

User Guide







Indications for Use

The ErecAid® Esteem® 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.

Osbon ErecAid® Esteem® - Vacuum Therapy System



Manufactured For: Timm Medical Technologies, Inc. Lake Forest, IL 60045

Toll Free: 800-438-8592

email: www.timmmedical.com

Device and Component Patent: #4,378,008; #4,856,498; #5,244,455; #5,306,277; #5,234,402; 5,643,290

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

Patient Bill of Rights

This Patient Bill of Rights informs you of your rights prior to receiving services from Timm Medical Technologies, Inc.

Timm Medical Technologies, Inc. treats the patient in a dignified and respectful manner.

Timm Medical Technologies, Inc. respects the patient's right to and need for effective communication.

Timm Medical Technologies, Inc. respects the patient's cultural and personal values, beliefs, and preferences.

Timm Medical Technologies, Inc. respects the patient's right to privacy.

Timm Medical Technologies, Inc. allows the patient to access, request amendment to, and obtain information on disclosures of his or her health information, in accordance with law and regulation.

Timm Medical Technologies, Inc. honors the patient's right to give or withhold informed consent.

Timm Medical Technologies, Inc. protects the patient and respects his or her rights during research, investigation, and clinical trials.

The patient and his or her family have the right to have complaints reviewed by Timm Medical Technologies, Inc.

Timm Medical Technologies, Inc. informs the patient about his or her responsibilities related to his or her care, treatment, or services (Included in order forms and systems manuals.)

Timm Medical Technologies, Inc. informs the patient that they may contact the Joint Commission Office of Quality Monitoring to report any unresolved concerns or complaints related to patient safety and quality of care by either calling (800) 994-6610 or email complaints@jointcommission.org.

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.
- For judicial or administrative proceedings, such as in response to a court or administrative order, search warrant, subpoena, or similar process.

Notice of Privacy Practices (continued)

- 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 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.

Notice of Privacy Practices (continued)

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 six 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 six 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. We will post a copy of the current notice on our website, http://www.timmmedical.com/_l/pdf/npp.pdf. The notice will contain an effective date at the top of the first page.

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 our Privacy Officer at: Timm Medical Technologies, Inc., 150 S. Saunders Rd., Suite 120, Lake Forest, IL 60045 or call toll free: (800) 438-8592

User Guide

ErecAid® Esteem® Manual and Automatic Vacuum Therapy System

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Principles of Operation

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 or band holds the blood in the penis, keeping the erection long enough to have sexual intercourse. When the ring or band is removed, the erection quickly goes away.

Using A Vacuum Therapy Device

Please read the following information carefully before using your ErecAid. While no serious injury has been reported from proper use of this device, it is still important to observe some simple precautions. If you have any questions, call Timm Medical Technologies, Inc.'s toll free help line at **800-438-8592**.



!\ Contraindications

External vacuum therapy is a proven way to treat Erectile Dysfunction, or impotence. However, some patients should <u>not</u> 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.
- 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.

For the general population, there is no inherent or significant risk in properly using a vacuum device. Misuse of the device or tension rings, however, may result in painful or permanent injury to the penis. Users should therefore read and follow instructions very carefully.



Caution Talk to your doctor if any complications occur in using this device. Stop using the device if complications continue.

Caution 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.

Caution 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).

- 1. 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 the 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.
- 2. Ask your doctor about using the ErecAid if you are taking anticoagulant (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.
- 3. Do not use the vacuum pump under the influence of drugs or alcohol. These substances may reduce your sensitivity to pain or impair your ability to follow directions properly.
- 4. The vacuum pump may bruise the blood vessels just below the surface of the skin, which may cause petechiae (very tiny spots beneath the skin) when you first begin using your 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 about five to seven days.
- 5. 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.

- 6. 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.
- 7. If you notice a bend or curve in your penis when you first use your ErecAid, talk to your physician.
- 8. 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.
- 9. 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.
- 10. Tension rings are not a means of birth control. Do not rely on tension rings to avoid pregnancy.
- 11. Always use the lowest amount of tension necessary to maintain the erection. Start by using the largest size ring with the lowest tension. Add tension, if necessary, by using the next lowest tension level. Do not skip a level when adding tension.
- 12. After a period of inactivity when the pump has not been utilized, exercise sessions will again be necessary to recondition penile tissue prior to resuming sexual activity.
- 13. If you will not be having sexual activity on a regular basis, you need to continue therapy exercise sessions on a regular basis.

Important – Initial Practice Sessions and Regular Exercises are Recommended for Most Patients

Before using your ErecAid® System for intercourse, you must become familiar with using the ErecAid system to create erections. You will be more satisfied with your results by taking the time to complete initial practice sessions and conducting ongoing exercises.

Initial Practice Sessions

After a period of sexual inactivity, 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, the best pumping rate for you and the most effective technique for getting a good seal and a firm erection. Practice sessions also help you understand what to expect from the ErecAid system, and the sessions can help you become more confident and more satisfied with your sexual experiences. Initial practice sessions should be conducted daily for the first two weeks of use.

Ongoing Exercises

Ongoing exercises help most patients maintain a comfort level with the use and operation of the ErecAid system. These sessions may also help maintain the condition of penile tissue and improve a user's satisfaction when creating erections for intercourse. Ongoing exercises should be conducted on a regular basis.

How to Do Initial Practice Sessions and Ongoing Exercises:

- The objective of these sessions is to create, hold, and release a series of erections so that your penis becomes accustomed to filling with blood.
- Sessions should last approximately 10 to 15 minutes.
- DO NOT use tension rings during initial practice or ongoing exercises.
- Create an erection following steps 1-4 in the appropriate section of this User's Guide.
 - o Manual Model refer to page 14.
 - \circ Automatic Model refer to page 28.
- Hold the erection for 30 to 60 seconds.
- Press the green button on your pump handle to release the vacuum pressure.
 This will cause your penis to become soft.
- Without removing the device, continue the cycle of creating an erection, holding the erection for 30 to 60 seconds, and releasing the erection. Do this for 10 to 15 minutes daily during the first two weeks of use and periodically thereafter for best results.

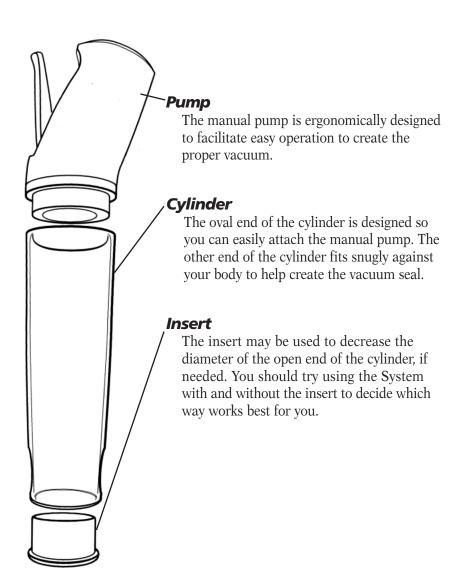
ErecAid® Esteem® Vacuum Therapy System

Manual Model



Components - Manual Model

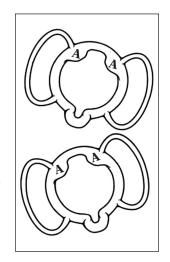
Study the diagram to become familiar with the name and purpose of each part of your new ErecAid Esteem System before you apply the device.



Pressure-Point™ Tension Rings

The patented pressure-point tension rings are medically engineered for safety, performance and comfort. You may use the rings individually or in various combinations to keep your erection once you have created it using the System (refer to Situation on page 34). You will have four pressure-point tension rings packaged with your System: one Medium and one Large ring in standard tension (beige); one Medium and one Large ring in high tension (pink). See Ring Tension Chart for tension and color details on page 9.

NOTE: Please note that tension rings are a disposable item. Actual service life depends upon use and storage.



Easy-Action® Ring Applicator

The Easy-Action ring applicator is a specially designed tool that lets you easily load the Pressure-Point tension ring(s) onto your ErecAid Esteem System cylinder.

The Easy-Action ring applicator consists of two parts – a top part, or cap, and a bottom part, or cone.

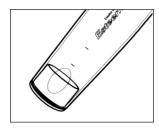


Lubricant

Osbon Personal Lubricant™ plays an important part in the overall function of the System. Proper application of our watersoluble lubricant to the head of the penis and to the open end of the cylinder helps create a good vacuum seal against the body. The lubricant also helps you to load and remove the tension rings. You should use only water-based Osbon Personal Lubricant. Other lubricants may damage the tension rings and other System parts, as well as void your limited lifetime warranty.



How to Assemble - Manual Model





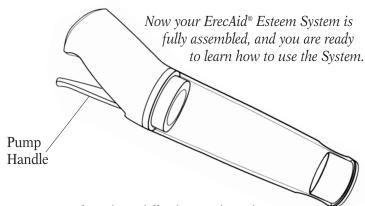
Step 1

Start with the insert in the smaller end of the cylinder, as packaged. The insert narrows the inside of the cylinder and keeps scrotal tissue from being drawn in while you create your erection. If your erection presses uncomfortably against the inside of the insert, remove the insert and use the cylinder without it.

Step 2

Align the large oval opening of the cylinder to the oval end of the pump.

The labeling on the cylinder should be facing up, with the pump handle facing down. Now, attach the pump to the cylinder by placing the bottom of the pump into the cylinder, then tilt or rock the pump into place. The pump should fit evenly into the cylinder but it may not be completely flush to the cylinder itself. A small gap is normal as the fit between the cylinder and the pump is designed to "wear in" over time.



PLEASE NOTE: If you have difficulty attaching the pump to the cylinder, using your index finger, apply a small amount of lubricant to the outer rim of the pump. This will allow the cylinder to connect more easily. Use only a small amount of lubricant as excess can seep into the pump and cause damage.

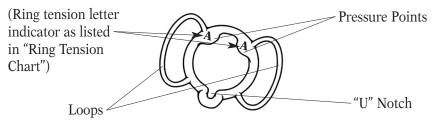
How to Select the Tension Ring

You will need to experiment to find the tension ring that's right for you. Begin with the largest Ring (A) and determine if it is comfortable and provides a satisfactory erection. If not, try the (B) Ring then and then the (C) Ring and then the (D) Ring. Always try to keep the erection with the least amount of tension. Correct positioning of the tension ring is also necessary to keep the erection. Tension rings should be positioned so that the "U" shaped notch is on the bottom of the penis and the pressure points are at the top of the penis.

NOTE: When using a combination of rings, the ring with the greatest amount of tension should be closest to your body. See page 34 for instructions on loading and transferring no more than two tension rings.

COLOR CODED TENSION RINGS

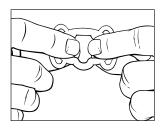
BEIGE	PINK
Standard Tension	High Tension



Ring Tension Chart		
Minimum	Level One	One large standard-tension ring (beige-A)
Tension	Level Two	One large high-tension ring (pink-B)
	Level Three	One medium standard-tension ring (beige-C)
	Level Four	One medium high-tension ring (pink-D)
Level Six Level Seven Maximum Tension	One medium standard-tension (beige-C) and One large standard-tension ring (beige-A)	
	Level Six	One medium high-tension (pink-D) and One large high-tension ring (pink-B)
	Level Seven nsion	One medium high-tension (pink-D) and One medium standard-tension ring (beige-C)

How to Load the Tension Ring Manually

Loading With Your Index Fingers:



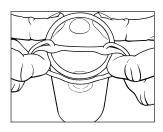
Step 1

Place the cylinder between your legs so the ErecAid labeling on the cylinder is facing you. Now, hold the tension ring so the U-notch is facing away from you, and your index fingers are on the inside of the ring.



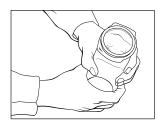
Step 2

Place the U-notch on the lip of the cylinder farthest away from you. With your index fingers inside the tension ring, pull the tension ring over the cylinder. **Do not** use the outer loops.



Step 3

Pull the tension ring over the lip of the cylinder by pushing on the cylinder with your thumbs and pulling the tension ring across with your index fingers.



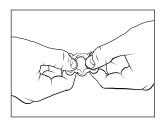
Step 4

The tension ring should now be around the lip of the cylinder. If you need to add additional rings to the cylinder, slide the first ring 1/4" towards the pump handle to allow space for the additional ring. Then, choose an additional ring and repeat steps 1 through 3.

How to Load the Tension Ring Manually

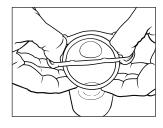
(continued)

Loading With Your Thumbs:



Step 1

Place the cylinder between your legs so the ErecAid labeling on the cylinder is closest to you. Now, hold the tension ring so the U-notch is pointing away from you, and your thumbs are on the inside of the ring.



Step 2

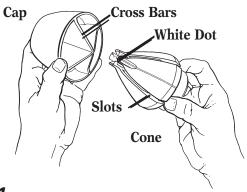
With your thumbs on the inside of the tension ring and the U-notch pointing away from you, begin stretching the tension ring over the lip of the cylinder. Use your index fingers as leverage to stretch the tension ring over the lip of the cylinder with your thumbs. Start from the part of the cylinder closest to you and move out.

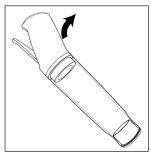


Step 3

The tension ring should now be around the lip of the cylinder. If you need to add additional rings to the cylinder, slide the first ring 1/4" towards the pump handle to allow space for the additional ring. Then, choose an additional ring and repeat steps 1 through 2.

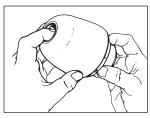
How to Load the Tension Ring Using the Easy-Action® Ring Applicator





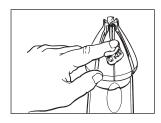
Step 1

Remove the pump and the insert from the cylinder. Put a towel on a table or counter top and stand the cylinder on top of the towel with the large end of the cylinder face down. The towel will keep the cylinder from slipping.



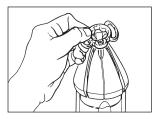
Step 2

Separate the Easy-Action ring applicator by holding the base of the cone in your hand and then pushing the button on the top of the cap. Place the base of the ring applicator cone in the small open end of the cylinder. Twist the cone so that the white dot on top of the cone lines up with the cylinder groove opposite the cylinder label.



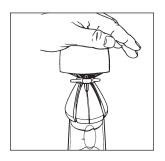
Step 3

Lubricate the entire cone surface with Osbon Personal Lubricant[™] or the tension ring can be damaged.



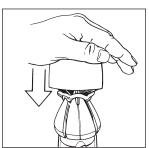
Step 4

Place the tension ring on the cone, making sure to align the **U-notch** on the tension ring with the **white dot** on the cone.



Step 5

Place the cap back on the cone and tension ring, lining up the cross bars of the underside of the cap with the slots on the top of the cone.



Step 6

Press straight down on the cap of the ring applicator with one hand while holding the cylinder in an upright position on the towel with your other hand to help stabilize it.



Step 7

The tension ring should now be transferred to the cylinder in the correct position. If you need to add additional rings to the cylinder, slide the first ring 1/4" towards the pump end of the cylinder to allow space for the additional ring(s). Then, choose another ring and repeat steps 2 through 6.



Step 8

After you have loaded your tension ring(s), remove your ring applicator from the cylinder and replace the insert. Place the pump handle back on to the cylinder. You are now ready to create an erection with your ErecAid® Esteem® System.

How to Create an Erection – Manual Model

Assemble your System according to the two-step procedure on page 8.

* Please see page 4 for instructions of practice and exercise sessions.



Step 1

Apply Osbon Personal Lubricant[™] to the following:

- 1. two inches inside the open end of the cylinder;
- 2. the rim of the cylinder which meets the body to form the vacuum seal; and
- 3. the entire head of the penis.



Applying lubricant properly will help you achieve the best erection possible.

Tip: Trimming the pubic hair around the base of the penis with a pair of scissors may also prove helpful in creating an airtight seal.



Step 2

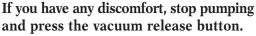
It is recommended that you stand for this step (the System can also be used when you are sitting or lying down).

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

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

Step 3

Pump slowly to remove the air from the cylinder. Begin by pressing the pump handle two times to create the vacuum seal. Then 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.



Then begin pumping again. Continue slowly for best results, waiting 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 find out how many times you'll need to pump.





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.

NOTE: It may take a bit longer than expected for some men to get an erection. By repeating the exercise sessions, you'll be able to get a firmer erection more quickly and be able to use less vacuum.



How to Keep the Erection – Manual Model

With the tension ring loaded on your cylinder, follow the steps you've learned already to create an erection using the System. Remember to use Osbon Personal LubricantTM and to place the cylinder over your penis ensuring the "U" notch is to the bottom of the penis and the loops are to the top.

NOTE: 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.



Step 2

Note: You may also push 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.

Removing the Tension Rings

Remove the tension ring(s) after sexual activity. 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 **SLIGHTLY** outward, away from the penis. Hold the loops outward for at least 10 seconds or until the penis loses some firmness.

NOTE: Lying down will help the blood flow into the body faster.

Step 3

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

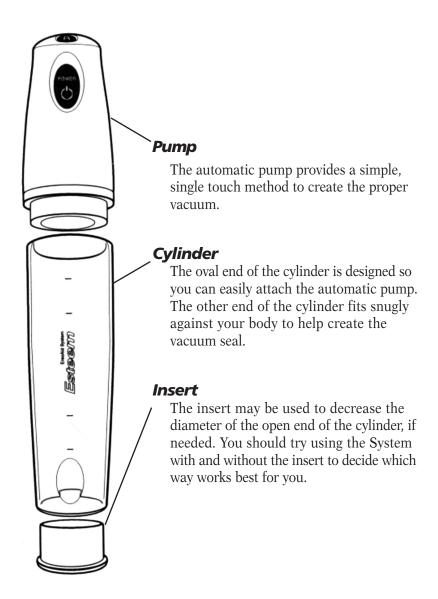
ErecAid® Esteem® Vacuum Therapy System

Automatic Model



Components – Automatic Model

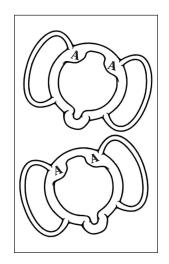
Study the diagram to become familiar with the name and purpose of each part of your new ErecAid Esteem System before you apply the device.



Pressure-Point™ Tension Rings

The patented pressure-point tension rings are medically engineered for safety, performance and comfort. You may use the rings individually or in various combinations to keep your erection once you have created it using the System (refer to Situation on page 34). You will have four pressure-point tension rings packaged with your System: one Medium and one Large ring in standard tension (beige); one Medium and one Large ring in high tension (pink). See Ring Tension Chart for tension and color details on page 23.

NOTE: Please note that tension rings are a disposable item. Actual service life depends upon use and storage.



Easy-Action® Ring Applicator

The Easy-Action ring applicator is a specially designed tool that lets you easily load the Pressure-Point tension ring(s) onto your ErecAid Esteem System cylinder.

The Easy-Action ring applicator consists of two parts – a top part, or cap, and a bottom part, or cone.



Lubricant

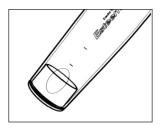
Osbon Personal Lubricant™ plays an important part in the overall function of the System. Proper application of our watersoluble lubricant to the head of the penis and to the open end of the cylinder helps create a good vacuum seal against the body. The lubricant also helps you to load and remove the tension rings. You should use only water-based Osbon Personal Lubricant. Other lubricants may damage the tension rings and other System parts, as well as void your limited lifetime warranty.



How to Assemble – Automatic Model

Step 1

Start with the insert in the smaller end of the cylinder, as packaged. The insert narrows the inside of the cylinder and keeps scrotal tissue from being drawn in while you create your erection. If your erection presses uncomfortably against the inside of the insert, remove the insert and use the cylinder without it.



Step 2

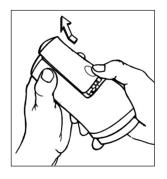
Align the large oval opening of the cylinder to the oval end of the pump.

The labeling on the cylinder should be facing up and in line with the power button on the pump. Now, attach the pump to the cylinder by placing the bottom of the pump into the cylinder, then tilt or rock the pump into place. The pump should fit evenly into the cylinder but it may not be completely flush to the cylinder itself. A small gap is normal as the fit between the cylinder and the pump is designed to "wear in" over time.



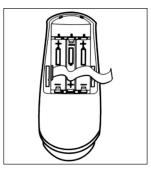


How to Load the Batteries – Automatic Model



Step 1

The battery compartment door is located on the back of the pump. Remove the door by pressing firmly and sliding it towards the vacuum release button.



Step 2

Load the batteries to match the diagram inside the compartment. The System operates on three (3) AA-size batteries. Slide the battery compartment door back in place.

NOTE: Be sure to load your new batteries on top of the ribbon found in the compartment. By doing this, you can pull up on the ribbon to easily lift them out of the compartment when it is time for replacement.

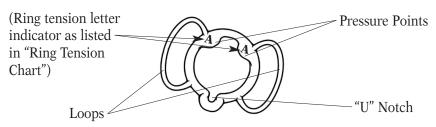
How to Select the Tension Ring

You will need to experiment to find the tension ring that's right for you. Begin with the largest Ring (A) and determine if it is comfortable and provides a satisfactory erection. If not, try the (B) Ring then and then the (C) Ring and then the (D) Ring. Always try to keep the erection with the least amount of tension. Correct positioning of the tension ring is also necessary to keep the erection. Tension rings should be positioned so that the "U" shaped notch is on the bottom of the penis and the pressure points are at the top of the penis.

NOTE: When using a combination of rings, the ring with the greatest amount of tension should be closest to your body. See page 34 for instructions on loading and transferring no more than two tension rings.

COLOR CODED TENSION RINGS

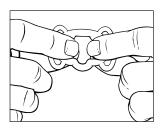
BEIGE PINK Standard Tension High Tension



Ring Tension Chart			
Minimum Level One	One large standard-tension ring (beige-A)		
Tension	Level Two	One large high-tension ring (pink-B)	
	Level Three	One medium standard-tension ring (beige-C)	
	Level Four	One medium high-tension ring (pink-D)	
Level Six Level Seven Maximum Tension	One medium standard-tension (beige-C) and One large standard-tension ring (beige-A)		
	Level Six	One medium high-tension (pink-D) and One large high-tension ring (pink-B)	
	Level Seven nsion	One medium high-tension (pink-D) and One medium standard-tension ring (beige-C)	

How to Load the Tension Ring Manually

Loading With Your Index Fingers:



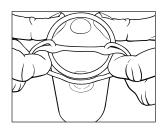
Step 1

Place the cylinder between your legs so the ErecAid labeling on the cylinder is facing you. Now, hold the tension ring so the U-notch is facing away from you, and your index fingers are on the inside of the ring.



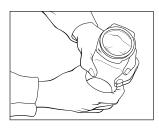
Step 2

Place the U-notch on the lip of the cylinder farthest away from you. With your index fingers inside the tension ring, pull the tension ring over the cylinder. **Do not** use the outer loops.



Step 3

Pull the tension ring over the lip of the cylinder by pushing on the cylinder with your thumbs and pulling the tension ring across with your index fingers.



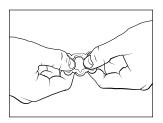
Step 4

The tension ring should now be around the lip of the cylinder. If you need to add additional rings to the cylinder, slide the first ring 1/4" towards the pump handle to allow space for the additional ring. Then, choose an additional ring and repeat steps 1 through 3.

How to Load the Tension Ring Manually

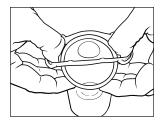
(continued)

Loading With Your Thumbs:



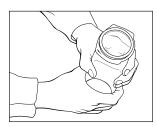
Step 1

Place the cylinder between your legs so the ErecAid labeling on the cylinder is closest to you. Now, hold the tension ring so the U-notch is pointing away from you, and your thumbs are on the inside of the ring.



Step 2

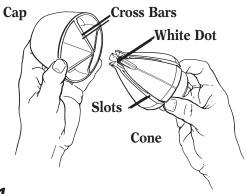
With your thumbs on the inside of the tension ring and the U-notch pointing away from you, begin stretching the tension ring over the lip of the cylinder. Use your index fingers as leverage to stretch the tension ring over the lip of the cylinder with your thumbs. Start from the part of the cylinder closest to you and move out.

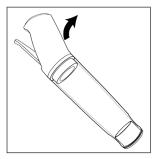


Step 3

The tension ring should now be around the lip of the cylinder. If you need to add additional rings to the cylinder, slide the first ring 1/4" towards the pump handle to allow space for the additional ring. Then, choose an additional ring and repeat steps 1 through 2.

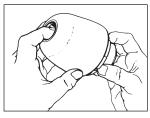
How to Load the Tension Ring Using the Easy-Action® Ring Applicator





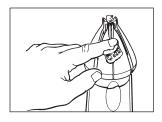
Step 1

Remove the pump and the insert from the cylinder. Put a towel on a table or counter top and stand the cylinder on top of the towel with the large end of the cylinder face down. The towel will keep the cylinder from slipping.



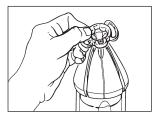
Step 2

Separate the Easy-Action ring applicator by holding the base of the cone in your hand and then pushing the button on the top of the cap. Place the base of the ring applicator cone in the small open end of the cylinder. Twist the cone so that the white dot on top of the cone lines up with the cylinder groove opposite the cylinder label.



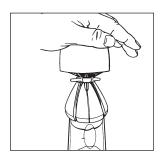
Step 3

Lubricate the entire cone surface with Osbon Personal Lubricant[™] or the tension ring can be damaged.



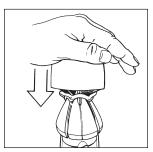
Step 4

Place the tension ring on the cone, making sure to align the **U-notch** on the tension ring with the **white dot** on the cone.



Step 5

Place the cap back on the cone and tension ring, lining up the cross bars of the underside of the cap with the slots on the top of the cone.



Step 6

Press straight down on the cap of the ring applicator with one hand while holding the cylinder in an upright position on the towel with your other hand to help stabilize it.



Step 7

The tension ring should now be transferred to the cylinder in the correct position. If you need to add additional rings to the cylinder, slide the first ring 1/4" towards the pump end of the cylinder to allow space for the additional ring(s). Then, choose another ring and repeat steps 2 through 6.



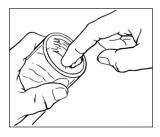
Step 8

After you have loaded your tension ring(s), remove your ring applicator from the cylinder and replace the insert. Place the pump handle back on to the cylinder. You are now ready to create an erection with your ErecAid® Esteem® System.

How to Create an Erection – Automatic Model

Assemble your System according to the two-step procedure on page 21.

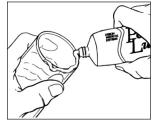
* Please see page 4 for instructions of practice and exercise sessions.



Step 1

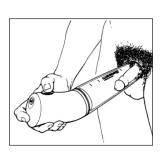
Apply Osbon Personal Lubricant[™] to the following:

- 1. two inches inside the open end of the cylinder;
- 2. the rim of the cylinder which meets the body to form the vacuum seal; and
- 3. the entire head of the penis.



Applying lubricant properly will help you achieve the best erection possible.

Tip: Trimming the pubic hair around the base of the penis with a pair of scissors may also prove helpful in creating an airtight seal.

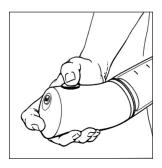


Step 2

It is recommended that you stand for this step (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. With one hand, hold the cylinder at a downward 45° angle with the open end snugly against the body.

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







Press the power button on the pump to remove the air from the cylinder. Now begin creating the vacuum by pressing the power button on the pump for several seconds. Then stop the pump and wait 5 to 10 seconds to increase blood flow. If the vacuum pressure increases too quickly, you may feel discomfort.

If you have any discomfort, stop the pump and press the vacuum-release button. Then turn the pump on again for several seconds. Rather than running the pump continually, it is recommended that the pump be turned on for several seconds then turned off for 5 to 10 seconds.

Continue this until you have achieved an erection. You may need to press the vacuum-release button several times. The amount of vacuum needed for a firm erection will vary according to the individual. Experiment to find out how long you'll need to keep the pump running.



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.

NOTE: It may take a bit longer than expected for some men to get an erection. By repeating the exercise sessions, you'll be able to get a firmer erection more quickly and be able to use less vacuum.

How to Keep the Erection – Automatic Model

With the tension ring loaded on your cylinder, follow the steps you've learned already to create an erection using the System. Remember to use Osbon Personal Lubricant TM and to place the cylinder over your penis ensuring the "U" notch is to the bottom of the penis and the pressure point bumps are to the top.

NOTE: 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.



Step 2

Press the green vacuum-release button and remove the cylinder. Set the cylinder aside during sexual activity. 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.

Removing the Tension Rings

Remove the tension ring(s) after sexual activity. 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 **SLIGHTLY** outward, away from the penis. Hold for at least 10 seconds or until the penis loses some firmness.

Step 3

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

NOTE: Lying down will help blood flow into the body faster.

Tips for Best Results

After a period of sexual inactivity, the vessels in the penis need to become accustomed to being filled with blood again. After a period of inactivity when the pump has not been utilized, exercise 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 exercise sessions on a regular basis. Follow the practice session outlined on page 4 to ensure best results.

- **1.** Be sure the cylinder is firm against your body. If you allow air to enter the cylinder, the vacuum will not be sufficient to create an erection. If getting a good seal is difficult for you, trim the pubic hair around the base of the penis so the cylinder can make better contact with your skin. Remember to apply lubricant to the rim of the cylinder. The lubricant is designed to help create a proper seal.
- **2.** Allow your erection to develop slowly. Increasing the vacuum too quickly may cause discomfort or temporary bruising.
- **3.** If you lose your erection with the tension ring in place, you may need to increase the amount of tension. Refer to the chart on page 23 to select the best tension for you.
- **4.** You may also lose the erection if air enters the cylinders 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).
- **5.** Be sure to remove the tension ring(s) within 30 minutes. Do not fall asleep with the tension ring(s) in place. Remove the tension ring(s) before urinating.
- **6.** An erection achieved with the System usually has greater girth (thickness), since the blood vessels are filled to their maximum potential. However, ErecAid Esteem System is not an enlargement device; it simply allows the penis to obtain its largest natural state.
- **7.** Keep in mind that 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.

NOTE: For automatic model, be sure the batteries are in good working order before applying the System. Insufficient power may not provide enough vacuum to create an erection. Be sure to remove batteries if anticipating an extended period between applications of the System. Whenever you turn off the automatic pump, be sure to press the vacuum-release button briefly before restarting the pump motor.

Situations and Recommendations

Just as there are many causes of Erectile Dysfunction, many different situations may occur with its management. Some situations may require special attention as you use ErecAid® Esteem® System. If you encounter any of the situations described on the following pages, follow the recommendations outlined to achieve a comfortable erection with your ErecAid System.

This information is not intended to take the place of medical advice from your prescribing physician.

Situation – Erection Not Suitable for Intercourse

You have used the pump and cylinder to obtain an erection, but have not achieved an erection suitable for intercourse.

Recommendation

- 1. Liberally lubricate the head of your penis, two inches (5 cm) inside the open end of the cylinder and the rim of the cylinder, as previously described.
- 2. Place the lubricated penis into the cylinder. Pump slowly, pausing for 5 to 10 seconds between pumps.
- 3. If the penis starts to tingle or feels uncomfortable while pumping, push the vacuum-release button until that particular feeling goes away. Resume pumping until the uncomfortable feeling starts again or until you achieve an erection.
- 4. Release the vacuum, allowing the penis to become soft. Without removing the cylinder, repeat steps two and three.

Practice this process 10 to 15 minutes daily without the tension ring(s) until you can achieve and maintain an erection within the cylinder. Repeat for a minimum of two weeks and periodically thereafter.

Situation - Initial Loss of Firmness

You lose firmness when you transfer the tension ring(s).

Recommendation

Reapply vacuum with ring(s) still in place. Be sure 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.

Situation – Loss of Firmness During Sexual Activity

You have used each of the tension rings individually but still lose firmness during sexual activity. In other words, Tension Levels 1-4 (described in the tension chart below) have not provided sufficient firmness.

		Ring Tension Chart
Minimum	Level One	One large standard-tension ring (beige-A)
Tension	Level Two	One large high-tension ring (pink-B)
	Level Three	One medium standard-tension ring (beige-C)
	Level Four	One medium high-tension ring (pink-D)
	Level Five	One medium standard-tension (beige-C) and
		One large standard-tension ring (beige-A)
	Level Six	One medium high-tension (pink-D) and
		One large high-tension ring (pink-B)
	Level Seven	One medium high-tension (pink-D) and
Maximum Tension		One medium standard-tension ring (beige-C)

Recommendation

Remove the single tension ring from the penis. Follow the steps below to position and transfer no more than <u>two</u> tension rings.

- 1. Begin with one medium and one large standard-tension ring (Tension Level 5, described on pages 9 & 23). Continue adjusting ring tension up to Tension Level 7 until sufficient firmness is achieved. 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.
- 2. Position the ring with the greater amount of tension on the cylinder <u>first</u>. Once loaded on the cylinder, slide the first ring 3/4" away from the end of the cylinder to allow room for the second ring.
- 3. Position the second ring (lower tension) on the cylinder and recreate the erection.
- 4. Transfer the lowest tension ring onto the base of your penis this will break the vacuum seal.
- 5. *NOTE:* If you are using the insert, remove it now to reposition the cylinder over the tension ring on the penis. Twist the cylinder slightly to move it over the applied ring and re-create the vacuum. The lower tension ring will now be inside the cylinder.
- 6. Re-create the vacuum until the penis again lifts from the floor of the cylinder. Transfer the second ring (higher tension) onto the base of the penis, so that it leap frogs over the first ring and is closest to the body.
- 7. If you continue to lose firmness during sexual activity after trying all seven tension levels outlined in the chart above, call Timm Medical Technologies, Inc.'s Technical Support for assistance.

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Situation – Scrotal Tissue Pulled into Cylinder

The force of the vacuum pulls body or scrotal tissue into the cylinder.

Recommendation

- 1. Remember to pump slowly.
- 2. Try using the optional adapter insert.
- 3. In the beginning, do not apply lubricant to the rim area of the cylinder that comes into contact with scrotal tissue. However, 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.
- 4. 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.
- 5. If these steps do not solve the issue, an EZ™ Tension Ring will be helpful.

NOTE: Call Timm Medical Technologies, Inc.'s Technical Support for assistance and information about optional EZ Tension Rings at 800-438-8592.

Situation – Erect Penis has Distortion or Curvature

While using your ErecAid Esteem system, you discover that the erect penis has a distortion or curvature.

Recommendation

If you notice a distortion, bend or curve in your penis when you first use your ErecAid 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. See Glossary for definition.

Situation - Unable to Release Vacuum

You have achieved an erection and the release button does not release pressure.

Recommendation

- 1. Press and hold release button.
- 2. Place one finger between the cylinder and body to manually release vacuum.

Don't Worry If . . .

...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 fast. Simply press the vacuum-release button, wait a moment and begin again.

...Your penis turns slightly dusky or bluish in color after you apply the tension ring(s). This is a normal response to the increase of blood in the penis. The discoloration should disappear when you remove the tension ring(s).

...You experience some petechiae (very tiny reddish spots beneath the skin) or bruising of the penis when you first begin using your 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 – about five to seven days.

...You notice a slight drop in the temperature of the penis. This coolness is not harmful. It is a normal response to the reduced blood flow caused by the tension ring. It is possible to warm your penis by wrapping a warm washcloth around it for several moments.

...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 guide the penis into the vagina or try different positions with your partner for successful intercourse.

...Your semen does 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). (Note: Tension rings are NOT a means of contraception.)

...Your cylinder develops condensation on the inside. This is simply the result of the heat from your body reacting with the lubricant. (Note: This "fogging" can be reduced by running warm water over your cylinder and then drying it before you use the System.)

System Care

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

- **1.** Remove the vacuum pump and the insert, if used, from the cylinder. Separate the Easy-Action® ring applicator into its two parts, being sure the cap button remains depressed.
- **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 cylinder, insert, tension ring(s) and ring applicator with warm, soapy water. **Never place any ErecAid® component in dishwasher or microwave.** We recommend that you use liquid soap when cleaning your System. Rinse thoroughly.
- **4.** Let all the parts air-dry thoroughly in a ventilated place before storing. Be sure to store the System unassembled.

Glossary of Terms

ERECTILE DYSFUNCTION (ED) the inability to get and keep a penile erection suitable for sexual intercourse.

ERECTION the bodily process in males which fills and stores blood in the penis, making it rigid.

IMPOTENCE a common name for Erectile Dysfunction.

PETECHIAE tiny, round purplish-red spots caused by broken or swollen blood vessels just beneath the surface of the skin.

PEYRONIE'S DISEASE a condition in which the penis curves or bends abnormally due to a build-up of scar tissue inside the penis.

PRIAPISM an erection that lasts more than four hours; an abnormally prolonged erection.

SCROTUM the soft pouch or sac at the base of the penis which contains the testes.

URETHRAL STRICTURE scar tissue inside the penile urination channel which may cause the channel to narrow, blocking the flow of urine and/or semen.

Notes and Cautions



This symbol means: Attention, consult accompanying documents.



This symbol indicates Type BF equipment.



This symbol indicates that the ErecAid Automatic System should be disposed of properly according to your local laws on regulation.



CAUTIONS:

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



This device requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.



This device may be affected by portable and mobile RF communications equipment.



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



NOTE ON CLASSIFICATION:

This device is classified as internally powered.

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.



Guidance and manufacturer's declaration – electromagnetic emissions

The Esteem Automatic is intended for use in the electromagnetic environment specified below. The customer or the user of the Esteem Automatic should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Esteem Automatic uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Esteem Automatic is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	



Guidance and manufacturer's declaration – electromagnetic immunity

The Esteem Automatic is intended for use in the electromagnetic environment specified below. The customer or the user of the Esteem Automatic should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Esteem Automatic requires continued operation during power mains interruptions, it is recommended that the Esteem Automatic be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE UT is the a.c. mains voltage prior to application of the test level.



Guidance and manufacturer's declaration – electromagnetic immunity

The Esteem Automatic is intended for use in the electromagnetic environment specified below. The customer or the user of the Esteem Automatic should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Esteem Automatic, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	d = 1.2√P
			d = 1.2√P 80 MHz to 800 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 2.3√P 800 MHz to 2.3 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Esteem Automatic is used exceeds the applicable RF compliance level above, the Esteem Automatic should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Esteem Automatic.



Recommended separation distances between portable and mobile RF communications equipment and the Esteem Automatic

The Esteem Automatic is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Esteem Automatic can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Esteem Automatic as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of	Separation distance according to frequency of transmitter			
150 kHz to 80 MHz W	150 kHz to 80 MHz d = 1.2 P	80 MHz to 800 MHz d = 1.2 P	800 MHz to 2.5 GHz d = 2.3 P	
0.01	.12m	.12m	.23m	
0.1	.38m	.38m	.76m	
1	1.2m	1.2m	2.3m	
10	3.8m	3.8m	7.6m	
100	12m	012m	23m	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

For Further Assistance

If you still have questions on the application of your ErecAid® Esteem® System after reading this Guide and viewing your video, call Timm Medical Technologies, Inc.'s Customer Care team at 800-438-8592.

When you call our Customer Care team, you will have a private conversation with a trained professional who has earned accredited certification in vacuum therapy training with ErecAid Esteem System. Most patients find that spending a few minutes receiving professional instruction from a Customer Care Specialist will quickly help resolve any difficulties that may be encountered when using the ErecAid system.

Please note that Customer Care Specialists have earned accredited certification in a vacuum therapy training with ErecAid Esteem System but they are not physicians. If you have a question or a problem that requires medical attention, please contact your physician.

Patients who obtained their ErecAid system outside of the United States should contact the local distributor for assistance or instruction.

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Caution: US federal law restricts this device to sale by or on the order of a physician.



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