when the organisms are either contacted by the steam directly or are contained in a small volume of aqueous (primarily water) liquid. Under these conditions, steam at a pressure about 15 psi; attaining temperature (121°C) will kill all organisms and their endoscopes in about 15 minutes.

Effectiveness of autoclave or optimum conditions:



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Figure 10: graph showing relationship between temperature and pressure

Principle of autoclaving:

A basic principle of chemistry is that when the pressure of a gas increases, the temperature of the gas increase proportionally. For example, when free flowing steam at a temperature of 100°C is placed under a pressure of 1 atmosphere above sea level pressure – that is, about 15 pounds of pressure per square inch (psi) --- the temperature rises to 121°C. Increasing the pressure to 20 psi raises the temperature to 126°C. The relationship between temperature and pressure is shown in table 2. In this way steam is a gas, increasing its pressure in a closed system increases its temperature. As the water molecules in steam become more energized, their penetration increases substantially. This principle is used to reduce cooking time in the home pressure cooker and to reduce sterilizing time in the autoclave. It is important to note that the sterilizing agent is the moist heat, not the pressure.

Table 6	The relationship between the pressure and temperature of steam at sea level
Pressure (psi in excess of atmospheric pressure)	Temperature (°c)
0 psi	100
5 psi	110
10 psi	116
15 psi	121
20 psi	126
30 psi	135

Microbial death rates:

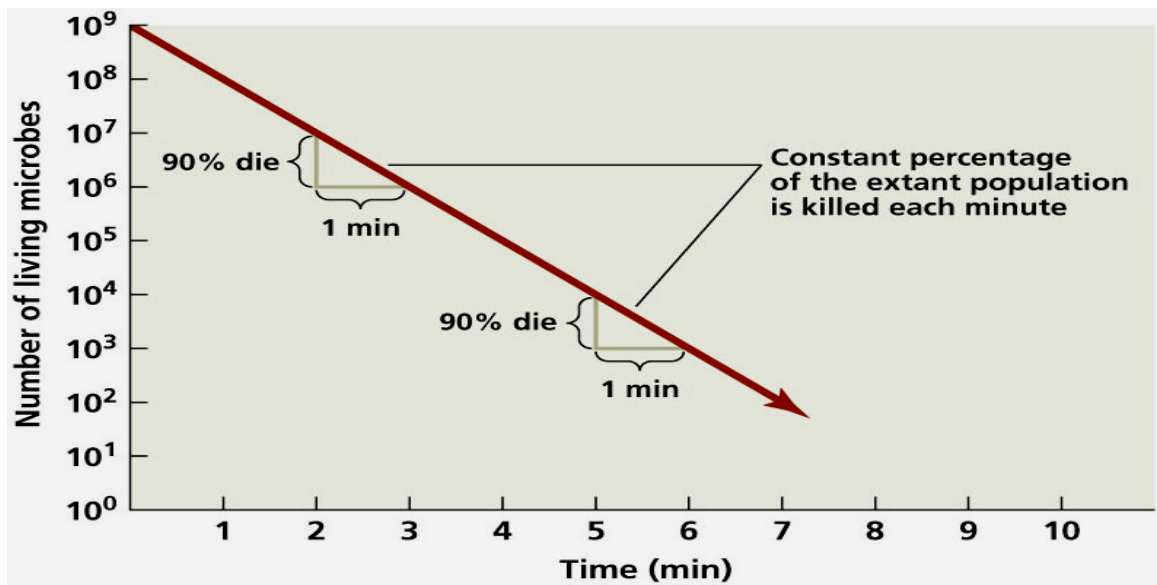


Figure 11. Graph showing relationship between numbers of living microbes with time

Rules implied for autoclaving:

Sterilization by autoclaving is invariably successful if properly done and if two common-sense rules are followed:

First: articles should be placed in the autoclave so that steam can easily penetrate them.

Second: air should be evacuated so that the chamber fills with steam.

Working of autoclave:

Most autoclaves contain a sterilizing chamber into which articles are placed and a steam jacket where steam is maintained. As steam flows from the steam jacket into the sterilizing chamber, cool air is forced out and a special valve increases the

pressure to 15 pounds/square inch above normal atmospheric pressure. The temperature rises to 121.5°C, and the superheated water molecules rapidly conduct heat into microorganisms. The time for destruction of the most resistant bacterial spore is now reduced to about 15 minutes. For denser objects, up to 30 minutes of exposure may be required. The conditions must be carefully controlled or serious problems may occur.

Uses of autoclave:

Autoclaving is used to sterilize culture media, instruments, dressings, intravenous equipment, applicators, solutions, syringes, transfusion equipment, and numerous other items that can withstand high temperatures and pressures. The laboratory technician uses it to sterilize bacteriological media and destroy pathogenic cultures. The autoclave is equally valuable for glassware and metal ware, and is among the first instruments ordered when a microbiology laboratory is established. Autoclaves are also used on large industrial scale. Large industrial autoclaves are called retorts, but the same principle applies for common household pressure cooker used in the home canning of foods

Advantages and disadvantages of autoclave:

- Advantages:
 - Good penetration
 - Maintains integrity of liquids (e.g. Lubricants) due to the 100% humidity within the chamber.
- Disadvantages:
 - Non stainless steel metal items corrode
 - May damage plastic and rubber items
 - Sharp instruments get dulled.

The autoclave also has certain limitations. For example, some plastic ware melts in the high heat, and sharp instruments often become dull. Moreover, many chemicals breakdown during the sterilization process and oily substances cannot be treated because they do not mix with water.

Heat requires extra time to reach the center of solid materials, such as canned meats, because such materials do not develop the efficient heat-distributing convection currents that occur in liquids. Heating large containers also requires extra time. Table 3 shows the different time requirements for sterilizing liquids in various container sizes. Unlike sterilizing aqueous solutions, sterilizing the surface of a solid requires that steam actually contact it.

Table 7		The effect of container size on autoclave sterilization times for liquid solutions
Container size	Liquid volume	Sterilization time (min)
Test tube: 18×150 mm	10 ml	15
Erlenmeyer flask: 125 ml	95 ml	15
Erlenmeyer flask: 2000 ml	1500 ml	30
Fermentation bottle: 9000 ml	6750 ml	70

Indicator of sterilization achievement:

Several commercially available methods can indicate whether sterilization has been achieved by heat treatment. Modern autoclaves have devices to maintain proper pressure and record internal temperature during operations. Regardless of the presence of such a device, the operator should check pressure periodically and maintain the appropriate pressure. Chemical reactions in which an indicator changes color when the proper times and temperatures have been reached. In some designs, the word "sterile" or "autoclaved" appears on wrappings or tapes. These tapes are not fully reliable because they do not indicate how long appropriate conditions were maintained. Tapes or other sterilization indicators should be placed inside and near the center of large packages of determine whether heat penetrated them. In another method, a pellet contained within a glass vial melts. A widely used test consists of preparations of specified species of bacterial endospores such as bacillus stearothermophilus, impregnated into paper strips. The spore strip and an ampoule of medium are enclosed in a soft plastic vial. The vial is placed in the center of the material to be sterilized and is autoclaved. After autoclaving, these can then be aseptically inoculated into culture media. Growth in the culture media indicates survival of the endospores and therefore inadequate processing. Other designs use endospore suspensions that can be released, after heating, into a surrounding culture medium within medium within the same vial.

Important points to remember for autoclaving:

Steam under pressure fails to sterilize when the air is not completely exhausted. This can happen with the premature closing of autoclave's automatic ejector valve. The principles of heat sterilization have a direct bearing on home canning. To sterilize dry glassware, bandages, and the like, care must be taken to ensure that steam contacts all

surfaces. For example, aluminum foil is impervious to steam and should not be used to wrap dry materials that are to be sterilized; paper should be used instead. Care should also be taken to avoid trapping air in the bottom of a dry container because trapped air will not be replaced by steam, which is lighter than air. The trapped air is the equivalent of a small hot-air oven, which, as we will see shortly, requires a higher temperature and longer time to sterilize materials. Containers that can trap air should be placed in a tipped position so that the steam will force out the air. Products that do not permit penetration by moisture, such as mineral oil or petroleum jelly, are not sterilized by the same methods that would sterilize aqueous solutions. This precaution is necessary because when an object is exposed to heat, its surface becomes hot much more quickly than its center. (When a large piece of meat is roasted, for example, the surface can be well done while the center remains rare).

Pre-vacuum autoclave:

In large laboratories and hospitals, where great quantities of materials must be sterilized, special autoclaves, called pre-vacuum autoclaves, are often used. This machine draws air out of the sterilizing chamber at the beginning of the cycle. Saturated steam is then used at a temperature of 132°C to 134°C at a pressure of 28 to 30 lb/in². The time for sterilization is now reduced to as little as 4 minutes. A vacuum pump operates at the end of the cycle to remove the steam and dry the load. The major advantages of the pre-vacuum autoclave are the minimal exposure time for sterilization, the reduced time to complete the cycle and the costs of sterilization are greatly decreased.

Application:

steam autoclave is used mostly for surgical instruments. This method is not well suited for heat sensitive materials and instruments. Many surgical instruments are not designed to withstand prolonged heat and moisture of the steam sterilization process. This leads to alternative sterilization categories: chemical sterilization and radiation sterilization, which allow heat and moisture sensitive materials to be sterilized.

2.3.4: common chemical sterilization:

Ethylene oxide (ETO) gas:

Ethylene oxide gas was introduced in the 1950's, and it is an effective, low temperature chemical sterilization method. It also takes longer than steam sterilization, typically, 16-18 hours for a complete cycle. Temperatures reached during sterilization are usually in the 50-60°C range. Ethylene oxide (eto) is a chemical agent that kills microorganisms, including spores. Eto gas must have direct contact with microorganisms on the items to be sterilized. Due to eto being highly flammable and explosive in air, it must be used in an explosion-proof sterilizing chamber in a controlled environment. Items sterilized by this process must be packaged with wraps and be aerated. The aeration time may be long and is needed to make sterilized items safe for

handling and patient use.[4]note: there are also gas sterilizers available that use a mixture of eto with carbon dioxide or chlorofluorocarbon (cfc) to represent it as nonflammable for use in healthcare facilities. In addition to safety concerns, this type of sterilization process requires an even longer aeration process compared to pure eto sterilization.

In general, eto gas is a reliable and safe agent for sterilization when handled properly. Osha1 also has special handling guidelines for ethylene oxide. Application:

eto is used to sterilize items that are heat or moisture sensitive. Disadvantages of eto gas are that it can leave toxic residues on sterilized items and it possesses several physical and health hazards to personnel and patients that merit special attention.

Since eto poses several health hazards, there are currently two alternative technologies that are currently available: sterrad, a plasma phase hydrogen peroxide-based sterilizing agent and steris, a per acetic acid based technology.

Starred:-

Low temperature hydrogen peroxide plasma (a johnson & johnson product) introduction to low temperature plasma: low temperature plasma sterilization was introduced to fill the gap between autoclave: high temperature steam sterilization (safest, fastest and least expensive) and eto gas sterilization, which leaves toxic residuals. It is a low temperature, non-toxic, but fairly expensive sterilization method. In this process, hydrogen peroxide is activated to create a reactive plasma or vapor. Note: plasma is ionized gas made up of ions and electrons and is distinguishable from solid, liquid, or gas. Plasma is often referred to as the fourth state of matter. The starred system is a hydrogen peroxide gas plasma sterilization system with an operating temperature range of 45-50°C. Operating cycle times range from 45-70 minutes, depending on size of system. This sterilization system uses a combination of hydrogen peroxide and low temperature gas plasma to quickly sterilize most medical instruments and materials without leaving any toxic residues. Hydrogen peroxide is a known antimicrobial agent that is capable of inactivating resistant bacterial spores.[6] sterilization by this method occurs in a low moisture environment. The hydrogen peroxide plasma process using starred: the process consists of two consecutive and equal sterilization phases. Vacuum / preplasma stage:

- When a low pressure is achieved in the vacuum stage, low temperature air plasma is generated. This helps in removing residual moisture from the chamber. The system is then vented to atmospheric pressure at the end of this stage. Sterilization stage:
- Pressure in chamber is reduced and an aqueous solution of hydrogen

peroxide is injected and vaporized into chamber.

- The hydrogen peroxide diffuses throughout the chamber, surrounds the items to be sterilized, and starts the inactivation of the microorganisms.
- After the pressure is reduced, applying radio frequency (rf) energy creates an electric field and thus forms low temperature plasma.
- Free radicals are generated in the plasma by breaking apart the hydrogen peroxide vapor. Once the activated components react with the organisms and kill them, they lose their high energy and re-combine to form oxygen, water vapor, and nontoxic by-products.
- This is half of the total sterilization process. The other half of the cycle is completed by repeating the above sterilization steps.

- At the completion of the second half cycle, the source of rf energy is turned off, vacuum is released, and chamber is returned back to atmospheric pressure by introduction of filtered air.[6]

application:

this system is best suited to sterilize heat sensitive medical equipment such as endoscopic equipment. With two systems, sterrad provides sterilization solutions for both smaller and larger applications. Steris system 1sterile processing system(a steris corporation product)the steris system 1 is another, more common, low temperature sterile processing system. It uses the steris 20 sterilant concentrate that combines peracetic acid, alchemical biocidal agent, and a proprietary anti-corrosion formulation to kill microorganisms at low temperature.[7] the process is achieved at a temperature of 50-56°C.

The steris 20 sterilant concentrate is mixed with sterile water to create the solution that flows into the sterilization chamber. The sterilization time is 12 minutes. This is followed by repetitive sterile water rinses to complete the process. The entire process is completed in less than 30 minutes for a standard cycle.[9] peracetic acid, by itself, is an oxidant and disinfecting agent for liquid immersion. It maintains its effectiveness when high levels of organic debris are present. It is an acetic acid plus an extra oxygen atom that reacts with most cellular components to destroy cells.

Application:

Only immiscible instruments can be used with this method, and only a few instruments can be sterilized at one time. No packaging required.D.Cidex opa solution –alternative to glutaraldehyde(a johnson & johnson product) cidex® opa solution is a high level disinfectant (hld) for use in reprocessing heat sensitive medical devices. Cidex opa solution provides high-level disinfection in 12 minutes at room temperature (20°C) and is particularly active against mycobacteria, including glutaraldehyde-resistant strains of *M. Chelonae*. [10] cidex opa solution has the broad materials compatibility of glutaraldehyde (but does not contain glutaraldehyde), requires no activation, and has minimal odor. The cidex opa solution is replacing cidex and cidex plus due to their toxicity concerns.

this solution is frequently used on surgical cameras (endoscopes). The item to be disinfected must be thoroughly cleaned and dried before immersion. After immersion, the item must be rinsed thoroughly with sterile water prior to use.

2.3.5: common radiation sterilization:

Gamma, beta sterilization:

Irradiation is an effective sterilization method, but it is limited to commercial use only. The product to be sterilized is exposed to radiation for 10 to 20 hours depending on the strength of the source. The highest temperatures reached in gamma sterilization are usually 30-40°C. Gamma radiation is popular for sterilize before shipment and it can be done through the packaging. A dose of 2.5 megarad is generally selected for many items. Ionizing radiation produces ions by knocking electrons out of atoms. These electrons are knocked out violently, and strike an adjacent atom and either attach themselves to it, or dislodge an electron from the second atom. The result is ionic energy that becomes converted to thermal and chemical energy. This energy kills microorganisms by disruption of the DNA molecule, therefore preventing cellular division and propagation of biologic life. The principal sources of ionizing radiation are beta particles and gamma rays. Beta particles, free electrons, are transmitted through a high-voltage electron beam from a linear accelerator. These high-energy free electrons will penetrate into matter before being stopped by collisions with other atoms. This means their usefulness in sterilizing an object is limited by the density, thickness of the object and by the energy of the electrons. These free electrons produce their effect by ionizing the atoms they hit, producing secondary electrons that kill microorganisms. Cobalt 60 is a radioactive isotope capable of breaking down to produce gamma rays. Gamma rays are electromagnetic waves that have the ability to penetrate a much greater distance than beta rays before losing their energy from collision. Because they travel with the speed of light, they must pass through thickness measuring several feet before making sufficient collisions to lose all of the energy. Cobalt 60 is the most commonly used source for irradiation sterilization. [3]

Application:

the radiation can change the properties of some materials like plastics and have adverse effects on glues or adhesives. As you can see, each of the six common methods discussed above have their advantages and disadvantages.

2.3.6: other sterilization methods:

In this section, the other, less common sterilization methods are described. These methods are either existing, being replaced by new sterilization, or are still in development.

2.3.6.1. Other high temperature / pressure sterilization

Dry heat:

This process is conducted at 160-170°C for a minimum of two hours. Due to its high temperatures, its applicable use is limited. Dry heat in the form of hot air is used primarily to sterilize anhydrous oils, petroleum products, and bulk powders that steam and ethylene oxide gas cannot penetrate. In the absence of moisture, higher temperatures are required than when moisture is present because microorganisms are destroyed through a very slow process of heat absorption by conduction.

2.3.6.2. Other chemical sterilization

a. Glutaraldehyde (cidex plus and cidex)(a johnson & johnson product)

Cidex plus and cidex are two of the brand names for glutaraldehyde, which has been a known disinfectant in the medical industry. It has been found that these two solutions can provide sterilization after 10 hours of use, but the manufacturer has not verified this claim.

- cidex plus solution is a disinfectant that is used to disinfect medical instruments. It is a 3.4% alkaline glutaraldehyde solution, which has tuberculocidal and high level disinfection capabilities. It achieves high-level disinfection in 20 minutes at 25°C and has up to a 28-day reuse life.[10]
- cidex activated dialdehyde solution is used to disinfect medical instruments and endoscopes. This solution can also be used in an automated reprocessor.(An automated reprocessor is the machine used to disinfect endoscopic and medical devices with a high level disinfectant solution.) It is a 2.4% alkaline glutaraldehyde solution, which has tuberculocidal and high-level disinfection capabilities. It achieves high-level disinfection in 45 minutes at 25°C and has up to a 14-day reuse life.[10]both have been used as a cold liquid high-level disinfectant for heat sensitive equipment.

Note: cidex (glutaraldehyde) products are being withdrawn from the European market due to concerns that it is toxic and harmful to health care staff in hospitals. Also, the u.s. Market is requiring glutaraldehyde-free chemical solutions, which led to the formulation of the cidex opa solution. Cidex opa solution is now known as the alternative to glutaraldehyde.(a product of steris corporation)vhp (vaporized hydrogen peroxide) md series sterilization system for medical devices is yet another low temperature sterilization system. It is also a product of steris corporation. It is different from the sterrad system, in that it only uses

hydrogen peroxide in vaporized form for sterilization, while the sterrad system uses vaporized hydrogen peroxide to initiate the sterilization, and then plasma (created by rf energy) to complete the sterilization process. In the vhp process, hydrogen peroxide vapor is injected into the chamber via a series of pulses to sterilize packaged medical and diagnostic devices. The cycle time is 2 hours and the operating temperature ranges from 30-40°C. Note: this system is large capital equipment that uses hydrogen peroxide as the sterilant and it can sterilize multiple pieces of equipment at one time. On the other hand, steris corporation's other product, the steris system 1 is a portable tabletop system that uses peracetic acid as the sterilant and it is used to sterilize equipment right before use. The vhp system is relatively new (out on market for a year) and has yet to be commonly used in medical sterilization applications. Like the sterrad system, it is intended to fill the gap between steam sterilization and eto gas sterilization.

Chlorine dioxide:

Chlorine dioxide is a chemical liquid sterilization process. The best operating temperature range for this process is 25-30°C, while using low concentrations of clo₂. The process requires 6 hours of contact time to achieve sterilization. The presence of organic matter reduces activity. A processor converts a compound of dilute chlorine gas with sodium chlorite to form clo₂ gas and this gas is then exposed to the equipment in a sterilizing chamber. Note: this alternative may corrode some materials and must be generated onsite. Prehumidification of the clo₂ is also required.[13]

Ozone:

Ozone sterilizes by oxidation, a process that destroys organic and inorganic matter. It penetrates membrane of cells causing them to explode. In this process, a generator is used to convert oxygen to ozone, as a 6 to 12 percent concentration of ozone continuously flows through the chamber. Ozone penetration is controlled by vacuum pressure or by adding humidity. After the process is complete, oxygen is allowed to flow

through the chamber to purge the ozone. The cycle time may be up to 60 minutes depending on the size of the chamber or load of items to be sterilized.[3]

ozone is formed by applying electrical energy to the oxygen molecule, which splits some portion of those oxygen molecules in half, into singlets of o. Therefore ozone molecules contain three atoms of oxygen and are unstable. Due to ozone gas being corrosive and it being able to damage moisture sensitive equipment, there has not been

much use of it in the medical industry.

2.3.7: other radiation sterilization:

A. E-beam radiation

In this process, the e-beam generator delivers a high dose of electrons in a narrow beam at the items to be sterilized. The electrons from the e-beam generator have limited penetrating power, less than gamma radiation. For example, a 10mev e-beam will penetrate about 5 cm of a unit-density material.[11]

b. X-ray sterilization

This is a new developing process that is based on obtaining x-rays through conversion of electron beams. The x-rays produced have the same penetrating properties as the rays produced by cobalt-60. But with this, treatment is faster, more flexible, and more environmentally friendly. X-rays offer excellent product penetration in sterilization, thoroughly treating the surface and interior of a product.

2.3.8: continuous sterilization:

Continuous sterilization is the rapid transfer of heat to medium through steam condensate without the use of a heat exchanger. Once the media is in a holding loop, steam is injected to the system via a nozzle. The medium stays in this loop for a predetermined holding time until the entire medium is sterile. This is more efficient than batch sterilization because instead of expending energy to heat, hold, and cool the entire system, small portions of the inlet streams are heated at a time. By looping sterile media tubes (which are at higher temperatures) past inlet tubes, the difference in temperature is used to help heat the unsterile medium. So instead of having a cold-water stream cool the sterile media, the lower temperature unsterile media stream absorbs heat from the warm stream, cooling the sterile media. Finally, the sterile media is flash cooled through an expansion valve to adjust the temperature to meet process parameters.

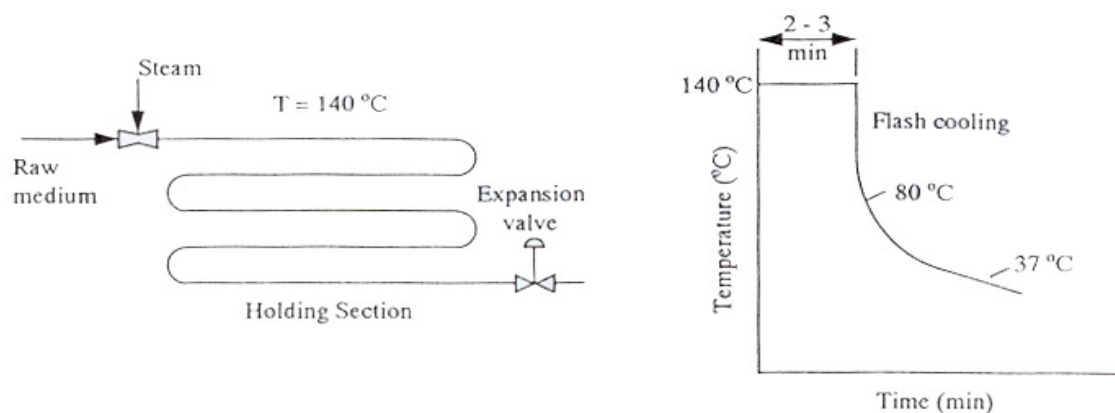


Figure12. Mechanism of continuous sterilization

Advantages:

- Uniform steam requirements throughout the duration of the sterilization
- Simplified process control
- Shorter sterilization time means less thermal degradation of medium

Disadvantages:

- High demand for steam in a shorter period of time than batch
- Concentration of media becomes dilute due to steam condensation
- Since steam is actually dispersed in media, steam must be clean to avoid contamination

2.3.9: cosmetics sterilization

Spx is a world leader in UHT technology with a comprehensive portfolio of tried and tested UHT plant solutions including plate, tubular, injection and infusion UHT plant technologies. Infusion is the most efficient technology for UHT sterilized products. UHT infusion involves heating products very rapidly from 20°C to 150°C with clean steam, keeping the product at that temperature for a few seconds and cooling it down to 30°C very rapidly. The high temperature, combined with strong thermal shocks, destroys the most resistant micro-organisms. The rapidity of heating and cooling avoids any product deterioration. This treatment is applied to end products and the equipment can be easily installed between existing process tanks and filling machines.

Why choose spx UHT technologies:

- 30 years of experience in UHT technologies particularly infusion technology
- Broad experience in cosmetic and pharmaceutical plant realization
- Turnkey plants including design, software, assembly, commissioning, documentation, training and qualification according to current international regulations
- Components with special pharmaceutical design
- Trials conducted in a large test centre
- Ensures full maintenance and re-qualification in the world

Process diagram and benefits:

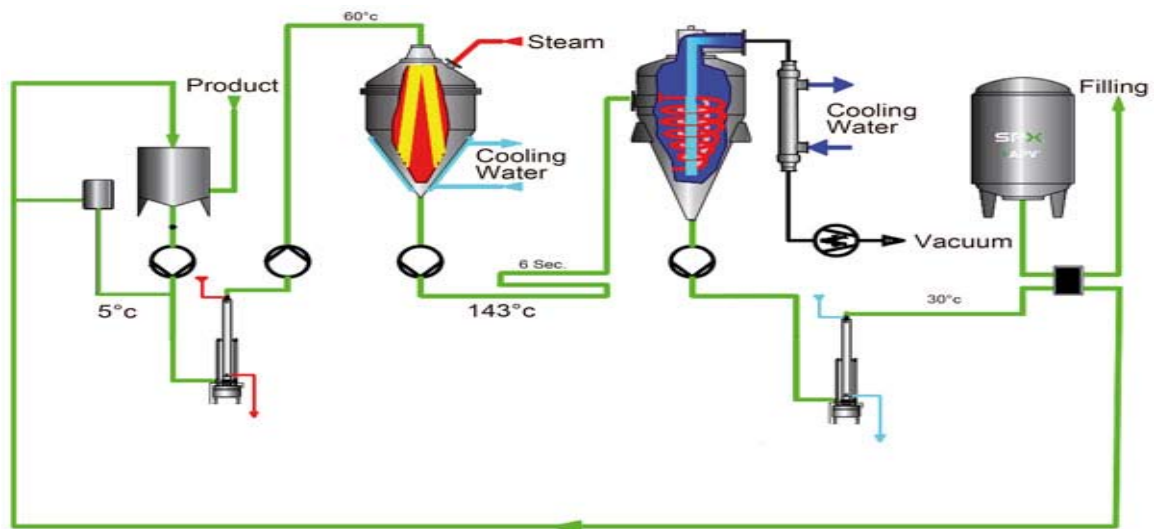


Figure 13: process diagram of cosmetics sterilization

- Accurate control of sterilization temperature and holding time
- High sterilization effect
- Maintains and sometimes improves product characteristics such as: viscosity, perfume, color and smoothness
- High product flexibility
- Integrated cip/sip technology
- Highly automated and operator friendly
- Scalable materials from pilot to industrial plants
- Many spx components included in system: (heat exchangers, infusion, pumps, dynamic mixers, membrane valves) for one source development and after-sales support

Installation flexibility:

- Preassembled skid can be easily connected to upstream and downstream equipment
- Customized solution to fit in customer specifications
- Possible flow rates from 100 to 4000 l/h, depending on batch sizes to be treated
- Equipment is adaptable to various inlet and outlet product temperatures
- Sterilization temperature can be varied from 100 to 150°C and holding time from 0.05 to 10 seconds or more

Why UHT treat cosmetics?

Cosmetics usually contain different chemical additives in order to avoid bacteria and fungi contamination. But more and more consumers are concerned about possible health affects those preservatives such as parabens in cosmetics present. Alternatives to preservatives, such as alcohol or essential oil can also create allergies. A unique

solution to avoid using additives is sterilizing products with ultra high temperature (UHT) treatment. The product must then be filled in adequate packaging to keep the sterility, even after use by the consumer. Spx brand apv has applied its vast knowledge of UHT systems, and adapted UHT infusion, to cosmetic applications.

UHT pilot plant to test your products

Spx innovation centre:

The spx innovation centre operates several UHT pilot plants capable of running all the main UHT systems. These pilot plants are used for product testing and new process development. Our customers also test new processes and optimize existing process parameters assuring production scalability. Because the centre is equipped with mixing tanks, aseptic filling machines, complete laboratory facilities and all utilities, customers can simulate complete process line before investing.

Theory of operation:

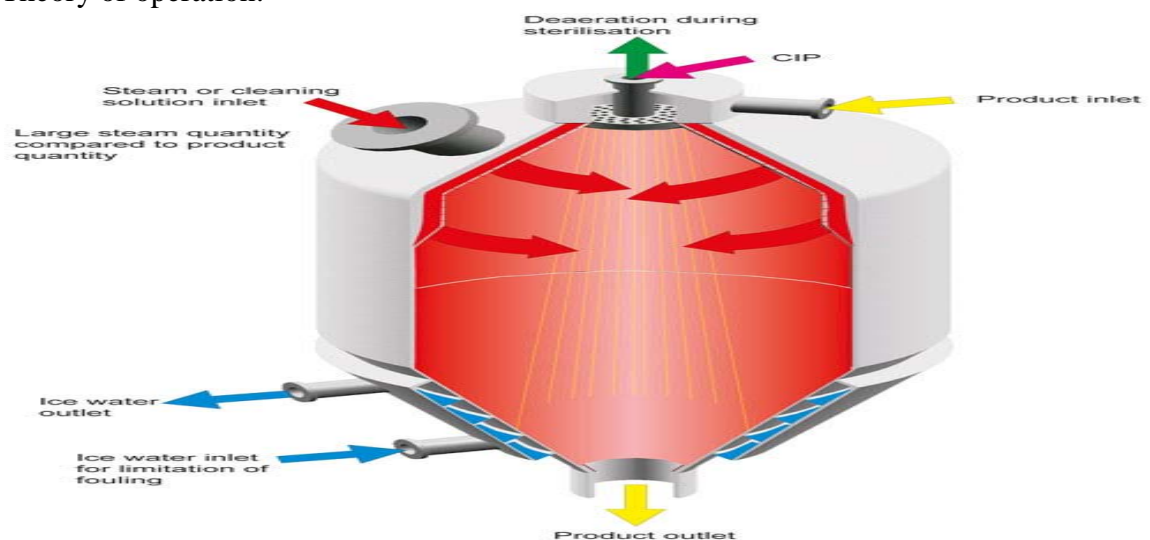


Figure 14: theory of operation

Sterilization is necessary for the complete destruction or removal of all microorganisms (including spore-forming and non-spore-forming bacteria, viruses, fungi, and protozoa) that could contaminate pharmaceuticals or other materials and thereby constitute a health hazard. Since the achievement of the absolute state of sterility cannot be demonstrated, the sterility of a pharmaceutical preparation can be defined only in terms of probability. The efficacy of any sterilization process will depend on the nature of the product, the extent and type of any contamination, and the conditions under which the final product has been prepared. The requirements for good manufacturing practice should be observed throughout all stages of manufacture and sterilization.

Classical sterilization techniques using saturated steam under pressure or hot air are the most reliable and should be used whenever possible. Other sterilization methods

include filtration, ionizing radiation (gamma and electron-beam radiation), and gas (ethylene oxide, formaldehyde).

For products that cannot be sterilized in the final containers, aseptic processing is necessary. Materials and products that have been sterilized by one of the above processes are transferred to presterilized containers and sealed, both operations being carried out under controlled aseptic conditions.

Whatever method of sterilization is chosen, the procedure must be validated for each type of product or material, both with respect to the assurance of sterility and to ensure that no adverse change has taken place within the product. Failure to follow precisely a defined, validated process could result in a non-sterile or deteriorated product. A typical validation program for steam or dry-heat sterilization requires the correlation of temperature measurements, made with sensory devices to demonstrate heat penetration and heat distribution, with the destruction of biological indicators, i.e. Preparations of specific microorganisms known to have high resistance to the particular sterilization process. Biological indicators are also used to validate other sterilization methods (see specific methods), and sometimes for routine control of individual cycles. Periodic revalidation is recommended.

2.4: quality assurance

To ensure that instruments and supplies are sterile when used, monitoring of the sterilization process is essential.

Administrative monitoring

Work practices must be supervised. Written policies and procedures must be strictly followed by all personnel responsible and accountable for sterilizing and disinfecting items, and for handling sterile supplies. If sterility cannot be achieved or maintained, the system has failed. Policies and procedures pertain to;

1. Decontaminating, terminally sterilizing, and cleaning all reusable items; disposing of disposable items.
2. Packaging and labeling of items.
3. Loading and unloading the sterilizer.
4. Operating the sterilizer.
5. Monitoring and maintaining records of each cycle.
6. Adhering to safety precautions and preventive maintenance protocol.
7. Storing of sterile items.
8. Handling sterile items ready for use.
9. Making sterile transfer to a sterile field.

2.4.1: mechanical indicators

Sterilizers have gauges, thermometers, timers, recorders, and/or other devices that monitor their functions. Most sterilizers have automatic controls and locking devices. Some have alarm systems that are activated if the sterilizer fails to operate correctly. Records are maintained and review for each cycle. Test packs (bowie-dick test) are

run at least daily to monitor functions of each sterilizer, as appropriate. These can identify process errors in packing or loading.

2.4.2: chemical indicators

A chemical indicator on a package verifies exposure to a sterilization process. An indicator should be clearly visible on the outside of every on-site sterilized package. This helps differentiate sterilized from unsterilized items. More importantly, it helps monitor physical conditions within the sterilizer to alert personnel if the process has been inadequate. An indicator may be placed inside a package in a position most likely to be difficult for the sterility to penetrate. A chemical indicator can detect sterilizer malfunction or human error in packaging or loading the sterilizer. If a chemical reaction on the indicator does not show expected results, the item should not be used. Several types of chemical indicators are available:

1. Tape, labels, and paper strips printed with an ink that changes color when exposed to one or more process parameters.
2. Glass tube with pellets that melts when a specific temperature is attained in sterilizer.
3. Integrating or wicking paper with an ink or chemical tablet at one end that melts and wicks along paper over time under desired process parameters. The color bar reaches the "accept" area if parameters are met.

2.4.3: Biological indicators:

Positive assurance that sterilization conditions have been achieved can be obtained only through a biologic control test. The biologic indicator detects no sterilizing conditions in the sterilizer. A biologic indicator is a preparation of living spores resistant to the sterilizing agent. These may be supplied in a self-contained system, in dry spore strips or discs in envelopes, or sealed vials or ampoules of spores to be sterilized and a control that is not sterilized. Some incorporate a chemical indicator also. The sterilized units and the control are incubated for 24 hours for *Bacillus stearothermophilis* at 131 to 141 f (55 to 66 c) to test steam under pressure, for 48 hours for *Bacillus subtilis* at 95 to 98.6 f (35 to 37 c) to test ethylene oxide.

A biologic indicator must conform to USP testing standards. A control test must be performed at least weekly in each sterilizer. Many hospitals monitor on a daily basis; others test each cycle. Very load of implantable devices must be monitored and the implant should not be used until negative test results are known. Biological indicators also are used as a challenge test before introducing new products or packaging materials, after major repairs on the sterilizer, or after a sterilization failure. All test results are filed as a permanent record for each sterilizer.

The following table summarizes the results

Table 8: Summarizes the results

	High Temperature/ Pressure	Chemical				Radiation
	Steam Autoclave	Sterrad	Steris System 1	EtO Gas	Cidex OPA	Gamma
Temperature (°C)	121-148	45-50	50-56	50-60	20	30-40
Cycle Time (minutes)	10-60	55-70	30	16-18 hours (Full day)	12	10-20 hours
Sterilant/ Disinfectant Type	Steam	-Hydrogen peroxide vapor -Gas plasma	-Peracetic acid -Proprietary anti-corrosion formulation	EtO gas	Ortho-phthalaldehyde	Radiation Energy
Sterilization	√	√	√	√		√
Disinfection					√	
Environmentally Friendly?	Yes	Yes	Yes	No Leaves toxic residuals	Yes	Yes
Advantages	-Safe -Effective -Economical -Reliable -Fast	-Safe -Effective -Low moisture environment -No toxic residues -No aeration needed -Heat sensitive materials can be sterilized	-Safe -Non-toxic -Short cycle time	-Effective -Low temperature -Handles heat or moisture sensitive equipment -Reliable	-Quick -Minimal odor -Primary use with surgical cameras. -Broad materials compatibility	-Simple -Reliable -Cost competitive -Fast
Disadvantages	-Wets and heats materials -Corrosion is possible -Not suited for heat sensitive materials	-Damages Nylon based materials -Very expensive	-Handles only small items -Have to soak in solution -Marketed for "point of use" applications only	-Long cycles -Toxic by product -Carcinogenic -Costly -Long aeration -Physical, health hazards	-Costly -Disinfectant, not a sterilant	-PVC, PTFE, and Acetal are incompatible materials

2.5: testing of healthcare garments:

Laboratory tests include water repellency, launder ability (if recyclable), burst strength and tear strength. The design of barrier fabrics is driven by the concern. Therefore for these fabrics test methods that would assist in the characterization of products as blood-resistant, blood proof or viral proof. These methods have been established as ASTM 1670-95 and 1671-97.

The demand wet ability method of measuring the absorbency characteristics of fabrics have been described by lichstein. This technique measures both capacity and absorption rate simultaneously at zero hydrostatic head. It is applicable to different absorbents, wicking fluids and multiple-ply structures with the absorbent at any angle to the fluid and under different pressures. Other textile products used in hospitals include bedding, clothing, shoe covers, mattress covers, etc.

Cleaning methods that do not achieve sterilization

This is a brief list of cleaning methods that may be thought to "kill germs" but do not achieve sterilization.

- Washing in a dishwasher: dishwashers often only use hot tap water or heat the water to between 49 and 60 °c (120 and 140 °f),^[citation needed] which is not hot enough to kill some bacteria on cooking or eating utensils.
- Bathing cannot sterilize skin, even using antibacterial soap.
- Disinfectants (for non-living objects) or antiseptics (for living objects such as skin) can kill or remove bacteria and viruses, but not all.
- Pasteurization of food also kills some bacteria and viruses, but not all.

2.6: preservation of sterility

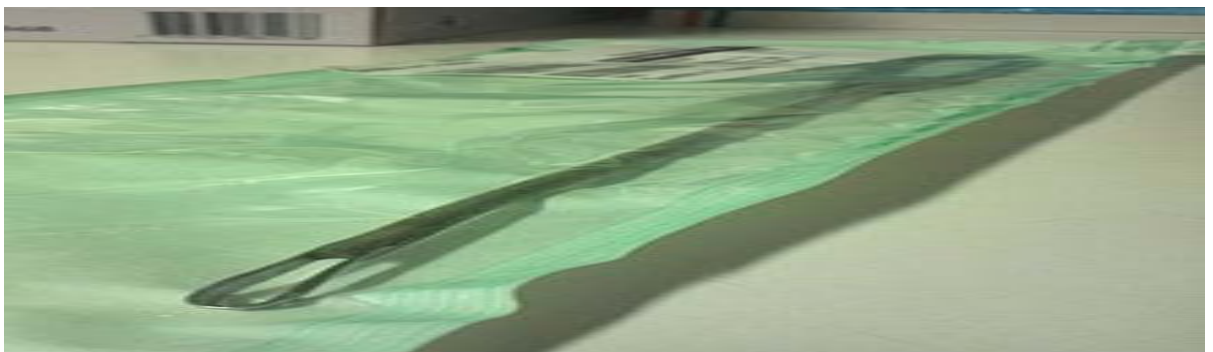


Figure 15: preservation by sterile packaging

Instruments that have undergone sterilization can be maintained in such condition by containment in sealed packaging until use.

Aseptic technique is the act of maintaining sterility during procedures.

CHAPTER-3

METHODOLOGY

Experimental details:

3.1 steam sterilization

Sterilization is a process intended to kill all microorganisms and is the highest level of microbial destruction. Sterilization refers to the use of different procedures to destroy all forms of microorganisms including bacterial spores. Steam sterilization is widely used in our country.

Steam autoclave is the oldest, safest, and most cost effective method of sterilization in the medical equipment industry. The steam reaches 100-120°C in the pressure chamber at 1.5-2 p.s.i. The sterilization period is dependent on the temperature and size of load and can range from 20-60 minutes. This type of sterilization is only intended for use in hospital operating rooms for urgently needed equipment. In the steam autoclave process, microorganisms are killed by heat, and this is accelerated by the addition of moisture. Steam by itself is not sufficient for sterilization, and pressure that is greater than atmospheric is needed to increase the temperature of steam for thermal destruction of microbial life. Steam, for a specified time at required temperature, must penetrate every fiber and reach every surface of items to be sterilized.

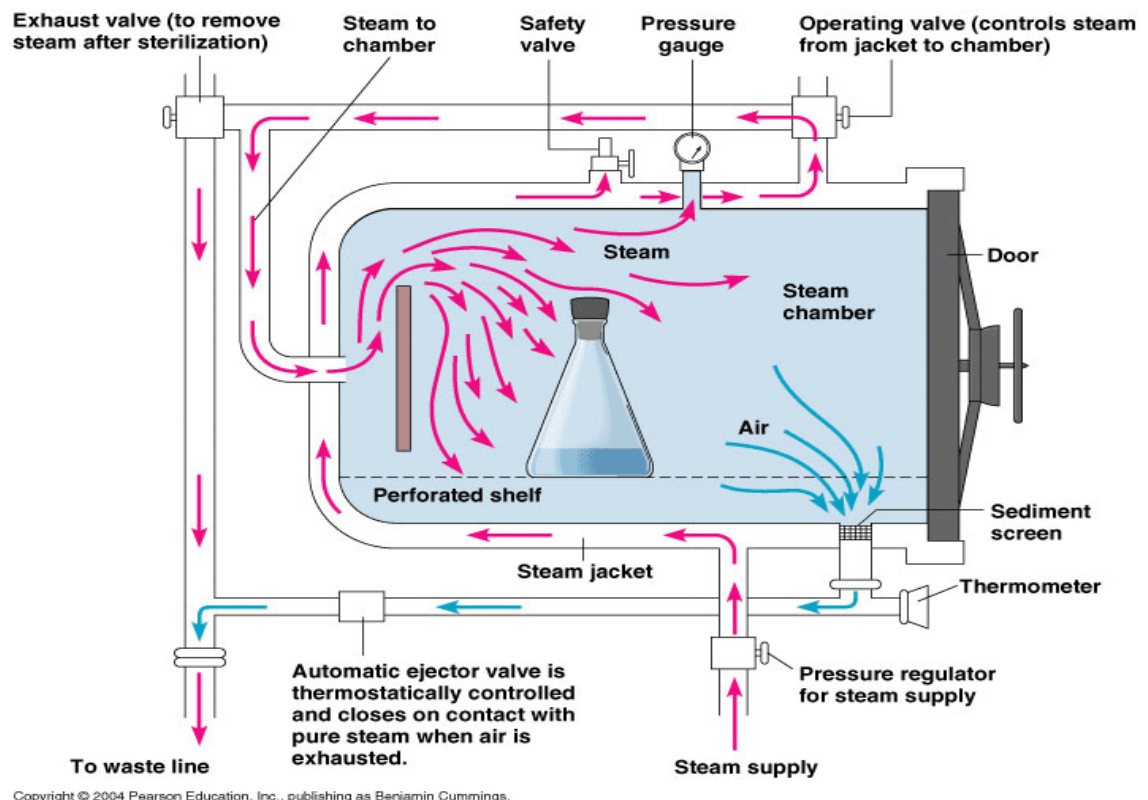


Figure 16: process of steam sterilization

3.2 study about autoclave sterilization

For the purpose of sterilizing, work has been carried out in three different places e.g.

- Jahurul islam medical college and hospital, bajitpur, kishoregonj
- Holy family red crescent medical college, Dhaka &
- Mymensingh medical college, Mymensingh.

In all the three places sterilization is carried out using autoclave.

3.2.1 Sterilization using autoclave in Jahurul islam medical college and hospital, bajitpur, kishoregonj.

M/C:	steam autoclave
Time:	30 minutes
Psi:	1.5-2
Temperature:	100 ° c

Jahurul islam medical college and hospital is the biggest and 1st privet medical college in Bangladesh. There are two autoclaves for sterilization. One is fully automatic and another is semi automatic. In Jahurul islam medical college and hospital, all surgical product are in different box according to their type.

In semi-automatic machine water level, temperature and time should be maintained manually but fully automatic machine take and do everything automatically. First machine take water and hot it boiling temperature then the steam go inside the machine, make it hot and create pressure. It takes about 30 mins. After then machine cooling and neutralize pressure. Then products are sterilized.



Figure 17: operator shows the machine function(Jahurul islam medical college and hospital, bajitpur, kishoregonj.)



Figure 18: shelves of autoclave room(Jahurul islam medical college and hospital, bajitpur, kishoregonj.)



Figure 19: front view of autoclave machine(Jahurul islam medical college and hospital, bajitpur, kishoregonj.)



Figure 20: auto-cleave room(Jahurul islam medical college and hospital, bajitpur, kishoregonj.)

3.2.1.1 Microbiological test

After collecting sample from autoclave, it was sent to Mymensingh medical college for microbiological test. The scan copy of the test reports is given below:

মাইক্রোবায়োলজী বিভাগ
Department of Microbiology
Mymensingh Medical College
Dhaka-Mymensingh Road, Mymensingh-2206, Bangladesh

Date: 20-01-2015

GAUGE EXAMINATION REPORT

Specimen	Test
Gauge - 1	Gauge for C/S

Specimen -
Culture at 37 °C aerobically for 24/48 hours incubation yielded no growth of any pathogenic organisms.

Prof./Assoc. Prof./Asst. Prof.

[Signature]
20/1/15
Clinical Microbiologist/Lecturer

Phone: 67001-7 Ex-273; Fax: 66064; E-mail: mmc.micro@gmail.com

Figure 21: Result of micro-biological test (gauge sample taken from Jahurul islam medical college and hospital).

3.2.2: Holy Family Red Crescent Medical College, Dhaka.

M/C: steam autoclave
Time: 30 minutes
Psi: 1.5-2
Temperature: 100 ° c-110 ° c

Holy Family Red Crescent Medical College has come a long way in last 12 years and achieved great reputation amongst the medical colleges in the country, since its establishment in the year 2000. This institute is recognized by the regulatory body of the country- Bangladesh Medical & Dental Council (BMDC), affiliated with University of Dhaka, approved by the Government of Bangladesh, listed in database of AVICENNA (Former WHO medical directory) & FAIMER International Medical Education Directory-IMED

In Holy Family Red Crescent Medical College, there are 3 machines. All are automatic. In Holy Family Red Crescent Medical College, hand gloves and cloths are sterilized separately using different temperature and pressure. Hand gloves are done in 100 ° c and cloths are 110 ° c.



Figure 22: front view of autoclave machine.(Holy Family Red Crescent Medical College, Dhaka.)



Figure 23: side view of autoclave machine..(Holy Family Red Crescent Medical College, Dhaka.)



Figure 24: pressure meter of autoclave machine.(Holy Family Red Crescent Medical College, Dhaka.)



Figure 25: temperature meter of autoclave machine. (Holy Family Red Crescent Medical College, Dhaka.)





Figure 26:me,in front of autoclave machine.



Figure 27:different types of box for auto-clave.

3.4: Microbiological test (sample-2)

After collecting sample from machine, send for microbiological test in Mymensingh medical college. The test reports are given below:

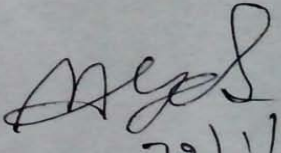
 **মাইক্রোবায়োলজী বিভাগ**
Department of Microbiology
Mymensingh Medical College
Dhaka-Mymensingh Road, Mymensingh-2206, Bangladesh 

Date: 01-02-2015

GAUGE EXAMINATION REPORT

Specimen	Test
Gauge - 2	Gauge for C/S

Specimen -
Culture at 37 °C aerobically for 24/48 hours incubation yielded no growth of any pathogenic organisms.


20/1/15
Clinical Microbiologist/Lecturer

Prof./Assoc. Prof./Asst. Prof.

Figure 28: Result of micro-biological test (gauge sample taken from Holy Family Red Crescent Medical College, Dhaka).

3.2.3: Mymensingh medical college, Mymensingh.

M/c : steam autoclave

Time: 30 minutes

Psi: 2

Temperature: 120°c

Mymensingh Medical College is one of the oldest, reputed and bright institutes in Bangladesh since its establishment in 1962. Mymensingh Medical College is a Government Medical College which administered by the Ministry of Health and Family Welfare. It was established as an institution of national importance. It is located in the eastern part of the town beside Mymensingh Dhaka highway

In Mymensingh medical college, there are many auto-clave room. which room i go there are 3 machine and all are fully automatic. in Mymensingh medical college, all product are sterilized together . The temperature and prassure are higher then others.



Figure 29: Autoclave room of Mymensingh medical college, Mymensingh.



Figure 30: Autoclave room of Mymensingh medical college, Mymensingh.



Figure 31: Front view of autoclave of Mymensingh medical college, Mymensingh.



Figure 32: meters of autoclave of Mymensingh medical college, Mymensingh

3.6: microbiological test (sample-3)

After collecting sample from machine, send for microbiological test in Mymensingh medical college. The test reports are given below:

মাইক্রোবায়োলজী বিভাগ
Department of Microbiology
Mymensingh Medical College
Dhaka-Mymensingh Road, Mymensingh-2206, Bangladesh

Date: 04-02-2015

GAUGE EXAMINATION REPORT

Specimen	Test
Gauge -3	Gauge for C/S

Specimen -
Culture at 37 °C aerobically for 24/48 hours incubation yielded no growth of any pathogenic organisms.

Prof./Assoc. Prof./Asst. Prof.

[Signature]
20/1/15
Clinical Microbiologist/Lecturer

Phone: 67001-7 Ex-273; Fax: 66064; E-mail: mmc.micro@gmail.com

Figure 33: Result of micro-biological test (gauge sample taken from Mymensingh medical college, Mymensingh).

3.7: A common test for sterilization practiced in the autoclave room.

During auto-clave treatment in the hospitals, the operators use a sterilization indicator tape for checking that whether the medical textiles are properly sterilized or not. It looks somewhat like ordinary scotch tape, some pictures are shown below (figure 3, 4& 5). Before autoclave treatment, a sample of gauze is wrapped with the indicator tape. Towards the end of operation the tape is observed, if the shaded line turns to deep black then the samples are sterilized, if not then further treatment is carried out.

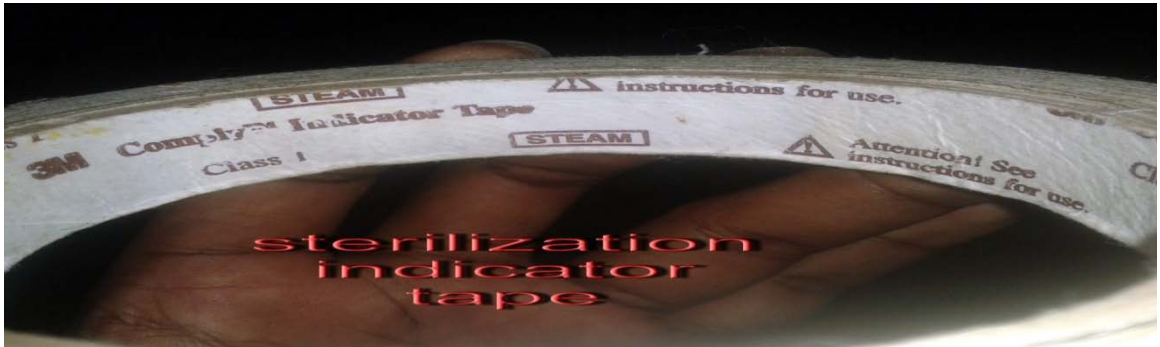


Figure 34 : a sterilization indicator tape



Figure 35 : before sterilization indicator tape



Figure 36 : after sterilization indicator tape

Table 9: Process details of autoclave treatment

Process details	Name of hospital		
		Jahurul islam medical college and hospital, bajitpur, kishoregonj.	Holy family red crescent medical college,Dhaka.
M/c types	Auto & semi-auto	Auto	Auto
Temperature	100° c	100° c-110 °c	120°c
Heat types	Steam	Steam	Steam
Psi	1.5-2	1.5	2
Time	30 minutes	30 minutes	30 minutes
Results	Perfectly sterilized	Perfectly sterilized	Perfectly sterilized

Table 10: Summary of microbiological test

The summary of microbiological test's which were done at Mymensingh medical college is given bellow:

Name	Sample of JIMEC	Sample of HFRMC	Sample of MMC
Test process	Gauge for c/s	Gauge for c/s	Gauge for c/s
Temperature	37°c	37°c	37°c
Time	24-48 hours	24-48 hours	24-48 hours
Pathogenic organisms	No	No	No
Sterilization	Ok	Ok	Ok

CHAPTER-4

DISCUSSION

OF

RESULTS

Chapter-4: discussion of results

4.1 importance of sterilization

Sterilization is a process intended to kill all microorganisms and is the highest level of microbial destruction. All the medical instruments must be heat sterilized before reuse. The medical items are surgical and other instruments used to penetrate soft tissue or bone; examples of critical instruments include forceps, scalpels, bone chisels, scalars, and burs. The present work is mainly concerned with textile materials e.g. surgical gauge & others.

4.2 Awareness of the medical personals

During working with the project we have talked to doctors and other medical personals and found that they very well aware and careful about aspect of sterilization. In fact doctors are very much careful about all sorts of materials used in surgical and related purposes. Therefore even if the gauzes are unsuitable from hygiene point of view but the hospital authority have their own sterilizing facility where they sterilize all the materials including gauzes & bandages.

4.3. Methods of sterilization:

Sterilization falls into the following three categories:

1. High temperature/pressure sterilization (autoclave)
2. Chemical sterilization
3. Radiation sterilization

4.3. Sterilization using autoclave

The process of sterilization using autoclave was studied in details. The principle of operation of autoclaves is same as the process applies for common household pressure cooker used in the home canning of foods. The operating conditions are shown in table 9. It found that very similar procedure is practiced in all the three organizations though the autoclave of Jahurul Islam medical college is semi automatic while other two autoclaves were automatic. But the performance of sterilization is perfectly alright in all the three places. It was found that the hospital authority also use the autoclave to sterilize other products e.g. glassware and metal ware etc.

4.4 Microbiological reports of the sterilized samples

To see the performance of the sterilization by autoclave, sterilized samples were collected from all the three organization and then all the samples were tested in the microbiological laboratory of Mymensingh medical college hospitals. The testing condition is shown in table 10. The results were shown in figure 21, 28 & 33 shows that sterilization was perfect in all the three places.

4.5 Use of sterilization indicator tape

The microbiological test to see the performance of sterilization is complicated, expansive and time consuming. Therefore the hospital authority uses an indicator tape which is somewhat like conventional litmus paper used to test acidity and alkalinity. During autoclave treatment a small amount of this tape is wrapped with one of the gauze sample. Normally the tape has a slightly visible shaded line but after sterilization the line become very black and visible. Thus looking at the indicator tape the technicians can understand whether the gauzes are sterilized or not. Use of sterilization indicator tape was shown in figure 34, 35 & 36.

CHAPTER-5

CONCLUSIONS

Conclusions:

The study shows that all the doctors are very much concerned about the hygiene aspects of textile materials i.e. gauze and bandages. Hospitals have their own autoclave facility where they sterilize all the gauzes and other glass ware and metals wares. The quality of sterilization of the three hospitals was absolutely perfect. There is a special indicator paper which is used by the autoclave technicians to ensure that sterilization is perfect.

REFERENCES

References:

- [1] Medical sterilization methods author: m ehul p atel
- [2] Medical applications of fibers and textiles by dr. P.g. Cookson
- [3] Handbook of technical textiles, edited by a r horrocks and s c anand
(Technical textiles by william c smith)
- [4] http://education.sterrad.com/c3/c3_chemical_eto.htm
- [5] <http://www.ciwmb.ca.gov/wpie/healthcare/epaetogluto.pdf>
- [6] <http://www.sterrad.com> (sterrad 100s sterilization system, pg. 1-2)
- [7] <http://www.steris.com>
- [8] http://education.sterrad.com/c3/c3_chemical_peracetic.htm
- [9] malchesky, paul s., peracetic acid and its application to medical instrument sterilization, 1992, pg. 149.
- [10] <http://www.cidex.com>
- [11] <http://www.wheatlonsci.com/html/plasticssterilization.html>
- [12] <http://www.iba-sni.com/pages/xray.htm>
- [13] http://p2library.nfesc.navy.mil/p2_opportunity_handbook/3_vii_1.html
- [14] robins, d. Stephen, health facilities management, state-of-the-art sterilization, may 96, vol.9, issue 5
- [15] <http://www.flashpak.com/frequent.html>
- [16] <http://wikipedia.org>
- [17] http://education.sterrad.com/c3/c3_types.htm
- [18] <http://www.steamatic-cr.com/bioclean/principles.html>
- [19] <http://www.urmc.rochester.edu/sterile/basics.html>