

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)

Author: NPCS Board of Consultants & Engineers

Format: Paperback

ISBN: 9789381039281

Code: NI257

Pages: 384

Price: Rs. 1,775.00 **US\$** 150.00

Publisher: NIIR PROJECT CONSULTANCY SERVICES

Usually ships within **5** days

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
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

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.

Our various services are: Detailed Project Report, Business Plan for Manufacturing Plant, Start-up Ideas, Business Ideas for Entrepreneurs, Start up Business Opportunities, entrepreneurship projects, Successful Business Plan, Industry Trends, Market Research, Manufacturing Process, Machinery, Raw Materials, project report, Cost and Revenue, Pre-feasibility study for Profitable Manufacturing Business, Project Identification, Project Feasibility and Market Study, Identification of Profitable Industrial Project Opportunities, Business Opportunities, Investment Opportunities for Most Profitable Business in India, Manufacturing Business Ideas, Preparation of Project Profile, Pre-Investment and Pre-Feasibility Study, Market Research Study, Preparation of Techno-Economic Feasibility Report, Identification and Section of Plant, Process, Equipment, General Guidance, Startup Help, Technical and Commercial Counseling for setting up new industrial project and Most Profitable Small Scale Business.

NPCS also publishes various 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

Sun, 20 Oct 2019 06:37:23 +0530