Handbook on Medical and Surgical Disposable Products (Blood Bags, Plastic Gloves, I.V. Cannula, Infusion Set, Gowns, Masks, Catheter, Cotton and Bandage, Surgical Wear, Syringes)
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Medical and surgical device manufacturers worldwide produce a multitude of items that are intended for one use only. The primary reason is infection control; when an item is used only once it cannot transmit infectious agents to subsequent patients. Like medicines and other health technologies, they are essential for patient care – at the bedside, at the rural health clinic or at the large, specialized hospital. The demand of these goods is not only because of their “one time use” property but also due to the hygienic methods adopted to produce them. From manufacturing to Marking, production of disposable goods is stacked with numerous standards and regulations. This book includes the basic manufacturing method and labeling requirements, required for the bulk production of such life saving devices. General medical disposables that are being in demand in domestic as well as in international market includes: medical gloves, syringes, gowns, catheters, blood transfusion units and so on.

The information provided is not only confined to the different methods involved in the manufacturing of medical disposables but also describes the raw material used and other information related to product, which are necessary for the manufacturers knowledge. The details given will be very good for an individual/entrepreneur who is willing to invest in the field of medical disposables.

The main demand of medical disposables are, nowadays not limited to the super specialty hospitals but is also continuously increasing in rural hospitals and clinics. The work provides an idea to reader about the final product, hygiene, safety, packaging, uses, manufacturers and suppliers of the machinery, raw material involved in the processes etc.

The book covers various aspects concerned with the disposable medical devices and presents an overview of the processes involved with their machineries and specifications. The work provides the complete details of the suppliers and manufacturers with machinery photographs for better understanding of the reader.

Tags
Blood bag manufacturing process, Blood bag production plant, Blood bag production plant, book on Medical and Surgical Disposable Products, Business Plan for a Startup Business, Business start-up, Catheter Production Equipments, cotton and surgical bandages manufacturing, Disposable Glove Making Machine, Disposable medical syringe & needle production plant, Disposable Plastic Gloves, Disposable Plastic Syringe: Manufacturing Business Idea, Disposable Plastic Syringes Manufacturing Plant, Disposable Surgical Gowns Products, disposable surgical wear manufacturing, Disposable syringe - Small Industry, Disposable syringe making machine, Disposable syringe manufacturing plant, Disposable syringe manufacturing process, Disposable Syringe Plant, Glove manufacturing process, Glove production line, Great Opportunity for Startup, Healthcare Disposable Surgical Instruments, Hospital Surgical Items List, How catheter is made - material, history, used, structure, procedure, how catheters are made, How to Manufacture Blood Bags, How to Manufacture Flexible PVC Blood Bags, How to manufacture Medical and Surgical Disposable products, How to manufacture Medical Disposable products, How to manufacture Surgical Disposable products, How to Start a Medical and Surgical Disposable Production Business, How to Start Medical and Surgical Disposable production Industry in India, Injection needle manufacturing process, Intravenous Cannula production, Iv Cannula - Manufacturing Plant, IV cannula manufacturing machine, List of disposable items used in hospitals, Manufacturing medical plastic like catheters and syringes, Materials for medical device packaging, Medical and Surgical Disposable products manufacturing Industry in India, Medical Based Small Scale Industries, Medical Blood Bag Production, Medical device manufacturing industry, Medical device manufacturing process, Medical Device Packaging, Medical Device Packaging Industry: Healthcare Packaging, Medical Devices and Surgical Disposables in India, Medical Disposable Blood Bag, Medical Disposable Products, Medical Disposable Products for hospital and surgical use, Medical disposables list, Medical disposables manufacturing in India, Medical Disposables and Surgical Disposables, Medical Glove Plant, Medical Products, Hospital Products, Surgical Products
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Sample Chapter:
INTRODUCTION

A hospital is a health care institution providing patient treatment by specialized staff and equipment. Hospitals are largely staffed by professional physicians, surgeons, and nurses, whereas in the past, this work was usually performed by the founding religious orders or by volunteers. Medical devices vary greatly in complexity and application. Examples range from simple devices such as tongue depressors, medical thermometers, and disposable gloves to advanced devices such as computers which assist in the conduct of medical testing, implants, and prostheses. The design of medical devices constitutes a major segment of the field of biomedical engineering.

Design, Prototyping and Product Development

Biomedical device product manufacturing is a long process requiring robust SOPs and guidelines for production. These days, with the aid of CAD or modeling platforms, the work is now much faster, and this can act also as a tool for strategic design generation as well as a marketing tool. Failure to meet cost targets will lead to substantial losses for an organization. In addition, with global competition, the R&D of new biomedical devices is not just a necessity; it is an imperative for biomedical device manufacturing companies. The realization of a new design can be very costly, especially with the shorter product life cycle. As technology advances, there is typically a level of quality, safety and reliability that increases exponentially with time.

Importance of Testing

For some types of products, package testing is mandated by regulations: food, pharmaceuticals, medical devices, dangerous goods, etc. This may cover the design qualification, periodic retesting, and control of the packaging processes. Processes may be controlled by a variety of quality management systems such as HACCP, statistical process control, validation protocols, ISO 9000, etc.

Disposable syringes are mostly injection moulded from polypropylene. Syringes are available in sizes of 1 ml, 2ml, 5 ml and 10 ml, in a variety of designs and consist of either two or three components construction. The number and size of injection moulding machines required depend upon syringe construction, number of mould cavities, annual production. Thus protection from fatal diseases, minor infections, their ease of usage, comfort, no sterilization has lead these devices to become vital part of medical services.

CE MARKING

The CE marking is required for many products and attests the verification by a manufacturer that these products meet EU safety, health or environmental requirements. CE Marking is most probably required if you export to the 27 European Union (EU) and 3 European Free Trade Association (EFTA) member states. This also applies to products made in third countries which are sold in the EEA and Turkey.

In Vitro Diagnostic Medical Devices

The “in vitro diagnostic medical device” means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

- Concerning a physiological or pathological state, or
- concerning a congenital abnormality, or

Notified Body

The organization, which will check whether the appropriate conformity assessment procedures have been followed, is known as the Notified Body. It is a certification organization, which the Competent Authority, of
a Member State designates to carry out one or more of the conformity assessment procedures described in the annexes of the Directives.

Periodic auditing of the Notified Body by the Competent Authority will ensure adherence to these criteria. A Notified Body will not necessarily have to carry out every part of the testing or auditing; some aspects may be sub-contracted. In such cases, the Notified Body must retain the final and overall responsibility.

In assessing the Quality Management System element in conformity assessment, some notified bodies have adopted the EN 46000 series of standards, particular requirements for Medical Device manufacturers in addition to the ISO 9000 Series.

Reproduce the CE Marking

Once you have satisfied the conformity assessment requirements for CE marking, you must attach the CE marking to your product or its packaging. There are specific rules for using the CE marking for your product, as well as rules for the reproduction of the CE marking logo.

In general, you should attach the CE marking to the product itself, but it may also be affixed to the packaging, in manuals, and on other supporting literature. Rules covering the use of the CE markings vary depending on the specific EU Directive that applies to the product, and it is advisable to study the applicable guidance.

**CLEANROOM TECHNOLOGY**

**Introduction**

They must be continually removed from the air. The level to which these particles need to be removed depends upon the standards required. The most frequently used standard is the Federal Standard 209E. The 209E is a document that establishes standard classes of air cleanliness for airborne particulate levels in cleanrooms and clean zones. Strict rules and procedures are followed to prevent contamination of the product. A cleanroom must certainly be “clean”.

A human hair is about 75-100 microns in diameter. A particle 200 times smaller (0.5 micron) than the human hair can cause major disaster in a cleanroom. Contamination can lead to expensive downtime and increased production costs. In fact, the billion dollars NASA Hubble Space Telescope was damaged and did not perform as designed because of a particle smaller than 0.5 microns.

Once a cleanroom is built, it must be maintained and cleaned to the same high standards. At present, the need for cleanrooms is a requirement of modern industries. The use of cleanrooms is diverse. Table 1.1 below shows you the needs of different industries:

**Key Elements of Contamination Control**

We will look at several areas of concern to get a better idea of the overall picture of contamination control. These are the things that need to be considered when providing an effective contamination control program.

HEPA (High Efficiency Particulate Air Filter) - These filters are extremely important for maintaining contamination control. They filter particles as small as 0.3 microns with a 99.97% minimum particle-collective efficiency.

CLEANROOM ARCHITECTURE - Cleanrooms are designed to achieve and maintain a airflow in which essentially the entire body of air within a confined area moves with uniform velocity along parallel flow lines. This air flow is called laminar flow. The more restriction of air flow the more turbulence. Turbulence can cause particle movement.

Filtration - In addition to the HEPA filters commonly used in cleanrooms, there are a number of other filtration mechanisms used to remove particles from gases and liquids. These filters are essential for providing effective contamination control.

Cleaning - Cleaning is an essential element of contamination control. Decisions need to be made about
the details of cleanroom maintenance and cleaning. Applications and procedures need to be written and agreed upon by cleanroom management and contractors (if used). There are many problems associated with cleaning.

Unidirectional Airflow Cleanrooms

Unidirectional airflow is used when low airborne concentration of particles of bacteria is required. This type of cleanroom was previously known as “laminar flow”, usually horizontal or vertical, at a uniform speed of between 0.3 and 0.45 m/s and throughout the entire air space.

International Standards

Cleanrooms are classified by the cleanliness of air. Standards are very important in designing process. Following the International Standards increase levels of safety, reliability, quality and efficiency. The history of cleanroom standards started in the USA. By order of American Air Force first standard was made in 1961. It was called Technical Manual 00-25 203. There was description of entering, designing and cleaning. Also it involves airborne particle requirements. Two years later was published Federal Standard 209. It is the first document that regulates cleanroom facilities. It was entitled “Clean Room and Work Station Requirements, Controlled Environments”. There was determined measured size of particle more than 0.5\(\mu\)m. It was so, because there was not better equipment to measure smaller particles at those days. In 1966 Federal Standard 2094 was fixed and named 209A.

Cleanroom Garment System

The largest cause of contamination in a cleanroom is personnel. To illustrate this, let us look at some statistics:

Personnel working in cleanrooms disperse large quantities of particles from their skin and clothing. It is therefore necessary for personnel working within a cleanroom to use clothing that will minimize this dispersion. Cleanroom clothing is made from fabrics that do not lint or disperse particles and act as a filter against particles dispersed from the person’s skin and indoor, or factory, clothing.

The type of clothing used in a cleanroom varies according to the type of cleanroom. In cleanrooms where contamination control is very important, personnel wear clothing that completely envelops them to ensure that particles and bacteria are not dispersed into the air. Whatever the choice of fabric or style of clothing, garments will have to be put on prior to entering the cleanroom. This should be done in such a manner that outside of the clothing is no contaminated. The majority of cleanrooms require that a garment be used more than once. It is therefore necessary to devise a method that ensures garments are removed and then stored in such a way to ensure that the minimum of contamination is deposited onto them.

In cleanrooms where contamination is not as critical, then a smock, cap and shoe cover may be sufficient.

Testing of Cleanroom Clothing

Laboratory testing can assess the contamination properties of different types of clothing. The first type of testing is that of the fabric; these tests will ascertain its likely filtration properties. The second type of test is concerned with the performance of the whole clothing system; this is usually carried out in a body box.

Comparison of Clothing made from Different Fabrics

As the air permeability increases, the amount of air pumped out of the garments’ closures, (i.e. cuffs, neck etc.) increases. The pressure inside a Gore-Tex suit is many times greater than a garment made of a woven fabric. This is reflected in the fact that a higher dispersion rate than expected was found. However, when a Gore-Tex garment with special closures to minimise air escape was tested, a further large reduction in bacterial dispersion was achieved. This gave a dispersion rate 170 times less than the open fabric. The above tests were also carried out to measure dust particles. Shown in Table is the particle dispersion per minute.

It is interesting to note the general ineffectiveness of cleanroom clothing in preventing the dispersion of small particles (2 0.5 \(\mu\)m). If the ‘special closures’ Gore-Tex clothing are excluded, it is seen that cleanroom
clothing gave only a small reduction in the dispersion of particles 2 0.5 pm (from 106/min to 105/min). However, these cleanroom garments were much more effective in removing larger (2 5.0 pm) particles.

Layout of Cleanroom Suite
The differences in the process requirements refer to the following key variations: the rooms are separated into clean and aseptic rooms. The barriers between them are created by the oven, autoclave and transfer hatch for items entering the aseptic suite, and through the separation of the “solution preparation” and “aseptic filling” rooms. Separate and more exact changing room control is provided for the aseptic suite, due to the differences between environmental control of the clean and aseptic suites. Also the isolator can be used in place of the unidirectional flow workstation.

Cleaning Methods and the Physics of Cleaning Surfaces
The main force that holds particles to cleanroom surfaces is the London van-der Waal's force, this being an inter-molecular force. Electrostatic forces can also attract particles to a surface. The importance of electrostatic forces will vary between cleanrooms, and depends on the type of materials used within the cleanroom. A third force can arise after wet cleaning. Particles that are left behind will dry on the surface, and may adhere to it through a bridge of material that has dried out from the liquid left behind.

MEDICAL DEVICE PACKAGING
Medical devices vary greatly in complexity and application. Examples range from simple devices such as tongue depressors, medical thermometers, and disposable gloves to advanced devices such as computers which assist in the conduct of medical testing, implants, and prostheses.

Packaging
The packaging industry is continuously evolving as medical product companies institute changes in the design, development, and manufacture of packaging systems. The package that protects the device during handling and shipping, and from the environment and microorganisms until the package is opened, is the need of the time. This includes allowing for any necessary sterilization. Packaging contains the product identification and other information.

Packaging Materials
Fulfilling the design control procedures discussed above should include using the most appropriate packaging materials available for the device. Although requirements for components, device master records, environmental control, etc., that affect the selection and use of packaging appear throughout the Quality System (QS) regulation. Also the design requirements for Class II, Class III, and the few Class I devices that require design control extend to the broad requirements. Device packaging and shipping containers should be designed and constructed to protect the device from adulteration or damage during the customary conditions of processing, storage, handling, and distribution.

Procurement, Acceptance and Storage
The supplier may test these components and provide the manufacturer with a protocol for testing and the test results for each batch (i.e., certificate of conformance to purchase specifications). The manufacturer could accept this specific data as sufficient certification based on his assessment of the supplier along with the review of the certificate or order his own testing.
Incoming components should be examined for damage and identity before being used. At a minimum, this examination should include visual inspection. Thereafter, the packaging should be handled and stored in such a way that it is kept clean and safe from damage. Packaging and devices to be sterilized should, obviously, be kept clean before sterilization.

Exhibits
The examples that follow will aid a company in preparing product packaging specifications and/or in purchasing standard packaging.
Product Specification: Pouch
This form is used to purchase specific pouches from a standard family of pouches. The finished device manufacturer completes the form with the desired size, material, style, etc. The form refers to other documents which define the technical characteristics of the pouches.

**Standard Tray with Undercuts**
This style tray is designed to be enclosed in a Peel Pouch or a Header Pouch which provides the sterile barrier. It does not have molded flanges for a heat-sealed lid. Typically used for catheters and other long-narrow devices. Some kit trays are also designed in this style.

**DIMENSIONING BOX**
Dimensions are described based on the opening of an assembled box. The opening can be located on the top or the side, depending on how the product will load into the box.
Length - The larger of the two dimensions of the opening.
Width - The smaller of the two dimensions of the opening.
Depth - The side perpendicular to the length and width.

**DISPOSABLE BLOOD BAGS**
Flexible PVC Blood Bags
PVC Blood bags enable better separation of blood components in a more sterile manner and safer transfusion of components. This has led to increasingly wider use of blood component therapy than whole blood use, thus enabling more effective use of the scarce donor blood that is available.
Though, the incidences of reported toxic problems resulting from plasticizer migration during transfusions are rare. Plasticizer migration from PVC medical devices has been an area of concern for the last few decades due to the large consumption of the polymer in its plasticized form.
As the unplasticized PVC is generally hard and brittle, addition of DEHP (low molecular weight additive, also known as di-octyl phthalate is a non toxic chemical with high versatility and low cost), facilitates processing operations such as sheet and tube extrusion and injection moulding.
Still, these compounds possess high mobility and are known to migrate from the plastics into the surrounding medium or environment such as food or blood. National Institute of Environmental Health Sciences, USA organized several international symposia on phthalate acid esters which reviewed many aspects of these substances including their metabolism, toxicity and methods for their detection in the environment and biological materials.

**Disposable Plastic Gloves**
Introduction
Disposable examination plastic gloves are now gaining popularity over latex base examination hand gloves. Latex is partly imported material in India. It can be replaced by plastic made hand gloves. For the manufacturing of examination disposable plastic gloves basic raw material is used L.H.D.P.E., which is indigenously available. Basic plant and machineries required is specially designed fine precision injection moulding machines by which disposable examination plastic gloves are manufactured.

**DISPOSABLE MASKS**
In modern times surgery has advanced considerably with lot of innovation, which necessitates surgical operational measures to be adopted. For that reason, these disposable surgical masks are extensively required.
While manufacturing disposable surgical masks, prior to packing, these are made sterile (i.e. asceptic) by sterilization process so that no infection pervades while performing an operation.
The raw material used for the manufacture of these disposable surgical masks is tissue paper; which has
very fine pores, which permit the passage of air to the surgeon for breathing while performing an operation.

Uses & Applications
- These disposable surgical caps and masks are used considerably while performing an operation or undergoing surgical measures.

Machinery Images for Masks

Mask Making Machine
This machine is the front stage machine for non-woven face masks production, it is fully automatic machine to produce blank masks from feeding raw material, inserting & cutting nose wire, pleating over edge, ultrasonic welding to piece cutting. The finished blank masks will be counted and collected on conveyer.

Disposable Surgical Catheters
The modern application of the catheter was in use at least by 1868 when Dr. N.B. Sornborger patented the Syringe and Catheter with features for fastening it to the body and controlling the depth of insertion. David S. Sheridan was the inventor of the modern disposable catheter in the 1940’s. In his lifetime he started and sold four catheter companies and was dubbed the “Catheter King” by Forbes Magazine in 1988. He is also credited with the invention of the modern “disposable” plastic endotracheal tube now used routinely in surgery. Previous to his invention, red rubber tubes were used, sterilized, and then re-used which often led to the spread of disease and also held a high risk of infection. As a result Mr. Sheridan is credited with saving thousands of lives.

In medicine a catheter is a tube that can be inserted into a body cavity, duct or vessel. Catheters thereby allow drainage or injection of fluids or access by surgical instruments. The process of inserting a catheter is catheterization. In most uses, when a catheter is a thin, flexible tube it is a “soft” catheter and when it is a larger, solid tube, it is said to be a “hard” catheter.

Disposable Surgical Wear
(Surgical Gowns, Bed sheets, Pillow cover, Caps)
A surgical drape is a covering made of a disposable non-woven material and is used to cover the area of a patient. A drape usually has a fenestration (an opening) to allow the surgeon to perform the operation. It comes in various sizes depending on the type of operation for which it is used. Drapes also vary from hospital to hospital. For example, for an eye operation, a drape measuring 15 sq. in. with a fenestration measuring 3 sq. in. might be sufficient, while for open heart surgery, the largest drape manufactured, a laparotomy drape which covers the entire body is required.

Disposable Bed Sheets

General Construction for Disposable Gowns
Most of the gowns examined were constructed from 3 to 5 major pieces. Although many of the gowns had no seams at the side, they had front and back panels defined clearly by the sleeve placement. Most of the gowns were partially assembled using traditional stitches and seams, commonly a 401 double thread chain stitch with a simple superimposed seam. Exceptions to this generalization included an Allegiance gown and the Compel reusable gown that were assembled using a lapped seam structure and two parallel rows of 401 stitching. A large stitch length was used to minimize puncturing of the fabric and limit interference with the barrier performance. Sleeve seams, critical zones for barrier performance, were typically fused.

A surgical gown or drape is made to the user’s specifications. Therefore, the amount of the subject fabric or other impervious or water-repellent fabric used in a gown or drape varies for each tender, depending on the specifications required. Usually, only the front part of the gown, from the chest to the feet, and the forearms, the parts that are exposed to fluids or that come in contact with the operating table, are made of an impervious or water-repellent fabric. Other parts of the gown are usually made of an anti-bacterial fabric. A
drape can also be made of a combination of anti-bacterial, water-repellent and impervious fabrics. The parts that are exposed to fluids more and more made of an impervious fabric.

Raw Material
Non-woven Fabric is a fabric like material made from long fibers, bonded together by chemical, mechanical, heat or solvent treatment. The term is used in the textile manufacturing industry to denote fabrics, such as felt, which are neither woven nor knitted. Non-woven materials typically lack strength unless densified or reinforced by a backing. In recent years, non-woven have become an alternative to polyurethane foam. The products like medical disposable gloves, examination gloves, oxygen mask and tracheal tube are made as per ASTM standards. Equal emphasis is being paid to ensure safe and hygienic packaging of products.

Disposable Plastic Syringes
Syringe is an instrument which is used for injecting any liquid into the body of human beings or of animals. It consists of a cylinder and an air tight piston. These syringes are used for injecting the medicine into the body or into the nerve of the body which are not possible to take in through mouth or takes much time in mixing with blood. These syringes are available in sizes varying from 2 C.C. to 100 C.C. Most popular and commonly used sizes are 2 C.C., and 5 C.C. Other sizes are also frequently used but up to lesser extent. Previously glass was used for making these syringes, the most commonly used glass is Pyrex glass. This glass is shock-resistant, temperature-resistant and has low thermal co-efficient of expansion. But with the development of plastic technology, this glass has been substituted by high grade plastics. Plastic can be used in place of glass for making syringes without any problem.

Uses
Therefore, disposable syringes often are favored over reusable syringes for vaccines, in order to avoid the risk of transmitting blood-borne diseases such as human immunodeficiency virus (HIV) and hepatitis from one person to another. Needle-exchange programs that provide intravenous drug users with disposable syringes and needles are based on the same idea, because reuse and sharing of infected needles by drug users is one of the principal ways HIV is transmitted in the developed world.

Parts of a Disposable Syringe
Nozzle
The male conical tip of the nozzle is of the lunar lock or luer type and shall comply with OS: 3234-1979. The main conical tip of the nozzle shall be of the luer type and shall comply with IS 3234-1979 then tip has a collar with the interval threaded to receive the corresponding needle and which when rotated shall securely hold it. Threaded dimensions shall be in accordance with IS 3236-1980 but window gap is to be excluded.

Raw Material Used for Manufacturing Disposable Syringes
The materials list for a modern three part syringe primarily includes polypropylene, polyethylene, polystyrene, natural rubber (from latex), synthetic elastic material, silicone oil and various inks for marking. The two-part syringe is composed of polypropylene and polyethylene and various inks for marking.

Polyolefin - (Polyethylene and Polypropylene)
Polyolefin are high molecular weight hydrocarbons. All are break resistant, non-toxic, and non-contaminating. These plastics are lighter than water. They withstand exposure to most common chemicals for up to 24 hours. Strong oxidizing agents may eventually cause these plastics to become brittle.

Polystyrene
This plastic is composed of chains of styrene “rings” similar to toluene in structure. It is not a polyolefin. It is rigid, clear, and generally non-toxic in its pure state. It has relatively good chemical resistance to aqueous solutions but is attacked by most organic solvents. Because of the latter, it has a tendency to absorb organic compounds to which it is exposed. This creates a much greater capacity for chemical interaction.
than the polyolefin.

Process Description

1st Stage
Moulding operation i.e. making of moulded
Take fixed quantity of polypropylene resin and mix with it 0.5-1% plasticizer on the weight basis of P.P.
resin. On the hopper of the injection moulding machine set shot wt. of the machine according to product
required (like moulded Barrel, Plunger, Cap, Hub, Gasket etc.).

2nd Stage
(I.V. Cannula) Needle production basically here we have not considered. The needle making system will
increase the cost of project too high. Here we consider purchasing needles from the needle manufacturers.

3rd Stage
Needles (I.V. Cannula) 21 gauges to 30 gauges size are assembled preformed syringe and then it is
formed complete set of disposable syringe.

4th Stage
Take fixed quantity of polypropylene resin and mix with it 0.5-1% plasticizer on the weight basis of P.P.
resin. On the hopper of the injection moulding machine set shot wt. of the machine according to product
required (like moulded Barrel, Plunger, Cap, Hub, Gasket etc.). Start heater to raise the temperature
130°C-140°C such that resin materials melted away.

Medium for Anaerobic Organism
The medium consists of meat extract containing a suitable concentration of peptone or is prepared by the
enzymic digestions, or proteins material.

Medium for Aerobic Organism
The medium is similar to that for anaerobic organism with the additions of either:

1. Sufficient heat coagulated muscle to occupy a depth of at least 1 cm at the bottom of the container
or.

2. About 0.05 per cent of eager together with other suitable substance which can decrease the
oxidation reduction potential of the final medium sufficiently to permit the growth to obligate anaerobic
organism an oxidation reduction potential indicator such as are Zunin Sodium may added after fuel
sterilization the ackobining of the medium lies between the limits represented by pH.7.2 and pH 7.8.

I.V. (INTRA-VENOUS) CANNULA
In general, the smallest gauge of catheter should be selected for the prescribed therapy to prevent damage
to the vessel intima and ensure adequate blood flow around the catheter, which reduces the risk of
phlebitis. In an emergency situation or when patients are expected to require large volumes infused over a
short period of time, the largest gauge and shortest catheter that is likely to fit the chosen vein should be
used.

Types of IV Catheters
Intravenous or IV therapy is beneficial for several conditions and medical situations including dehydration,
nutrition, shock, and surgery, blood transfusions, chemotherapy and medication administration. There are
many types and brands of IV access catheters, and nursingcenter.com explains they fall under two
designations, peripheral and central.

Midline Peripheral Catheter
Another type of IV catheter is called a midline, which is defined by Nursingcenter.com as a catheter that is
from 3- to 10-inches long. These catheters typically last for about four to six weeks. The tip of this catheter
reaches a much larger vein, causing less irritation.

Application of Cannula
**Nasal Cannula**

A nasal cannula or an oral–nasal cannula consists of a flexible tube, usually with multiple short, open-ended branches for comfortable insertion into the nostrils and/or mouth, and may be used for the delivery of a gas (such as pure oxygen), a gas mixture (as, for example, during anesthesia), or to measure airflow into and out of the nose and/or mouth.

**Butterfly Needle**

A Butterfly needle or, casually, a butterfly is named because of the plastic handles attached to the needle resemble butterfly wings.

Accidental needle sticks can occur in several ways. For example, a sudden movement by a patient can cause a healthcare worker to lose control of the needle, resulting in injury. Additionally, injuries can result when contaminated, 25 unprotected needles are left unattended or disposed of improperly. Moreover, attempts to manually recap a needle after a medical procedure can also result in injury.

In addition to accidental needle sticks, unnecessary exposure to blood borne pathogens can result when a healthcare worker mistakenly re-uses a contaminated needle on a patient.

Accidental needle sticks and the inadvertent reuse of a contaminated needle have the potential to expose patients and healthcare workers to life-threatening viruses that include hepatitis and HIV. Because of this potential exposure, healthcare providers are obligated to conduct extensive testing of exposed individuals.

**Raw Material**

**Polymers Used in Plastic Moulding**

The term “polymer” describes classes of molecules with large numbers of repeating structural units connected through covalent bonds. The major identifying feature distinguishing polymers from other molecules is the repetition of many similar, identical, or complementary subunits.

**Ethylene**

**Polyethylene Polymer**

Polyethene, Polythene, PE, LDPE, HDPE, MDPE, LLDPE

- LDPE (Low Density Polyethylene) is defined by a density range of 0.910 - 0.940 g/cm³. It has a high degree of short and long chain branching, which means that the chains do not pack into the crystal structure as well. It has therefore less strong intermolecular forces, as the instantaneous-dipole induced-dipole attraction is less. This results in a lower tensile strength and increased ductility. LDPE is created by free radical polymerization. The high degree of branches with long chains gives molten LDPE unique and desirable flow properties.

**Manufacturing Process of IV Cannula**

**Plastic Moulding**

Plastic Moulding is the process of shaping plastic using a rigid frame or mould. The technique allows for the creation of objects of all shapes and sizes with huge design flexibility for both simple and highly complex designs. A popular manufacturing option, plastic-moulding techniques are responsible for many car parts, containers, signs and other high volume items.

**Safe Blood Stopper**

Designed to ventilate air-allowing blood to reach wing chamber without the need to remove blood stopper, which protects blood from contamination.

**Packing**

Single use IVC individually blister packed in a high strength plastic medical film and superior quality medical grade paper guarantees higher puncture and water resistance, enabling extended shelf life even under adverse conditions.

The Salient features of the I.V. Cannula Assembly Line are:
Catheter Material as per USP standards Class VI

PROCESS DESCRIPTION OF THE ASSEMBLY LINE

Automatic Cup Forming Machine
This is the first operation in IV Cannula. Cup is formed at one end of Teflon tube to fix the slip ring. Machine has Double Stations, each Station having Six Tracks. Most of the parts are made on Cnc wire cut machine like punches, stripper plate, magazine plates & punch guides. For ease in operation we fix 2 stations on one table, because one operator can operate 4~6 stations. One station is fixed for one size. The rejection level in our machine is below 1%. (in most of the cases below 0.5%). Automatic Cup Forming Machine has 2 Stations and each station has a Fixed Gauge.

Automatic Needle Assembly Machine
The Needle Assembly Machine with automatic needle hub loading and automatically removing of assembled needles from station and put on linear feeder. Then the assembled needles are also unloaded automatically on the stands.

Output of this machine is approx 1400 pieces per hour with approx 99% needle orientation and Plus /Minus 0.1 mm length variation (which is very precise needle length). The loading as well unloading of the input & finished product is automatic.

Automatic Blister Packing Machine
In this machine PVC film of 184mm is used for 6 blisters in one stroke. Machine runs at 14~15 cycles per minute in medical grade paper and 9~10 cycles per minute in Tyvek Paper.

Ethylene Oxide (ETO) Sterilization Process
First, products need to go through a pre-conditioning phase to make microorganisms grow. The batch load goes through a dwell time under a controlled environment of:

- Temperature
- Humidity

Sterilizer Stage
During this cycle, accurate temperature control is important and a heating jacket is used. As the overall duration of this cycle is around 60 hours, high availability of the system is vital and system redundancy is required. Doubling sensors, actuators and controllers as well as changeover facilities on these components, helps to ensure the product is sterilized even on hardware or software failure.

After the doors have been shut down and sealed correctly, the cycle can be started either manually or automatically. If any problem with door sealing is detected the cycle is interlocked and cannot start. Security interlocks are also used between air and ETO valves.

Degasser Stage
Finally, products need to go through a degassing phase to remove any particle of ETO. The batch load goes over a dwell time under a temperature-controlled environment.

Machinery for IV Cannula Production Line

Automatic Needle Assembly Machine

Catheter Cutting Machine

Specification of the product are detailed below:

- Power consumption 2.5 Kw
- Reed switches of FESTO/ SMC/CKD and sensors of Sick Optics/ Omron/ German make
- Air Consumption 2.5~3.0 cfm at 5 bars
- Chilled water consumption 3 liters per minute
- PLC & HMI Mitsubishi, Keyence, Omron, Delta
- Machine Frame manufactured from Imported Aluminum Extruded Profiles
- Pneumatics used of Festo/SMC/ CKD makes
INFUSION SET & BLOOD TRANSFUSION SET

The most common way to receive a blood transfusion is through a tube inserted into the arm. This tube or cannula is connected to a drip. During the blood transfusion, blood will run from the drip through the tube and into the patient's arm. People who need frequent transfusions may receive the blood via a tube inserted into the chest. This procedure is called a central line blood transfusion. If frequent transfusions are given via the arm, irritation of the veins may lead to blood clots.

During an operation, it is possible for a patient's own blood to be used for a transfusion. This is called an autologous transfusion. Your own blood will be taken during the operation and then given back to you right away.

You can also give blood in the weeks before you have an operation if you are well enough. Many people choose this option if it is available due to fear of an infection from donated blood. Although risk of infection is very low, autologous transfusions are useful if the patient has a very rare blood type.

Blood Transfusion

A blood transfusion is a relatively simple medical procedure during which a patient receives whole blood or one of its parts through an intravenous line, or IV. This is a tiny tube that is inserted into a vein using a small needle.

While patients are likely to notice a brief pinch of the needle, a blood transfusion is relatively painless. Still, any procedure that involves a needle is likely to cause some anxiety for a child, so it helps to understand how a transfusion is done. That way you can feel confident about what is happening and help put your child at ease.

Blood is like the body’s transportation system. As blood circulates, it delivers oxygen and nutrients throughout the body. It also collects waste products and carries them to the organs responsible for making sure the wastes leave the body.

A blood transfusion can make up for a loss of blood or any part of the blood. Although whole blood can be transfused, it is rarely used. Instead, more specific parts of blood are transfused as needed. Red blood cells, the most commonly transfused part, are used to increase the blood’s ability to carry oxygen and prevent fatigue and other complications.

Transfusions take 1 to 4 hours, depending on how much blood and what type is given, and no special recovery time is needed. Most transfusions are done in a hospital, but can be done elsewhere when necessary.

Serious reactions to transfusions are rare, but as with any medical procedure, there are a few potential risks, which your doctor will review with you.

Product Description

Blood Transfusion Sets

The device is plastic, disposable and sterile blood transfusion set, which is intended to be used to administer the blood from the container to a patient's vascular system through a needle or catheter inserted into a vein via gravity method.

The blood transfusion set consists of protective cap of the closure-piercing device, closure-piercing device, tubing, drip, flow regulator, transfusion needle and needle sheath. In addition, there are two kinds of the transfusion set, one has a drug-adding feature and the other hasn’t.

There are two specifications of transfusion needle, which are 0.9# transfusion needle and 1.2# transfusion needle.

Infusion Set

Infusion therapy is a type of medical treatment in which medication is delivered directly into the body via a
blood vessel, the spinal cord, or a muscle. This type of therapy is used when oral therapy is not an option, for a variety of reasons ranging from swallowing disorders, which make it difficult for patients to swallow medications and food to the use of medications, which would be destroyed in the stomach, and must therefore be delivered directly. There are a number of applications for infusion therapy. Historically, this type of treatment took place on an inpatient basis, with the patient staying in the hospital and being monitored during the course of the treatment. More commonly today, infusion therapy is offered as an outpatient procedure. The patient can visit a clinic or infusion therapy center for treatments, and leave when the treatment is finished. This creates more flexibility for patients in addition to cutting down on costs.

**Infusion Therapy**

Common infusion drug therapies include intravenous antibiotics, antifungal and antiviral; pain management products; chemotherapy agents; immune globulin; growth hormones; colony stimulating factors; and other biotechnology and traditional drug products that must, for therapeutic reasons, be administered directly into the bloodstream.

Another common infusion therapy is total parenteral nutrition (also referred to as TPN, or intravenous hyper alimentation). Parenteral nutrition is designed to meet the daily caloric requirements and nutritional needs of patients whose digestive systems do not function sufficiently to absorb nutrients to maintain weight and strength through oral nutritional intake.

Diseases commonly requiring infusion therapy include infections that are unresponsive to oral antibiotics, cancer and cancer-related pain, dehydration, gastrointestinal diseases or disorders which prevent normal functioning of the gastrointestinal system, and more. Other conditions treated with specialty infusion therapies may include cancers, congestive heart failure, Crohn's Disease, hemophilia, immune deficiencies, multiple sclerosis, rheumatoid arthritis, and more.

Until the 1980s, patients receiving infusion therapy had to remain in the inpatient setting for the duration of their therapy. Heightened emphasis on cost-containment in health care, as well as developments in the clinical administration of the therapy, led to strategies to administer infusion therapy in alternate settings.

**The Compression Moulding Process**

Specifically designed to facilitate the replacement of metal components with polymers (and other composites), the compression moulding process is a method of moulding in which a preheated polymer is placed into an open, heated mould cavity. The mould is closed with a top plug and pressure is applied to force the material to contact all areas of the mould. Throughout the process heat and pressure are maintained until the polymer has cured.

While the compression moulding process can be employed with both thermo sets and thermoplastics, today most applications use thermo set polymers. Advanced composite thermoplastics can also be compression moulded with unidirectional tapes, woven fabrics, randomly orientated fiber mat or chopped strand.

Plastic extrusions are normally manufactured with thermoplastics, although thermo set plastics can also be extruded. Some of the materials regularly extruded are polytetrafluoroethylene (PTFE), polyurethane, nylon, vinyl and acrylic, among many others. Perhaps the most advantageous aspect of plastic extrusion is its low cost, which is virtually unsurpassed by any other plastic processing operation. Plastic extruding is also a highly efficient process, as it is a continuous operation that generates little wasted material. This is in contrast to injection molding, which encounters numerous changes while the melt is sent into the mold, and which involves higher pressures. In addition, the rotating screw central to any extruding system melts, mixes and drives the plastic through the opening, thereby economizing size and machine cost.

Screw extruders can involve a single screw or multiple screws, each of which has benefits and drawbacks. One drawback to most extrusion operations is that dimensional tolerances are relatively high, ranging up to 10% of the work piece. This varies based on the material used, as well as the specifics of the process in question (temperature, post extrusion techniques, etc.). In general, literature recommends precision
controlled down-system equipment, precise and continuous flow rates, and uniformity of melt-heat profile and mix.

Pneumatic Angled Tube Cutter
This tube-cutting unit is ideal where accurate cutting of angles or tubing lengths is critical. The tubing cutting mechanism is fully guarded to insure operator safety while cutting tubing.

Tubing Cutter - Pneumatic Operated
Molded Tubing - Cutting Machine
Tubing cutting machine with two rotary blades cuts breathing tubing blow-molded parts that are will be made into a filter for breathing tubes. The operator feed complete tubing parts into the machine where the ends of the tubing are simultaneously removed from both sides.

Plastic Tube Bending Oven
Plastic tube bending - Conveyer oven is designed to bend plastic tubing into angles. The machine will bend and form the most common catheter shapes such as: hooks, single curves, double curves, pigtails, “J’s”, Cobras and other shapes for ends of catheters. Production rates are 45 breathing tubes per minute. Safety interlocks on the tubing cutter are installed to protect machine operators. PLC controls the operation of the tubing cutter machine.

Automatic bending of plastic tubing for catheters and medical tubing
A permanent tubing coil can be bent and formed to plastic tubing by a modified Quick Coil-Tubing Coiling Machine. By use of plastic tubing coiled around heated mandrels, heat can set a permanent shape into the bent tubing. Ideal to form medical tubing sets such as drain line.

The IV Tubing Set Assembly Machine is a rotary style assembly machine to make IV line - plastic medical tubing sets.

SURGICAL COTTON & BANDAGES

Introduction
Surgical Bandages are the products manufactured from White Bleached Cotton gauge Cloth of suitable quality. These are available in various widths of running from 2.5 cm to 15 cms and of length from 3 meters or 4 meters. These are packed in a unit of doz. for sale. These are mainly used in hospital/Dispensaries for tying the wounds after dressing.

Cotton goods are made soft and absorbent by frequent washing with soap and chemical bleaching or drying in the sun. The processing removes the natural oils and waxes of the cotton fibres so that the water proof quality is lost. Generally about 15% of the raw cotton is removed in the treatment to render it suitable for surgical uses and this treatment is essentially the same for both absorbent cotton and the woven gauge.

Properties
Surgical Bandage
1. Surgical Bandage is made of very fine cotton yarn.
2. It is very soft.

Surgical Cotton
1. Surgical Cotton or absorbent cotton is snow white in colour.
2. It is completely sterilized by the action of chemicals.
3. It is very soft and is quite suitable for wound dressings.

Uses
• Absorbent Cotton also known as surgical Cotton is used mainly for medical purposes.
• Absorbent Cotton or medical Cotton is used by Doctors, Dentists, Industrial safety organizations in Hospitals and for individuals for first aid and home kits.
1. Surgical cotton and bandages are used in dispensaries and hospitals other places (Where facilities for treatment are provided) for dressing the wounds and the ulcers etc.
2. Surgical cotton and bandages are used for in case of sprain.
3. They are available in the shops of vaidyas, doctors, & Surgeon.

Process of Manufacture of Surgical Cotton
The process of manufacture of surgical cotton consists of the following steps:-
1. Mechanical Cleaning of Raw Cotton
It tears the entangled masses part. An air blast picks up the fibres and drives them against the meshes of a revolving cylindrical screen. The impurities and foreign matter pass through the meshes while the cotton sticks to the screen and is rolled with it. This mechanical operation is separated and carried on till the mechanical cleaning of the raw cotton is complete.
2. Boiling
The cleaned cotton is then boiled and by controlled chemical processing cotton laps prepared are charged into a large stainless steel basket or nets and lowered into the kier which is merely a cast iron cylinder with a lid and having steam heating arrangement. This process of boiling and bleaching removes nearly all waxy and fatty matter from the cotton under treatment. It softens and integrates any kind of foreign matter that may have remained after the mechanical cleaning operation.
3. Bleaching
The boiled and dilute alkali treated cotton obtained from the boiling operation is of absorbent type but it does not have good colour. For improving its colour it is bleached. A bleaching solution is run into the tank and circulated by pump for quite sometimes enough to de-colorize the cotton. The bleaching agent used is sodium hypo chlorite or Hydrogen peroxide.
4. Hydro-extraction
The bleached cotton is washed thoroughly and calculated amount of dilute sulphuric acid is added to neutralize any excess alkali. The cotton is again washed with water and fed through hydro extractor to remove as much water as possible.
5. Drying
Drying is usually accomplished by placing the wet lumps wire screens which are fitted above radiators containing steam under high pressure. The wet cotton laps are placed over the wire screens, dried and picked up.
6. Carding
The dried cotton is picked and carded; roll cotton is prepared by gathering together and packing the webs from various cards to give a product of desired bulk weight.

Machinery Images & specifications
1. Surgical Cotton Machinery
Wide Mouth Kier
Consisting
- Wide Mouth High Pressure Kier with accessories suitable for Surgical Cotton.
- KBC Pre-heater with accessories.
- KBC Pumping set.

Technical Details
- Capacity of the Vessel: 500 - 1500 kgs.
- Test Pressure 50 psi hydraulically.
- Working Pressure 30 psi

Preheater
- Test Pressure 50 psi hydraulically
• Working Pressure 30 psi

Pumping set
• Suitable Motor without any starter

3 Point Hydro-Extractor for Surgical Cotton
Consisting
Hydro-extractor type Half Lid Opening
Perforated Basket Stainless Steel
Outer shell Mild Steel / Stainless Steel
Cover & door Mild Steel / Stainless Steel
Opening of the door Manual / pneumatic

Continuous Fiber Dryer
Drying Section
• Drying sections of Mild Steel Chambers totally enclosed with insulating panels fabricated from double metal clad section with thick insulating material sandwiched between two covers.
• Each chamber consists of two sections. One houses conveyor and radiators while the other houses fan, fan housing and duct line.
• Each chamber is provided with the thermometer.

Conveyor
A conveyor of 1600mm width fabricated from perforated zinc coated CRC sheets duly reinforced, strengthened at the bottom and mounted on the conveyor chain. Conveyor is moved on sprocket wheels, which are situated outside the chamber.

Air Circulating Unit
Air circulating unit consists of strong, sturdy and balanced fans, fan housings and duct line fabricated from CRC sheets and duly painted with heat resisting aluminum paint.

Steam Radiators
Steam heated radiators having gilled pipes of the required capacity tested hydraulically up-to safe working of super heated steam pressure of 100 psi and painted with heat resisting aluminum paint.

Drive
Drive consists of 3 HP A.C motor with suitable gear box and necessary spur gear with inverter control drive will be supplied along with machine.