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)

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.

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
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
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  

---

**About NIIR**

**NIIR PROJECT CONSULTANCY SERVICES (NPCS)** is a reliable name in the industrial world for offering integrated technical consultancy services. NPCS is manned by engineers, planners, specialists, financial experts, economic analysts and design specialists with extensive experience in the related industries.


NPCS also publishes varies process technology, technical, reference, self employment and startup books, directory, business and industry database, bankable detailed project report, market research report on various industries, small scale industry and profit making business. Besides being used by manufacturers, industrialists and entrepreneurs, our publications are also used by professionals including project engineers, information services bureau, consultants and project consultancy firms as one of the input in their research.

---

**NIIR PROJECT CONSULTANCY SERVICES**, 106-E, Kamla Nagar, New Delhi-110007, India. **Email**: npcs.india@gmail.com  **Website**: NIIR.org