

# **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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**Format:** paperback

**Code:** NI257

**Pages:** 384

**Price: Rs.1775US\$ 150**

**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.

## 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

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ving to venture into Project. While expanding a current business or while venturing into new business, entrepreneurs are often faced with the dilemma of zeroing in on a suitable product/line.

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Wed, 27 Aug 2025 10:47:56 +0000