

# The Complete Book on Medical Plastics

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Plastics currently form one of the most important components of the medical industry. Medical device designers and engineers increasingly prefer plastics to conventional packaging materials such as metals owing to superior flexibility offered by plastics in fabrication process.

Advancements in sterilization techniques shift towards disposable devices, development of enhanced plastic materials, and technological innovations are factors driving the overall market growth and expansion. The development of novel materials such as biocompatible polymers for use in medical implants will furthermore provide the required impetus for the global medical plastics market. Every day, plastics are involved in critical surgeries, life saving efforts, and routine medical procedures. Plastic materials can be sterilized hundreds of times without degradation. Lightweight plastics are used to form replacement joints, non surgical supports, and therapy equipment. Clear plastics provide visibility for transfusions, surgeries, and diagnostic equipment of all kinds and plastics can be machined, molded, or formed into almost any shape imaginable. The use of plastics in health care field encompasses several distinct markets. Plastic is used on a large scale as medical devices like disposable syringes, optical and dental products, heart valves, contact lenses and many more medical products. This way plastic has very importance in making medical devices. The medical plastics industry is set to expand rapidly over the next decade taking up increasing proportions of GDP, as countries provide healthcare to an ageing population, access to medicine expands in developing regions and new technology is developed.

This book basically deals with significance of packaging for pharmaceuticals & medical industry, tablets & capsules liquids, creams and ointments, OPVC, OPP and oriented and non oriented pet containers, blister trays for ampoules, cartridge tubes etc., shrink packaging and stretch wrapping, conducting health based risk assessments of medical materials, performance properties of metallocene polyethylene, EVA, and flexible PVC films, polyurethane thin film welding for medical device applications, polyurethane film as an alternative to PVC and latex, opportunities for PVC replacement in medical solution containers, thermoplastic silicone urethane copolymers : a new class of biomedical elastomers, selecting materials for medical products : from PVC to metallocene polyolefins, injection molding engineering plastics, assessing the performance and suitability of parylene coating etc.

The present book contains the important information of plastics in medical field and their uses in various ways. This is very useful book for entrepreneurs, researchers, technocrats and technical institutions.

## 1. SIGNIFICANCE OF PACKAGING FOR PHARMA & MEDICAL INDUSTRY

Tablets & Capsules

Liquids

Creams and Ointments

Labels

Caps & Closures

Wadding Materials

Specific New Systems

Opvc, Opp and Oriented and Non-oriented Pet Containers

Blister Trays For Ampoules, Cartridge Tubes Etc.

Single-serve/Unit Dose Packages (Laminates of PPR, Plastics and Foil)

The Delcap Metered-dose

Form, Fill, Sealing of Plastic Bottles Under Aseptic Condition

Radiation Resistant PP Bottles

Double Derker Spray-aerosol

Single Dose Blister-break Open Packs

Capped Gabletop Cartons

Refillable, Reusable and Recyclable Aerosols

Shrink Packaging and Stretch Wrapping

Bulk Drug and Fine Chemicals

Packaging of Medical Devices

Materials & Technologies

Tyvek

Dot Coat Advantages

Tyvak vs. Paper

Peelable Paper Lidding Materials

Advantages

Applications

Medical Grade Pressure Sensitive Materials

Advantages

Applications

EvoH in Health Care Packaging (HCP)

Packaging Requirements For Health Care Products

Structure, Props & Uses

Barrier Bottles/Vials

Evoth

Other Important Area of Use

Packaging & Sterility

Plastics and Their Biomedical Applications

Pharmaceutical & Medical Packaging

New Development

Packaging Waste Directive

The Directive

Conclusion

## 2. TESTING

Conducting Health-Based Risk Assessments of Medical Materials

Nancy Stark

Standards and Guidances

Method

Hazard Identification

Dose-Response Assessment

Exposure Assessment

Risk Characterization  
Nitinol Implant  
Wound-Dressing Formulation  
Perchloroethylene Solvent  
Ligature Material  
Sources of Data  
Uncertainty Factors  
Safety Margins  
Conclusion  
Pharmaceutical  
Pharmaceutical Market Focuses on Cutting Costs, Not Value  
Some Segments Promising  
Regulatory Requirements  
Packaging Machinery  
Other Trends  
The Future

### 3. STERILIZATION

Traditional Processes  
New Processes  
Chemical Processes (Gas/Liquid)  
Peracetic Acid  
Hydrogen Peroxide  
Ozone  
Chlorine Dioxide  
Physicochemical Processes  
Plasmas  
Steam  
Synergetic Processes  
Psoralens and UVA (PUVA)  
Microwave and Bactericide  
Low-Temperature Steam and Formaldehyde  
Physical Processes  
Microwaves  
Pulsed-Light Systems  
Validation of Sterilizer Processes

### 4. HIGH PERFORMANCE PVC COMPOUNDS & TPE™S FOR MEDICAL APPLICATION

Long Term Contribution of PVC in Health Care  
Pvc™s Dominance in the Growing Market  
Challenges by Environmentalist to PVC  
Key Barriers to PVC Replacement  
The Major Factors Which Continue to Favour the Use of PVC are  
PVC Innovation  
ABC of Innovation  
Features of Hi-performance PVC Compounds  
The Use of Hi-performance PVC in Medical Devices  
TPE Based on Pvc Replaces Silicone  
TPE Based on PVC Outflexes Silicone Rubber

### 5. INNOVATIONS REMAKE PLASTIC INJECTION MOLDING

Useful Properties  
Parts on a Diet

Equipment and Processes  
Automating for Success  
Conclusion

## 6. POLYVINYL CHLORIDE IN CRITICAL HEALTHCARE PRODUCTS

Factors Which Made Polyvinyl Chloride the Material of Choice for the Fabrication of Medical Devices

Typical Medical Applications of PVC

Choice of Plasticisers

Containers for the Collection and Storage of Blood and Blood Products

Storage of Platelets

Containers for Intravenous Fluids and for Parenteral Nutrition

Containers for Constant Ambulatory Peritoneal Dialysis Solutions (Capd Bags)

Containers for the Collection and Storage of Cord Blood

Reported Deleterious Effects of Dehp Plasticised PVC and the Present Position

Trends in the Development of Newer Materials

## 7. ADVANCES IN MEDICAL PLASTICS

Microtagging

Thermosets

Antithrombogenic Coatings

Dryfilm Lubricant

Curing Process for Synthetic Polyisoprene Latex

Topas Cyclic Olefin Copolymer

## 8. MEDICAL APPLICATIONS OF POLYCARBONATE

Processing

Sterilization

Typical Applications

Renal Dialysis

Cardiac Surgery Products

Surgical Instruments

IV Connection Components

Polycarbonate Developments for the Medical Market

Radiation Grades

High-Temperature Grades

Polycarbonate Blends

Enhanced-Productivity Grades for Cleanroom Molding

Lipid-Resistant Grades

Conclusion

## 9. RADIO-FREQUENCY SEALING FOR DISPOSABLE MEDICAL PRODUCTS

Steve Myers

What is RF Sealing?

How RF Works

Sizing RF Sealers

Tooling

Efficient RF Sealing Techniques

Maximum Throughput With Automation

Double-cycle Sealing

Comparing RF With Other Sealing Technologies

Conclusion

## 10. PET BOTTLES AND APET SHEET FOR BLISTER PACKING FOR PHARMA APPLICATION

Pet Conversion Processes

Pet – A Pure Polymer

Pet Bottles for Pharma

Filling Lines for Pet Bottles

Case Study for Use of Pet Bottles in Pharma Industry

Conclusion

Generic Drugs That Can Be Packed in Pet Bottles

Ayurvedic Products That Can Be Packed In Pet

Cost-Competitiveness of Pet Bottle for Pharma Industry

Pet Bottles for Pharma Products – Useful Tips

Apet Sheet – Material, Processing & Applications

Apet Sheets – Total Consumption

Apet Thin Sheet

What is Apet Sheet

Factors For Growing Interest in Apet Sheet

Advantages of Apet Sheet

Blister Packing

Apet Sheet vs. PVC Sheet

Apet Sheet vs. PP Sheet

Gas/Moisture Barrier Properties Pet vs. Other Polymers

Salient Points of Apet Thin Sheet

Pet – Ecofriendly and Recyclable

Pet Converters – Expectations of Pharmaceutical Industry

Development Trials for Pharma Industry By RIL

Other Applications of Apet Thin Sheet

Conclusion

## 11. BREATHABLE TPE FILMS FOR MEDICAL APPLICATIONS

Barrier Films

Microclimate Dynamics

TPE Resin Chemistry

Soft Segments

Hard Segments

Film Manufacture

Lamination

Hot-Melt Screen Printing

Melt Printing

Porous Coating

Spray Coating

Medical Applications

Conclusion

## 12. THE CHANGING ROLE OF THE MEDICAL DEVICE CONTRACT MANUFACTURER

Growth, Growth & Growth

Outsourcing and Consolidation

Meeting the Challenge

## 13. MEDICAL PACKAGING

Rising Demand Predicted

Drug/Device Products Lead The Way

Cost Considerations

Test Methods  
Regulatory Picture  
Conclusion

#### 14. PERFORMANCE PROPERTIES OF METALLOCENE POLYETHYLENE, EVA, AND FLEXIBLE PVC FILMS

Experimental Procedure  
Results  
Conclusion

#### 15. POLYURETHANE THIN-FILM WELDING FOR MEDICAL DEVICE APPLICATIONS

Weldability of Thermoplastics  
Film-joining Methods  
RF Welding  
Ultrasonic Welding  
Direct Thermal Sealing  
Induction Welding  
Solvent Bonding  
Conclusion

#### 16. POLYURETHANE FILM AS AN ALTERNATIVE TO PVC AND LATEX

PVC  
Natural Rubber Latex (NRL)  
Thermoplastic Polyurethanes  
Concerns About PVC

#### 17. GAS PERMEABILITY AND MEDICAL FILM PRODUCTS

Materials and Experimental Methodology  
Results and Discussion  
Conclusion

#### 18. OPPORTUNITIES FOR PVC REPLACEMENT IN MEDICAL SOLUTION CONTAINERS

Ethylene-vinyl Acetate  
Polyester  
Polyolefin Blends  
Polyolefin Laminates  
Functionalized Polyolefins  
Conclusion

#### 19. PRODUCING BUBBLE/TAPER TUBING FOR MEDICAL APPLICATIONS

Extrusion-line Design  
Forming Considerations  
Cooling and Sizing  
Pulling and Cutting Systems  
Conclusion

#### 20. THERMOPLASTIC SILICONE-URETHANE COPOLYMERS : A NEW CLASS OF BIOMEDICAL ELASTOMERS

Silicones  
Thermoplastic Polyurethanes  
Silicone-modified Polyurethanes  
Silicone-urethane Copolymers  
Conclusion

## 21. SELECTING MATERIALS FOR MEDICAL PRODUCTS : FROM PVC TO METALLOCENE POLYOLEFINS

Fundamental Considerations

Selecting Materials

Material Performance Versus Product Performance

PVC Versus Metallocenes

Advantages of PVC

Disadvantages of PVC

Advantages of Metallocenes

Potential Metallocene Disadvantages

Challenges for Metallocene Materials

Safety and Quality

Product Design and Processing

Product Performance

Conclusion

## 22. COATING AND SURFACE TREATMENT TECHNOLOGIES

Ion-Beam Processingâ€™Spire Corp. (Bedford, MA).

Light-Activated Surface Modificationâ€™BSI Corp. (Eden Prairie, MN).

Plasma Surface Engineeringâ€™Talison Research (Sunnyvale, CA).

Antimicrobial/Antibiotic Coatingsâ€™STS Biopolymers, Inc. (Henrietta, NY).

Thromboresistant (Heparin) Coatingsâ€™Baxter Healthcare Corp. (Irvine, CA).

## 23. INJECTION MOLDING ENGINEERING PLASTICS

How It Works

Balancing Variables

Tool Design

Design Aids

Conclusion

## 24. GROWTH AND NEW CHALLENGES FOR DEVICE MARKET

Cost Concerns

Steady Growth

Regulatory Issues

Technology Issues

The Future

## 25. ASSESSING THE PERFORMANCE AND SUITABILITY OF PARYLENE COATING

Medical Coating Characteristics

Medical Coating Applications

Parylene Review

Parylene N

Parylene C

Parylene D

The Parylene Process

Conclusion

## 26. PAPER OR PLASTIC? MEDICAL NONWOVEN COMBINES BEST PROPERTIES OF BOTH TAPES

Thin-Film Coater Improves Process Control

Susan Wallace

Chips Propel Advances in Medical Imaging Equipment

Susan Wallace

## 27. PRODUCTS & SERVICES

Dispensing units

Slot-die system

Packaging system

Tube cutter

Automation equipment

Injection moulding machines

Catheter processing equipment

Benchtop moulder

## 28. REPROCESSING DISPOSABLE (SINGLE-USE) ITEMS

Background

How Safe Is Reprocessing

Benefits of Reprocessing

Definitions

Recycling

Reprocessing

Reprocessing Disposable (Single-use) Items

Reprocessing Disposable Surgical Gloves

Recycling or Reprocessing Disposable (Plastic) Syringes Andhypodermic Needles

Recycling Disposable Syringes

Reprocessing Disposable Syringes (and Needles)

Reprocessing Versus Disposal of Needles and Syringes

## 29. PLASTICS MEDICAL DISPOSABLES & AMPULE TRAYS WITH G.N. PRESSURE-FORMING TECHNOLOGY

Introduction

Ampule Package

Current Technology

Contact Heat, Cut-in-place, Pressure Thermoforming Technology

Quality Control

Flexibility

Efficiency

Simplicity

Applications of Contact Heat, Cut-in-place, Pressure Thermoformers

Design of Parts

Material

Production Volume

Cost

## 30. PVC IN MEDICAL APPLICATION

Introduction

Topic of Discussion

Medical Application For PVC

Benefits of PVC

Safety

Chemical Stability

Biocompatibility

Clarity & Transparency

Flexibility, Durability & Dependability

Sterilizability



Compatibility  
Resistance to Chemical Stress Cracking  
Low Cost  
Additives Used for PVC Compounding  
Plasticisers  
Stabilisers  
PVC In Medical Products – An Environmental Perspective  
Regulation and Product Standards  
Good Manufacturing Practice (GMP)  
Important Aspects Of GMP  
Plastic Processing in Clean Rooms  
I.V. Fluid Containers: Why PVC?  
Cost Effectiveness  
Reliability  
Simplicity in the Filling Process  
Safety in the Hospital  
Conclusion

## 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.

Our Detailed Project report aims at providing all the critical data required by any entrepreneur vying 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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