1.0 Purpose:

Recall is **an action taken to withdraw/remove the drugs from distribution or use including corrective action for which deficiencies are reported in quality,** efficacy or safety. The defective products related to quality includes Not of Standard Quality, Adulterated or Spurious drugs.

2.0 Policy:

A recall is a method by which a medicine or medical device that has been distributed is removed from sale or from use and returned to the source or is otherwise dealt with. The recall of orthopedic implant devices and any subsequent revision surgery is a serious matter that requires the collaborative efforts of manufacturers, insurers, regulatory bodies, hospitals, and orthopedic surgeons in order to ensure patient safety.

3.0 Responsibility: Pharmacy stores team, Surgeons, nurses & clinical support staff

4.0 Procedure:

4.1.The recall process involves the following phases of activity:

- An initiation phase when problem identification, risk assessment, the decision to recall and the planning for the recall occurs
- An implementation phase when the recall notice is issued by the sponsor and

the requested recall action is undertaken

- A review phase when monitoring and review of the effectiveness of the recall action is undertaken by the sponsor with oversight

4.2.Types of Recalls - Seriousness.

4.2.1.Class I recall: a situation in which there is a reasonable probability that the use of or exposure to a volatile product will cause serious adverse health consequences or death.

4.2.2 Class II recall: a situation in which use of or exposure to a volatile product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

4.2.3. Class III recall: a situation in which use of or exposure to a violative product is not likely tocause adverse health consequences.

4.2.4. Market withdrawal: occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

- **4.2.5.** Medical device safety alert: issued in situations where a medical device may present an unreasonable risk of substantial harm. In some case, these situations also are considered recalls Action to be taken by recipient, e.g.

- Please be aware that patients taking <product description> may have been undertreated

• Check any stock you may have, for example samples or supplies from practitioner supply orders.

- Patients with and without immediate symptoms and physical findings of device failure will seek advice from their orthopedic surgeon regarding replacement of their implant.
- Orthopedic Surgeons encourages physicians to talk with their patients about the risks of pain, disability, morbidity, and mortality associated with the implant and with revision surgery.
- Re-operation may prove to be the best option for patients whose implants have failed, who are in chronic pain as a result of their faulty implant, and/or whose function has been negatively affected by the failure.
- Adverse events should be reported once the individual patient's safety is ensured. While it is mandatory that hospitals and manufacturers reporting these events, surgeons have no such requirement. Surgeon reporting of any and all device failures and adverse events will provide clinical context to the report and improve the quality of the information available to the FDA as these events are evaluated.

Recall does not include:

• the removal of individual medical devices for modification due to technical improvement, other than when these improvements overcome inherent design or manufacturing defects

• the removal of an individual medical device for repair in the event of malfunction or failure as a result of normal ageing; nor for appropriate maintenance or lack of good maintenance.

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