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## **Handling of Product Approaching Expiration Date**

### **1. PURPOSE**

This SOP provides instructions for control of product approaching expiration dates in order to prevent use outside of the validated shelf life.

### **2. SCOPE**

This procedure covers product warehoused at the Company as well as product held in the field.

### **3. REFERENCES**

- 3.1. QM-01-00001: Quality Manual
- 3.2. SOP-01-0027: Returned Materials Authorization Procedure for Agents
- 3.3. SOP-01-0028: Returned Materials Authorization Operations Procedure
- 3.4. SOP-03-0005: Non-Conforming Product Process
- 3.5. FR-03-00032 Implant Expiry Notice
- 3.6. 21 CFR Part 820

### **4. DEFINITIONS AND ACRONYMS**


- 4.1. Finished Goods: Top level part numbers, as described on device master records that are available for sale or distribution.
- 4.2. Components: Parts that will be issued in their current state to create top level part numbers of sterile or non-sterile finished goods. UOC USA is not currently responsible for any components.
- 4.3. Raw Materials: Parts and materials that are used to create component level parts. UOC USA is not currently responsible for any raw materials.

### **5. RESPONSIBILITIES**

- 5.1. Quality function
  - Responsible for oversight and control of this procedure.
  - Responsible for reviewing, approving and following this procedure.
- 5.2. All Personnel who work with product inventory are responsible for understanding and complying with this procedure.

### **6. PROCEDURE**

- 6.1. Agent Agreements
  - 6.1.1. Agent agreements specify that agents are responsible for the status of their inventory. Each agreement clearly sets forth the terms surrounding expiring product.
  - 6.1.2. The agent agreement requires agents to verify expiration dates and return consigned product.
  - 6.1.3. Agent considered to have purchased Consigned Products that Agent fails to return to UOC that are set to expire in less than one (1) month.

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6.1.4. UOC may deduct from Agent's Commission the purchase price for Consigned Products at its discretion.

## 6.2. Inventory Policy

6.2.1. CS Department will notify agent in writing 90 days in advance of implant expirations. United will provide a return prepaid air bill for the return of expiring products and will send replacements for expiring products at the time the agent is notified of approaching implant expirations.

6.2.2. It is the agent's responsibility to identify expiring products and return them to United in advance of expiration to avoid potential liabilities which could occur from implanting expired products.

6.2.3. Agent shall return products approaching expiration within 60 days prior to expiration. In the event agent chooses to keep implants within 30 days of their expiration, agent may be subjected to additional charges per sales agent agreement.

6.2.4. If agent has assumed costs for choosing to keep expired products and the products are later returned to United, the purchase price will be credited back to the agent.

6.3. On a monthly basis, a representative of the CS department generates a report to forecast product expiration dates with the product location. The forecast is for 3 months.

6.4. Product that will expire the next month is pulled from the warehouse and quarantined (electronically and physically) for further processing through the NCM process. For example product that will expire in July is pulled from warehouse inventory in June.

6.5. Product that will expire within 60 to 31 days in the warehouse will be indicated by placing an expiry within 60 days notice sticker on the front of the implant box.


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

6.7. Attempts will be made not to ship consigned or restock products within 3 months of its expiration date. Agents will be alerted if filled orders will contain stock expiring within 60 days.

6.8. Beginning 3 months prior to expiration, an email is sent monthly to each agent who holds product that is set to expire. For example, if an agent holds inventory that expires in March, he/she will begin receiving an email in December.

6.9. The agent will receive monthly emails regarding the product The email specifies which part/lot number and quantity of product is expiring. It also includes return instructions as well as an RMA number.

6.10. Once received in the warehouse, returned expiring product is quarantined then processed through the NCM process and the agent is sent replacement product.

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6.11. If the agent does not return the expiring product by the first day of the month in which it is expiring, the agent is billed for the product. If the expired product is subsequently returned, the bill is reversed.

## 7. END OF PROCEDURE