# PURPOSE

The purpose of this procedure is to define the process for handling, storage, and distribution of product components and finished devices manufactured or distributed by GT Medical Technologies.

# SCOPE

All products manufactured or distributed by GT Medical Technologies require instructions regarding handling, storage, and distribution. Product manufactured by a contract manufacturer may be managed through contract manufacturer’s procedure.

# RESPONSIBILITIES

|  |  |
| --- | --- |
| Manufacturing Engineer, RA/QA | * Ensure handling, storage, and distribution conditions are maintained for all materials according to the requirements of this procedure. |

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# FORMS

## N/A

# PROCEDURE

## **Storage and Handling Conditions**

### All product components and finished products shall be properly identified during storage and handling.

### Storage areas shall be properly identified as to their contents, e.g., Quarantine, Scrap, Finished product, etc.

### Released stock shall be stored apart and physically separated from rejected, quarantine and on hold stock.

### Controlled storage areas shall be kept clean and free of potential sources of contamination, including protection from insect, rodent and bird contamination.

### Care shall be taken to prevent damage or mix-ups during handling of components and finished products.

## **Placement of Materials into Storage**

### Materials which are available for use or distribution may only be placed into accepted storage upon acceptance by RA/QA or manufacturing engineering.

### If material is deemed to be unacceptable and a non-conformance is present the non-conforming material shall be placed in quarantine.

## **Removal of Stock from Storage**

### Stock which will be used for manufacture of product or finished devices intended to be distributed may only be removed from storage/inventory upon confirmation of the RA/QA or manufacturing engineering release.

#### For materials with a limited shelf-life, the expiration date shall be checked prior to their use for production or distribution to preclude the use or sale of expired material.

## **Distribution Conditions**

### All product components and finished products shall be properly controlled to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution.

### Unless otherwise stated, First in – First Out, (FIFO) shall be used to distribute released stock from storage.

### Product should be tracked on an internal inventory control system stored outside of the eQMS.

### Records which include or refer to the location of the following shall be maintained:

* The name and address of the initial consignee
* The identification and quantity of devices shipped
* The date shipped
* Any control number(s) used

# DOCUMENT HISTORY

|  |  |
| --- | --- |
| Functional Area | Signature & Date |
| Operations |  |
| Quality |  |
| Regulatory |  |

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| --- | --- | --- |
| **REVISION HISTORY** | | |
| Rev. # | Released Date  (YYYY-MM-DD) | Author |
| 1 | 2019-11-05 | Austin Feldman |