How to Manufacture Blood Bags Flexible PVC Blood Bags, Blood Collection Bag (Medical and Surgical Disposable Products)

Introduction

Blood bag systems are the fundamentals for worldwide blood supply by standard blood donation. More than 90 percent of all blood donations are processed in these systems that have up to six different bags with variable functions.

Disposable plastic blood bags refer to the biomedical devices that are used for collection, storage, transportation, and transfusion of blood and its components. Globally, the disposable plastic blood bags market is witnessing significant growth due to increasing prevalence of blood related disorders and advancement in the technology.



In addition, growing aging population and rising government initiatives in the field are driving the disposable plastic blood bags market. There are different types of disposable blood bags based on the need of blood infusion; single blood bag, double blood bag, triple blood bag, quadruple blood bag and transfer blood bag. A blood bag package consists of collection tube, needle, needle cover, and a clamp. The disposable plastic blood bags have replaced the usage of glass bottle for collection and storage of blood and blood components. Disposable plastic blood bags also help in the separation of blood components, such as platelets, plasma and cryoprecipitate that are used to treat a range of blood disorders.



Increase in the healthcare facilities will further act as a driver for the growth of medical devices sector in India. The blood bag market is expected to grow further in the coming years owing to continuous developments and rising demand for better blood collection technology. The global disposable plastic blood bags market is estimated at USD 2, 44,286.8 thousand in 2014. It is likely to grow with a CAGR of 9.1% and reach USD 4, 13,084.8 thousand in 2020.









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.



Table of Contents

1. INTRODUCTION

Design, Prototyping and Product Development Importance of Testing

2. CE MARKING

Medical Devices

Active Implantable Medical Devices

In Vitro Diagnostic Medical Devices

Competent Authority

Notified Body

Guide to CE Marking



Reproduce the CE Marking

Steps for Class I Medical Devices Compliance

Class I Medical Devices: Conformity Assessment Routes

3. CLEANROOM TECHNOLOGY

Introduction

Humans in Cleanrooms

Contamination Process

Sources of Contamination

- 1. Facilities
- 2. People
- 3. Tool Generated
- 4. Fluids
- 5. Product Generated



Key Elements of Contamination Control

List of Some of Equipment and Supplies Needed to Clean the Cleanroom

Classification of Cleanrooms

Conventionally Ventilated Cleanrooms

Unidirectional Airflow Cleanrooms

Mixed Flow Cleanrooms

Isolator or Minienvironment

International Standards

Cleanroom Garment System

Testing of Cleanroom Clothing

Effect of the Garment Design on Dispersion

Comparison of Clothing made from Different Fabrics

Regulations



General Cleanroom Regulations

Personal Actions Typically Prohibited in Cleanrooms

Layout of Cleanroom Suite

Cleaning Methods and the Physics of Cleaning Surfaces

How Should a Cleanroom be cleaned?

Cleaning Methods with Respect to Area Type

Choice of Materials

Test Methods

Furniture

Electrical

Cleanroom Equipments

4. MEDICAL DEVICE PACKAGING

Packaging



Packaging Design Controls

User Preference

Packaging Materials

Package Validation

Procurement, Acceptance and Storage

Packaging Process

Exhibits

Product Specification: Pouch

Header Bag (Specification Form)

Mandatory Label Information

Product Identity Declaration

Language

Location



Net Quantity Declaration

Manner of Declaring

Different Stages of Packaging

Primary Packaging

Chevron Peel Pouch

Corner Peel Pouch

Chevron Peel Pouch

Squared Sealed (No-peel, Tear) Pouch

Standard Method of Dimensioning Pouches

Standard Tray with Undercuts

Tray with Molded Lid

Tray with Heat Sealed Lid

Dual Sterile Barrier – Inner & Outer Tray



Die Cut Backer Cards

Secondary Packaging

Folding Cartons

Corrugated Shipping Containers

Packaging Standards

ISO

ISO-11607

Packaging for Terminally Sterilized Medical Devices

ASTM

ASTM D Standards

ASTM International Standards Fall into Six Categories

ASTM F Standards

ASTM-F1929



Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging

by Dye Penetration

Current Good Manufacturing Guidelines for Finished Pharmaceutical Goods

Materials Examination and Usage Criteria

Labeling Issuance

Packaging and Labeling Operations

Drug Product Inspection

Expiration Dating

5. DISPOSABLE BLOOD BAGS

Introduction

Flexible PVC Blood Bags

Uses of Blood Bags

Properties of Disposable Blood Bags



Raw Material

Quality of the Raw Materials

- 1. Translucency so can Check it Full, and See Layers in Centrifuged Bags
- 2. Flexibility (Low Bending Stiffness) so can Process by Squeezing the Bag
- 3. Heat Resistance, so can Steam Sterilize Prior to Use
- 4. Materials Property-Melting Temperature
- 5. Must Not Burst in the Centrifuge, or Tear on Handling
- 6. Permeable to Oxygen, but not too Permeable to Water
- 7. Moderate Cost
- 8. Processing and Welding
- 9. PVC Plasticized Blood Bag sizes: 350 ml & 450 ml

Manufacturing Process

Flow Sheet Diagram



Bag Making

Tube Making

Blood Bag Forming Machine

Suppliers of Plant & Machinery

Raw Materials Addresses

6. DISPOSABLE PLASTIC GLOVES

Introduction

Properties

Uses

Manufacturing Process

Raw Material

Basic Plant and Machineries Required



Steps

- 1. Washing
- 2. Coagulation
- 3. Application
- 4. Dripping
- 5. Gelling
- 6. Leaching
- 7. Beading
- 8. Slurry
- 9. Stripping
- 10. Testing
- 11. Packaging

Process Flow Diagram



Glove Manufacturing Machines

PE Glove Machine

Disposable Glove Making Machine

Non-Woven Glove Sewing Machine

Non woven Glove Making Machine

Suppliers of Raw Material

Suppliers of Plant Machineries

7. DISPOSABLE MASKS

Introduction

Uses & Applications

Properties

Manufacturing Process of Disposable Surgical Masks



Sterilization

Flow Diagram for Disposable Surgical Mask

Machinery Images for Masks

Mask Making Machine

Surgical Mask Sewing Machine

Mask Blank Machine

Plant & Machinery Suppliers

8. DISPOSABLE SURGICAL CATHETERS

Introduction

Uses & Applications

Common Features of Central Venous Catheter (CVC)

Manufacturing Process of Catheters



Process Flow Diagram of Catheter

Catheter Production Equipments

Plant & Machinery Suppliers

Suppliers of Raw Materials

9. DISPOSABLE SURGICAL WEAR

(Surgical Gowns, Bed sheets, Pillow cover, Caps)

Introduction

Disposable Bed Sheets

Disposable Pillow Cover

General Construction for Disposable Gowns

Closures

Sizing Analysis of Disposable Gowns

Standards



The General Requirements for Manufacturers, Processors and Products -

EN 13795-1

Products: Description

Medical & Sanitary Articles

Nonwoven Medical Gown

CPE Shoe Covers

Face Masks

Non Woven Face Mask

Advantages

Dust Mask

Advantages

Description of Surgeon Gowns

Description of Patient Gown



Description of Surgeon Suits

Raw Material

Protective Materials

Spun Bond Polypropylene

SMMS

DuPont T Isolation Wear T Medical Fabrics

Coated Polypropylene

Breathable Laminate

Characteristic

Manufacturing Process

Machinery Images & Details

Surgical Gown Sewing Machine

Non-Woven Gown making Machine



Disposable Surgical Cap Making Machine

Process Flow Diagram

Surgical Disposable Products Photograph

Surgical Gowns

Disposable Apron

Disposable Gown

Disposable Surgeon Gown

Disposable Coverall

Disposable Surgical Cap

Disposable Bouffant Cap

Disposable Mob Cap

Disposable Surgical Bed Sheets

Plant & Machinery Suppliers



Raw Materials Suppliers

10 DISPOSABLE PLASTIC SYRINGES

Introduction

Uses

Necessity of Disposable Syringes

Parts of a Disposable Syringe

Nozzle

Piston

Raw Material Used for Manufacturing Disposable Syringes

Polyolefin - (Polyethylene and Polypropylene)

Polyethylene

Polypropylene



Polystyrene

Natural Rubber

Synthetic Polymeric Material

Silicone Oil

Leakage Test

Sterility

Packing

Outer Container

Marking of Outer Containers

Manufacturing Process

Process Description

1st Stage of Process

2nd Stage of Production



3rd Stage of Process

4th Stage of Production

Process Flow Diagram

Assembling Operation and Packing

Machinery Images

Single Barrel Moulds

Syringe Plunger Moulds

Injection Moulding Machine

Disposable Syringe Packaging Machine

Storage of Sterilized Articles

Test for Detection of Aerobic and Anaerobic Organism

Media



Medium for Anaerobic Organism

Medium for Aerobic Organism

- A. Benzathine Penicillin, Benzyl Penicillin
- **B.** Other Antibiotic
- C. Test for Detection of Fungi Medium

Suppliers of Raw Material

11. I.V. (INTRA-VENOUS) CANNULA

Introduction

Types of IV Catheters

Peripheral

Midline Peripheral Catheter

Peripherally Inserted Central Catheter



Central Venous Catheter

Uses and Application

Application of Cannula

Nasal Cannula

Veterinary Use

Body Piercing

Butterfly Needle

Application of Butterfly Needle

Needle Gauge

I.V. Cannula: General Features

Needle

Needle Hub

Needle Protector



Catheter

Flash Back Chamber

Threaded Stopper

Blister Packing

Raw Material

Polymers Used in Plastic Moulding

1. Nylons

2. Polyamides, PA

Properties

3. Polyethylene

Properties

LDPE Properties

HDPE Properties



4. Polypropylene

Polypropene, PP

Properties

5. Polyvinyl Chloride (PVC)

Properties

Medical Grade Plastic

Manufacturing Process of IV Cannula

Plastic Moulding

Plastic Moulding Techniques

Rotational Moulding Technique

- 1. Preparing the Mould
- 2. Heating and Fusion
- 3. Cooling the Mould



- 4. Unloading/Demoulding
- **Plastic Injection Moulding**
- 1. Preparing the Mould
- 2. Injection of Polymer Melt into the Mould
- 3. Cooling the Mould
- 4. Unloading/Demoulding
- **The Blow Moulding Process**
- A. Injection Blow Moulding
- **B. Extrusion Blow Moulding**
- C. Stretch Blow Moulding
- **The Compression Moulding Process**
- **Plastic Extrusions**
- **Manufacturing Process Assembly Line**



Wings

Needle

Tubing

Silicon Valve

Safe Blood Stopper

Packing

Catheter Material as per USP standards Class VI

Process Description of the Assembly Line

Automatic Cup Forming Machine

Semi Automatic Body Assembly/Wing Assembly Machine

Semi Automatic Tip Forming Machine

Automatic Silicon Tube Cutting Machine

Automatic Needle Assembly Machine



Automatic Luer Lock & Flash Back Chamber Assembly Machine

Automatic Catheter Cutting Machine

Automatic Blister Packing Machine

Ethylene Oxide (ETO) Sterilization Process

Pre-Conditioning Stage

Sterilizer Stage

Degasser Stage

Process Flow Diagram

Machinery for IV Cannula Production Line

Automatic Needle Assembly Machine

Automatic Luer Lock & Flash Back Chamber Assembly Machine

Cannula Assembly Machine

Body Assembly Machine



Tip Forming Machine

Cup Forming Machine

Catheter Cutting Machine

Suppliers of Raw Material

12. INFUSION SET & BLOOD TRANSFUSION SET

Introduction

Blood Transfusion

Before the Blood Transfusion

During the Blood Transfusion

After the Blood Transfusion

Blood Transfusion Process Protocol

Product Description



Blood Transfusion Sets

Features

Disposable Infusion Set

Infusion & Transfusion Sets

Micro Flo Air Micro Drip Set

Micro Flo Eco Micro Drip Set

Blood Transfusion Set (Double Chamber)

Blood Transfusion Set Haemodrip (Double Chamber)

Blood Transfusion Set-Easy (Single Chamber)

Blood Donor Set

Infusion Set

Infusion Therapy

Manufacturing Process



Plastic Injection Moulding

- 1. Preparing the Mould
- 2. Injection of Polymer Melt into the Mould
- 3. Cooling the Mould
- 4. Unloading/Demoulding

The Blow Moulding Process

- 1. Injection Blow Moulding
- 2. Extrusion Blow Moulding
- 3. Stretch Blow Moulding

Stretch Blow Moulding

The Compression Moulding Process

Plastic Extrusions

Assembly Processes



Process Flow Diagram

Description of Machinery

Tubing Cutter

Pneumatic Angled Tube Cutter

Tubing Cutter - Pneumatic Operated

Molded Tubing - Cutting Machine

Plastic Tube Bending Oven

Double Ended Hose Assembly Machine

10 Vibratory Bowl Feeders for Hose Assembly Machine

Tape Dispenser

Floor Standing Coiling Machine

Tubing Taping Machinery

Suppliers of Plant and Machinery



Suppliers of Raw Material

13. SURGICAL COTTON & BANDAGES

Introduction

Properties

- (a) Surgical Bandage
- (b) Surgical Cotton

Uses

Process of Manufacture of Surgical Cotton

- 1. Mechanical Cleaning of Raw Cotton
- 2. Boiling
- 3. Bleaching
- 4. Hydro-extraction



- 5. Drying
- 6. Carding
- 7. Sterilization
- 8. Packing

Flow Sheet for the Manufacture of Surgical Cotton

Process of Manufacture for Bandage

- 1. Mechanical Cleaning
- 2. Drawing
- 3. Combing
- 4. Spinning
- 5. Weaving
- 6. Washing and Bleaching



- 7. Starching & Natural Drying
- 8. Cutting the Bandages Cloth into Bandage
- 9. Packing

Flow Sheet for the Manufacture of Surgical Bandage

Machinery Images & Specifications

- 1. Surgical Cotton Machinery
- 2. Bandages Making Machines

Plant & Machinery Suppliers



Niir Project Consultancy Services (NPCS) can provide Process Technology Book on Medical and Surgical Disposable Products (Blood Bags, Plastic Gloves, I.V. Cannula, Infusion Set, Gowns, Masks, Catheter, Cotton and Bandage, Surgical Wear, Syringes)

See more

http://goo.gl/3LI9Za

http://goo.gl/IH6fTG

http://goo.gl/PFAylU



VISIT US AT

www.entrepreneurindia.co



TAKE A LOOK AT NIIR PROJECT CONSULTANCY SERVICES ON #STREETVIEW

https://goo.gl/VstWkd



Locate us on Google Maps

https://goo.gl/maps/BKkUtq9gevT2



Contact us

Niir Project Consultancy Services

106-E, Kamla Nagar, Near Spark Mall,

New Delhi-110007, India.

Email: <u>npcs.ei@gmail.com</u>, <u>info@entrepreneurindia.co</u>

Tel: +91-11-23843955, 23845654, 23845886, 8800733955

Mobile: +91-9811043595

Fax: +91-11-23841561

Website:

http://www.niir.org

http://www.entrepreneurindia.co

Take a look at NIIR PROJECT CONSULTANCY SERVICES on #StreetView

https://goo.gl/VstWkd



NIIR PROJECT CONSULTANCY SERVICES

AN ISO 9001:2008 COMPANY



Who are we?

- One of the leading reliable names in industrial world for providing the most comprehensive technical consulting services
- We adopt a systematic approach to provide the strong fundamental support needed for the effective delivery of services to our Clients' in India & abroad



What do we offer?

- Project Identification
- Detailed Project Reports/Pre-feasibility Reports
- Business Plan
- Industry Trends
- Market Research Reports
- Technology Books and Directory
- Databases on CD-ROM
- Laboratory Testing Services
- Turnkey Project Consultancy/Solutions
- O Entrepreneur India (An Industrial Monthly Journal)



How are we different?

- We have two decades long experience in project consultancy and market research field
- We empower our customers with the prerequisite know-how to take sound business decisions
- We help catalyze business growth by providing distinctive and profound market analysis
- We serve a wide array of customers, from individual entrepreneurs to Corporations and Foreign Investors
- We use authentic & reliable sources to ensure business precision



Our Approach

Requirement collection

Thorough analysis of the project

Economic feasibility study of the Project

Market potential survey/research

Report Compilation



Who do we serve?

- Public-sector Companies
- Corporates
- Government Undertakings
- Individual Entrepreneurs
- O NRI's
- Foreign Investors
- Non-profit Organizations, NBFC's
- Educational Institutions
- Embassies & Consulates
- Consultancies
- Industry / trade associations



Sectors We Cover

- O Ayurvedic And Herbal Medicines, Herbal Cosmetics
- Alcoholic And Non Alcoholic Beverages, Drinks
- O Adhesives, Industrial Adhesive, Sealants, Glues, Gum & Resin
- Activated Carbon & Activated Charcoal
- Aluminium And Aluminium Extrusion Profiles & Sections,
- O Bio-fertilizers And Biotechnology
- Breakfast Snacks And Cereal Food
- O Bicycle Tyres & Tubes, Bicycle Parts, Bicycle Assembling



- Bamboo And Cane Based Projects
- Building Materials And Construction Projects
- O Biodegradable & Bioplastic Based Projects
- Chemicals (Organic And Inorganic)
- Confectionery, Bakery/Baking And Other Food
- Cereal Processing
- Coconut And Coconut Based Products
- Cold Storage For Fruits & Vegetables
- Coal & Coal Byproduct



- Copper & Copper Based Projects
- Dairy/Milk Processing
- O Disinfectants, Pesticides, Insecticides, Mosquito Repellents,
- Electrical, Electronic And Computer based Projects
- O Essential Oils, Oils & Fats And Allied
- Engineering Goods
- Fibre Glass & Float Glass
- Fast Moving Consumer Goods
- O Food, Bakery, Agro Processing



- Fruits & Vegetables Processing
- Ferro Alloys Based Projects
- Fertilizers & Biofertilizers
- Ginger & Ginger Based Projects
- Herbs And Medicinal Cultivation And Jatropha (Biofuel)
- Hotel & Hospitability Projects
- Hospital Based Projects
- Herbal Based Projects
- Inks, Stationery And Export Industries



- Infrastructure Projects
- Jute & Jute Based Products
- Leather And Leather Based Projects
- Leisure & Entertainment Based Projects
- Livestock Farming Of Birds & Animals
- Minerals And Minerals
- Maize Processing(Wet Milling) & Maize Based Projects
- Medical Plastics, Disposables Plastic Syringe, Blood Bags
- O Organic Farming, Neem Products Etc.



- O Paints, Pigments, Varnish & Lacquer
- O Paper And Paper Board, Paper Recycling Projects
- Printing Inks
- Packaging Based Projects
- Perfumes, Cosmetics And Flavours
- O Power Generation Based Projects & Renewable Energy Based Projects
- Pharmaceuticals And Drugs
- O Plantations, Farming And Cultivations
- O Plastic Film, Plastic Waste And Plastic Compounds
- O Plastic, PVC, PET, HDPE, LDPE Etc.



- Potato And Potato Based Projects
- Printing And Packaging
- O Real Estate, Leisure And Hospitality
- O Rubber And Rubber Products
- Soaps And Detergents
- Stationary Products
- Spices And Snacks Food
- Steel & Steel Products
- Textile Auxiliary And Chemicals



- Township & Residential Complex
- Textiles And Readymade Garments
- Waste Management & Recycling
- Wood & Wood Products
- Water Industry(Packaged Drinking Water & Mineral

Water)

Wire & Cable



Contact us

Niir Project Consultancy Services

106-E, Kamla Nagar, Near Spark Mall,

New Delhi-110007, India.

Email: <u>npcs.ei@gmail.com</u>, <u>info@entrepreneurindia.co</u>

Tel: +91-11-23843955, 23845654, 23845886, 8800733955

Mobile: +91-9811043595

Fax: +91-11-23841561

Website:

http://www.niir.org

http://www.entrepreneurindia.co

Take a look at NIIR PROJECT CONSULTANCY SERVICES on #StreetView

https://goo.gl/VstWkd



Follow Us



https://www.linkedin.com/company/niir-projectconsultancy-services



>https://www.facebook.com/NIIR.ORG



>https://www.youtube.com/user/NIIRproject



>https://plus.google.com/+EntrepreneurIndiaNewDelhi



https://twitter.com/npcs_in



https://www.pinterest.com/npcsindia/





THANK YOU!!!

For more information, visit us at: www.entrepreneurindia.co

