



Quality Policy

GeoSurgical, LLC is an environmentally responsible reseller/distributor of unused, in-date Prescription Medical Devices ("PMDs") used in surgical facilities, hospitals, and doctor's offices. GeoSurgical sources its inventory from their sister companies, West Coast Medical Resources, LLC (WestCMR) and Ware Consulting, LLC. GeoSurgical, a reseller/distributor of PMDs in the secondary market, is not regulated by the Food and Drug Administration ("FDA").

GeoSurgical's mission is simple: To provide quality products, customers are already purchasing but at a fraction of the price and with flexibility when purchasing. GeoSurgical's sister company, 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.

GeoSurgical operates as a compliant commercial enterprise and has established quality control systems. The company's facility is a climate-controlled warehouse maintained by inventory control specialists. The facility is under 24-hour video/security surveillance. GeoSurgical 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

GeoSurgical currently enforces the following "Sales Protocols" to ensure the safety and efficacy of the secondary market ("PMDs") within the market. The customer must be a person or entity with the 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, veterinary, research & development, cadaver lab).
- b. If the customer is a re-seller, they must have a licensed company to purchase products through.
- c. If the customer is a remanufacturer of the PMDs, or a repackager, GeoSurgical obtains the customer's FDS registration number.
- d. GeoSurgical does not sell any merchandise to a manufacturer's representative/agent.

Payment

Domestic entities such as Universities, Veterinary Clinics, Medical Supply Relief Organizations, and Manufacturers will have the opportunity to establish NET terms and a credit limit for orders based on a credit report.

International customers are required to prepay for inventory at the time of purchase.

Forms of payment that GeoSurgical will accept are:

- ACH
- Paymode-X
- Commerce Bank Private Network Card
- Credit Card (Visa/MC/Discover/AMEX)
- By Check

Quality Systems Procedures

To ensure product integrity, GeoSurgical has committed to the following Quality Systems Procedures throughout the receipt and delivery process (Which is handled by WestCMR):

- 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/GeoSurgical 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/GeoSurgical 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/GeoSurgical inspects each unit to ensure that the product is in-date. In addition, WestCMR/GeoSurgical logs each individual lot number during the scanning and integration process, to ensure the product received is not subject to a recall.
 - iv. Temperature Gauge Inspection: Upon receipt and again before the product is being packed 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, GeoSurgical exceeds requirements by voluntarily tracking and recording lot numbers. GeoSurgical's inventory system tracks Expiration, Product Number, and LOT Number. This real-time fulfillment system guarantees accurate order completion.

GeoSurgical data is kept offsite in a top-of-the-line data center that provides enterprise-class scale and reliability. GeoSurgical data is protected by encrypted communications and backups, firewalls, and multilayer access controls. In addition, GeoSurgical data is automatically scanned using enterprise-class anti-virus technology. The GeoSurgical 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 the highest quality practices, GeoSurgical 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

GeoSurgical utilizes FedEx Ship Manager and UPS upon customer request, which is synced with the ERP system to provide a high level of quality control and 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/UPS account number (the customer is responsible for all fees/charges associated with this option). GeoSurgical does not charge a handling fee.

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

All orders are packaged with care, and GeoSurgical utilizes a Pack/Verify ERP process that ensures orders are picked correctly. To guarantee high quality, GeoSurgical 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.

Product Recalls

GeoSurgical closely monitors products for recall. In the event of a recall, the product is identified, pulled from inventory, and destroyed. When recalls are identified, GeoSurgical 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>

GeoSurgical's 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, GeoSurgical will issue a refund.

Product Returns/Return Goods Authorization

GeoSurgical does not routinely accept returned goods because all items are sold as-is without warranty. However, under extenuating circumstances, GeoSurgical can make exceptions.

- 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 – GeoSurgical **will not grant credit** for items that were sold 180 days or more prior.