



ErecAid® Classic OTC Vacuum Therapy System

User Guide

Indications for Use

The ErecAid® Classic OTC Vacuum Therapy System is intended to artificially produce an erection in males suffering from erectile dysfunction (impotence) in order to facilitate sexual intercourse, or to create and maintain erections by providing arterial (oxygen-rich) blood flow to the penis during recovery from prostatectomy. A vacuum is applied to the penis, causing it to become erect and rigid as blood is drawn into the corpora cavernosa. A constriction ring is then placed on the base of the penis to restrict venous blood flow out of the penis. The device is intended to be used at home or in a doctor's office or clinic.

Please Read This User Guide in its Entirety Before Using the Device

This User Guide is not intended to provide medical guidance or recommendations. Medical guidance can only be provided by a licensed Healthcare Practitioner.

Osbon® ErecAid® Classic OTC - Vacuum Therapy System



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Customer Care: 1-800-438-8592
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Device and Component Patent: #5,643,290 and #6,248,059

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How Does the ErecAid® Classic OTC Vacuum Therapy System Work?

A human erection is a complex event that involves the brain, hormones, blood vessels, nerves and muscles inside the penis. When these work together properly, the penis fills with blood to produce an elongated and hard erection. In simple terms, an erection is a blood-filling and blood-storing event, which takes place inside a man's penis.

A vacuum pump pulls blood into the penis to produce an erection. A tension ring holds the blood in the penis, keeping the erection long enough to have sexual intercourse. When the ring is removed, the erection quickly goes away.

An erection achieved with the System usually has greater girth or thickness, since the blood vessels are filled to their maximum potential. However, the ErecAid® Classic OTC System is not an enlargement device; it simply allows the penis to obtain its largest natural state.

Is a Vacuum Therapy System Right for Me?

Please read the following information carefully before using the ErecAid® Classic OTC System. While no serious injury has been reported from proper use of this System, it is still important to observe some simple precautions. If you have any questions, call Timm Medical Customer Care at 1-800-438-8592 or contact your physician.

Contraindications

External vacuum therapy is a proven way to treat Erectile Dysfunction, or impotence. For the general population, there is no inherent or significant risk in properly using a vacuum device. However, some patients should not use the device. These include:

1. Men with a previous history of spontaneous priapism, an erection that lasts more than four hours. This may be extremely painful and may cause permanent damage to the penis.
2. Men who have sickle cell trait or disease, or hypercoagulability, excessive blood clotting, are more likely susceptible to suffer from priapism.
3. Men who have a bleeding disorder or who bruise easily. Use of a vacuum device may cause painful bruising of the penis in these men.

General Warnings and Precautions

1. Talk to your doctor if any complications occur while using this device. Stop using the device if complications continue.
2. Do not leave the ring on your penis for more than 30 minutes. Do not fall asleep wearing the ring. Leaving the ring on too long may damage your penis by keeping blood from flowing into it.
3. Allow at least 60 minutes between uses of ErecAid®. Using the rings too often may cause bruising at the base of the penis, where the penis is joined to the body.
4. If you have symptoms of Erectile Dysfunction, not being able to get or keep an erection that allows you to have sex, talk to your doctor before using ErecAid® to prevent a delay in discovering and treating the cause. Common causes of Erectile Dysfunction are heart disease, diabetes, multiple sclerosis, cirrhosis of the liver, chronic renal failure and alcoholism.
5. Ask your doctor about using ErecAid® if you are taking anti-coagulant, blood-thinning, medicine; if you have a penile implant; or if you have Peyronie's disease, leukemia or other blood disorders where bleeding or clotting may be a problem. The effects of the ErecAid® System on the components of implanted penile prostheses have not been adequately investigated. Therefore, if you have a penile prosthesis, consult your physician prior to use.
6. Do not use ErecAid® under the influence of drugs or alcohol. These substances may reduce your sensitivity to pain or impair your ability to follow directions properly.
7. ErecAid® may bruise the blood vessels just below the surface of the skin, which may cause petechiae when you first begin using your System. Petechiae are very tiny spots beneath the skin. This is a response to placing the penis under vacuum pressure too long, too quickly or after a long period of inactivity. If this happens, discontinue use of the System until discoloration completely disappears, which can take about 5 to 7 days.
8. Always use the least amount of vacuum pressure necessary to produce an erection. Using too much pressure or increasing the vacuum pressure too quickly may cause discomfort, pain or bruising. Release vacuum pressure immediately if pain occurs.
9. Improper use of the vacuum pump could result in the swelling of the penis and/or serious, permanent injury to the penis. Improper use may also worsen pre-existing medical conditions such as Peyronie's disease, priapism and urethral strictures.

General Warnings and Precautions

10. If you notice a bend or curve in your penis when you first use ErecAid®, consult your physician.
11. If your hands are impaired, you should not use this product. You must have full use of your hands to safely use the rings and pump. If you do not have enough strength in your hands, you may not be able to remove the ring. Delayed ring removal could damage your penis.
12. The vacuum pump may not be safe for men who cannot feel pain in the area around their penis. If you have diabetes, you may have a reduced ability to feel pain. Pain may be a sign that your penis is being bruised.
13. Tension rings are not a means of birth control. Do not rely on tension rings to avoid pregnancy.
14. After a period of inactivity when the pump has not been utilized, practice sessions will again be necessary to recondition penile tissue prior to resuming sexual activity. If you will not be having sexual activity on a regular basis, continue therapy practice sessions on a regular basis unless otherwise instructed by your physician.

Item Checklist-ErecAid® Classic OTC Vacuum Therapy System

Please check to make sure that you received the following items:

- ☐ Easy Carrying Case
- ☐ Inverse Tapered Clear Cylinder with Insert
- ☐ ErecAid® Classic Pump
- ☐ Clear Rubber Conduit Tubing 18"
- ☐ Osbon® Personal Lubricant
- ☐ Two Pressure Point Tension Rings
 - ☐ Ring C: Medium Beige Standard-Tension
with inside diameter of 0.75" (19 mm)
 - ☐ Ring D: Medium Pink High-Tension
with inside diameter of 0.75" (19 mm)

In the event that you did not receive any of these items please call
Timm Medical Customer Care at 1-800-438-8592.

Components of the ErecAid® Classic OTC Vacuum Therapy System

Study the diagram to become familiar with the name and purpose of each part of the ErecAid® Classic OTC System before you begin to use the device.

Cylinder and Coupler

The end of the cylinder with the small circular coupler is designed to attach the clear rubber conduit tubing. The other end of the cylinder fits over the penis and against the body to help create the vacuum seal.

Tubing

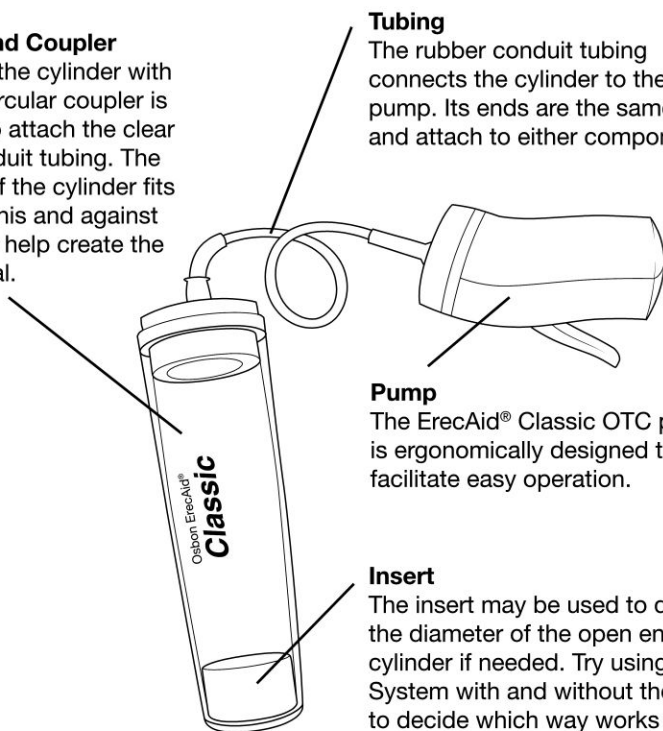
The rubber conduit tubing connects the cylinder to the pump. Its ends are the same and attach to either component.

Pump

The ErecAid® Classic OTC pump is ergonomically designed to facilitate easy operation.

Insert

The insert may be used to decrease the diameter of the open end of the cylinder if needed. Try using the System with and without the insert to decide which way works best.

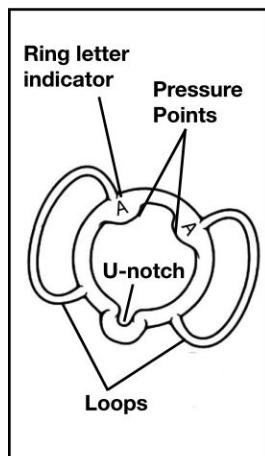


How to Assemble the ErecAid® Classic OTC System

Simply attach one end of the tubing to the Pump and the other end of the tubing to the Coupler on the end of the Cylinder.

Components of the ErecAid® Classic OTC Vacuum Therapy System

Pressure Point Tension Rings

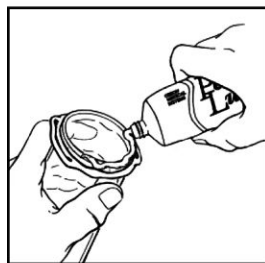


The patented Pressure Point Tension Rings are medically engineered for safety, performance and comfort. The rings can be used individually or in various combinations to maintain an erection once you have created it using the System. Four Pressure Point Tension Rings are available:

- Ring A: Large Beige Standard-Tension with inside diameter of 0.875" (22 mm)
- Ring B: Large Pink High-Tension with inside diameter of 0.875" (22 mm)
- Ring C: Medium Beige Standard-Tension with inside diameter of 0.75" (19 mm)
- Ring D: Medium Pink High-Tension with inside diameter of 0.75" (19 mm)

Depending on the System you purchased you may have some or all of the above Pressure Point Tension Rings. Tension Rings are a reusable item and generally last 1-6 months, depending on use and storage.

Osbon® Personal Lubricant



Osbon® Personal Lubricant plays an important part in the overall function of the System. Proper application of our lubricant to the head of the penis and to the open end of the cylinder is essential for the creation of a proper vacuum seal against the body. The lubricant also helps you to load and remove the tension rings. You should only use our water soluble Osbon® Personal Lubricant. Other lubricants may damage the tension rings and other System parts, as well as void the System warranty.

Getting Started with Practice Sessions

Now the ErecAid® Classic OTC System is fully assembled and you are ready to learn how to use the System.

Before using the ErecAid® System for intercourse, you must practice creating an erection. After an extended period without erections, the vessels in the penis need to become accustomed to being filled with blood again. Practice sessions help you learn your individual comfort level, the amount of vacuum you need, and the best pumping rate for you. Practice sessions ultimately help you understand what to expect from the System and become more confident and satisfied with your sexual experiences.

After a period of inactivity when the pump has not been utilized, practice sessions will again be necessary to recondition penile tissue prior to resuming sexual activity. If you will not be having sexual activity on a regular basis, you need to continue therapy practice sessions on a regular basis unless otherwise instructed by your physician. These sessions will provide a slow but steady increase of blood through the vessels of the penis, giving you a better erection.

Practice sessions should be at least 10 –15 minutes daily for a minimum of two weeks. Do not use a tension ring during practice sessions. You will only be practicing how to create an erection. Later, when you become comfortable with creating your erection, you will learn how to load and transfer tension rings. Proper use of the tension rings lets you keep a full erection suitable for intercourse.

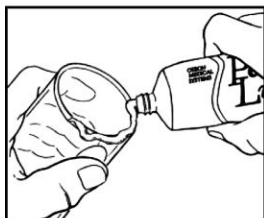
How to Create an Erection



Step 1

Apply Osbon® Personal Lubricant to the following areas:

1. Inside the open end of the cylinder, approximately two inches up
2. The rim of the cylinder which meets the body to form the vacuum seal
3. The entire head of the penis



Proper application of the lubricant will help you achieve the best erection possible.

Trimming the pubic hair around the base of the penis may be necessary to create an airtight seal.



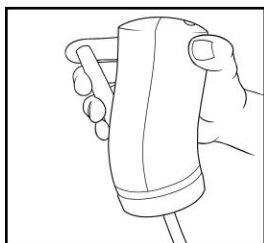
Step 2

It is recommended that you stand for this step, however, the System can also be used when you are sitting or lying down.

Place the lubricated penis inside the cylinder with the label on the cylinder facing up and pump handle pointing down. With one hand, hold the cylinder at a downward 45° angle with the open end snugly against the body.

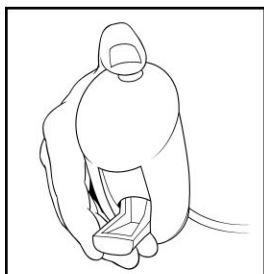
Rotate cylinder slightly back and forth to make an airtight seal against the body. Make sure the testicles are not drawn into the cylinder.

How to Create an Erection

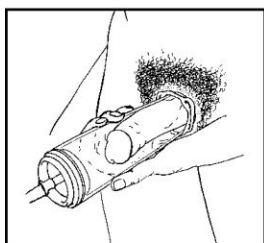


Step 3

Pump slowly to remove the air from the cylinder. Begin by pressing the pump handle two times to create the vacuum seal. Wait 5 to 10 seconds between pumps to increase blood flow. You should not force the pump handle past its stopping point. If the vacuum pressure increases too quickly, you may feel discomfort.



If you have any discomfort, stop pumping and press the green vacuum release button on the top of the pump. Then begin pumping again. Wait 5 to 10 seconds between pumps. You may need to press the vacuum release button several times while creating the erection. The number of pumps needed for a firm erection will vary according to the individual. Experiment to determine how many pumps you personally require to get an erection.



Step 4

Usually the penis will lift slightly from the floor of the cylinder when the erection is complete. This process may take a few minutes. If your erection begins to press uncomfortably against the inside of the insert, remove the insert and start over without it.

It may take a bit longer than expected for some men to get an erection. By repeating the practice sessions, you will be able to get a firmer erection more quickly and be able to use less vacuum pressure.

You Have Practiced...

Now You're Ready for Intercourse

How to Select a Pressure Point Tension Ring

Two Pressure Point Tension Rings come with the ErecAid® Classic OTC System:

- Ring C: Medium Beige Standard-Tension with inside diameter of 0.75" (19 mm)
- Ring D: Medium Pink High-Tension with inside diameter of 0.75" (19 mm)

Two additional Pressure Point Tension Rings are available for purchase:

- Ring A: Large Beige Standard-Tension with inside diameter of 0.875" (22 mm)
- Ring B: Large Pink High-Tension with inside diameter of 0.875" (22 mm)

You will need to experiment to find the tension ring that is right for you. Begin with the largest and lowest tension ring you have; and determine if it provides a satisfactory erection with the use of the System. If the initial ring does not provide a satisfactory erection, progress to the next tension ring level as shown in the table below. Continue to test each tension ring level until a satisfactory erection is achieved. Tension ring levels 1-4 require one ring, while tension levels 5-7 require two rings. You always want to use the lowest tension ring level that allows you to maintain your erection.

Pressure Point Tension Ring Levels		
 Minimum Tension	Level One	Ring A
	Level Two	Ring B
	Level Three	Ring C
	Level Four	Ring D
Maximum Tension	Level Five	Ring A & Ring B
	Level Six	Ring B & Ring D
	Level Seven	Ring C & Ring D

To purchase additional tension rings, call Timm Medical Customer Care at 1-800-438-8592, visit our website at www.timmmedical.com or mail your order using the form you received with your System purchase.

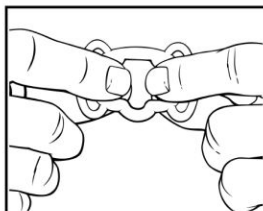
How to Load a Tension Ring Manually

Loading Tension Rings with your Index Fingers or Thumbs

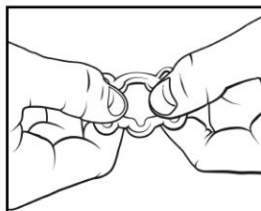
Step 1

Place the cylinder between your legs so the ErecAid® labeling on the cylinder is facing you. Hold the tension ring so the U-notch is facing away from you, and your index fingers or thumbs are on the inside of the ring. Do not pull the outer loops.

If using Index Fingers

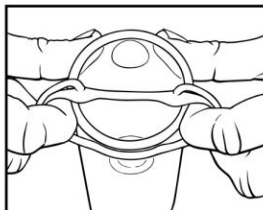


If using Thumbs



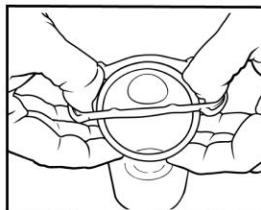
Step 2

If using Index Fingers



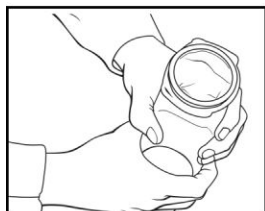
Place the U-notch on the lip of the cylinder farthest away from you. Use your thumbs as leverage on the cylinder to stretch the tension ring over the lip of the cylinder with your index fingers, starting from bottom of the cylinder up.

If using Thumbs



Place the pressure point side of the ring on the lip of the cylinder closest to you. Use your index fingers as leverage on the cylinder to stretch the tension ring over the lip of the cylinder with your thumbs, starting from the top of the cylinder down.

Step 3



The tension ring should now be around the lip of the cylinder. If you need to add an additional ring to the cylinder, slide the first ring 1/4" towards the pump handle to allow space for the additional ring. The ring with the lowest tension should always be positioned on the cylinder first. Repeat Steps 1 and 2 to position the second, higher tension ring.

Maintaining an Erection

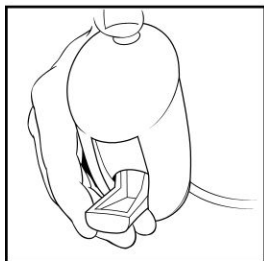
With the tension ring loaded on your cylinder, follow the four steps you've learned already to create an erection using the System on pages 9 and 10. Remember to use Osbon® Personal Lubricant and to place the cylinder over your penis ensuring the U-notch of the tension ring is to the bottom of the penis and the pressure points are to the top.

If you are not sure if the ring is positioned correctly, remove the ring from the cylinder and repeat the ring loading steps.



Step 1

Slide the tension ring(s) from the cylinder to the base of your erect penis, one at a time. Keep the cylinder snug to the body while sliding off the ring(s). Many men find it easiest to slide the ring off by holding one side of the ring against the body while tipping the pump away from the body in the opposite direction, being sure not to break the vacuum seal. If you are using two tension rings, the ring with the highest tension should be closest to your body.



Step 2

Remove the cylinder by tipping the pump away from the body, breaking the vacuum seal or by pushing the green vacuum release button to remove the cylinder. The penis will remain erect until you remove the tension ring(s). Do not leave the tension ring(s) on your penis longer than 30 minutes. Leaving the ring(s) on too long may damage your penis by keeping blood from flowing into it.

An erection achieved with the System will remain rigid until you remove the tension ring(s). Most men are able to continue intercourse after ejaculation/orgasm, if desired.

It is not uncommon for semen to not flow through at point of climax. The pressure of the tension ring(s) sometimes interferes with ejaculation. This is not harmful and does not affect climax. Instead, your semen may flow out when you remove the tension ring(s). Tension rings are not a means of contraception.

Removing the Tension Rings

Remove the tension ring(s) after sexual activity. Lying down will help the blood flow into the body faster. Remember do not keep the ring(s) on your penis for longer than 30 minutes.



Step 1

Apply a small amount of lubricant in front of the ring and on the penis.

Step 2

Grasp the loops and pull gently outward, away from the penis. Hold the loops outward for at least 10 seconds or until the penis loses some firmness.

Step 3

Slowly pull the ring(s) forward and off your penis.

System Care

After each use, carefully clean and store the System as follows:

1. Remove the pump handle and tubing from the cylinder.
2. Wipe the pump with a damp cloth. Never wash or immerse the pump in water. Immersing the pump handle will void your warranty.
3. Wash the cylinder, tubing, insert and tension ring(s) with warm, soapy water. We recommend that you use liquid soap when cleaning your System. Rinse thoroughly. Never place any ErecAid® component in a dishwasher or microwave.
4. Let all the parts air-dry thoroughly in a ventilated place before storing. Be sure to store the System unassembled.

Tips and Reminders

1. After a period of inactivity when the System has not been utilized, practice sessions will again be necessary to recondition penile tissue prior to resuming sexual activity. If you do not have sexual activity on a regular basis, you need to continue therapy practice sessions on a regular basis, unless otherwise instructed by your physician. These sessions will provide a slow but steady increase of blood through the vessels of the penis, giving you a better erection.
2. Rotate cylinder slightly back and forth to make an airtight seal against the body, make sure the testicles are not drawn into the cylinder.
3. Trimming the pubic hair around the base of the penis can help the cylinder make better contact with your skin, thus improving the vacuum seal needed to create an erection.
4. Allow your erection to develop slowly. Increasing the vacuum too quickly may cause discomfort or temporary bruising.
5. If you lose your erection with the tension ring(s) in place, you may need to increase the amount of tension. Refer to the table on page 11 to select the best tension level for you.
6. You may lose your erection if air enters the cylinder before the tension ring(s) is/are in place. Be sure you position the tension ring(s) on the penis before releasing the vacuum. Keep the cylinder pressed firmly to your body during transfer of the tension ring(s).
7. If you are using two tension rings, be sure to load the ring with the least amount of tension onto the cylinder first, followed by the ring with the higher tension. This results in the highest tension ring being closest to your body when you transfer the rings.
8. Removing the tension ring(s) while lying down will help blood flow into the body faster.
9. Be sure to remove tension ring(s) within 30 minutes.
10. Do not fall asleep with the tension ring(s) in place.
11. Remove tension ring(s) before urinating.
12. Tension rings are a re-usable item and will generally last 1-6 months, depending on use and storage.

Frequently Asked Questions

What if...

1. ...I haven't been able to achieve an erection suitable for intercourse?

If you have used the System to obtain an erection, but have not achieved an erection suitable for intercourse, complete practice sessions without a tension ring until you can achieve and maintain an erection within the cylinder. Repeat for a minimum of two weeks. See page 8 for more detail on practice sessions.

2. ...my penis loses firmness when I transfer the tension ring?

Ensure you are not breaking the vacuum seal and that you have adequately lubricated the cylinder. Place cylinder over your partially erect penis and tension ring(s). Hold the cylinder firmly against the body. Then slowly pump a few additional times until you achieve sufficient firmness.

3. ...I have used each of the tension rings individually but I still lose firmness during sexual activity?

You likely need more tension to hold the blood in the penis, and therefore may need to use two tension rings. Refer to the Pressure Point Tension Ring Levels table on page 11 and begin with the Level 5 tension ring combination progressing toward maximum tension until the firmness of your erection is maintained. Do not use more than two tension rings.

Level Five tension requires Rings A and B, which are available for purchase by calling Timm Medical Customer Care at 1-800-438-8592, visiting our website at www.timmmedical.com or mailing your order using the form you received with your System purchase.

Once the optimal combination of rings is in place at the base of the erect penis, do not adjust them or firmness will be lost.

If you continue to lose firmness during sexual activity after trying all seven tension levels, call Timm Medical Customer Care at 1-800-438-8592 for assistance.

Frequently Asked Questions

What if...

4. ...the vacuum created by the System pulls my scrotal tissue into the cylinder?

Remember to pump slowly, and if you are not already, try using the insert at the base of the cylinder. If your scrotal tissue is still being pulled into the cylinder, try removing the lubricant from the rim area of the cylinder that comes into contact with scrotal tissue. If you find that you need to apply lubricant to the entire rim to get an airtight seal, be sure to wipe off any excess lubrication from around the scrotal sac. Also, make sure the underside of the penis is in contact with the floor of the cylinder. Reach underneath the cylinder with a dry cloth and gently remove the scrotal tissue from the cylinder. If you lose pressure, pump a few more times.

If these steps do not solve the issue, an EZ™ Ring may be helpful. An EZ™ Ring fits on the end of the cylinder like a lid, and ensures that the scrotal tissue is not drawn into the cylinder of the pump. This design gives many users a more comfortable fit and provides a better seal between body and cylinder to assist in creating an erection. To order an EZ™ Ring, call Timm Medical Customer Care at 1-800-438-8592, visit our website at www.timmmedical.com or mail in your order using the order form you received with your System purchase.

5. ...I have achieved an erection but the vacuum release button doesn't work?

Place one finger between the cylinder and body to manually release vacuum. Reposition vacuum cylinder and re-initiate pumping. Once an erection has been achieved, press and hold green release button for 5 to 10 seconds to release pressure. If device fails to release, manually release the vacuum as stated above and contact Timm Medical Customer Care at 1-800-438-8592.

6. ...I notice that my erect penis has a distortion or curvature?

If you notice a distortion, bend or curve in your penis when you first use your System, discontinue use and seek your physician's advice. Some men who have not been sexually active for some time may have Peyronie's Disease, a condition in which the penis curves or bends abnormally due to a build-up of scar tissue inside the penis.

Frequently Asked Questions

What if...

7. ...I 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 fast. Simply press the green vacuum release button, wait a moment and begin again slowly, waiting 5 to 10 seconds between pumps to increase blood flow.

8. ...my penis turns slightly dusky or blue when I put on the tension ring(s)?

This is a normal response to the reduced blood flow caused by the tension ring(s). The discoloration should disappear when you remove the tension ring(s).

9. ...my penis is bruising or has tiny reddish spots beneath the skin when I use the System?

This is a response to placing the penis under vacuum pressure too long, too quickly or after a long period of inactivity. If this happens, discontinue use of the System until discoloration completely disappears. This can take approximately 5 to 7 days.

10. ...my penis feels slightly colder than usual when wearing tension ring(s)?

This coolness is not harmful. It is a normal response to the reduced blood flow caused by the tension ring(s). It is possible to warm your penis by wrapping a warm washcloth around it for several moments.

11. ...my erection has a “hinge effect” when I apply the tension ring(s)?

The penis may pivot at its base when the ring is in place. If this occurs, you may find it necessary to guide the penis into the vagina or try different positions with your partner for successful intercourse.

12. ...I do not ejaculate, or my semen does not flow through, at the point of climax?

The pressure of the tension ring(s) sometimes interferes with ejaculation. This is not harmful, and does not affect climax. Instead, your semen may flow out when you remove the tension ring(s). Tension rings are not a means of contraception.

13. ...my cylinder starts to develop condensation, or moisture beads, on the inside?

This is simply the result of the heat from your body reacting with the lubricant. This “fogging” can be reduced by running warm water over your cylinder and then drying it before you use the System.

Notice of Privacy Practices

Timm Medical Technologies, Inc.
Effective November 2012

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

In this notice, the words “we” and “us” mean Timm Medical Technologies, Inc. and its designees, and the terms “information” or “health information” include any information we maintain that reasonably can be used to identify you and that relates to your physical or mental health condition, the provision of health care to you, or the payment for such health care.

We are required by law to protect the privacy of your health information. We are also required to provide you with this notice, which explains how we may use and disclose health information about you and describes your rights and our obligations regarding the use and disclosure of that information. We are required by law to abide by the terms of this notice.

HOW WE MAY USE AND DISCLOSE HEALTH INFORMATION ABOUT YOU

For Treatment. We may use health information about you to provide you with health care services or products. We may disclose health information about you to health care professionals who are involved in your care and who are part of the entity providing your care.

For Payment. We may use or disclose health information about you so that we may bill any applicable payors or programs for your health care services or products. For example, we may disclose health information to your health plan to determine whether your plan will cover certain health care services or products – unless you have asked that we not bill your health plan.

For Health Care Operations. We may use or disclose health information about you as necessary to operate and manage our business activities. For example, we may use your health information to perform quality assessment activities.

For Treatment Alternatives or Other Health-Related Products or Services. We may use or disclose your health information to tell you about treatment alternatives or other health-related products or services that may be of interest to you and to contact you about accessories that may be relevant to your treatment.

Additionally, we may use or disclose health information about you, without your authorization, for the following purposes, subject to all applicable legal requirements and limitations:

- **As required by federal, state, and local law.**
- **To avoid a serious threat to the health or safety** of you, another person, or the public.
- **For research**, such as research related to the evaluation of certain treatments or the prevention of disease or disability, if the research study meets privacy law requirements.
- **For specialized government functions**, such as military and veteran activities and national security and intelligence activities.
- **For workers’ compensation** as authorized by, or to the extent necessary to comply with, state workers’ compensation laws that govern job-related injuries or illness.
- **For public health activities**, such as preventing or controlling disease, injury, or disability, or reporting deaths, suspected abuse or neglect, or problems with products.
- **To a health oversight agency for oversight activities**, such as audits, investigations, inspections, or licensure activities. These disclosures may be necessary for certain state and federal agencies to monitor the health care system, government programs, and compliance with civil rights laws.

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- **For judicial or administrative proceedings**, such as in response to a court or administrative order, search warrant, subpoena, or similar process.
- **To law enforcement officials for law enforcement purposes**, such as providing limited information to locate a missing person or report a crime.
- **To coroners, medical examiners, and funeral directors** to identify a deceased person, determine the cause of death, enable funeral directors to carry out their duties, or as otherwise authorized by law.
- **To correctional institutions**, if you are an inmate of a correctional institution and the use or disclosure of your health information is necessary for the institution to provide you with health care, protect your health and safety or the health and safety of others, or ensure the safety and security of the institution.
- **To family and friends** if we obtain your verbal agreement to do so or if we give you an opportunity to object to such a disclosure and you do not raise an objection. We may also disclose health information to your family or friends if we can infer from the circumstances, based on our professional judgment, that you would not object.
- **To business associates** that perform functions on our behalf or provide us with services, if the information is necessary for such functions or services. Our business associates are required, under contract with us, to protect the privacy of your information and are not allowed to use or disclose any information other than as specified in our contract.
- **For data breach notification purposes**. We may use your contact information to provide legally-required notices of unauthorized acquisition, access, or disclosure of your health information.
- **If information is not personally identifiable**. We may use or disclose health information about you in a way that does not personally identify you or reveal who you are. Except for the uses and disclosures described and limited as set forth in this notice, we will not use or disclose your health information without your written authorization. If you give us authorization to use or disclose health information about you, you may revoke that authorization, in writing, at any time. If you revoke your authorization, we will no longer use or disclose information about you for the reasons covered by your written authorization, but we cannot take back any uses or disclosures already made with your permission.

YOUR RIGHTS REGARDING HEALTH INFORMATION ABOUT YOU

You have the following rights regarding health information we maintain about you:

Right to Inspect and Copy. You have the right to inspect and request a copy of your health information, such as medical and billing records that we use to make decisions about your care. In some cases, you may also receive a summary of this health information. You must submit a written request to inspect and/or copy your health information. Mail your request to the address listed at the end of this notice. If you request a copy of the information, we may charge a reasonable fee for the costs of copying, mailing, or other associated supplies. We may deny your request to inspect and/or copy in certain limited circumstances. If you are denied access to your health information, you may ask that the denial be reviewed. If such a review is required by law, we will select a licensed health care professional to review your request and our denial. The person conducting the review will not be the person who denied your request, and we will comply with the outcome of the review.

Right to Amend. If you believe health information we have about you is incorrect or incomplete, you may ask to amend the information. You must submit a written request to amend your health information and provide the reasons for the requested amendment. Mail your request to the address

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listed at the end of this notice. We may deny your request for an amendment if it is not in writing or does not include a reason to support the request. In addition, we may deny your request if you ask us to amend information that:

- We did not create, unless the person or entity that created that information is no longer available to make the amendment.
- Is not part of the health information that we keep.
- You would not be permitted to inspect and copy.
- Is accurate and complete.

Right to an Accounting of Disclosures. You have the right to request an accounting of every disclosure of your health information we have made for up to three years prior to the date of your request, other than disclosures to you, disclosures authorized by you in writing, disclosures for treatment, payment, and health care operations, or other disclosures for which federal law does not require us to provide an accounting. To obtain a list of disclosures, mail your request to the address listed at the end of this notice. Your request must state a time period, which may not begin more than three years prior to the date of the request.

Right to Request Restrictions. You have the right to request a restriction or limitation on the health information we use or disclose about you for treatment, payment, or health care operations. You also have the right to request a restriction or limitation on the health information we disclose about you to someone who is involved in your care or the payment for it, like a family member or friend. We are not required to agree to your request. If we do agree, we will comply with your request unless the information is needed to provide you emergency treatment. To request a restriction, mail your request to the address listed at the end of this notice.

Right to Request Confidential Communications. You have the right to request that we communicate with you about medical matters in a certain way or at a certain location. For example, you can ask that we only contact you at work or by mail. We will not ask you the reason for your request. We will accommodate all reasonable requests. You must submit your request in writing, and your request must specify how or where you wish to be contacted. Mail your request to the address listed at the end of this notice.

Right to a Paper Copy of This Notice. You have the right to a paper copy of this notice. Even if you have agreed to receive it electronically, you are still entitled to a paper copy. To obtain such a copy, mail your request to the address listed at the end of this notice.

CHANGES TO THIS NOTICE

We reserve the right to change the terms of this notice, and to make the revised or changed notice effective for health information we already have about you as well as any information we receive in the future.

COMPLAINTS

If you believe your privacy rights have been violated, you may file a complaint with us at the address listed at the end of this notice. You may also file a complaint with the Secretary of the Department of Health and Human Services. You will not be penalized for filing a complaint.

CONTACT INFORMATION

If you have any questions about this notice, please contact Timm Medical Technologies, Inc., 540 Pennsylvania Ave., Suite 200, Fort Washington, PA 19034 or call Customer Care at 1-800-438-8592.

Notes and Cautions



CAUTIONS:

This device is not intended for use in the presence of flammable mixtures.

This device should not be used adjacent to or stacked with other ErecAid® equipment and that if adjacent or stacked use is necessary, the ErecAid® Esteem® System should be observed to verify normal operation.



NOTE ON CLASSIFICATION:

This device is classified as ordinary equipment without protection against ingress of water.

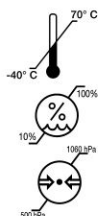


This device is classified as suitable for continuous operation.



NOTE ON DISPOSAL:

This device contains electronic components and should be disposed of according to local, state and national regulations. Please contact your local authorities for proper disposal of small electronics devices. Remove batteries and recycle them according to regulations as well. Many retail outlets that sell batteries provide for free recycling.



NOTE ON TRANSPORT AND STORAGE:

Ambient temperature range: -40°C to +70°C

Relative humidity range: 10% to 100%, including condensation

Atmospheric pressure range: 500hPa to 1060 hPa.

Warranty

1 Year Limited Warranty – ErecAid® Classic OTC

Timm Medical Technologies, Inc. protects the major components of your ErecAid® Classic OTC System with a one-year limited replacement warranty. This means that we will repair or replace the cylinder and pump free of charge if they fail during the warranty period due to defective workmanship or materials, as determined by Timm Medical Technologies, Inc. The one-year limited warranty is granted only to the original registered owner of the System and requires return of the damaged or defective component. The one-year limited warranty does not cover accessory items such as tension rings, inserts, ring loader, lubricant or carrying case. This one-year limited warranty is in place of any other warranties expressed or implied and is only available for Systems purchased directly from Timm Medical Technologies, Inc.

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Manual Model



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