



Applied Sterilization Technologies

## Gamma Irradiation: Processing Requirements and General Information

### IT'S AS EASY AS 1, 2, 3

1. Include an individual label for each container
2. Ensure each label clearly indicates:
  - Item ID\*
  - Lot numberPlease ensure each container has only one identification label affixed.
3. Include a packing slip clearly indicating:
  - Customer name and shipping address
  - All item IDs and lot numbers
  - Case quantities
  - Purchase order number, if requested/required

\* The item ID is the Customer product code, as defined by the Customer.

Updated November 11, 2010

### Current STERIS Customers

When sending product to be processed, please ensure the steps outlined below have been followed and the information requested is included.

The second page of this pamphlet contains a copy of our receiving report. This report outlines the four pieces of information necessary to process your product efficiently.

- ✓ Please include an individual label for each container to be processed. Each label should indicate corresponding item ID and lot number.
- ✓ Please ensure that if containers are being re-used, the previous label is removed or covered by the current label.
- ✓ Please include a corresponding packing slip. Packing slips should indicate Customer name and shipping address as well as all item IDs, lot numbers, case quantities and purchase order number.
- ✓ Please ensure that all information on the packing slip regarding item IDs or lot numbers is identical to what is indicated on the container labels.
- ✓ Please do not include ANY documentation inside containers. As a policy, STERIS DOES NOT open any containers received for processing.

*NOTE: Please DO NOT indicate on the packing slip any internal case quantities. If there are four containers with four items in each container, the quantity is four, NOT 16.*

*NOTE: Any exceptions to these guidelines must be communicated to and agreed upon by STERIS QS/RC.*

### New STERIS Customers

In order for STERIS to process product for a new Customer, the following documents must be completed, signed and returned prior to processing.

- ✓ Terms and Conditions
- ✓ Assignment of Responsibility
- ✓ Gamma Processing Instructions
- ✓ Customer Address and Contact Information form
- ✓ Gamma Dose Specification Authorization
- ✓ Credit Application
- ✓ If product is labeled "Sterile", a Non-Sterile Shipping Agreement form must be completed

*NOTE: All completed documentation must be reviewed and approved by facility management. Without prior approval and input into our data management system, product cannot be received into our facilities. Once all of the required documents have been completed and returned to STERIS, the product can be processed.*

*NOTE: If a sample case for validation or any other test is shipped to STERIS for processing, please complete a Special Radiation Request form and include with shipment.*

Please refer to the *Current STERIS Customers* section for instructions on proper labeling and documentation. If these steps are followed your product will be processed without delay.

**SAMPLE RECEIVING REPORT**

**A CORPORATION**

*Product received from:*

A CORPORATION  
123 Main Street  
Mentor, OH 44060

Frt Carrier: Federal Express

Trailer #: N/A

Bill of Lading: A123

Seal: None

PO Number: 110910

ETA:

Unload / Count: AB / AB

Pallet Count: 25

Product counts verified by **STERIS**

Bill of Lading # and an identifier such as a P.O. (if applicable)

Item lot # specific to each product and on each case/container

**Gamma**

| <u>Item ID</u> | <u>Pkg</u> | <u>Lot Number</u> | <u>Cust Qty</u> | <u>STERIS Qty</u> | <u>UOM</u> | <u>CD</u> | <u>WH Loc</u> | <u>Dmg Qty</u> | <u>Other Info</u> |
|----------------|------------|-------------------|-----------------|-------------------|------------|-----------|---------------|----------------|-------------------|
| Medical Device | 5          | 81234             | 125             | 125               | CS         |           |               |                |                   |
| Totals:        |            |                   | 125             | 125               |            |           |               |                |                   |

Item IDs specific to each product and on each case/container

Case/Container count specific to item lot #

**Signature Manifest**



Reviewed By:

**Sue Smith (Associate)**

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