Returned Materials Authorization Operations Procedure

1. Purpose

The purpose of this document is intended to provide all UOC USA INC. ("UOC") employees with the proper guidelines for managing products returned from the field including agent or customer product or material returns.

2. Scope

This procedure applies to all UOC Customer Service ("CS") employees. It documents the process used to assign return materials authorizations ("RMA") and facilitate product return and processing into the warehouse.

3. References

3.1 QM-01-0001: Quality Manual
3.2 SOP-01-00013: Device Master Record/Device History Record/Quality System Record Procedures
3.3 SOP-01-00021: Inventory receiving /inspection procedure
3.4 SOP-01-00004: Complaint and Feedback Processing
3.5 FR-01-00032: RMA Log
3.6 FR-01-00033: RMA Form
3.7 US FDA 21 CFR PART 820 Quality System Regulation

4. Definitions and Acronyms

4.1 Sales Agent :A person who is qualified to attend cases with surgeons or surgical support staff. These representatives may be direct employees, or individuals contracted by the Company (including distributors).
4.2 Customer: A licensed medical facility or clinician, established as a customer.
4.3 CS: Customer Service
4.4 Distribution Record: a physical and/or electronic file that contains the details related to the consignee, the appropriate trace numbers, the date shipped and the quantity and identification of the devices shipped
4.5 Independent Agent: A trained independent representative of the Company.
4.6 Purchase Order/P.O.: A customer document requesting the purchase of product, specifying product type, quantity, delivery, billing, price, etc.
4.7 RMA: Returned Materials Authorization

5. Responsibilities

- Customer Service: Responsible for reviewing, approving and following this procedure.
- Quality: Responsible for reviewing, approving and following this procedure. Responsible for oversight via auditing of this procedure. Responsible for

reviewing, approving and following this procedure. Responsible for ensuring that all practices comply with the necessary quality and regulatory systems.

- All Personnel performing activities required by this procedure: Responsible for understanding and following current version of this procedure.

6. Procedure

6.1 Products cannot be authorized for return unless a Returned Materials Authorization ("RMA") Number is issued by CS to the agent.

6.2 An RMA number may be issued for customer product and material return or management requested product returns.

6.3 CS accesses the RMA log in order to obtain the next available RMA number. The RMA number is a numerical running sequence number that acts as a specific identifier to the company of the shipment details. *See RMA Log FR-01-00032*. When using the electronic file, data entry should not be performed if the access mode is "read only" to maintain document integrity.

6.4 The "read only" mode indicates the file is in use or being edited by another user and should be accessed only after the file is no longer in use by another user. Additionally, the file should be saved after editing to save work prior to exiting the document. The RMA log file should be closed as soon as data entry has been completed so other users may access the file for data entry.

6.5 The RMA number is the unique identifier that pertains to the product(s) being returned, and helps identify the nature of the return upon receipt. Only one RMA number should be issued for one specific type of return, however management exceptions may allow in appropriate cases. For example, one (1) RMA number should not be issued for excess implants and a broken instrument, two (2) separate RMA numbers should be issued as a best practice method.

6.6 In the RMA log, select the next available RMA number from the RMA log. The next available RMA number will be the next line item and number that have not yet been allocated or designated to a product return.

6.7 CS will provide the assigned RMA number to the requestor.

6.8 Requestors returning product have been trained or are instructed to indicate the RMA number legibly on the box and how to properly packaging the return for shipping in clean, appropriate packaging sufficient to protect the product from damage during shipment return.

6.9 CS may issue the requestor shipping return labels which indicate the RMA number assigned for the product return which will be referenced in the memo section of the return label, or the requestor may reference the RMA number on the outside of the return shipment box.

6.7 On the line item of the available RMA number, complete the RMA log fields with information pertaining to the return. The RMA number may be written on the return box to help indicate the RMA return or indicated in the shipping return label to facilitate identification of the return contents.

6.8 Complete the following fields in the RMA log:

a. Date of issuance

b. Name of the requestor or shipping party

c. Transfer from location, the TipTop inventory site location where the inventory is electronically housed

d. Name of preparer

e. RMA number issued

f. Product type for return and supporting details if required

g. Nature or reason for return

6.9 After completing the RMA form, the form shall be printed and placed in the RMA binder located in the warehouse until it can be matched to the returned product upon arrival.

7. Processing Procedure

7.1 When the product return arrives at the branch warehouse, the return goods will be staged in a designated Receiving area, which may be a receiving table or inventory cart or labeled as “Inbound Processing”.

7.2 Before opening the returned goods, the coinciding RMA form should be brought to the product so that the processor may clearly identify the nature and condition anticipated for the returned products.

7.3 The CS responsible for processing the return shall input the return tracking number in the tracking information field on the RMA.

7.4 Appropriate PPE precautions should be followed by the processor or any other employee handling the product return.

7.5 The CS employee processing the RMA shall review the relevant details related to the return. If additional unexpected items have been included in the return, follow up with the shipper and proceed accordingly to document the return of extra items.

7.6 The RMA traveler shall remain with the return at all times for identification until the product is ready to be released into circulation or dispositioned into quarantine.

7.7 Returned goods shall be inspected for product content, condition, expiration, and conformity and according to the Inspection and Receiving Procedure. The processor may inform department management at any time if there are any concerns related to the return.

7.8 RMA transfer returns shall transferred in the Tip Top platform to electronically move the product to indicate the transfer of product to the branch warehouse and to capture traceability. The TipTop memo field in the inventory transfer application may be used to reference the RMA return. For example if the RMA return number is 501, the memo may indicate RMARET501 which indicates RMA 501 is the product being transferred on said transfer order.

7.9 Before the RMA may be shelved into circulation, the order must be verified by an auditor for accuracy. The auditor shall be someone within the department, or designated as trained to do so, and will be required to check the accuracy of the product return against the transfer order. The auditor serves to identify no products have been transferred in error and that all products have accurately

been captured. The auditor may also inspect the transfer order to the product prior to posting the transfer order if preferred.

7.10 Once the RMA has been electronically transferred and posted, the processor shall update the RMA log to indicate the RMA has been received and shall save all changes before exiting the log.

7.11 Product, packaging or shipping container damage should be documented and management notified. Management shall determine the course of action according to the level of damage. In severe cases the shipper may need to be notified immediately by the manager with supporting documentation or reference.

7.12 The processor shall reference the RMA number in the memo field of the inventory electronic transfer system for tracking and recognition. The format for the memo depicts the RMA is a return of product and includes the RMA number for identification. Memo format: RMARET001

7.13 Electronic transfers should be confirmed for accuracy. A photograph may be taken as documentation indicating the set as it was returned. Instrument sets may be photographed and saved electronically.

7.14 Upon completing the RMA inspection and verification, the auditor shall initial and date the RMA form in the designated auditor fields.

7.15 Once the product return has been processed and verified, the transfer order may be posted electronically to capture traceability and stock changes according to the inventory return procedure. Attach the posted transfer order to the RMA traveler.

7.16 The release of goods shall be indicated by a signature and date on the return documentation.

7.17 Product should be shelved according to expiration date using the First In First Out (“FIFO”) method. Shelves shall be periodically checked to ensure that product is staged by expiration date. Instrumentation may be shelved according to product designation.

7.18 Once the RMA log has been updated with the return details the RMA traveler with the associated posted transfer return is filed in the “Closed RMA file” by numerical order.

7.19 The RMA log shall be monitored regularly to close out outstanding unreturned RMAs.

8. Nonconforming Material

All incoming products are inspected for conformity. If nonconforming materials are detected during inspection, the RMA shall be indicated as nonconforming. Nonconforming materials shall be processed according to the Nonconforming Materials Standard Operating Procedure. Copies of transfers to Quarantine will be printed and remain with the RMA form and transfer postings.

End of Procedure.