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Order Fulfilment

1. PURPOSE

To describe a system for the control and documentation of restock and fulfillment of orders.

2. SCOPE

This procedure applies to filling customer loaners or consignment requests and surgery replenishment orders.

3. REFERENCES

- 3.1 QM-01-00001: Quality Manual
- 3.2 SOP-01-00021: Incoming Inspection Procedure
- 3.3 SOP-01-00002: Document Change Orders
- 3.4 SOP-03-00002: Supplier Control
- 3.5 FR-03-00002: Usage Ticket Form
- 3.6 FR-03-00001: Inventory Request Form Knee
- 3.7 FR-03-00004: Inventory Request Form Hip
- 3.8 FR-03-00006: Request form log
- 3.9 FR-03-00007: Back Order Form
- 3.10 FR-03-00031: Shipping Log
- 3.11 US FDA 21 CFR PART 820 Quality System Regulation

4. DEFINITIONS AND ACRONYMS

DCO: Document Change Order


FIFO: First In First Out

BOM: Bill of Material

NCM: Non-Conforming Material

5. RESPONSIBILITIES

- 5.1 Regulatory/Quality
 - Responsible for reviewing, approving, and following this procedure.
 - Responsible for oversight and control of this procedure.
- 5.2 Customer Service
 - Responsible for reviewing, approving, and following this procedure.
- 5.3 All Personnel performing activities described in this procedure
 - Responsible for understanding and complying with this procedure.

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6. **PROCEDURE**


When an inventory request order form is received for either loaners or consignment, or a sales order requires restocking the order, the following procedure shall apply.

A request will be sent by the agent or customer to customer service. The request will be reviewed and it will be determined if the request can be filled and if the company wishes to fulfill the request.

If the request will not be filled, or if there may be a delay in filling, Customer Service will communicate with the requestor regarding their request. Goods sold from a loaner set may not require order fulfillment if the loaner will be returned to United.

If a loaner or consignment inventory request is to be filled, the following steps should be followed:

- A request form number should be assigned to the request and routed to the warehouse for processing
- Obtain the applicable BOM to fulfill the request.
- Pull sterile product on a FIFO basis or according to expiration as needed to fulfill the request.
- Include a copy of bill of materials and packing slip with the shipment. Alternates, optional or back orders should be denoted on the BOM.
- Package the order into boxes/totes with bag liners. Do not over pack the container.
- Electronically transfer the inventory.
- Before sealing the container, confirm that all product being shipped has appropriate inspection paperwork (i.e. make sure the product all passed inspection and that the paperwork is in order)
- A second person should review/audit the items against the order, BOM, and packing slip. This should also include the shipping details. Their signature shall be signed and dated on the paperwork and indicates that the order has been audited for accuracy.
- If the shipment is a loaner or other product that is to be used and returned, also include a return air bill for the product to be returned to UOC USA.
- A confirmation of the order including but not limited to photographs of the order, packing slips and tracking information, notification of back orders shall be sent to the recipient.
- The request form log should be updated accordingly, care should be taken to keep a record of back orders using the back order form in the event back orders need to be fulfilled.
- Implants in implant loaner kits or consignment orders that are set to expire within 60 days shall be indicated by an expiry notice sticker on the front of the implant box indicating expiry within 60 days for that product.

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- Products sent out as part of loaner kits may be sent up to 1 month from its expiration date.


If replenishing a surgical case restock, the following steps should be followed:

- Pull sterile product on a FIFO basis or according to expiration as needed to fulfill the request.
- Implants that are set to expire within 60 days shall be indicated by an expiry notice sticker on the front of the implant box indicating expiry within 60 days for that product.
- Print and include copy of the packing slip with the shipment
- Package the order into boxes. Multiple orders to the same recipient with the same shipping address may be combined. Do not over pack the container.
- Electronically transfer the inventory.
- Before sealing the shipping container, confirm that all product being shipped has appropriate inspection paperwork (i.e. make sure the product all passed inspection and that the paperwork is in order)
- A second person should review/audit the items against the order. This should also include the shipping details. Their signature shall be signed and dated on the paperwork and indicates that the order has been audited for accuracy.
- A confirmation of the order including but not limited to photographs of the order, packing slips and tracking information, notification of back orders shall be sent to the recipient.
- Care should be taken to keep a record of back orders using the back order form in the event back orders need to be fulfilled.
- The request form log should be updated accordingly, care should be taken to keep a record of back orders using the back order form in the event back orders need to be fulfilled.
- Attempts will be made not to ship consigned or restock products within 3 months of product expiration date. Agents will be alerted if filled orders will contain stock expiring within 60 days.

The Shipping log form will be utilized by Customer Service as a means of capturing and auditing shipping information for all outbound orders. The log shall be updated throughout the day as shipments are prepared and packaged for shipment and tracking information will be retained within the log.

If it is discovered during fulfillment of these requests that any product is out of specification or damaged, the product will be quarantined and the NCM process will be initiated. If any paperwork is out of order, this could also result in initiation of an NCM. If there is a simple issue with paperwork that can be immediately corrected, the correction should be made prior to shipment with no need for an NCM.

If it is determined that an order for instrument kits cannot be fulfilled in its entirety due to

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back order or stock shortage, Customer Service and Quality management approval for release is required to ship the order and justification should be provided for the back order prior to shipment. In addition to the justification and management approval, the recipient shall be notified in advance of shipment of the stock back order or shortage. If Quality management is not available for approval Marketing management or Executive management such as the President may provide approval for the exception in writing which needs to be

captured with the paperwork retained on file.

6.4 Records

- 6.4.1 Regulatory/Quality will assure the proper maintenance of all records.
- 6.4.2 The records maintained should accurately reflect the sequence of all authorized changes using the DCO system.
- 6.4.3 Regulatory, if requested, will provide copies of these records to the FDA or other authorized regulatory agency in accordance with company policy.

END OF PROCEDURE