

### WestCMR Quality Policy

West Coast Medical Resources, LLC (WestCMR) is an environmentally responsible reseller/distributor of unused, in-date Prescription Medical Devices ("PMDs") used in surgical facilities, hospitals, and doctor's offices. WestCMR purchases its inventory from a variety of suppliers, including hospitals, surgery centers, medical device distributors, and other resellers. WestCMR also provides supplemental cost savings and flexibility when sourcing those same surgical supplies to customers. WestCMR, a reseller/distributor of PMDs in the secondary market, is not regulated by the Food and Drug Administration ("FDA").

WestCMR's mission is simple: To change how not only our customers, but everyone in healthcare thinks about how excess surgical supplies are managed. WestCMR institutes a compliance program designed to provide a commercially reasonable process to eliminate, or substantially reduce, the possibility that WestCMR could inadvertently purchase products from a seller that could not demonstrate its legitimate ownership. This program was undertaken because the FDA has made a regulatory decision to limit the regulatory tracking, registration and listing requirements for distributors of prescription medical devices. The compliance program implemented by WestCMR includes specific purchasing protocols to validate the nature of those sellers from which WestCMR purchases inventory; these protocols include the following elements:(a) Restrictions on eligible vendors; (b) Required paperwork for all transactions including purchase order, invoice and bill of sale; (c) Restrictions as to payment method; (d) Quality Systems Procedures to ensure the accuracy and integrity of the products upon receipt, storage and distribution.

WestCMR operates as a compliant commercial enterprise and has established quality control systems. The company's facility is a climate controlled warehouse maintained by our inventory control specialists. The facility is under 24 hour video / security surveillance and utilizes an advanced inventory tracking software that resides on enterprise-class servers in an offsite data center where data is backed up daily and stored securely.



## Our Process

WestCMR currently enforces the following "Sales Protocols" to ensure the safety and efficacy of secondary market ("PMDs") within the market:

1. The customer must be a person or entity with authority to own the merchandise pursuant to Title 21, United States Code.
  - a. The customer may be a provider of medical services (ex. hospital, clinic, surgical center).
  - b. WestCMR does not sell any merchandise to a manufacturer's representative/agent.
2. All sellers must be able to prove they have good and marketable title to the merchandise being sold.
  - a. Proof of the purchase of the merchandise along with a copy of the invoice and evidence of payment for the merchandise.
    - i. The proof of purchase must show that the merchandise was purchased from a person or entity with authority to own the merchandise pursuant to Title 21 of the United States Code.
    - ii. Merchandise was paid for in a routine business way, typically a company check. The payee of the check must match the name of the party who sold the goods to the vendor.
    - iii. An inventory/property control sheet of the vendor printed on the stationery of the vendor from whom you purchased the merchandise and bearing all marks typical of such documents - such as inventory control numbers, storage locations, purchase dates, manufacturer name, expiration dates. The document must be provided to WestCMR by the employee/agent of the vendor.
    - iv. If the merchandise is capital equipment it should bear the manufacturer's original serial number in all places where the serial number is engraved, embossed or attached to the device.



3. All transactions made by WestCMR require the following documentation:
- a. A purchase order addressed to WestCMR for the merchandise. The purchase order must show the customer's name and full business address.
  - b. All WestCMR sales are concluded with an invoice on WestCMR company stationery.
  - c. WestCMR invoices clearly show WestCMR's federal tax identification number.
  - d. All WestCMR invoices must be paid by company check or cashiers check made payable to WestCMR. Wire transfers and major credit cards are also accepted.

### Quality Systems Procedures

To ensure product integrity, WestCMR has committed to the following Quality Systems Procedures throughout the receipt and delivery process:

- a. Upon receipt, each unit is individually inspected to ensure it meets quality assurance standards. Our inspection process includes but is not limited to:
  - i. Visual Package Integrity Inspection: WestCMR carefully inspects each product received whether received as a full box or by the individual unit to ensure received inventory is free from defect, discoloration and is in marketable condition.
  - ii. Sterile Seal Inspection: WestCMR inspects each product to confirm sterility by visually inspecting the blister pack for damage to ensure the sterile seal has not been compromised.
  - iii. Lot Number and Expiration Date Inspection: WestCMR inspects each unit to ensure that the product is in-date. In addition, WestCMR logs each individual lot number during the scanning and integration process to ensure the product received is not subject to recall.
  - iv. Temperature Gauge Inspection: Upon receipt and again before the product is being packed up for shipping, the temperature indicators located on BIO/temperature sensitive products are inspected to guarantee product integrity.



- b. Once all steps of the visual product inspection have been completed, the inventory is scanned into an advanced inventory tracking software program. The software provides systematical management of the Recall and picking processes to guarantee complete accuracy when picking orders.

### **Data Integrity**

Although not required within the FDA best practices, WestCMR exceeds requirements by voluntarily tracking and recording lot numbers. WestCMR's inventory system tracks Expiration, Product Number, and LOT number. This real time fulfillment system guarantees accurate order completion.

WestCMR data is kept offsite in a top-of-the-line data center that provides enterprise-class scale and reliability. WestCMR data is protected by encrypted communications and backups, firewalls and multilayer access controls. In addition, WestCMR data is automatically scanned using enterprise-class anti-virus technology. The WestCMR server backs-up data each night and retains it for 90 days.

### **Storage Requirements**

Product is separated by vendor and category and stored using the industry standard in healthcare product storage. All products are stored off the ground on shelving and suitably spaced for proper cleaning and inspection. All expired, rejected, damaged, recalled, and/or returned medical devices are immediately removed from inventory and destroyed.

### **Temperature**

Once products are logged into the tracking software and shelved, a daily temperature monitoring system is implemented to safeguard the product against humidity and temperature fluctuation. The storage facility temperature requirements are maintained in the temperature range of 68 – 72 F.

### **Sanitation of Facility**

A cleaning log is maintained to ensure that the storage facility is cleaned on a daily basis. No smoking, eating, or drinking is permitted in areas used for storage and handling. The storage area is designed and equipped to prevent the entry of insects and other pests.



**Exposure to Outside Elements**

The storage facility is designed to protect products from water infiltration as well as sunlight exposure. The packing zones as well as the receiving dock are isolated from the storage facility to eliminate unwanted exposure.

**Expired Product Control / Stock Rotation**

To ensure highest quality practices, WestCMR has implemented a monthly expired pull. The ERP system directs which products are close to its expiration date and are pulled before expiration in order to maintain a proper stock rotation and a high level of product control.

**Shipping and Delivery**

WestCMR utilizes FedEx Ship Manager which is synced with the ERP system in order to provide a high level of quality control and a quick turnaround time. The shipping options can be selected during check-out/order fulfillment. Customers who prefer to be billed directly will be asked to provide a FedEx account number (the customer is responsible for all fees/charges associated with this option). WestCMR does not charge a handling fee.

WestCMR's fully integrated system allows us to ship all orders received by 5:00PM Eastern Standard Time the same day with some exceptions. WestCMR does not assume responsibility for delays in shipping due to orders received after 5:00PM Eastern Standard Time.

All order are packaged with care and WestCMR utilizes a Pack/Verify ERP process that ensures all orders are picked correctly. To ensure high quality WestCMR follows the proper provisions which include:

- I. Product is protected from unacceptable heat, cold, light, moisture.
- II. Product is not contaminated.
- III. Product is properly identified.
- IV. Product is securely packed.
- V. Product is shipped with a packing slip and the proper carrier labels.

Upon request, a tracking number can be sent to the customer for order tracking and/or record keeping.



## West Coast Medical Resources, LLC (WestCMR)

Proudly serving the Surgical Community since 1997

### Product Recalls

WestCMR closely monitors products for recall. In the event of a recall, the product is identified, pulled from inventory, and destroyed. When recalls are identified, WestCMR immediately contacts appropriate parties.

Recall alerts are often received from our customers who in turn voluntarily pass on the information and are also monitored by our internal Inventory Operations Department via the FDA MAUDE (Manufacturer and User Facility Device Experience) Database:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

WestCMR advanced inventory tracking system triggers a warning message if an item scanned is on our recall database table in the Enterprise Resource Planning (ERP) system. The customized automated process interlinked with our Warehouse Management System (WMS) and ERP systems helps us manage and control our recalls more efficiently.

Item(s) purchased that are subject to a voluntary or involuntary recall from a manufacturer or FDA will be replaced with an identical product not under the recall at no charge. If supply is not available, WestCMR will issue a refund.

### Product Returns/Return Goods Authorization

In the event of an order error our customers are able to return the items following the table below.

- 1-30 days – The facility may return items for full credit less a 10% re-stocking fee.
- 31-60 days – The facility may return items for a credit equal to 75% of the purchase price.
- 61-180 days – The facility may return items for a credit equal to 50% of the purchase price.
- > 180 days – WestCMR **will not grant credit** for items that were sold 180 days or more prior.

