

# Medical Device Packaging 2017 to 2021

## Section I:

### Introduction

- A. Medical device packaging defined
- B. Medical device packaging defined
  - 1. Medical devices defined
  - 2. Combination devices
  - 3. Medical device packaging
  - 4. Sterile barrier
  - 5. Sterile field
  - 6. Sterility acceptable limits
- C. Study organization
- D. Study methodology
- E. Geographic regions
- F. Conventions

## Section II:

### Regulations and Standards

- A. Regulations and standards
  - 1. Global device and packaging regulations
  - 2. Testing standards
  - 3. Additional concepts
- B. ISO 11607 key concepts
  - 1. Responsibilities
  - 2. Scope of medical device
  - 3. Packaging system
  - 4. Health care facilities
- C. ISO 11607 review
  - 1. General requirements
  - 2. Materials
  - 3. Forming and sealing the package
  - 4. Final package
- D. Packaging development process
  - 1. Material selection
  - 2. Package design
  - 3. Design the manufacturing process
  - 4. ISO 11607 in practice

- 5. Conclusion
- E. Approval submissions and response times
  - 1. Classes of medical devices
  - 2. Approval options
  - 3. Device approval process and timeline
- F. Marketing considerations
  - 1. Packaging producers
  - 2. Equipment suppliers
  - 3. ISO quality systems
  - 4. Clean room production
  - 5. Material and process changes
- G. Labeling
- H. Combination healthcare products

### Section III:

#### Technology

- A. Technology drivers and trends
  - 1. Product safety
  - 2. Labeling
  - 3. In-package sterilization
  - 4. Sterility procedures
  - 5. Packaging cost
  - 6. Product and package integrity
  - 7. Easy-open feature
  - 8. Combinations devices
  - 9. Transparency
  - 10. Packaging process automation
  - 11. Environmental factors
  - 12. In-line thermoforming
  - 13. Seal validation
- B. UDIS and labeling
  - 1. Uniform device identification system (UDIS)
  - 2. Bar codes
  - 3. Label space
  - 4. Anti-counterfeiting
- C. Sterilization technology
  - 1. Heat sterilization
  - 2. Ethylene oxide (EtO) gas sterilization
  - 3. Gamma radiation sterilization
  - 4. Electron beam radiation sterilization
  - 5. Other sterilization methods

- 6. Other sterilization technologies (emerging)
- 7. Sterility assurance limits
- 8. Contract sterilization
- D. Packaging materials
  - 1. Non-wovens and paper
  - 2. Papers for medical device packaging
- E. Packaging structures
  - 1. Papers and non-wovens
  - 2. High-barrier materials
  - 3. Film and sheet
- F. Finished packaging
  - 1. Finished package types
  - 2. Unique medical device package types
  - 3. Suppliers
- G. Medical device packaging equipment
  - 1. Automated packaging equipment
  - 2. Pouch and bag machines
  - 3. Tray formers
  - 4. Thermoform/fill/seal
  - 5. Tray sealers
  - 6. Sealers
  - 7. Horizontal wrappers
  - 8. Four-side-seal
  - 9. Other packaging equipment
  - 10. In-line printing
  - 11. In-line sterilization
  - 12. Machine vision quality systems
- H. Environmental considerations
  - 1. Source reduction
  - 2. Raw material selection
  - 3. Package recycling
- I. Cost reduction trends
  - 1. Reduced thickness
  - 2. Package size
  - 3. Rigid trays to semi-rigid trays
  - 4. In-house thermoforming
  - 5. Flow packaging
  - 6. Non-woven vents on lids
  - 7. Peelable heat-seal films
  - 8. Non-wovens
- J. Catheter segment

- K. Drapes
  - 1. Drapes
- L. Electro-mechanical devices
  - 1. High-value electro-mechanical devices
  - 2. Commodity electro-mechanical devices
- M. Gloves
- N. Injection Systems
- O. Minimally-invasive devices
- P. Orthopedic devices
- Q. Other (includes kits)
- R. Sutures
- S. Tubing
- T. Wound care
- U. In-hospital packaging
  - 1. Sterilization wraps
  - 2. Sterilization cases
  - 3. Pouches and bags
  - 4. Sterilization methods
- V. Summary

#### Section IV:

##### Market Trends and Projections

- A. Global healthcare industry
  - 1. Global healthcare spending
  - 2. Population and GDP factors
  - 3. Healthcare and GDP considerations
  - 4. Sources of healthcare spending
  - 5. Disparity of healthcare spending
  - 6. Demographics and healthcare spending
  - 7. Summary
- B. Medical device drivers and trends
  - 1. Global medical device revenue
  - 2. Device export activity
  - 3. Demographics
  - 4. Competing drug delivery methods
  - 5. Medical tourism
  - 6. Disposable versus reusable devices
- C. Packaging drivers and trends
  - 1. Medical device demand
  - 2. Export activity

3. Sterilization method
  4. Types of users
  5. Packaging automation
  6. Rigid versus flexible
  7. Downgauging
  8. Non-woven versus paper (porous packaging)
  9. Patch film rollstock
  10. Direct seal films
  11. Barrier packaging
  12. Custom kits
  13. Insert packaging
  14. Clean room package production
  15. Qualification process
  16. Security
  17. Printing and labeling
  18. Globalization and ISO standardization
- D. Primary packaging volume segmented by end-use
1. Catheters
  2. Drapes
  3. Electro-mechanical devices
  4. Gloves
  5. Injection systems
  6. Minimally-invasive devices
  7. Orthopedic devices
  8. Sutures
  9. Tubing
  10. Wound care
  11. Other (kits)
  12. In-hospital
  13. Summary
- E. Primary packaging value segmented by end-use
1. Primary packaging value segmented by end-use
- F. Primary packaging purchases
1. Catheters
  2. Drapes
  3. Electro-mechanical devices
  4. Gloves
  5. Injections systems
  6. Minimally-invasive devices
  7. Orthopedic devices
  8. Sutures
  9. Tubing

- 10. Wound care
- 11. Other and kits
- 12. In-hospital
- 13. Summary
- G. Primary packaging volume segmented by package type
  - 1. Pouches and bags
  - 2. Header bags
  - 3. Lidding
  - 4. Bottom web
  - 5. Rigid trays
  - 6. Other
- H. Primary packaging value segmented by package type
  - 1. Pouches and bags
  - 2. Header bags
  - 3. Lidding
  - 4. Bottom webs
  - 5. Rigid trays
- I. Primary packaging volume segmented by material type
  - 1. Paper
  - 2. Non-woven
  - 3. Polymer
  - 4. High-barrier
  - 5. Other
- J. Primary packaging value segmented by material type
  - 1. Polymer
  - 2. High-barrier
  - 3. Non-woven
  - 4. Paper
- K. Primary packaging volume segmented by geographic region
  - 1. Europe
  - 2. North America
  - 3. Japan
  - 4. China
  - 5. Asia
  - 6. ROW
- L. Medical device volume segmented by sterilization method
  - 1. EtO
  - 2. Gamma
  - 3. Electron beam
  - 4. Heat
  - 5. Other
- M. Medical device volume segmented by level of automation

1. Manual and semi-automated
  2. Automated
- N. Insert, secondary, and tertiary packaging – volume and value
1. Insert packaging volume by material type
  2. Insert packaging value by material type
  3. Secondary packaging volume by package type
  4. Secondary packaging value by package type
  5. Tertiary packaging volume segmented by package type
  6. Tertiary packaging value by package type

Section V:

Packaging Producer Profiles

Section VI:

Paper/Nonwoven Supplier Profiles

Section VII:

Equipment Supplier Profiles

Section VIII:

Glossary

Figures: 20

Tables: 58