



Gesiva Medical, LLC
Vacuum Therapy System
User Guide

Read this User Guide Prior to Using the Device

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Introduction

The Gesiva Medical Vacuum Therapy System uses a battery-powered motor to create a limited amount of negative pressure (vacuum) inside a plastic cylinder. When a man inserts his non-erect penis into the clear plastic cylinder and activates the pump, the negative pressure environment causes blood to be drawn into the penis. Over a short time, more blood is drawn into the penis and the man develops an erection. Once a satisfactory erection is obtained, the user may release the vacuum by pushing the red vacuum release button or maintain the erection by transferring a constriction ring to the base of his penis.

IMPORTANT - Most men will need to practice using the device for several weeks to achieve best results.

Practice sessions involve using the Vacuum Therapy System to draw blood into the penis and then releasing the vacuum to allow the blood flow back into the body.

Repeating this process several times during a practice session helps the user get accustomed to the feeling of vacuum therapy. Since the purpose of the practice sessions is for the user to develop an individualized technique for using the system to create an erection, constriction rings are not used for practice sessions.

Indications for Use

The Gesiva Medical Vacuum Therapy System can be used to create and/or maintain penile rigidity adequate for sexual intercourse. Men suffering from erectile dysfunction (ED), including ED following prostate surgery, can use the Vacuum Therapy System.

Vacuum Therapy Systems are simple to use and have been in use for over 30 years with no report of serious injury with proper use. However, misuse of the device or the tension rings can cause pain or result in permanent injury to the penis. **It is important to read the entire User Guide before using this device.**

Alternative Treatment Options

The Gesiva Medical Vacuum Therapy System is one of many options available for the management of erectile dysfunction. Alternative treatment options may include drug therapy, hormonal therapy, implanted prosthetic devices (penile implants), and counseling.

Men should discuss the relevant treatment options, and their associated risks and benefits, with their health care professional to select the treatment option that is best for them.

Contraindications

Certain Patients MUST NOT Use this Device:

Men with a History of Erections Lasting More than 4 Hours.

Do not use this device if you have ever had an erection that lasted more than 4 hours. This is a serious medical condition known as priapism and it can result in permanent damage to your penis.

Men with Disorders that Can Cause Excessive Blood Clotting.

Do not use this device if you have sickle cell trait, sickle cell disease, or other disorders that could cause your blood to clot excessively. These conditions can make you more susceptible to developing an erection that lasts more than 4 hours, which could result in permanent damage to your penis.

Men at Increased Risk of Bruising and/or Hematoma.

Do not use this device if you have a bleeding disorder, bruise easily or are taking large quantities of aspirin or other blood thinners. Using a vacuum device in these situations can make you more susceptible to painful bruising of your penis.

Men with a Penile Implant.

Do not use this device if you have a penile implant as the effects of vacuum pressure on penile implants has not been evaluated.

The Gesiva Medical Vacuum Therapy System is NOT an appropriate treatment option for these patients.

Warnings

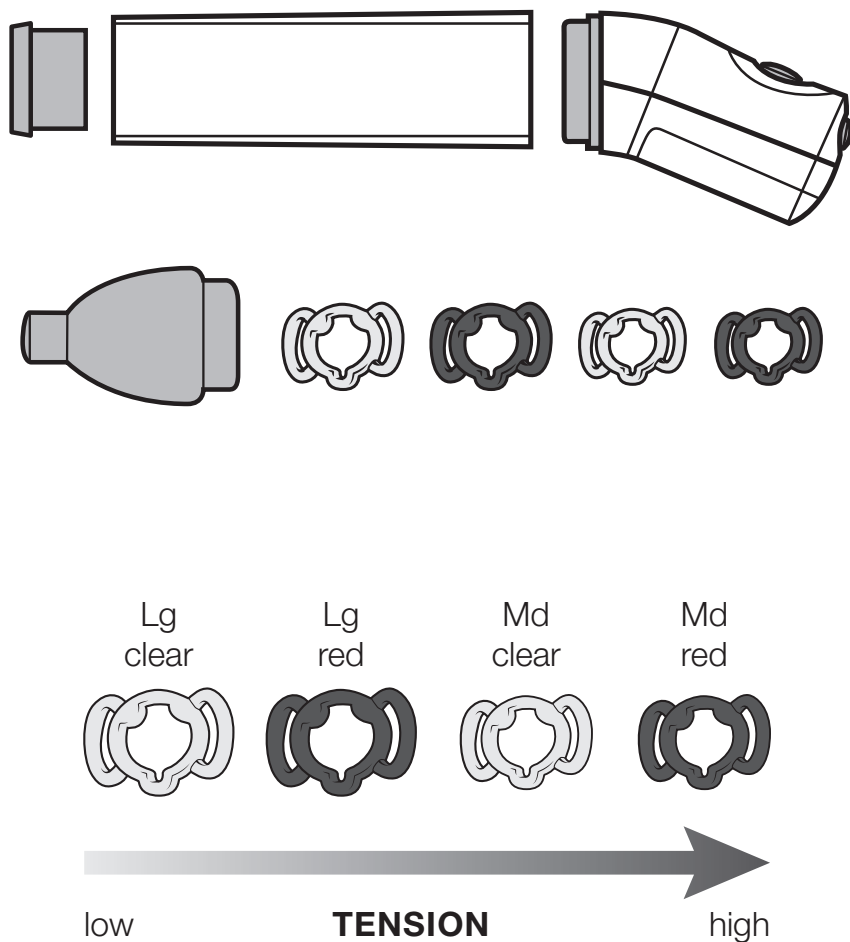
- Consult your health care professional if you have symptoms of erectile dysfunction (i.e., inability to achieve an erection that is sufficient for sexual intercourse) to avoid a potentially harmful delay in diagnosing any of the common causes of this condition such as diabetes, multiple sclerosis, cirrhosis of the liver, chronic renal failure, or alcoholism.
- Misuse of the vacuum device or constriction rings may cause bruising, painful injury, or permanent damage to the penis.
- Do not leave constriction rings on the penis for more than 30 minutes. Do not fall asleep with constriction rings in place on the penis. Leaving constriction rings on the penis for more than 30 minutes can cause injury or permanent damage to the penis.
- When using constriction rings, allow at least 60 minutes between uses, as more frequent use may increase the risk of injury or damage to the penis.
- Stop using this vacuum therapy system and consult your health care professional if you experience pain or other complications when using this device.
- **Risk to Men with Impaired Perception of Pain.** Do not use the vacuum device or the constriction ring if you have decreased sensation of pain in the area of the penis, as you may not know whether or not you are being injured when using the vacuum device.
- **Risk to Men Under the Influence of Alcohol or Drugs.** Do not use this vacuum device or the constriction ring if you are under the influence of alcohol or drugs. Alcohol and drugs may impair your judgment and increase the risk of injury to your penis.
- **Risk to Men with Decreased Hand Strength.** Do not use the vacuum device if you have decreased hand strength. This may make removal of the vacuum device or removal of the constriction rings difficult. Delayed removal of the vacuum device or constriction ring can result in damage to the penis.
- **Risk of Pregnancy.** Constriction rings do not prevent pregnancy.
- **Risk of Damage to the Device.** Do not use petroleum-based lubricants with this device. Petroleum-based lubricants may damage the device vacuum pump, the device cylinder, and/or the constriction rings. Use only high quality water based lubricants. Consult with your health care professional if you need assistance choosing an appropriate water-based lubricant.

Precautions

- Use of a vacuum pump or a constriction ring may aggravate already existing conditions such as Peyronie's disease (the formation of hardened tissue in the penis that causes pain, curvature, and distortion, usually during erection); priapism (persistent, usually painful erection of the penis as a consequence of disease and not related to sexual arousal); and urethral strictures (urethral stricture is an area of hardened tissue, which narrows the urethra sometimes making it difficult to urinate).
- Use of a vacuum pump may bruise or rupture the blood vessels within the penis or scrotum, resulting in petechiae (small purplish spots on a body surface caused by minor bleeding), hemorrhage (flow of blood from ruptured blood vessels), or the formation of a hematoma (localized swelling filled with blood resulting from a break in a blood vessel).
- Apply only the minimum amount of vacuum pressure necessary to achieve an erection; excessive vacuum pressure may bruise or injure the penis.
- Choose the least constrictive ring that maintains an erection, since excessive constriction could injure the penis.
- Do not use, wash, or submerge the battery powered Gesiva Medical Vacuum Therapy pump handle in water as this will permanently damage the pump mechanism and make your device unusable.

General Overview and Assembly Instructions

The Gesiva Medical Vacuum Therapy System consists of a battery powered vacuum pump handle, a clear plastic cylinder, a cylinder insert that can be used for comfort, four constriction rings of different sizes and tensions, and a cone shaped device to help install constriction rings onto the clear cylinder.

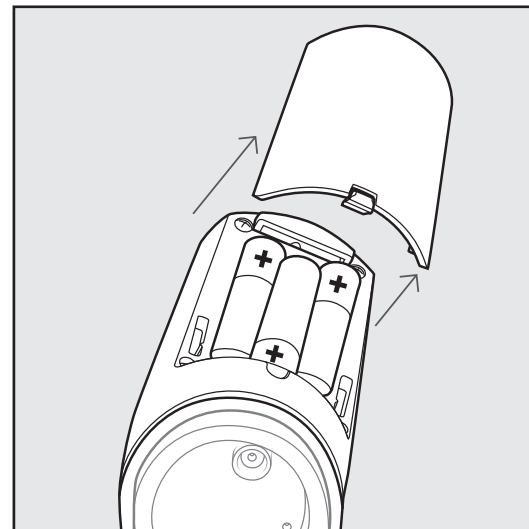


Step 1 – Prepare the Battery Powered Pump Handle

Remove the battery cover and insert three (3) “AA” Duracell alkaline batteries taking care to ensure proper orientation of the battery’s positive and negative terminals.

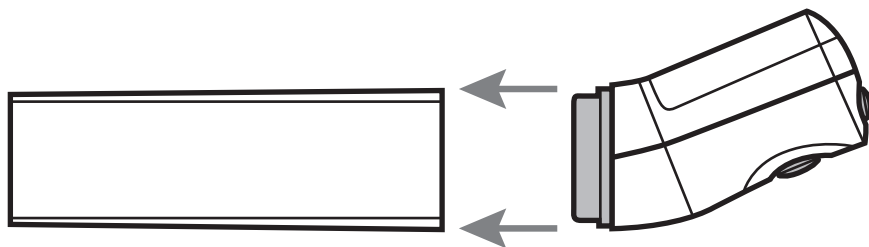
NOTE – Use Duracell Alkaline batteries only. Using other batteries, including rechargeable batteries, may damage the unit and will VOID the warranty.

Remember to remove the batteries if the Vacuum Therapy System will not be used for an extended period of time.



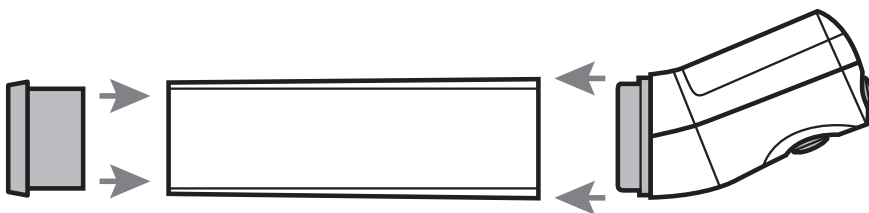
Step 2 – Attach the Pump Handle to the Cylinder

Insert the battery powered pump handle into the wide end of the clear plastic cylinder.



Step 3 – Install Cylinder Insert (Optional)

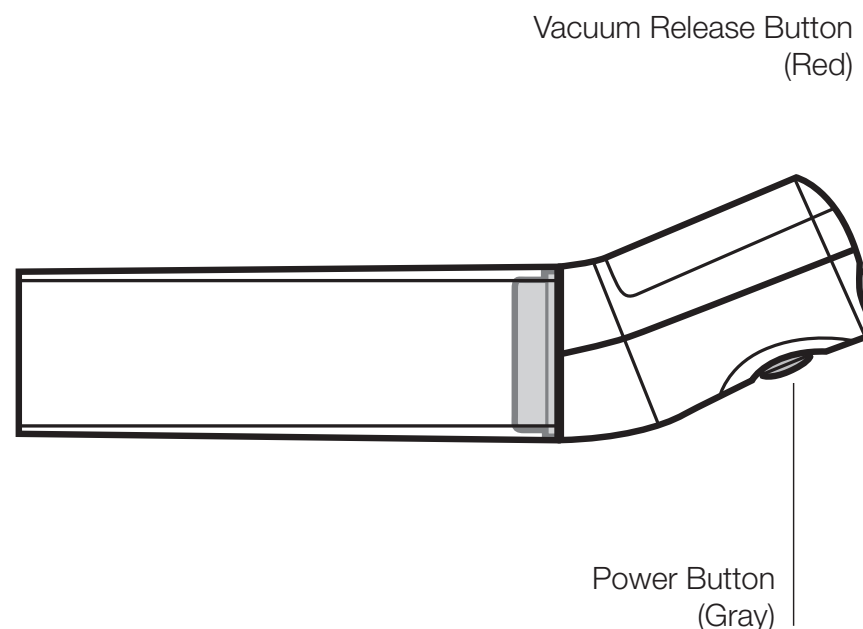
Your Vacuum Therapy System includes an optional cylinder insert that may be placed at the narrow end of the cylinder. Some users find that this insert improves comfort and helps create a seal between the Vacuum Therapy System and the user's body. Others prefer to use the Vacuum Therapy System without the cylinder insert.



Step 4 – Familiarize Yourself with the Operating Controls

Your Vacuum Therapy System has two simple operating controls located on the pump handle:

- 1) **GO - Gray** oval-shaped button that activates the battery powered vacuum pump.
- 2) **Release - Red** round button that manually releases vacuum pressure.

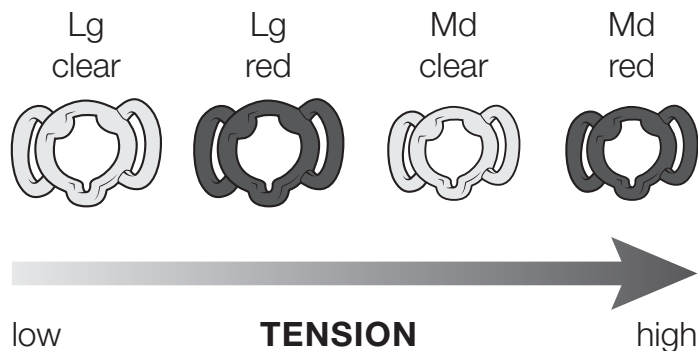


Using the Vacuum Therapy System

Step 1 – Choosing the Right Constriction Ring

Four different constriction rings are included with the Vacuum Therapy System. Constriction rings are used to prevent blood from leaving the penis. To accomplish this, the user first loads a constriction ring onto the narrow end of the cylinder. The user then creates an erection using the Vacuum Therapy System. Once the penis is erect, the user slides the constriction ring off of the cylinder and onto the base of the erect penis. This enables the user to maintain the erection for up to 30 minutes.

All Gesiva Medical constriction rings have a special shape with “bumps” inside the ring that are placed on top of the penis to help retain blood and a “U” shaped notch for the urethra that is located on the underside of the penis. One or more of these constriction rings may be used to maintain the erection for intercourse.



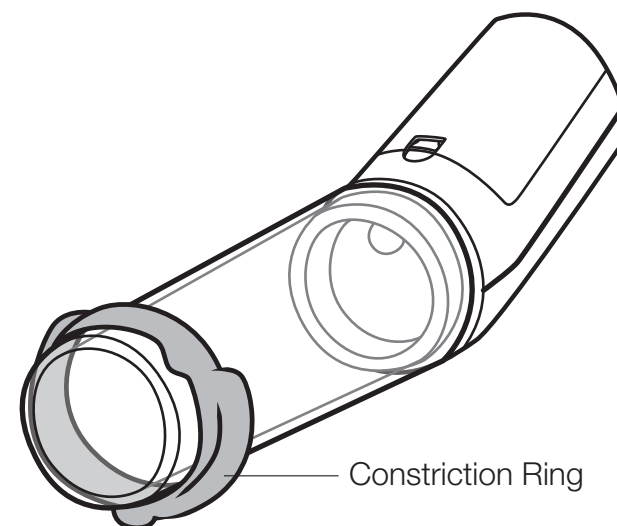
Choose the lowest amount of constriction necessary to maintain the erection. Users should start with the large, standard tension ring (clear in color) first and try different constriction rings only if necessary.

Step 2 – Load the Constriction Ring onto the Cylinder

The constriction ring must be placed onto the outside of the clear plastic cylinder before the erection is created. This allows transfer of the constriction ring from the clear plastic cylinder to the base of the penis without loss of the erection.

There are two methods that can be used to place the constriction ring on the outside of the clear plastic cylinder.

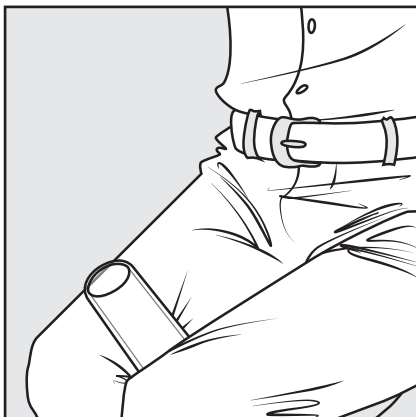
One method is to manually stretch the constriction ring onto the cylinder. The other method is to use the ring-loading cone that is included with the Vacuum Therapy System.



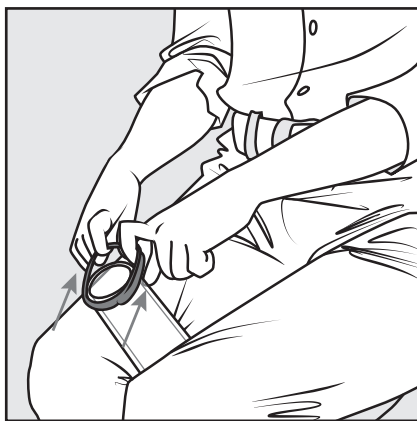
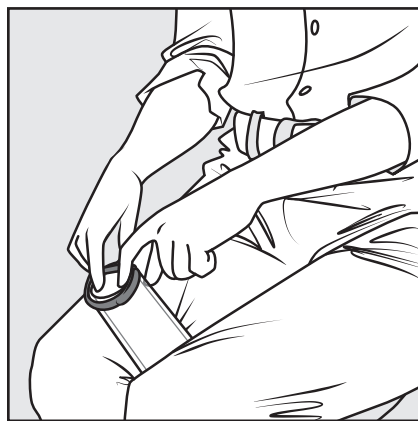
Manually Loading the Constriction Ring

- Remove the pump handle and the cylinder insert (if used) from the clear plastic cylinder.

Place the clear plastic cylinder between your legs (knee to thigh region), so the narrow end of the cylinder is facing up.

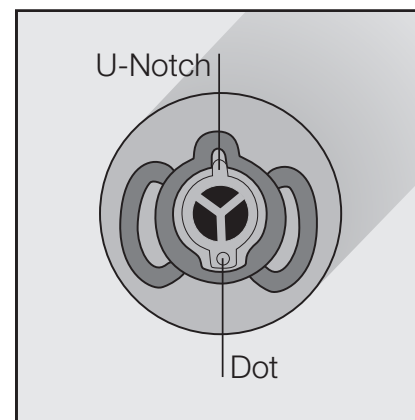
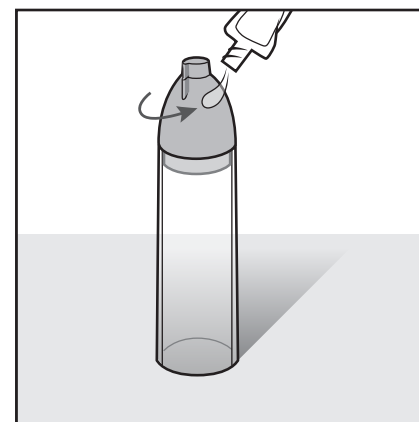


- Insert either your fingers or your thumbs inside the constriction ring. Place one part of the constriction ring on the cylinder and use your fingers or thumbs to stretch the constriction ring until it is large enough to be placed onto the cylinder.



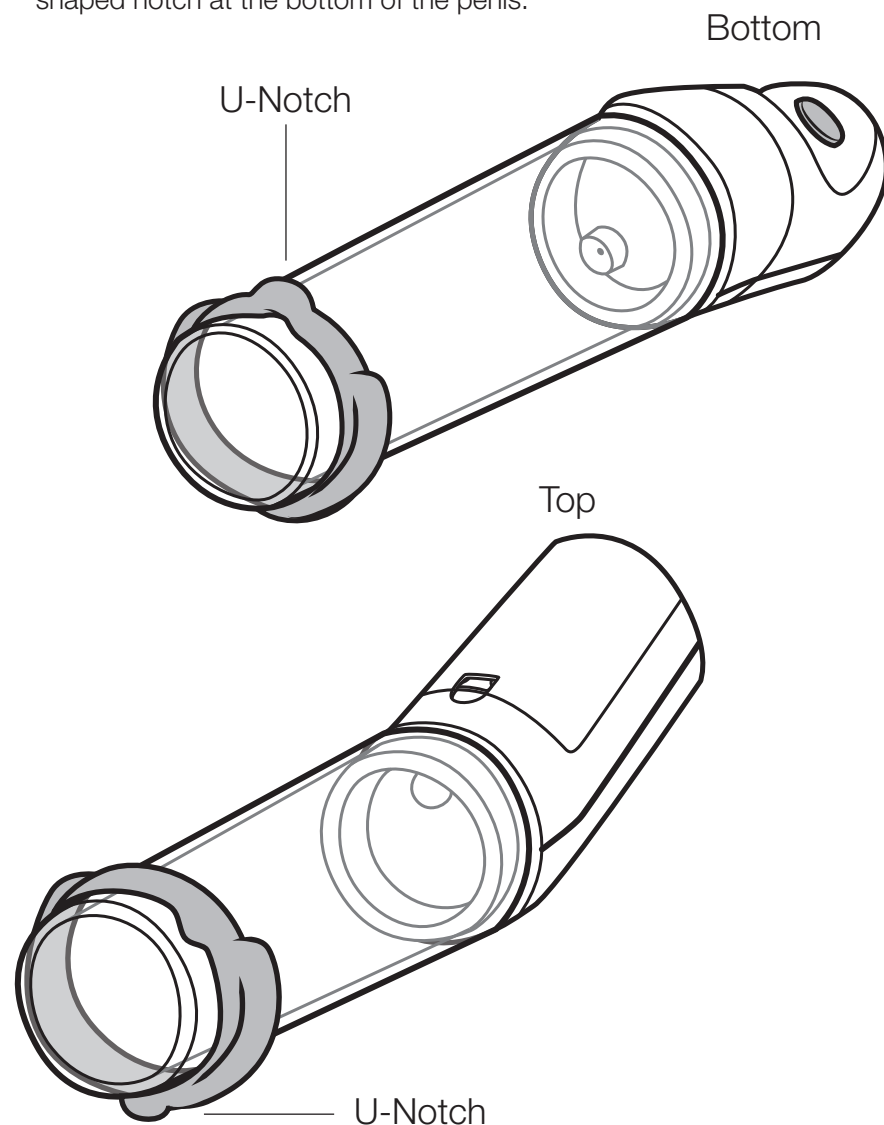
Using the Ring Loading Cone

- Remove the pump handle and the cylinder insert (if used) from the clear plastic cylinder.
- Place the clear plastic cylinder on a hard surface such as a countertop, so the narrow end is facing up. Place the ring-loading cone into the narrow end of the cylinder and apply a liberal amount of water based lubricant to the cone.
- Place your desired ring at the top of the cone and match the “U” shaped notch in the ring to the white dot on the loading cone. Place one hand on the cylinder to steady it in place and use the other hand to gently push the ring onto the cylinder.



Step 3 – Reassemble the Vacuum Therapy System

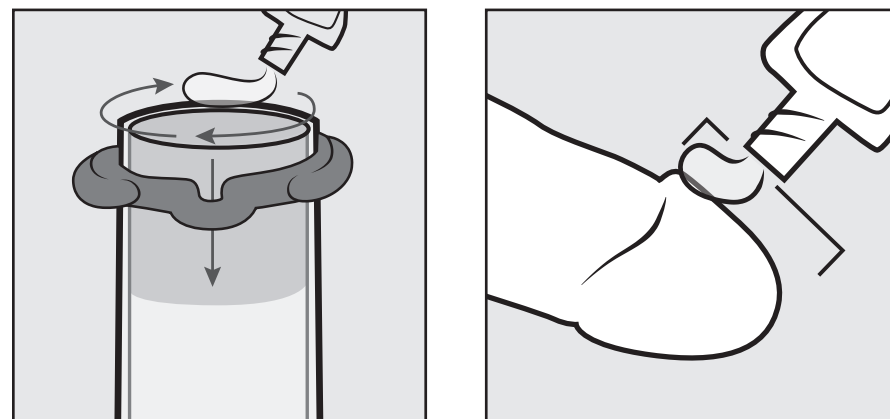
- Reattach the vacuum pump handle at the wide end of the clear plastic cylinder.
- Make sure that the constriction ring is oriented properly with the “U” shaped notch at the bottom of the penis.



Step 4 – Apply Water-Based Lubricant

Water-based lubricant is used to create a seal between the Vacuum Therapy System and the body and to help the penis glide smoothly within the clear plastic cylinder as the erection is being created.

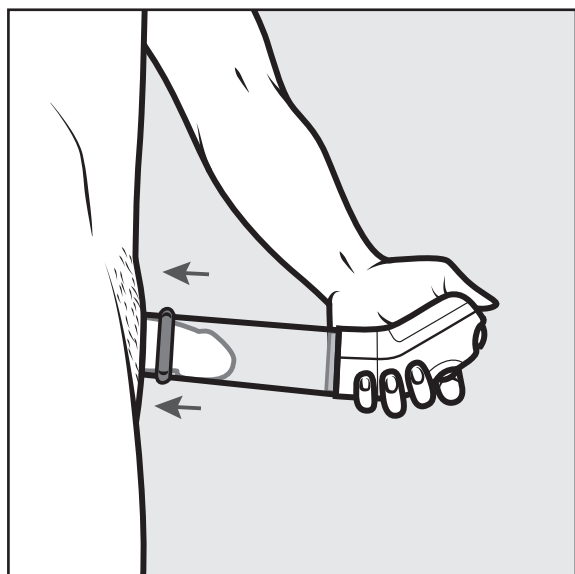
At the narrow end of the clear plastic cylinder, place a quarter-sized pool of lubricant inside at the bottom and a thick bead of lubricant on the edge that will be against your body. Optionally, a small amount of lubricant may be added to the head and bottom side of the penis.



IMPORTANT! - Use only thick water-based lubricants. Thin lubricants will not help create a seal and may run into the vacuum intake and permanently damage your vacuum pump handle. Non water-based lubricants may damage your device and VOID the warranty.

Step 5 – Position the Vacuum Therapy System for Use

Insert the penis into the open end of the clear plastic cylinder. Press the Vacuum Therapy System firmly against your body and gently twist back and forth a few times to help distribute the lubricant.

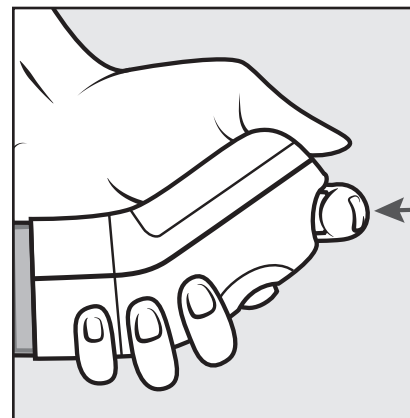


NOTE – Trimming the pubic hair at the base of the penis may make it easier to create a vacuum and will make it easier to remove a constriction ring. Use of trimming devices specifically designed for removing body hair, typically with protective guards, is suggested.

Step 6 – Activate the Battery Powered Vacuum Pump

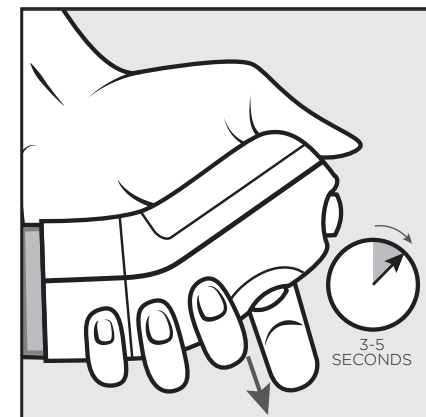
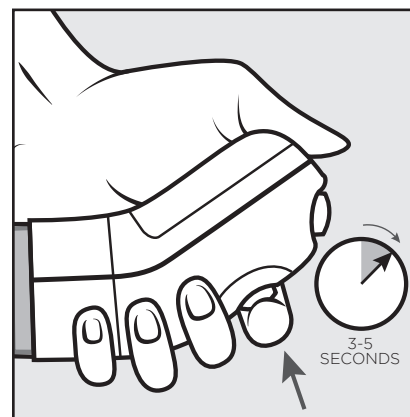
IMPORTANT - Erections are created when the minimum amount of vacuum pressure is applied gradually, giving enough time for blood to enter the penis slowly.

Use the minimum amount of vacuum necessary to create an erection.

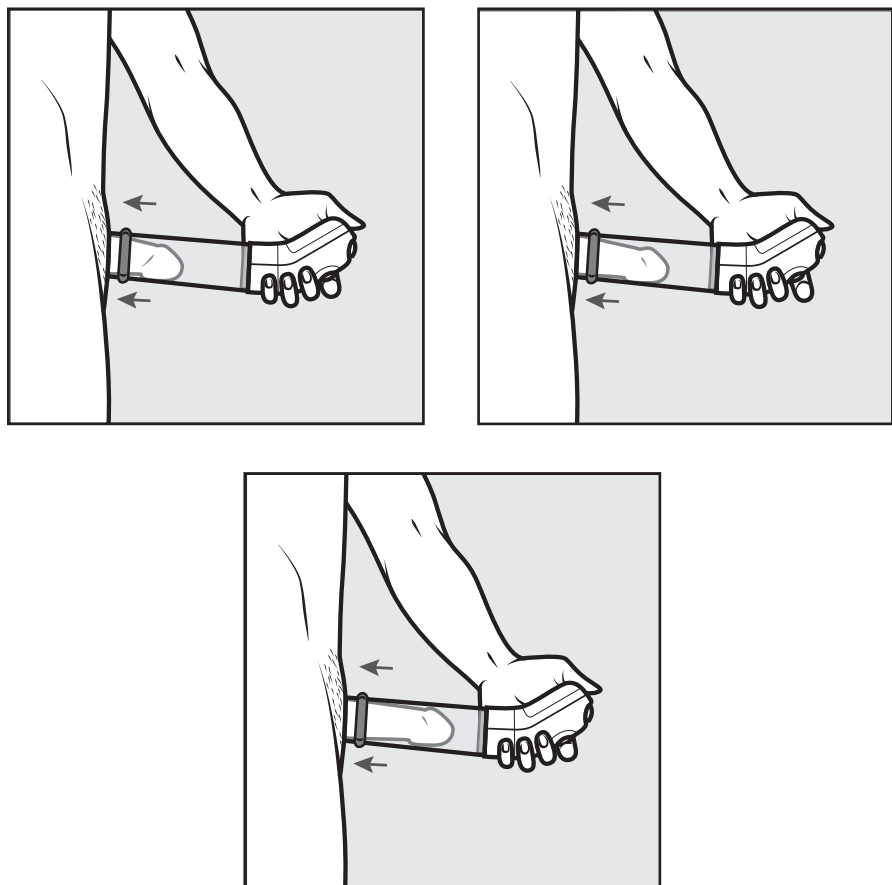


Press the **Red RELEASE** button to release the vacuum pressure if you feel pain or discomfort at any point in this process.

Start the process by pushing the **Gray GO** button to activate the vacuum pump for a few seconds, and then stop to allow time for blood to enter the penis slowly.



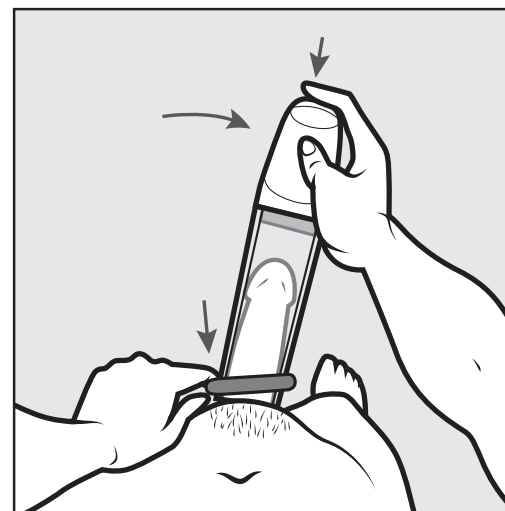
Repeat this process of pumping and pausing to gradually increase the amount of vacuum until the penis is filled with enough blood to create an erection good enough for sexual intercourse. Typically, this is when the penis has lifted off the bottom of the cylinder.



Step 7 – Transfer the Constriction Ring to the Penis

Gently push and hold one side of the constriction ring toward the body, while at the same time, tipping (NOT pulling straight away from your body) the Vacuum Therapy System in the opposite direction. This should cause the constriction ring to slide to the base of the penis (as close to your body as possible) just as the vacuum is released.

NOTE - If the seal has not broken using the above process, press the **Red RELEASE** button to release the vacuum pressure.



WARNING - Do not leave constriction rings on the penis for more than 30 minutes. Do not fall asleep with constriction rings in place on the penis. Leaving constriction rings on the penis for more than 30 min can cause injury or permanent damage to the penis.

WARNING - When using a constriction ring, allow at least 60 minutes between uses, as more frequent use may increase the risk of injury or damage to the penis.

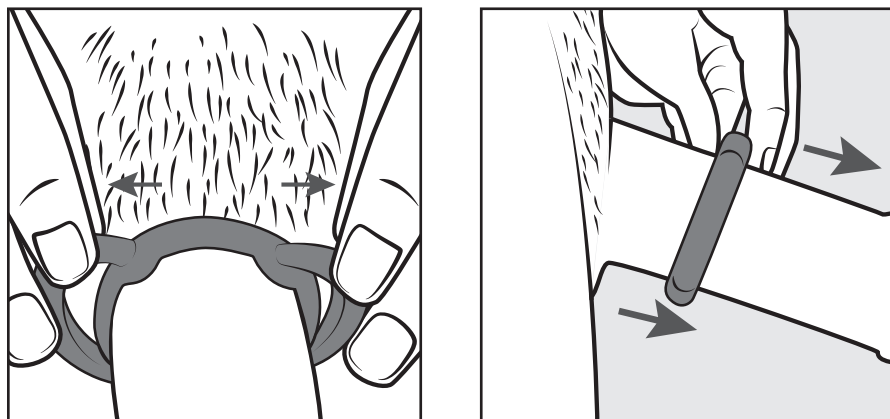
Most men will need to experiment with the device to determine the level of constriction that is necessary to maintain an erection for intercourse.

Step 8 – Remove the Constriction Ring Within 30 Minutes

Constriction rings must not be used for more than 30 minutes.

To remove the constriction ring, grasp each of the tabs on the side of the ring and pull the tabs out gently. Do not use excessive force or the ring may break.

Continue to pull the tabs gently for about 10 seconds or until blood flows back into the body and the penis loses firmness. The constriction ring can be removed once the penis is no longer fully erect.



NOTE - It may be helpful to place water-based lubricant around the penis ahead of the constriction ring to make it easier for the constriction ring to slide off.

Cleaning the Vacuum Therapy System

WARNING - Do NOT wash the Vacuum Therapy System or any of its components in a dishwasher as this may cause permanent damage.

Clean the entire vacuum therapy system after each use according to the instructions below.

Vacuum Pump Battery Powered Handle:

- **WARNING** - Do NOT rinse or submerge this handle, it is not water resistant. Liquid entering the pump handle will permanently damage the device and VOID the warranty.
- Clean the vacuum pump handle with a soft, slightly damp towel.

Clear Plastic Cylinder, Insert and Constriction Rings:

- Clean the clear plastic cylinder, cylinder insert, and constriction ring(s) with a soft cloth and warm soapy water. Rinse and dry the parts prior to storage.

General Troubleshooting Guide

Managing Common Problems with a Vacuum Therapy 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 device for air leaks	Problem generally resolves as user gains more experience
Partial erection	Lack of adequate vacuum; not enough practice sessions; cylinder insert too tight	More practice using device; remove cylinder insert	Problem generally improves with continued use of the device.
Rapid loss of erection (in less than 5 min)	Vacuum lost (air leak, faulty equipment, poor seal, inadequate lubrication, excessive pubic hair), or improper constriction ring.	Same as for "No erection." Also: use cylinder insert, use higher tension constriction ring or rings.	Requires practice to create and maintain vacuum and to determine proper constriction ring size and tension.

General Troubleshooting Guide

Managing Common Problems with a Vacuum Therapy System (continued)

Problem	Likely Cause	Remedy	Comments
Delayed loss of erection (after 5-10 min) or during intercourse	Insufficient tension from constriction rings	Use a higher tension constriction ring or use multiple constriction rings	Requires experimenting to determine proper constriction ring size and tension
Pulling scrotum or scrotal skin	Lubricant on scrotum; improper pumping technique; cylinder opening too large; user inexperience	Remove lubricant from scrotum; use cylinder insert; follow pumping technique described; angle cylinder downward during pumping; pull scrotal tissue down before and/or during pumping	Problem generally resolves as user gains more experience with the device
Penis pivots or "hinges" at its base	Constriction of blood flow to the penis; improperly placed constriction rings	If possible, achieve a partial erection before applying vacuum; be sure the constriction ring is at the base of the penis	

General Troubleshooting Guide

Troubleshooting Discomfort or Pain

Problem	Likely Cause	Remedy	Comments
Pain during pumping	Pumping is too rapid; pulling of scrotal tissue	Follow pumping technique described; remove lubricant from scrotum; use cylinder insert; angle cylinder downward during pumping; pull scrotal tissue down before pumping	Vacuum is a new sensation, problem generally resolves as user gains more experience with the device
Pain from constriction ring	Constriction ring too small; improper ring transfer technique	Use larger constriction ring; follow ring transfer technique described	Problem generally resolves as user gains more experience with the device; talk to your health care professional if problem persists
Pain during intercourse	Inadequate lubrication; pressure on sensitive area	More lubrication; position changes	
Pain during ejaculation	Potential infection or inflammation of the prostate gland; long period of abstinence	Consult your health care professional if this problem persists	
Redness, irritation, or bruising	Pumping is too fast; pumping too much	Slower pumping; Fewer pumps for less vacuum pressure	Consult your health care professional if this problem persists
Penis feels cold	Constriction of blood flow to the penis; cold lubricant	Remove constriction ring; wash off lubricant; warm lubricant before use	

90 Day Satisfaction Guarantee Program

Gesiva Medical understands the expense and frustration associated with unsuccessful treatment of ED and wants you to know that vacuum therapy systems work for approximately 90% of men who take the time to practice and learn how to use a device. For that reason, we offer a 90-day satisfaction guarantee period in which you may return the Gesiva Medical vacuum system for your money back if you are not fully satisfied with the product.

To be eligible for this return program, you must:

1. Have purchased your system directly from Gesiva Medical and registered within it 30 days of your purchase (registration instructions can be found on page 29); and you have not returned a vacuum therapy system, components, or accessories to Gesiva Medical in the past 3 years;
2. Contact a Gesiva Medical representative (by phone, in person, or both) to receive instructions for return;
3. Obtain a return authorization (RA) number from the Gesiva representative;
4. Ship all required components within 10 calendar days of receiving the return authorization number; and
5. Follow the shipping instructions as directed by Gesiva Medical.

NOTE: Gesiva Medical will refund the amount of the original purchase price, less shipping charges, via mail of a company check to the purchaser and address identified on the product registration card.

This satisfaction guarantee program is offered only on devices purchased directly from Gesiva Medical and only to the original owner of the device. Gesiva Medical reserves the right to change this policy for future purchases.

IMPORTANT - Do not return any device, kit, or component to Gesiva Medical, LLC without obtaining a return authorization number. Packages without RA numbers will be refused and returned to the sender.

Call **866-34-GESIVA** for help with your system or to obtain an RA number and shipping instructions.

Limited Warranty

Your Gesiva Medical vacuum pump handle and clear plastic cylinder are backed by a limited warranty. This means that Gesiva Medical will repair or replace a defective individual component should failure be due to defects in materials or workmanship.

To be eligible for this warranty, you must:

1. Be the original owner of the Gesiva Medical vacuum therapy system;
2. Have purchased your Gesiva Medical vacuum therapy system directly from Gesiva Medical and registered it within 30 days of your purchase (registration instructions can be found on page 29);
3. Call Gesiva Medical at **866-34-GESIVA** to report and discuss the problem with a representative;
4. Obtain a return authorization (RA) number (if necessary);
5. Ship all required components within 10 calendar days of receiving the return authorization number if Gesiva Medical determines that returning the product is necessary; and
6. Follow the shipping instructions as required by Gesiva Medical.

If Gesiva Medical confirms the failure is due to a defect in materials or workmanship, Gesiva Medical will, at its option, either repair or replace the defective system or component. Repair or replacement is your exclusive remedy for a defective product. This warranty applies for three years from the initial purchase of the product.

Except as is expressly provided in this Limited Warranty, Gesiva Medical expressly disclaims any representation or warranty of any kind, express or implied, whether as to merchantability, fitness for a particular purpose or any other matter. The remedies set forth in this Limited Warranty are the only remedies available to you for breach of warranty. Gesiva Medical shall have no liability to you or any other person for incidental or consequential damages of any description, whether arising out of warranty, other contract, tort, under statute, or otherwise, even if you or any other person have been advised of the possibility or likelihood of such damages.

IMPORTANT!

You Must Register Your Gesiva Medical Vacuum Therapy System In Order to be Eligible for the 90-Day Satisfaction Guarantee and the Limited Warranty

To Register Your System:

1. Go to **www.gesiva.com**
2. Look for the “Register My Device” option
3. Complete the form making sure to provide all required fields
4. Hit “Submit”

Notes

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Notes

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