SURGISHOP
DISCOUNT SURGICAL SUPPLIES

SurgiShop Standard Operating Procedures

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Responsible Department: Operations/Quality Assurance

Surgishop
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Standard Operating Procedures
Prescription Medical Device ("PMD")
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1.0 Standard Operating Procedures – Building and Storage Policy

SurgiShop is governed by rules which are necessary to protect the public health, safety, and welfare. These rules include but are not limited to the below.

SurgiShop's physical storage facility and office must:

a) Be appropriately sized, and constructed such that it can be properly cleaned, maintained, and operated;

b) Be designed to include adequate lighting, sanitation, humidity, security, and temperature control;

c) Have a designated area for the storage of PMDs which are out-of-date, damaged, or not sterile;

d) Be kept clean and orderly, and free from infestation by insects, birds, rodents, or pests of any kind;

e) Be able to store all PMDs within the recommended temperature range, and under the recommended conditions;

f) Maintain all records that relate to purchasing, receiving, managing inventory, selling, billing, invoicing, shipping, refunding, and operating SurgiShop. Records are maintained in both a physical and digital format.

2.0 Standard Operating Procedures – Security Policy

SurgiShop is governed by rules and procedures to ensure public health, safety, and welfare. The rules listed include all security measures utilized by SurgiShop.

On-site Warehouse Security:

a) Access from outside the premises is to be restricted and logged;

b) The outside perimeter of the facility must be kept well-lit and visible;

c) All entry to PMD storage room(s) is limited to authorized personnel;

d) SurgiShop's warehouse must be equipped with an alarm system to detect unauthorized entry during non-business hours;

e) The alarm system will be activated by a manager upon his/her departure and will remain armed until the start of the next day. Furthermore, a security patrol shall monitor the outer premise of SurgiShop's facility in case of fire, theft, or any other unforeseen event after closing hours.

Customer and Vendor Database Security

a) Access to SurgiShop's computer systems and files is only granted to authorized personnel. An establishment which is used for wholesale PMD distribution must be secured by authorized computer system entry programs, confidential file software, and industrial grade anti-virus computer software;

b) SurgiShop must install back-up storage programs that allow real-time back up;

c) SurgiShop has adopted physical paper shredding policies to maintain security and confidentiality of customer information.

3.0 Standard Operating Procedure – PMD Receiving Procedures

SurgiShop is governed by rules which are necessary to ensure the public health, safety, and welfare. Some such rules relate to SurgiShop's receiving policy, as outlined below.

Physical Examination of Incoming Goods and Associated Records:

a) Once goods are received, a thorough examination of the outside container is performed to ensure that damaged or contaminated PMDs are not accepted. A review of SurgiShop's purchase order (as related to the acquisition of the PMDs) is performed for accuracy and completeness;

b) Each item is then individually inspected for damage, stains, dings, or any other apparent visual defects that may compromise the PMD's integrity. Each item's manufacturer, reference number, expiration date, lot number, quantity, and condition are recorded into SurgiShop's digital database, and the item is placed into climate-controlled storage.

Returned, Damaged, or Expired PMDs:

a) Outdated, damaged, stained, misbranded, or otherwise objectionable PMDs are separated from other PMDs until they are destroyed, donated, or returned to the supplier. These objectionable PMDs are to be stored in a "quarantine section" that is isolated from other PMDs;

b) If a PMD is returned, and there is doubt as to its safety, identity, or quality, the PMD is destroyed or returned to the supplier;

c) PMDs which are stored at SurgiShop's physical warehouse for commercial sale are to be examined at least once per month for expiration dating. Those PMDs which have passed their expiration date are removed and placed in the "quarantine section" to await destruction or donation.

Procedure for Physical Receipt of PMDs:

1) Upon delivery of PMDs via FedEx or UPS, the following actions must be performed:

a) Log relevant details about the shipment on SurgiShop's "Shipping Received Form", including the date of delivery, the method of delivery, the facility from which the PMDs were shipped, and the quantity of boxes;

b) Ensure that the PMD purchase order reflects the actual PMDs received. Perform the PMD physical examinations and record the manufacturer, reference number, expiration date, lot number, quantity, and condition of each PMD received (as discussed above). Transfer PMDs to climate-controlled storage space, noting relevant shelf number on "Shipping Received Form". Initial "Shipping Received Form" when complete;

c) Physically remove all customer shipping labels from the boxes which the PMDs arrived in. Place labels into shredding bin;

d) Log all relevant information on the "Shipping Received Form" into SurgiShop's digital database.

4.0 Standard Operating Procedure – PMD Shipping Procedures

SurgiShop is governed by rules which are necessary to protect the public health, safety, and welfare. These rules include SurgiShop's shipping Policy, which is outlined below.

Physical Examination of Outbound Goods and Associated Records:

Sales Department:

a) Create an invoice which confirms the customer's bill to/ship to addresses, purchase order number, desired delivery date, and desired PMDs (noting quantity, pricing, and fees);

b) Print two copies of the invoice, one for the shipping department and one for the accounting department.

Shipping Department:

a) When a customer invoice is received, pull relevant PMDs from storage. Confirm that each PMD pulled matches the customer invoice in manufacturer reference code, quantity requested, and expiration dating. Additionally, each PMD must be thoroughly checked for identity and integrity. If customer order includes temperature sensitive BIO PMDs, confirm that invoice reflects an overnight shipping option and note that the package must be packed with dry gel-ice. When finished, the employee shall initial the invoice;

b) Items will then be moved from storage to the shipping room. A second employee from the Shipping Department must double-check that the proper PMDs were pulled, and that they conform to all the conditions outlined above about identity, integrity, quantity, expiration dating, and temperature sensitivity. When this is confirmed, the second employee shall initial the invoice;

c) Once approved for shipment, the order must be packed in a container. It must be packed such that movement during transit is minimized. The invoice is then placed on top, the shipping label is affixed to the container, and the container is moved to the region of the room designated for outbound packages;

d) Just before FedEx pick-up at 4:30 PM, a final visual inspection of the PMDs in the container is made. The container is sealed with shipping tape and left to await

pick-up in the “Outbound” region of the room. An employee of SurgiShop must witness FedEx pick-up and scan the containers.

5.0 Standard Operating Procedures – PMD Recordkeeping Procedures

SurgiShop is governed by rules which are necessary to protect the public health, safety, and welfare. SurgiShop's recordkeeping policies are within the scope of these rules.

SurgiShop must meticulously maintain inventories and records for all transactions regarding the receipt as well as the distribution of any PMDs. These records will provide a full audit trail from receipt to sale and be readily available for review. Below are some of SurgiShop's general policies:

a) The records must provide the source of the PMD, including name and principal address of the hospital/surgery center, and the address of the location from which the PMD was shipped;

b) The records must include the quantities, manufacturer reference codes, expiration dates, and lot numbers of the PMDs being received or shipped out;

c) The records must include the dates of receipt and distribution of the PMD;

d) The records must contain financial documentation that supports the PMDs sale or transaction;

e) Records discussed in this section are kept onsite and can be immediately retrieved by a computer or other electronic means, thus allowing for review at any time.

6.0 Standard Operating Procedure – FDA Policies

SurgiShop is governed by a set of rules and standards that require keeping records of PMDs for the protection of the public health, safety, and welfare. Rules listed include all actions and recordkeeping measures utilized by SurgiShop as required for the Reporting of Adverse Consequences on the field.

Upon hearing that an adverse consequence has occurred on the field, a manager ought to be immediately notified. The manager must confirm the following details from the client:

a) Facility name;
b) Address;
c) Contact name;
d) Contact phone number;
e) Date of contact from customer.

The manager must also confirm the following details regarding the failed PMD:

a) Manufacturer;
b) Part number;
c) Description;
d) Lot number;
e) Expiration date;
f) General description of how the product failed;

The manager must then research the customer file to verify all relevant details including the invoice and shipping receipt. They will then print and file a copy with the CEO.

6.1 Standard Operating Procedures – Procedures for FDA Tracked PMDs

SurgiShop is governed by rules and guidelines for the protection of the public safety, health, and welfare. These rules will include all actions and recordkeeping procedures used by SurgiShop as required for the Reporting of Tracked Devices.

The FDA has issued orders to manufacturers who are required to track all the following implantable devices:

a) Cardiovascular Permanent Implantable Pacemaker Electrode;
b) Automatic Implantable Cardioverter/Defibrillator;
c) Abdominal Aortic Aneurysm Stent Grafts;
d) Temporomandibular Joint (TMJ) Prothesis;
e) Mandibular Condyle Prothesis;
f) Glenoid Fossa Prothesis;
g) Cultured Epidermal Autografts;
h) Silicone Gel-Filled Breast Implants;
g) Implantable Infusion Pumps;
h) Implanted Diaphragmatic/Phrenic Nerve Stimulator;
i) Implantable Cerebellar Stimulator;
j) Replacement Heart Valve (Mechanical only);
k) Implantable Pacemaker Pulse Generator.

The FDA requires tracking for the following PMDs which are used outside of a device-user facility:

a) Breathing Frequency Monitors;
b) DC-defibrillators and Paddles;
c) Continuous Ventilators;
d) Ventricular Bypass (Assist) Device.

Upon receipt of the above mentioned PMDs, SurgiShop must record the reference number and lot number from each of the tracked device(s) onto the purchase order in accordance with PMD receiving SOP 3.0.

Upon shipping of a Tracked Device, SurgiShop must record reference numbers and lot numbers from each of the Tracked Device(s) onto the Customer's invoice in accordance

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with the PMD Shipping SOP 4.0

6.2 Standard Operating Procedure – Monitoring and Reporting FDA Recall of PMD Procedures

SurgiShop is governed by rules and procedures that require keeping such records of PMDS for the protection of the public health, welfare, and safety. Rules shall include all the following actions and recordkeeping practices used by SurgiShop as required for the Monitoring and Reporting of a PMD Recall.

SurgiShop must regularly review the FDA website (WWW.FDA.GOV) for voluntary and/or involuntary PMD product recalls. The "Recall Folder" is to be signed off and dated every week, regardless of whether a recall is in effect or not.

If a recall occurs, it is immediately printed, logged, and kept in a special dedicated folder for all past noted recalls.

a) SurgiShop's Shipping/Receiving manager is immediately notified and given a copy of the recall so that SurgiShop's current inventory stock may be properly checked to ensure it is not affected. If SurgiShop is in possession of any recalled products, SurgiShop will immediately pull them off the shelf and dispose of/destroy the items;

b) If a recall is in effect, the Shipping/Receiving Department must verify whether any recalled PMDs have been shipped to any clients during the recall period. If so, the clients are notified and the PMDs in question are requested for return. Client accounts which return recalled PMDs are to be credited.

7.0 Standard Operating Procedures – Physical Inventory Procedures

SurgiShop is governed by a set of rules that are intended to protect the public health, safety, and welfare. These rules include the procedures for physical counting and recording of PMDS, which are outlined below.

A physical inventory count is to be conducted at least every two months for all PMDs in storage at SurgiShop's warehouse. This physical inventory count must conform to the following guidelines:

a) All inbound PMDs arriving on the day of the physical inventory count are to be segregated in the "quarantine section" as detailed in section 3.0. Procedures relating to these inbound PMDs will continue as described in section 3.0, except for the placing of the PMDs in the storage room. Once the physical count has been completed, these inbound PMDs may be placed into storage as usual;

b) All customer orders placed during SurgiShop's bi-yearly physical inventory count are to be completed as normal. If a sale is confirmed, the shipping/inventory manager must adjust records to reflect the most current count before proceeding;

c) The inventory manager must assign "count areas" to authorized personnel. Once assignments have been made, each employee must note the sections of the "Master Inventory Sheet" that correlate to their assigned area. Starting from the top, they check to see if the information on the "Master Sheet" lines up with what is on the shelves. The following are things to check for: manufacturer's reference number, lot number, expiration date, quantity (noting boxes vs. eaches where relevant), and condition;

d) If employees of SurgiShop come across a PMD that is short-dated (i.e., which has only 6 months of shelf-life or less remaining) during the physical inventory count, they must remove this item and place it in the "Short-dated Section" of the storage room;

e) Each employee must record the relevant information on their copy of the "Master Sheet";

f) PMDs which are in storage but not listed on the “Master Sheet” must be recorded. Note the manufacturer, the reference number, expiration date, lot number, quantity, unit of measure, and condition;

g) PMDs which are on the “Master Sheet” but not in storage must be similarly noted. Once each employee completes logging their assigned areas, they must input all findings into SurgiShop’s database.