INSTRUCTIONAL MANUAL



Prescription systems including:



BOS 2000-3 Twist ● MVP-700



ADVANTAGE • MOS • BOS

Please read all instructions prior to use.

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Who Needs the Vacuum Therapy System?

- Men with erection problems of all ages, even those who haven't achieved an erection in several years.
- Men who sometimes fail to get a full erection due to stress, excitement or fear.
- Men with a problem of too soft an erection.

Vacuum therapy systems are meant for the treatment of men with erectile dysfunction. Millions of men are estimated to be affected. Erectile dysfunction could be a sign of the existence of a serious blood flow or nerve problem, which could cause stroke or heart attack. Erectile dysfunction is often the side effect of a medication you may be taking. If you suspect this, talk to your doctor. You should never change or stop taking medication without first consulting your doctor. Smoking, alcoholism and drug abuse can all contribute to an erectile dysfunction disorder.

Other accepted forms of treatment for erectile dysfunction are:

- 1. Counseling
- 2. Hormonal Therapy
- 3. Medications (oral and injectable)
- 4. Intraurethral medications
- 5. Vascular Reconstructive Surgery
- 6. Prosthetic Implants (surgical)

Any of the above listed treatments should be under doctors care or by prescription.

About the Vacuum Therapy System

The vacuum therapy system consists of a vacuum pump, adapter bushing(s), a penile tube, ring loading cone and tension rings. The intended use of the system is to assist users in achieving a full erection, i.e., to create an erection in men with erectile dysfunction (as described above) by means of applying vacuum to the penis, which draws blood into the penile corpora cavernosa, causing the penis to become erect and rigid. The tension rings are then placed around the base of the erect penis to restrict the flow of venous blood leaving the penis. Vacuum therapy has become one of the most accepted forms of treatment for erectile dysfunction. It is better to train yourself with the system alone, before including your partner. It may take a period of a few weeks to develop the proper technique with the system.

Warnings and Precautions

Vacuum Therapy System Warnings

If you do not follow these instructions you may cause personal injury.

- 1. If you have signs of erectile dysfunction, (i.e., unable to get an erection that is good enough for sexual intercourse), talk to your doctor before using this system to avoid a possible harmful delay in figuring out any of the most common causes of this condition, such as diabetes, multiple sclerosis, cirrhosis of the liver, chronic renal failure, or alcoholism.
- 2. The user should apply the least amount of vacuum pressure that will get an erection. Use of too much vacuum pressure could bruise or injure the penis.
- 3. The user should stop using the vacuum therapy system if pain occurs.
- 4. The vacuum therapy system should not be used while using alcohol or drugs.
- 5. Use of a vacuum therapy system may bruise or break the blood vessels either right below the surface of the skin or within the deep structures of the penis or scrotum, resulting in bleeding or the forming of a blood filled swelling. Do not be too concerned if you notice some bruising of the penis, or small reddish spots below the skin.

You should stop using the system until the problem has cleared up (5 or 6 days). When you do use the system again, be careful not to apply more vacuum than feels comfortable. Use caution and plenty of water soluble sealing gel when removing the tension ring.

- 6. Caution is advised when using a vacuum therapy system following the removal of a penile implant because of possible scarring and later impairment. Apply the vacuum gradually. Watch for bruising or distortion of the penis. We suggest that you keep in close contact with your doctor during early use of the system after an implant removal.
- 7. Do not use if you have decreased sensation or pain in the area of the penis.
- 8. Do not use if you have decreased hand strength that will make the removal of the rings difficult.
- 9. The vacuum therapy system will not cure relationship problems or correct physical problems such as low sex drive, decreased sensation, and absent or premature ejaculation.

10. If you have Sickle Cell Trait or Sickle Cell Disease, a history of prolonged erections, or are taking large quantities of aspirin or other blood thinners, do not use the vacuum therapy system without consulting your doctor.

Carefully read these instructions completely before use of a <u>battery operated</u> system.



STEP 1. To remove the battery cover press on the arrow head and push up.

STEP 2. Insert the batteries as indicated in the battery compartment. (Use AA size batteries)

STEP 3. Slide the battery cover back in place.

If Directions Are NOT Followed, The Unit WILL NOT Work.

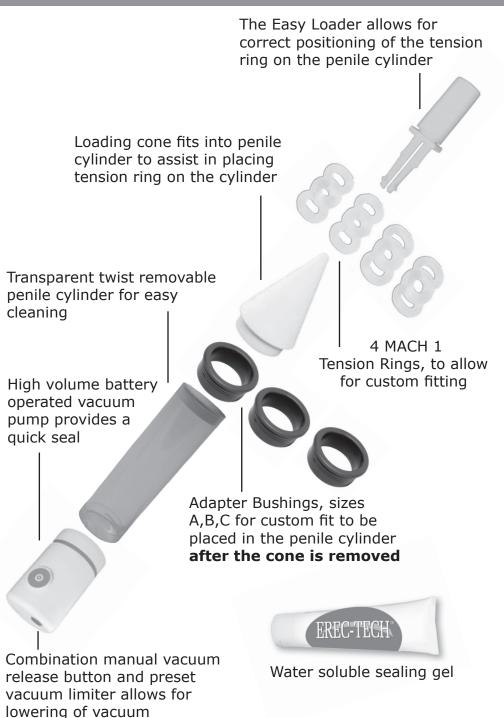
Tension Ring Warning

- 1. Do not wear the tension ring longer than 30 minutes. It could cause pain, bruising, a blood blister, or permanent injury to the penis. Call your doctor if any problems occur and stop using the system if they continue.
- 2. Allow a minimum of 60 minutes between uses.
- 3. Do not fall asleep wearing the tension ring.
- 4. Tension rings should not be used as a birth control method.
- 5. Use the largest ring which holds an erection.
- 6. Do not use tension rings while using alcohol or drugs.
- 7. Frequent use of a tension ring may result in bruising at the base of the penis (where the shaft of the penis meets the pubic area).
- 8. Do not use oil based lubricants such as petroleum jelly as they will be harmful to the tension rings and other latex type material such as condoms. Only use water soluble sealing gel.
- 9. Use of the tension ring may cause bruising. Do not be overly concerned if you notice some bruising of the penis or some small red spots below the skin. Use caution and plenty of water soluble sealing gel when removing the tension ring.

Don't be overly concerned if...

- 1. You feel pressure while applying the vacuum. This is not harmful. If you feel discomfort, however, it may be a signal that you are pumping too quickly. Simply press the manual vacuum release button, wait a moment and start again.
- 2. Your penis turns slightly bluish in color after you apply the tension ring. This may be a normal response to the increase of blood in the penis. The bluish color should disappear when you remove the tension ring.
- 3. You experience some petechiae (tiny reddish spots beneath the skin) or bruising of the penis when you first begin using your system. This may happen by placing the penis under too much vacuum pressure for too long, and too fast, or after a long period of not having an erection. If this happens, stop using your system until spots or bruises completely disappear, about five to seven days.
- 4. You or your partner notice a slight drop in the temperature of the penis. This coolness is normal and not harmful. It is a normal response to the reduced blood flow caused by the tension ring.
- 5. Your erection has a "hinge" effect. The penis may pivot at its base when the ring is in place. If this occurs, you may find it necessary to try different positions with your partner for successful intercourse.
- 6. Your semen does not flow through at point of climax. The pressure of the tension ring may interfere with the ejaculation process. This is not harmful, and does not affect climax. Your semen may flow out when you remove the tension ring. Tension rings are not a means of contraception or birth control and should not be used to avoid pregnancy.
- 7. Your penile tube develops condensation on the inside. This is simply the result of the heat from your body reacting with the lubricant. "Fogging" can be reduced by running warm water over the tube and then drying it before use.

BOS 2000-3 TWIST



MVP-700

The Easy Loader allows for correct positioning of the tension ring on the penile cylinder |

Loading cone fits into penile cylinder to assist in placing tension ring on the cylinder

Transparent twist removable penile cylinder for easy cleaning

High volume manually operated vacuum pump provides a quick seal

4 MACH 1 Tension Rings, to allow for custom fitting

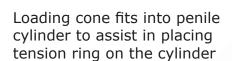
Adapter Bushings, sizes
A,B,C for custom fit to be
placed in the penile cylinder
after the cone is removed

Combination manual vacuum release button and preset vacuum limiter allows for lowering of vacuum

EREC-TECH

MOS

The Easy Loader allows for correct positioning of the tension ring on the penile cylinder



Transparent slip removable penile cylinder for easy cleaning

High volume manual operated vacuum pump provides a quick seal

4 MACH 1
Tension Rings, to allow for custom fitting

Adapter Bushing, size Lg and Sm, for custom fit to be placed in the penile cylinder **after the cone is** removed



BOS

The Easy Loader allows for correct positioning of the tension ring on the penile cylinder

Loading cone fits into penile cylinder to assist in placing tension ring on the cylinder

Transparent slip removable penile cylinder for easy cleaning

High volume battery operated vacuum pump provides a quick seal

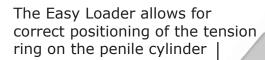
4 MACH 1 Tension Rings, to allow for custom fitting

Adapter Bushing, size Lg and Sm, for custom fit to be placed in the penile cylinder after the cone is removed

Combination manual vacuum release button and preset vacuum limiter allows for lowering of vacuum

EREC-TECH

ADVANTAGE



Loading cone fits into penile cylinder to assist in placing tension ring on the cylinder

Transparent slip removable penile cylinder for easy cleaning

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Adapter Bushing, size Lg and Sm, for custom fit to be placed in the penile cylinder after the cone is removed

High volume manual operated vacuum pump provides a quick seal

Combination manual vacuum release button and preset vacuum limiter allows for lowering of vacuum



How it Works

The system creates a vacuum around the penis to help the natural flow of blood into the penis. Most men will also need to use one of the tension rings to hold their erection.

The system will assist you in maintaining a full and satisfying erection in most cases.

Ring Loading Cone

The ring loading cone is used to help place the tension ring on the penile tube before the bushing is installed.



Tension Rings

One of the most important steps is properly fitting the tension ring. To keep blood in the penis, the ring must fit comfortably tight, but should be no tighter than necessary. If the vacuum therapy system is giving you a good erection but with the tension ring on, your erection is becoming soft in five minutes or less, you need to try the next smaller ring. DO NOT WEAR A TENSION RING MORE THAN 30 MINUTES. Thirty minutes is the maximum time period for wearing the

tension ring. If worn longer, permanent damage is possible.

How to Load the Tension Rings Without a Ring Loader

- 1. Start with the largest tension ring. If you are unable to hold the erection with the larger ring, gradually use the next smallest tension ring until the ring is able to hold the erection.
- 2. Ensure the pump head and adapter bushing are removed from the penile tube. Place a towel on a firm, flat surface (waist high works best). Place the penile tube on the towel with the smooth end of the tube facing up. The towel will help the tube remain in place while loading the tension ring. (See Illustration #1.)
- 3. Place the loading cone into the smooth end of the penile tube. Generously lubricate the entire surface of the loading cone, top to bottom, and all around. Use only water soluble sealing gel. (See Illustration #2.)
- 4. Generously lubricate the entire surface of the cone with water soluble sealing gel, grasp the two handles of the tension ring as shown. Place your thumb tips on top of the tension ring next to the cone surface, press the tension ring down. Your thumb tips will glide along the surface of the cone. Place the tension ring near the end of the cylinder for easy off loading to the base of the penis.



ILLUS. #1

(Do not load the tension ring onto the cylinder by pulling the handles, they may tear.) (Illustration #3)

5. Remove the cone from the penile tube and attach the penile tube to the vacuum pump. Place the adapter bushing in the open end of the penile tube. If loose scrotal tissue travels into the tube use the smaller bushing. If you use more than one ring, choose a second ring and repeat steps 1 through 4.



How to Load the Tension Rings With a Ring Loader Look at the images below as you read the instructions.

1. Set the ring loading system on it's flat end, with the fingers pointing upward. While turning the hex nut, slide it to the stop point toward the tip of the fingertips, this will bring the system fingers together. Lightly moisten the inside center of the tension ring with water soluble sealing gel.

Place the system fingertips inside the center of the tension ring. Slide the hex nut back to the handle of the system.

Turn the ring a quarter of a turn to help seat in place. Ensure the ring stays in place.

- 2. With the ring remaining on the loading system fingertips, grasp the system handle. Place the ring on the tip of the loading cone. Ensure the loading system is held straight up and down. Using your upper body along with your hand and wrist strength, quickly push down on the loading system, using one fluid motion until it comes to a stop.
- 3. The tension ring will be transferred to the penile tube at this time. If the ring fails to transfer to the tube, gently nudge the handles downward toward the tube and it will complete the transfer.











Adapter Bushing

The bushing is used to fit the tube to the penis. Start by using the largest bushing available.



Using the System

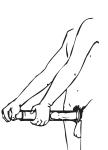
- 1. Lubricate your penis, the inside of the penile tube and pubic hair area (the area that comes in contact with the adapter bushing), with water soluble sealing gel. This helps form a good vacuum seal at your body and prevents the penis from sticking to the walls of the tube.
- 2. Insert the penis into the penile tube and start the vacuum process.
- **3.** Operate the **battery** pump by depressing the activation button. This should develop a low level of vacuum sufficient to create a seal between the system and your body.

Operate the **manual** pump by pushing and pulling the handle. Each time you pull the handle or pumphead back (approximately 2 inch stroke) you create vacuum in the penile tube. Three to five strokes should create a low level vacuum sufficient to create a seal between the system and your body.

Repeat this step 4 to 5 more times until you have developed a sufficient vacuum. Use the least amount of vacuum necessary to obtain the erection.

- **4.** As soon as the desired erection is achieved, transfer the tension ring onto the base of the penis with your fingertips. Make sure the ring is transferred all the way around. Any vacuum that is left can be released by depressing the manual vacuum release button. Practice a few times without the tension ring. If a condom is desired it should be applied after erection is formed.
- 5. Following use, the tension ring, bushing and tube should be rinsed with warm water, dried and stored. Make sure the tension ring bag is air free and tightly sealed for longer life. NEVER PUT THE PUMPHEAD IN WATER.

After you have been using the system for 30 to 60 days, you may want to recheck the sizing of the tension ring. For example, you may find that you are now able to use the next size larger ring.



Using the larger ring may increase comfort. Some couples may prefer to stop intercourse at least once and reuse the vacuum therapy system.

We are always happy to discuss any problems that you may have with the use of the system. If you have questions or would like to order replacement parts, please call our user help line (800)279-7434.

Manual Vacuum Release Button

If you feel slight pain when your penis becomes filled, try a lower vacuum by pushing the manual vacuum release button. (With a little practice you should find the correct vacuum so that you can create a full erection.)

The manual vacuum release button can be pushed to lower the vacuum level. If too much vacuum is released, it can be easily increased by depressing the activation button.

To remove your penis from the tube, push the manual vacuum release button until the vacuum pressure is gone. Then remove the tube from the penis. If you find that you are keeping enough of an erection for intercourse, you may not need to use the tension ring. You may be able to have a good sex life with only the use of the vacuum portion of the system.

Most men with erectile dysfunction will lose most of their erection soon after removing their penis from the penile tube. This problem can be solved by correctly fitting the tension ring. Your penis should become filled and rigid without pain in 10 to 90 seconds. You may feel pressure when your penis starts to become erect from the vacuum. This is normal.

Removing the Tension Ring

DO NOT WEAR A TENSION RING MORE THAN 30 MINUTES. Remove the ring by pulling outward on the side loops. The ring will stretch, allowing blood to move from the penis. You can then pull the tension ring off. To prevent tangling the tension ring in the pubic hair, try a little sealing gel in the hair before putting on the ring.

TO REMOVE

HOW TO MANAGE COMMON PROBLEMS WITH A VACUUM ERECTION SYSTEM

| HOW TO MANAGE COMMON PROBLEMS WITH A VACUUM ERECTION SYSTEM | | | | | | |
|--|--|--|---|--|--|--|
| PROBLEM | LIKELY CAUSE | REMEDY | COMMENTS | | | |
| No erection | No vacuum because of air leak caused by poor seal | Use more lubricant; apply firm pressure to body; trim pubic hair; check system for air leaks | Problem is most often associated with inexperience and stops as you become better at using the system | | | |
| Partial Erection | Not Enough practice sessions | More practice using system | Problem most often improves with continued use of system | | | |
| Rapid Loss of erection (in less than 5 to 10 minutes) | Vacuum lost because of air leak, poor seal, poor lubrication, or too much pubic hair, too large tension ring | Same as for "No Erection". Use smaller or double tension ring; remove tension ring carefully. | Problem most often improves with continued use of system | | | |
| Pulling of the skin of the scrotum | Lubricant on scrotum; improper pumping technique; inexperience with system | Remove lubricant from scrotum; use the modified pumping technique (call our support line); continue with practice sessions; angle cylinder downward during pumping | Problem usually stops as you become better at using the system | | | |
| Discomfort or pain | Discomfort or pain | | | | | |
| During pumping | Too rapid pumping; pulling of scrotal tissue | Slower pumping; continue to use the system | Problem usually stops as you become better at using the system | | | |
| From tension ring | Tension ring too small; anxiety | Use larger tension ring; continue to use the system | Problem usually stops as you continue to use the system | | | |
| During intercourse | Poor lubrication; pressure on a sensitive area | More lubrication; position changes | | | | |
| During ejaculation | Long periods without sex; infection or swelling of the prostate gland | Continue to use system | Consult your doctor if this problem continues past the first few practice sessions | | | |
| Redness, irritation or bruising | Too rapid pumping; over pumping | Slower pumping; fewer pumps | Consult your doctor if this problem continues past the first few practice sessions | | | |
| Penis feels cold (to you or your partner) | Constriction of blood flow to the penis; lubrication | Wash off lubricant or warm lubricant before use | | | | |
| Penis pivots on its base | Constriction of blood flow to the penis | If manageable, apply the system after you have a partial erection | | | | |

Warranty Information

Our **prescription systems** offer a lifetime warranty (under normal use, lifetime is 5 years) on all major components. The Tension Rings and Ring Loader are not considered major components and have a 30-day warranty. You must have proof of purchase to be eligible for warranty or repair. Customer must pay in-bound freight. **Prescription systems are:**

◆ADVANTAGE◆BOS 2000-3 Twist◆MVP-700◆MOS◆BOS

To activate warranty you must immediately complete the registration card and mail it in or call (800)279-7434 to register your system within 30 days.

ATTENTION: Warranty is void if the product has been tampered with.

There is no warranty if moisture is found in the pump head. Some men dribble a small amount of urine when using a vacuum therapy system. If you have this problem, protect your pump head by placing some cotton balls in the penile tube just below the pump. Be sure to change the cotton balls after each use.

30-Day Return Policy

This policy is effective only at the original point of purchase.

If your system does not physically produce an adequate erection for sexual intercourse please call (800)279-7434. You will then need to speak with one of our trained Support Specialists.

Return Authorization may only be permitted within 30 days from date of receipt. Proof of purchase is required and the return must be to the point of purchase.

In order for you to return your system, your Support Specialist must issue a Return Goods Authorization (RGA). If authorized, you must return all components, booklets and DVD to the point of purchase.

Any system returned to Uromatrix/Pos-T-Vac, Inc. Without a returned goods authorization number will be refused and returned to sender without a refund being processed.

Upon authorization of return only the cost of the system will be refunded, not shipping and handling.

UroMatrix/Pos-T-Vac is able to provide the means for erection, but not patient motivation or a willing sex partner. Our company

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provides access to a committed staff to insure that each and every patient has the opportunity of being successful with vacuum therapy treatment.

Vacuum therapy does not necessarily elevate man's libido, overcome a bad relationship, or restore lost youth. Vacuum Therapy is designed to allow a couple to control their sexual intimacy by providing a predictable and immediate method to create an erection for intercourse. There are also profound benefits of vacuum therapy as a rehabilitation tool and to prevent penile deterioration.

We are always happy to discuss any problems that you may have with the use of the system. If you would like to order replacement parts, please call (800)279-7434.

Our hours of operation are: Monday - Friday, 8:00 a.m. to 5:00 p.m. CST.

Scope of Services

We market a complete line of vacuum therapy systems for the treatment of Erectile Dysfunction (ED). We also offer support services for patients having difficulty achieving good results.

Mission Statement

Pos-T-Vac's mission is to provide safe, effective, non-invasive and affordable vacuum therapy systems for the treatment of ED. We also provide patients and physicians with quality, product education, service and support for the treatment of ED.

Delivery

We will verify insurance information, have Patient's Assignment of Benefits on file and a written order from the Physician. When all information is accumulated then delivery will take place by UPS or Priority Mail.

Compliance and Commitment

Pos-T-Vac is committed to complying with all federal and state regulations. If you have any questions or concerns regarding any of our activities, please contact your service location at (800) 279-7434.

Patient Complaint Procedure

Pos-T-Vac strives to provide the highest quality health care services to all our patients. That is why your concerns are our concerns. To ensure that our services meet your complete satisfaction, we ask you to describe any complaint, problem, concern or compliment you may have by calling us at (800)279-7434. Be assured that all complaints will be addressed in less than 10 days and we will send you a written response detailing the resolution of the complaint.

Patient's Bill of Rights and Responsibilities You have the right to:

- 1. Considerate and respectful service.
- 2. Obtain service without regard to race, creed, national origin, sex, age, sexual orientation, disability or illness, or religious affiliation.
- 3. Confidentiality of all information pertaining to you, your medical care and service.
- 4. A timely response to your request for service and to expect continuity of services.
- 5. Select the medical equipment supplier of your choice.
- 6. An explanation of charges including policy for payment.
- 7. Voice grievances without fear of termination of service or other reprisals.
- 8. Have your communication needs met.

- 9. Restrict the use of your confidential healthcare information. If you object to your confidential information being disclosed as described in this agreement you may request a "restriction of Information/Consent" form. Upon completion of this form the company will abide by the restrictions you request. However, the company may choose to refuse to provide continuing service to you if the restrictions you request would interfere with the company maintaining normal treatment, payment, or healthcare operations in regard to your account.
- 10. Receive confidential communication about your health status and the products and services provided to you.11. Review and photocopy any/all portions of your healthcare
- information.

 12. Make changes to your healthcare information.
- 13. Know who has accessed your confidential healthcare information
- and for what purpose.

 14. Possess a copy of this Privacy Notice upon request. This copy

can be in the form of an electronic transmission or on paper.

- 15. The company is required by law to protect the privacy of its patients. It will keep confidential any and all patient healthcare information and will provide patients with a list of duties or practices that protect confidential healthcare information.16. The company will abide by the terms of this notice. The company reserves the right to make changes to this notice
- and continue to maintain the confidentiality of all healthcare information. Patients will receive a mailed copy of any changes to this notice within 60 days of making the changes.

 You have the responsibility to:

1. Ask questions about any product or service provided to you

- that you do not understand.
 2. Supply us with needed insurance information necessary to
- 2. Supply us with needed insurance information necessary to obtain payment for products received.
- 3. Assume responsibility for charges not covered. You are responsible for settlement in full of your account.
- *This notice of Patient's Rights and Responsibilities is effective as of 10/01/11.

Business Hours:

Monday through Friday 8:00 AM to 5:00 PM Central Time Saturday Closed

Sunday Closed

Major Holidays Closed

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Medicare Supplier Standards

- 1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements and cannot contract with an individual or entity to provide licensed services.
- 2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
- 3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.
- 4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs or from any other Federal procurement or non-procurement programs.
- 5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment and of the purchase option for capped rental equipment.
- 6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law and repair or replace free of charge Medicare covered items that are under warranty.
- 7. A supplier must maintain a physical facility on an appropriate site. This standard requires that the location is accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
- 8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours and must maintain a visible sign and posted hours of operation.
- A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machines or cell phone is prohibited.
- 10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items this insurance must also cover product liability and completed operations.
- 11. A supplier must agree not to initiate telephone contact with beneficiaries with a few exceptions allowed. This standard prohibits suppliers from contacting a Medicare beneficiary based on a physician's oral order unless an exception applies.
- 12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare covered items and maintain proof of delivery.
- 13. A supplier must answer questions and respond to complaints of beneficiaries and maintain documentation of such contacts.
- 14. A supplier must maintain and replace at no charge or repair directly or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.

- 15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
- 16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.
- 17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.
- 18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
- 19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
- 20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint and any actions taken to resolve it.
- 21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.
- 22. All suppliers must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals). *Implementation Date October 1, 2009*
- 23. All suppliers must notify there accreditation organization when a new DMEPOS location is opened.
- 24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
- 25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
- 26. Must meet the surety bond requirements specified in 42 C.F.R. 424.57(c). *Implementation date May 4, 2009*
- 27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
- 28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f).
- 29. DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers.
- 30. DMEPOS suppliers must remain open to the public for a minimum of 30 hours per week with certain exceptions.

Privacy Notice

Our organization is dedicated to maintaining the privacy of your identifiable health information. In conducting our business, we will create records regarding you and the treatment, products and services we provide to you. We are required by law to maintain the confidentiality of health information that identifies you. We are also required by law to provide you with this notice of your legal duties and privacy practices concerning your health information.

THE FOLLOWING NOTICE DESCRIBES HOW YOUR MEDICAL INFORMATION MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW THE INFORMATION CAREFULLY.

- Your confidential healthcare information may be disclosed to employees or business associates of the company when needed to provide you with products and/or services to secure payment for products and/or services provided, and as needed to operate our business. Employees and business associates of the company will only be provided with the minimum necessary information needed to complete their duties.
- Your confidential healthcare information may be released to other healthcare professionals for the purpose of providing you with quality healthcare.
- Your confidential healthcare information may be released to your insurance provider for the purpose of the company receiving payment for providing you with needed healthcare products and services.
- 4. Your confidential healthcare information may be released to a public health organization or federal organization in the event of the need to report a communicable disease or to report a defective device.
- 5. Your confidential healthcare information may be released to public or law enforcement officials in the event of an investigation in which you are a victim of abuse, a crime or domestic violence.
- 6. Your confidential healthcare information may not be released for any other purpose than that which is identified in this notice without requesting a specific authorization from you to release information for a specific purpose.
- You may be contacted by the company to notify you of other health services that may be of interest to you.

You have the right to complain to the company if you believe your rights to privacy have been violated. If you feel your privacy rights have been violated, please mail your complaint to the company.

ATTN: Ed Stewart Pos-T-Vac 500 Park St. Dodge City, KS 67801

All complaints will be investigated by: Jennifer Schrock Operations Manager (800)279-7434

If not completely satisfied contact: The Joint Commission Quality Monitoring (800)994-6610 One Renaissance Boulevard Oakbrook Terrace, IL 60181

Made in the U.S.A.

 $C \in$

MANUFACTURED BY:
Pos-T-Vac, INC.
500 Park Street
Dodge City, KS 67801 USA

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| with 5 being 1. The products were delivered in | excellent and 1 b | eing poor. | 12345 |
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| 4. The financial responsibilities al | • | ained to me. | |
| 5. Overall the services I received | were to my satisfaction | on. | 12345 |
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