Product Recall Process

1. **PURPOSE:** The purpose of this procedure is to document the procedure used by UOC management to process product recalls.

2. **SCOPE:**
   - 2.1 This document outlines the requirements, responsibilities, and processes used to manage a product recall. The determination to initiate a recall is determined at the manufacturer level by the Quality department of the parent company United Orthopedic in Taiwan and therefore they manage the risk assessment process internally and notify the branch UOC of any disposition or removal and correction.
   - 2.2 In the event of a recall, qualified management who have been trained on the recall process, are responsible for the identification and coordinating returns of affected products. Customers identified who have implanted products of affected products would be contacted within 48 business hours of said alert with pertinent information. Contact may be issued in writing via facsimile and/or electronically. UOC's quality system is managed by quality policies and procedures that govern the recall process. Components of the quality system include appropriate communication and responsiveness, device tracking, return materials, and instructional support to customers.

3. **REFERENCES:**
   - 3.1 QM-01-00001 Quality Manual
   - 3.2 FR-01-00009 Recall Notice Letter
   - 3.3 FR-01-00008 Recall Event Log
   - 3.4 SOP-03-00001 Returned Material Procedure for Customers
   - 3.5 FR-01-00003 Recall Communication Form
   - 3.6 SOP-01-00021 Inventory receiving procedure
   - 3.7 FR-01-00028 Healthcare Evaluation Template

4. **DEFINITIONS:**
   - 4.1 **Recall**: a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery. A recall would occur as a result of a defective product where there is reasonable probability that the use or exposure will result in a serious adverse event or if used improperly contrary to instructions, may lead to an unsafe condition, or risk to health.
   - 4.2 **Risk Assessment**: a systematic process of evaluating the potential risks that may be involved in a projected activity or undertaking.
   - 4.3 **Recall Strategy:** a specific course of action planned in the event of a recall which addresses the depth of recall, need for consumer warnings, and extent of effectiveness checks for the recall.

4.4 **Removal:** the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

4.5 **Correction**: repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

5. RESPONSIBILITY AND AUTHORITY:

5.1 All employees and Distributors of UOC USA INC. (UOC) are responsible for following the procedure requirements that support a product recall.

5.2 If required, a designated employee will be assigned to conduct discussions with the FDA. The designated employee is responsible to monitor and track recall related records.

6. REQUIREMENTS:

6.1 UOC shall maintain all records regarding corrections and removals regardless if the corrections or removals are required to be reported to the FDA.

6.2 UOC will make available any requested documentation regarding the details of a product recall if asked by an FDA officer.

7. PROCEDURE:

7.1 Upon notification from the manufacturer of a product recall, the company will designate a team responsible for managing the recall, product returns and customer notification. The team shall consist of qualified management who have been trained on the company recall policies and procedures. All pertinent information surrounding the details of the recall or removal shall be gathered accordingly with as many facts as possible.

7.2 The manufacturer will notify UOC of the type of recall, classification, and affected product information which may include part number, product description, lot number, expiration date, revision number and or reason for recall or removal.

7.3 The team designated to coordinate the recall are responsible for overseeing to communication related to the recall, planning returns and replenishments, device tracking, reporting obligations, and maintaining related records related to the recall The team shall consist of at least one employee from Quality and one employee from Customer Service who have been trained on the recall procedures.

7.4 UOC may also initiate a recall or other actions independently of the manufacturer.

7.5 The HHE (Health Hazard Evaluation Template) may be used as a guidance/documentation tool whenever a situation is suspected of requiring some inventory retrieval or recall.

7.6 If UOC initiates a recall, the same process will be followed as when the manufacturer initiates the recall. Additionally, UOC will work with and communicate pertinent details to the manufacturer.

7.7 UOC shall notify appropriate company personnel about the details relating to the recall.

7.8 The recall team will immediately place a stop ship on affected product and quarantine all affected product. A stock check will be performed to verify and identify the quantity and location of affected product.

7.9 The Recall Log shall be populated with required fields and maintained throughout the recall process, until the recall is closed.

7.10 A Notice of Recall (may be a letter or email, but must be written communication) will be generated and distributed to notify customers who are affected by the recall. The notice shall inform the customer of the identity of affected product and provide detailed instructions for the customer to handle the product materials. The notification shall include the following:

a. Identify part number, lot number, product description and expiration date if applicable
b. Explain the reason or nature of the recall or correction and removal
c. Include any potential hazard involved
d. Include instructions regarding product handling

7.11 If necessary, management will direct UOC Customer Service on how to respond to inquiries from outside sources pertaining to the removal.

7.12 Any Agent or Customer in possession of affected stock will be contacted with instructions for returning affected materials. Customer Service will issue Return Material Authorization numbers and shipping labels for all such returns. Customer service will document all conversations whether verbal or written, with Agents or customers using the Communication form, and all records shall be saved accordingly.

7.13 A report shall be compiled by the employee overseeing the recall or removal to summarize recall activities, confirm that all impacted product has been retrieved, and close out the recall

7.14 All returns will be issued a Return Material Number (“RMA”) according to the return materials handling procedure. The internal RMA form shall indicate the recall number assigned from the Recall log. Returned materials shall be processed using the inventory receiving procedure. All returns will be tagged with identifying information including, RMA number, Recall Number, distributor’s name and customer number, part number, lot number and quantity. All such returns shall be processed according the Inventory receiving procedure (SOP-01-00021), documented and placed in quarantine until such a time that it is returned to the manufacture or otherwise disposition.

7.15 Recalled or manufacturer requested product returns shall be taken out of released goods, tagged for identification, and quarantined until it may be returned to the manufacture for correction or disposal. The inventory will be transacted out of stock using the transfer to manufacturer warehouse in the tip-top system. All such documents shall be maintained and backed up accordingly.

7.16 The team responsible for monitoring the recall or removal shall monitor all stocks and product returns of recalled product to ensure that all affected products are removed from customers and available stocks and are returned to the manufacture. All records and communication forms shall be maintained according to the policy.

8. Expanded Correction or Removal

If, after submitting a report to the FDA, it is determined that there are additional actions or removals that should be extended to additional lots or batches of the same device the manufacturer or importer shall within 10-working (business) days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number.

The report shall include:

1. The original report number
2. All contact information for the manufacturer or importer as required under 21 CFR 806.10(c)(2)
3. Any other information that differs from the original report

9. Exempt Actions from FDA Reporting

9.1 A Correction or Removal Action is NOT a Recall if it is:

- 9.1.1 Changes – changes which improve the quality of the product but do not reduce a risk to health or remedy a violation.
- 9.1.2 Market Withdrawal – a firm's removal or correction of a distributed product which involves no violation or a minor violation that would not be subject to legal action by the FDA. Example: normal stock rotation practices routine equipment adjustments and repairs, etc.
- 9.1.3 Stock Recovery – a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm.
- 9.1.4 Safety Alert – notification by responsible persons to device users that the use of a device may, in certain circumstances, circumstances, pose a risk of substantial harm.
- 9.1.5 Routine Servicing – any product that needs routine servicing or scheduled maintenance.

9.2 Records:

All records shall still be maintained as part of the quality management system.

END OF PROCEDURE