Inventory Request Procedure

1. Purpose

This procedure is intended to provide UOC USA INC. ("UOC") personnel, whether such individuals are agents or distributors (collectively "Distributors"), with the guidelines required for placing inventory requests for loaners or consigned goods.

2. Scope

This procedure describes the process used to submit requests for UOC product requests related to loaners or consignments.

3. References

3.1 QM-01-0001: Quality Manual: Section Product Realization
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-03-00001: Inventory Request Form
3.6 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
4.8 Inventory Request Form: Form used to generate and facilitate product requests for customers.

5. Responsibilities

- Customer Service: Responsible for reviewing, approving and following this procedure. Responsible for communicating with customers concerning product inquiries, contracts, and order handling

Company documentation is considered PROPRIETARY and is made available for business operations and review by regulatory agencies. Distribution to third parties without prior permission is prohibited.

- 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 All inventory requests should be facilitated using the inventory request form.

6.2 All fields must be legibly filled and in ink. Any changes or corrections should be made by a single line strikethrough which is initialed and dated.

6.3 All “loaner” requests should indicatethe surgery date or in-service date.

6.4 The “Implant,” “Instrument,” “Literature” or “Demo” fields should be used to indicate which product line(s) are requested.

6.5 Care should be taken to avoid blank fields such as Requestor name and quantities needed.

6.6 Requests should be submitted to CS via fax or email.

6.7 Same day shipments should be received by 3:00pm to help accommodate same day shipping.

6.8 Forms will be reviewed and approved by UOC management prior to fulfilling. Advance notice is appreciated in order to facilitate inventory needs for all customers.

6.9 Tracking information will be provided to the requestor upon order fulfillment.

6.10 Consignment products are reviewed on a monthly basis to monitor set turns and managed by UOC accordingly.

6.11 Loaners not returned to UOC forty-eight (48) hours after the day of the surgery, are subject at UOC’s discretion to a late fee according to the terms set out in the Agency Agreement. Contact UOC Customer Service for anticipated loaner return issues.

6.12 Agent must notify UOC within 24 hours of receipt of any Product, regardless of shipping origin, if there is any issue with or damage to the shipment. A failure to notify UOC of any such issue or damage will result in Agent accepting responsibility for the shipment in its entirety and it shall be presumed that there are no issues or damage associated with the shipment.

End of Procedure.

Company documentation is considered PROPRIETARY and is made available for business operations and review by regulatory agencies. Distribution to third parties without prior permission is prohibited.