



SALES POLICIES

RETURNS

All product returns must have a Spinal Simplicity issued RMA. To obtain the RMA, contact customer service. The RMA request should include:

- Part Number
- Description
- Lot #
- Expiration Date
- Quantity
- Reason for Return

An RMA will be issued within 24 hours.

All returns should contain a packing slip. The RMA should be on the outside of the shipping container, legible and large enough to be seen by the receiver.

Returns should be securely packed within the shipping container to prevent damage to the product during shipping. Use bubble wrap or another packing material to secure the package contents. Implants should not be overpacked – any damaged boxes will be subject to a fee incurred by the Agent. Implants should not be shipped with an instrument set to prevent damage to the implant boxes.

Products being returned should be unused, undamaged and in original packaging. No pen, pencil, marker or stickers allowed on the product.

Instrument Sets being returned must be sent in a container sturdy enough to contain the set without breaking through during shipping. Secure the set inside the container with bubble wrap or another packing material to prevent damage.

Send returns to:

Spinal Simplicity
Attn: Returns
6600 College Blvd Ste 220
Overland Park, KS 66211



Pricing

Spinal Simplicity has established a price list for all products. Agents and agent reps are not to sell any product above or below the published list price unless prior WRITTEN authorization has been granted by Spinal Simplicity.

All facility pricing agreements must be in writing between the facility and Spinal Simplicity, signed by both parties.

Spinal Simplicity reserves the right to change product prices and to discontinue product without prior notice.

Discounting

List price will be billed unless a discount has been approved by Spinal Simplicity management. All discount requests should be sent in writing.

Sales Tax

Taxes in the U.S.:

Unless a customer possesses and provides an exemption certificate, Spinal Simplicity will bill and collect for applicable sales, use, excise or other municipal, state or federal taxes.

Taxes Outside the U.S.:

The amount of any applicable sales, use, excise or other municipal, state or federal taxes will be billed and collected by the selling company.

Terms of Payment

The terms of Net 30 days from date of invoice is applicable for all customers unless prior approval has been issued by Spinal Simplicity.

Shipping

All shipping charges will be paid by the distributor. Any exceptions must be approved in writing by the Director of Customer Service.

Orders placed before 4pm CST will be shipped the same day. Orders after 4pm will be shipped the next business day.

All orders are shipped FedEx Ground unless otherwise stated in writing.



Compliance

Physician Payments

Distributors and their reps are required to fully cooperate in assisting Spinal Simplicity in meeting its transparency and reporting obligations under the “Sunshine Provisions” of the Patient Protection and Affordable Health Care Act and similar laws. This includes maintaining complete and accurate records of all payments, transfers of value, and other applicable transactions with healthcare professionals and hospitals. These records are to be submitted monthly, due by the 10th day of the month following the payment.

Examples of expenses:

MEALS

Any meal provided to a healthcare professional must be in conjunction with a bona fide business purpose; not be part of any recreational or entertainment event; be in a location conducive to business discussions; and not cost more than the \$125.00 per person, including alcohol, gratuity, and taxes.

- It is our rule that any meals provided to a healthcare professional be modest and occasional, and such meals may not be provided to any guests of the healthcare professional, such as spouse, unless such guests have a bona fide interest in the business being discussed.
- It is not appropriate to provide office lunches/dinners to a healthcare professional’s office or administrative staff if such staff does not participate in the business presentation or discussion.
- Alcoholic beverages may be provided in moderation to a healthcare professional as part of a business meal, so long as the maximum allowable cost per person of \$125.00 is not exceeded.
- **ABSOLUTELY NO ENTERTAINMENT OR RECREATIONAL EVENT OR ACTIVITY** should be provided to healthcare professionals. Such activities include, but are not limited to: theatre, sporting events (e.g. golf, ticketed sporting events including baseball, basketball, soccer, hockey, football, etc., skiing, hunting), sporting equipment, and leisure or vacation trips.

GIFTS & EDUCATIONAL ITEMS

Educational items may be provided by Spinal Simplicity to healthcare professionals if they are educational and patient related.

However, no items capable of use by the healthcare professional for non-educational or non-patient related purposes may be provided. Examples: an unlocked flash drive, a DVD player or other device would not be appropriate even though they may have educational information on them because they are capable of being used for other purposes.

Absolutely no gifts should be provided to any healthcare professionals. This general prohibition includes, but is not limited to:

- Cookies, wine, flowers, chocolates, gift baskets, or holiday gifts
- Gifts provided on life occasions such as birthdays, anniversaries, births, deaths, etc.



- Any branded or non-branded items such as pens, notepads, mugs and other such items.

TRAVEL

Any air travel for healthcare professionals generally should be booked through Spinal Simplicity's office. Air travel should be coach class for all domestic travel. However, business class tickets may be purchased for domestic travel when (1) the duration of the trip is more than four consecutive hours AND (2) one of the following is true: (i) the size of the passenger warrants business class, (ii) the trip involves overnight travel, or (iii) the health of the passenger warrants business class.

Business class tickets may also be purchased for international flights that exceed four consecutive hours. Any business class ticket for domestic surgeon travel must be pre-approved by Compliance.

Any other travel accommodations (e.g. hotels, ground transportation) made on behalf of a healthcare professional should be modest and reasonable and provided only for the amount of time necessary to accomplish the bona fide business objectives. An example would be extra days or extended weekends for leisure or personal activities.

No travel accommodations should be provided for any guests or spouses of a healthcare professional if such guests do not have a bona fide business interest in the relevant activity or meeting.

HIPPA

Distributors and their reps will comply with HIPAA's Standards for Privacy of Individually Identifiable Health Information and the Security Rule, 45 C.F.R. Part 160 through 164, as applicable and as amended from time to time.

The Security Rule requires covered entities to maintain reasonable and appropriate administrative, technical, and physical safeguards for protecting PHI.

Distributors and reps must ensure the confidentiality, integrity, and availability of all PHI they create, receive, maintain or transmit, including electronic records.

Distributors and reps must identify and protect against reasonable anticipated threats to the security or integrity of the information.

Distributors and reps must protect against reasonably anticipated, impermissible uses or disclosures; and ensure compliance by their workforce.

The Security Rule defines "confidentiality" to mean that e-PHI is not available or disclosed to unauthorized persons. The Security Rule's confidentiality requirements support the Privacy Rule's prohibitions against improper uses and disclosures of PHI. The Security rule also promotes the two additional goals of maintaining the integrity and availability of e-PHI. Under the Security Rule, "integrity" means that e-PHI is not altered or destroyed in an unauthorized manner. "Availability" means that e-PHI is accessible and usable on demand by an authorized person.



Bill Only

The sales rep is required to submit the completed Bill Only form within 24 hours of a procedure.

The form must be filled out completely and accurately, using legible handwriting.

The facility issued PO# **MUST** be included on the form prior to submitting to Spinal Simplicity.

Implant stickers are included in each product box and should be adhered to the Bill Only form.

A patient sticker or identifier is to be adhered/written legibly in the appropriate section of the form.

Bill Only forms are subject to acceptance by Spinal Simplicity at our sole discretion. Spinal Simplicity shall send to the sales rep a notice of rejection of a Bill Only and an indication of the basis of rejection.

All Bill Only forms shall be submitted to Spinal Simplicity via email to billonly@spinalsimplicity.com.

PROPER PROMOTION POLICY

The FDA prohibits a manufacturer from promoting its product for uncleared uses, even though a healthcare professional may, in his or her own judgement, use the products in any manner that he/she sees fit for the patient.

Spinal Simplicity employees and distributors/agents may not promote Spinal Simplicity products for use outside the scope of their FDA clearance. This is also referred to as off label use. Spinal Simplicity will not engage other parties to promote such off-label use. (i.e. consultants)