Reporting Complaints from the Field Procedure

1.0 PURPOSE

This procedure is intended to provide UOC USA INC. ("UOC") personnel, whether such individuals are agents or distributors (collectively "Distributors"), with the guidelines for reporting a product complaint to UOC.

2.0 SCOPE

This procedure applies to all finished goods. Complaints expressed by clinical investigators, customers and employees during use of the product are reported using this procedure.

3.0 REFERENCES

3.1 01-00001: Quality Manual

3.2 21 CFR 806: Medical Devices; reports of corrections and removals

3.3 21 CFR 820.100: Corrective and Preventive Action

3.4 21 CFR 820.198: Complaint Files

3.5 SOP-01-00010: Corrective and Preventive Action

3.6 SOP-03-00002: Sales Order Processing

3.7 SOP-01-00025: Reporting of Customer Complaints to Regulatory Agencies

3.8 SOP-01-00026: Reporting Complaints from the Field Procedure

3.9 FR-01-00006: Complaint Log

3.10 FR-01-00005: Complaint Record

4.0 DEFINITIONS AND ACRONYMS

4.1 Definition of a Complaint - Any written or oral expression of dissatisfaction relative to:

a. The product's identity, quality, durability, reliability, safety, effectiveness, or performance.
b. The product's packaging or labeling (including manuals and inserts).
c. The use of the product (procedural complaint).
d. Service received.

4.2 Urgent Complaint – Any complaint where the safety is directly compromised due to the nature of the complaint.

4.3 Non-Urgent Complaint- Any complaint that is non-life threatening and safety is not directly and immediately compromised.

5.0 RESPONSIBILITIES

Company employees, representatives and distributors are responsible for reporting all

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customer complaints to UOC Customer Service ("CS").

6.0 PROCEDURE

6.0 All non-urgent product complaints are required to be reported to UOC within 48 hours upon discovery of complaint.

6.1 All urgent complaints involving safety must be reported immediately, and no later than 24 hours, directly to UOC Customer Service. Failure to report an urgent complaint within the proper time frame will be subject to disciplinary action taken in the discretion of the President or his designee up to and including termination.

6.2 When reporting a complaint, the following information will be required:

a. Surgeon name if applicable
b. Hospital name if applicable
c. Product number
d. Lot number
e. Description of complaint
f. Date of occurrence
g. Location of occurrence, in surgery or other

6.3 Failure of a QA/QC released product during internal use, customer training, or observed during installation/servicing is also documented using this procedure.

6.4 CS will create the complaint report authorization form and assign a complaint number to the report.

6.5 CS may request photographs to assist with documenting the incident.

6.6 CS will forward the complaint to the responsible manager for investigation.

6.7 CS will coordinate the return of the complaint using the Returned Materials Procedure and will schedule the shipment for replacement product if applicable.

6.8 All personnel are required to comply with UOC requests to ship affected product as pertains to complaints or recalled materials.

6.9 CS may request additional information or follow up if more information about the complaint is required.

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COMPLAINT TYPES

Complaint Type	**Examples/Urgency**
1 - device problem	- device failure – 24 hours immediate report - breakage or incorrect assembly – 24 hours immediate report
2 - packaging problem	- product damaged in transit – 24 hours immediate report - torn shrink-wrap – 48 hours - damage to exterior – 48 hours - compromised inner package – 24 hours immediate report
3 - labeling problem	- error, omission, or contradicting information in labels, insert, manuals, or product specifications. – 24 hours immediate report - difficulty in understanding instructional insert – 24 hours immediate report - difficulty in following instructional insert – 24 hours immediate report
4 - service problem	- incorrect shipment method or location – 48 hours - shipment of wrong product – 48 hours - shipment of incorrect quantities – 48 hours - untimely response to customer inquiry – 48 hours
5 - other	- Self explanatory

METHODS TO SUBMIT COMPLAINTS

Type	**Submit**
Email	Us.compliance@unitedorthopedic.com
Call	949-328-3366
Fax	949-328-3368
Mail	15251 Alton Parkway, Suite 100 Irvine, CA 92618

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