INSTRUCTIONAL MANUAL



Systems including:

PTV Manual 3000 PTV Manual 1000 MVP-700

Please read all instructions prior to use.

Table of Contents

Brief Description & Intended Uses			
Who Needs the System	1		
About the System	1		
Warnings & Precautions	2-3		
Use of the System			
System Content	5		
How it Works			
Loading Cone	6		
Tension Ring			
Loading the Tension Ring			
Adapter Bushing			
Using the System			
Manual Vacuum Release Button			
Removing the Tension Ring			
Warranty Information			
Compliance and Commitment			
Common Problems			

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.

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. 1

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, hypercoagulability, a bleeding disorder or bruise easily or are taking large quantities of aspirin or other blood thinners, do not use the vacuum therapy system without consulting your doctor.
- 11. Do not rely on the tension rings as a means of birth control.

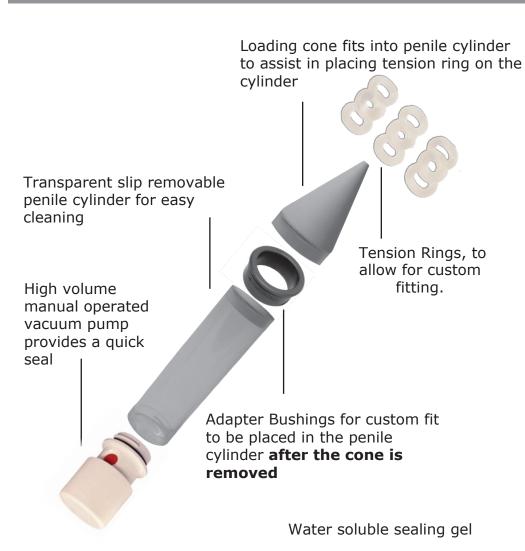
Tension Ring Warning

- 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. 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.

Manually Operated System The number of accessories included will vary depending on the device.



Red 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.

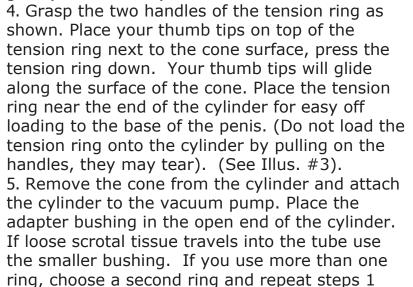


- Start with the largest tension ring. If you are unable to hold the erection with the larger ring, gradually use the next smallest tension ring until the ring is able to hold the erection.
- 2. Ensure the pump head and adapter bushing are removed from the penile cylinder. Place a towel on a firm, flat surface (waist high works best). Place the penile cylinder on the towel with the smooth end facing up. The towel will help the cylinder remain in place while loading the tension ring. (See Illus. #1).



Illus. #1

3. Place the loading cone into the smooth end of the penile cylinder. Generously lubricate the entire surface of the loading cone, top to bottom, and all around. Use only water soluble sealing gel. (See Illus. #2).





Illus. #2



Adapter Bushing

through 4.

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 cylinder and pubic hair area (the area that comes in contact with the adapter bushing), with water soluble sealing gel. Make sure the testicles are not drawn into the cylinder. This helps form a good vacuum seal at your body and prevents the penis from sticking to the walls of the cylinder.
- 2. Insert the penis into the cylinder and start the vacuum process.



3. Operate the manual pump by pushing and pulling the handle. Each time you pull the handle or pump head 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 fingertip. 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 cylinder 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)438-8592.



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 pressing the activation button. To remove your penis from the cylinder, push the manual vacuum release button until the vacuum pressure is gone. Then remove the cylinder 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.

Most men with erectile dysfunction will lose most of their erection soon after removing their penis from the cylinder. 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 .



Warranty Information

Our systems offer a warranty (under normal use) on all major components. The slip systems have a five year warranty and the twist systems have a one year warranty. The warranty is only valid for customers in the US. 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. Customer must pay in-bound freight.

To register your device go to www.timmmedical.com. You could be eligible for a free tension ring.

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.

**Please clean product prior to returning for warranty purposes.

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

Our Vacuum Therapy Systems allow men to produce controllable and predictable erections. 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)438-8592. Our hours of operation are: Monday - Friday, 8:00 a.m. to 5:00 p.m.

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)438-8592. **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)438-8592.

Cleaning instructions (We recommend after every use)

- Pump Head- wipe down with a damp cloth
- Tension Rings- warm water only then store in the bag
- All other accessories may be cleaned with warm water
- Return all items to carrying case for storage

Service Life (With normal use)

- Device including pump head, cylinder, cone and bushings- 10 years
- Ring Loader- 1 year
- Tension Rings- 90 days
- Lubricant- noted on container by expiration date
- We recommend that you change the batteries after 30 uses.

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			
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	

For EU Users:



Pos-T-Vac Medical







1 units

Medical Device Class I for correction of erectile dysfunction and for sexual fitness





FOR PERSONAL USE ONLY



Restrictions of use for the device are identified in the instructions manual. Read instructions before using the product.



Store in cool and dry conditions. Non sterile/non measuring product.





Made in USA by:

Pos-T-Vac Medical, Inc, 2111 W Wyatt Earp, PO Box 1436, Dodge City, KS 67801 USA



European authorized representative/ Responsible Union Europea: CEpartner4U, Esdoorlaan 13, 3951 DB Maarn, the Netherlands

For UK Users:



Pos-T-Vac Medical



Vacuum Therapy System



1 units

Medical Device Class I for correction of erectile dysfunction and for sexual fitness





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Pos-T-Vac Medical, Inc, 2111 W Wyatt Earp, PO Box 1436, Dodge City, KS 67801 USA



UK authorized representative/ Responsible Union UK: UKCApartner4U Ltd.

7 Campion Way, Bingham, Nottingham NG13 8TR UK

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.

- 1. 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 information needed to complete their duties.
- 2. Your confidential healthcare information may be released to other healthcare professionals for the purpose of providing you with quality healthcare.
- 3. Your confidential healthcare information may be released to your insurance provider for the purpose of the company receiving payment for providing your 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.
- 7. 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.

All Complaints will be investigated by:

Cara Slovacek, Compliance Manager

Pos-T-Vac

2111 W Wyatt Earp Blvd

Dodge City, KS 67801

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