| | Level 2 – Standard Operating Procedure | |
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| | Material Handling | |
| | Doc. Number: | 932-MC15-001 |
| | Rev Number: | 05 |

# 1 Purpose

The purpose of this document is to establish the Material Handling process and procedure for parts and finished medical devices thereby fulfilling the regulatory requirements as referenced in the Cynosure Quality Manual 931-QA01-001, as applicable**.**

# 2 Scope

This procedure applies to the processes and documentation pertaining to all material handling activities for parts and finished devices, from receiving to shipping at Cynosure facilities.

# 3 Responsibility

- It is the responsibility of the departments and individuals called out in the procedure to ensure that this procedure is followed as required.

# 4 Reference Documents

- 931-QA01-001 Cynosure Quality Manual
- 932-MC15-002 Material Storage
- 932-MC15-003 Packaging, Preservation and Delivery
- 932-OP01-001 Work Environment
- 932-OP08-001 Product Identification and Traceability
- 932-QA13-001 Control of Nonconforming Product
- 932-SM03-001 Contract Review and Distribution
- 932-SM19-001 Servicing and Installations
- 933-MC15-002 Distribution of Kitted Materials
- 933-MC15-003 Stockroom Put-Away FIFO Procedure
- 933-QA08-004 Finished Medical Laser Serialization
- 933-QA10-002 Incoming Inspection
- 933-QA10-003 In-Process Inspection
- 933-QA10-005 Final Inspection & Product Release
- 933-QA10-007 Sterilization Procedure
- 933-QA13-002 Material Purge Procedure
- 933-QA13-003 Quarantine Procedure
- 933-QA15-003 Receiving
- 991-5101-000 PCB and Sub-Assembly Label Procedure
- 991-7012-207 Stockroom Optic Handling Procedure

# 5 Approvals

- QA
- Regulatory Affairs
- Operations, Engineering
- Materials Management

# 6 Tools and Materials Required

- Common Tools used in shipping / receiving such as pallet jacks, strapping tools, taping tools, etc.

# 7 Definitions

- N/A

# 8 Procedure

8.1 Work Environment

8.1.1 Cynosure manages the work environment as described in 932-OP01-001 Work Environment to ensure conformity to product specifications and requirements.

8.2 Control of production and service provision

8.2.1 Cynosure manufactures, reworks, and tests products under controlled conditions (see work instructions for specific assemblies). It is the responsibility of the Manufacturing and Service department heads to ensure that the work instructions are followed as required. The Production Group Leader/Supervisor is responsible for kitted materials in the assembly area.

8.2.2 The Production Group Leader, Supervisor and/or Process Engineer monitors assembler and technician activities to ensure that proper tools and techniques are used, areas are properly maintained, and environmental conditions (such as lighting, temperature, and humidity) are suitable.

8.2.3 Cynosure maintains records by serial number and/or lot number as applicable for each medical device that ships to provide traceability and warranty data per 932-OP08-001 Product Identification and Traceability.

8.3 Cleanliness of product and contamination control

8.3.1 Cynosure documents required cleanliness of product by following work instructions and documentation for any specific product. Cynosure does not sterilize any products in house. Any sterilized product sold is sterilized by Cynosure suppliers per 933-QA10-007 Sterilization Procedure.

8.4 Installation and Service Activities

8.4.1 Training is provided to personnel and outside sources to install and service Cynosure products in the field in accordance with 932-SM19-001 Servicing and Installations.

8.5 Preservation of Product

8.5.1 Cynosure has established documented procedures or work instructions for protecting the parts and finished product from alteration, contamination and damage when exposed to expected conditions and hazards and preserving the conformity of product during manufacturing and delivery. This preservation shall include identification, handling, packaging, storage, and protection and is defined in 932-MC15-002 Material Storage. For finished devices, suitable shipping containers have been designed, documented and are specific to the product being shipped.

8.5.2 Preservation of the medical devices and sub-assemblies that are contained within is maintained by following work instructions and specific documentation used to manufacture and test products.

8.5.3 Control of product with a limited shelf-life is defined in 933-MC15-003 Stockroom Put-Away FIFO Procedure. Control of product requiring special storage conditions is defined in 932-MC15-002 Material Storage.

8.6 Device Labeling

8.6.1 Cynosure controls labeling activities to prevent labeling mix-ups through the following procedures and work instructions: 932-OP08-001 Product Identification and Traceability, 932-MC15-002 Material Storage, and 991-5101-000 PCB and Sub-Assembly Label Procedure.

8.6.2 Cynosure personnel are responsible for ensuring label accuracy and current revision in all applicable functional areas as defined in 933-QA15-003 Receiving, 933-MC15-002 Distribution of Kitted Materials, 933-QA10-003 In-Process Inspection, 933-QA10-005 Final Inspection & Product Release, and 933-QA08-004 Finished Medical Laser Serialization.

8.7 Device Packaging

8.7.1 Cynosure ensures medical devices and components are protected from damage during packing, shipping, and delivery activities in accordance with 932-MC15-003 Packaging, Preservation and Delivery.

8.8 Handling and Storage

8.8.1 Cynosure maintains handling and storage instructions to prevent material mix-ups, damage, deterioration, contamination, or any adverse effects. These instructions are defined in 932-OP08-001 Product Identification and Traceability and 932-MC15-002 Material Storage.

8.8.2 Receiving personnel check incoming packages for damage and distribute material to appropriate locations per 933-QA15-003 Receiving. If required, incoming inspection personnel inspect product to ensure it conforms to specific requirements per 933-QA10-002 Incoming Inspection.

8.8.3 Any nonconforming conditions are documented per 932-QA13-001 Control of Nonconforming Product.

8.8.3.1 Previously accepted material suspected of nonconformance may be collected and processed for re-inspection per 933-QA13-002 Material Purge Procedure.

8.8.3.2 The 933-QA13-003 Quarantine Procedure is used to prevent the production use of material in inventory as necessary.

8.8.4 Stockroom personnel store and monitor material to be issued to production for manufacture of Cynosure products. Material is moved from the stockroom to other locations as appropriate per 933-MC15-003 Stockroom Put-Away FIFO Procedure. If special conditions exist where extra packaging and special precautions must be taken for optics moved from the stockroom to other locations, ensure proper packaging as defined in 991-7012-207 Stockroom Optic Handling.

8.8.4.1 For sterile products, stockroom personnel shall store such product in a manner that keeps them segregated from non-sterile products. Stockroom storage locations that contain sterile products may not have non-sterile products stored in that same location.

8.8.5 For Cynosure shipments, shipping personnel pack systems and any accessories as specified on the Sales Order, ensuring proper product packaging as defined in 932-MC15-003 Packaging, Preservation and Delivery. If special conditions exist where extra packaging, packing and special precautions must be taken to assure product integrity during shipment, notes will be documented on the Sales Order as well as the Pick Ticket. Both documents are maintained on file.

8.9 Distribution

8.9.1 Control and distribution of products and retention of records for traceability of all products and customers is carried out in accordance with 932-SM03-001 Contract Review and Distribution.

# 9 Flow Chart

N/A