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# A Couple's Guide

for the Treatment of Erectile Dysfunction

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## *Dear Couple,*

*Until a few years ago, you had few choices for treating Erectile Dysfunction or impotence. This is not the case today. Thanks to a large amount of creative work in the past twenty years, virtually every man experiencing Erectile Dysfunction can be treated successfully. The choices range from psychological therapy to surgery, from external devices to internal ones, and from oral medications to injections.*

*Urologists administer most of these treatments. General practitioners have also discovered that they can safely prescribe many of the treatments. This is important because Erectile Dysfunction is often the first symptom of other more serious conditions like diabetes, high blood pressure and vascular disease.*

*It is well documented that ten to 15 percent of all men experience some degree of Erectile Dysfunction. This statistic includes one out of every three men over the age of 60. These men tend to visit a family doctor on occasion. If this physician is alert and inquisitive about sexual function, the opportunity exists to discover the Erectile Dysfunction, determine its underlying cause and offer successful treatment.*

*No couples have to live with Erectile Dysfunction any longer because of the availability of many good treatments. One hour of your time reading this guide will help you and your partner learn about treatments that can dramatically change your lives.*

*Timm Medical Technologies, Inc., a leader in Erectile Dysfunction research is honored to present this information to you. It is our belief that being better informed will help caring couples pursue the best treatment option available. Please feel free to contact us should you need any further information as you make your treatment decisions.*

*Sincerely,*

*Timm Medical Technologies, Inc.*

## **Admitting Impotence to Yourself**

Many men develop Erectile Dysfunction (ED) or impotence, but never admit it to themselves or their partners. Sadly, this denial prevents couples from enjoying sexual activity on a regular basis. Over 30 million American men have ED, but fewer than 10 million have been treated.

Ignoring the problem was normal behavior years ago, but today sexual wellness is often viewed as an indicator of total health. As couples are living longer, they have an interest in treating Erectile Dysfunction. Their pride factor does not inhibit treatment as it once did. Today, there are many effective treatments to choose from, but the first step is admitting the problem.

## Examine Your Thoughts and Beliefs

### What Men Think About Erectile dysfunction

*“If I can’t have normal sex with my wife, I’m a failure as a man and lover. I feel like a real loser and I can’t stop thinking about the problem.”*

Men who equate sexual satisfaction solely with performance may think of themselves as failures. This problem causes a lapse of confidence and a crisis in self-esteem. Men commonly report that the problem occupies a lot of their mental energy and that they can not seem to stop thinking about their problem.

*“If I show her affection, she’ll want to have intercourse and then what?”*

Men with erectile difficulties tend to emotionally and physically withdraw from their partners. They fear that any physical affection will precipitate a request or desire for intercourse from their mates and remind them of their inability to achieve an erection. Compounding the problem, women may also cease being affectionate.

*“Something must be wrong with me. I feel that I have no control over my own body and now that sex is out, I’m lonely. She won’t touch me anymore.”*

Many men, especially older ones, think that it is inappropriate to need nurturance and affection. So, they frequently do without the warmth, comfort and emotional support often more available to women. It is frequently considered inappropriate for a man to admit that he needs a hug and someone to hold him. When a man cannot perform intercourse and satisfy his own (and his partner’s) sexual needs, he feels emasculated, devastated and very much alone.

*“If I can’t meet her sexual needs, she will leave me.”*

Men, too, share fears of abandonment. Younger men, particularly, feel vulnerable and concerned that their partner will seek a new,

more fulfilling, less problematic relationship. To some extent, their fears are realistic. A younger woman may want to have an active sexual life and over a long period of time be less patient and supportive.

*“Before I developed my erectile problem, I found my partner sexually stimulating. Not any more. The thrill is gone. I wonder if I’ve fallen out of love? She just doesn’t appeal to me anymore.”*

When a man or a woman loses a loving sexual relationship due to Erectile Dysfunction, either or both individuals may choose to “desexualize” their mate. After experiencing the pain associated with rejection and partner apathy, men and women will divert their attention to other matters in order to compensate for the loss of their sexual partner. It may take counseling intervention before couples can rekindle romance and “reprogram” themselves and once again think of each other as desirable, stimulating sexual companions.

## **What Women Think About Erectile Dysfunction**

When confronted with their partner’s sexual dysfunction, women begin to explore possible reasons for this problem. After initial feelings of self-blame, women share many of the same concerns.

*“Maybe he is sick and there’s a medical reason for this problem.”*

Approximately 85% of all cases of impotence are caused by specific, diagnosable, physical conditions. Most of these problems are treatable and some are curable. Men who are sexually impaired should have a medical evaluation.

*“I wonder if something is wrong with our relationship?”*

Sometimes potency problems are a screen for more serious emotional or relationship issues. If there is loving affection and a committed friendship between partners, almost all problems can be improved or resolved. Couples’ counseling may be a good place to begin problem-solving and bridging communication gaps.

*“Maybe he’s angry at me. Maybe I’m angry with him too.”*

Anger whether or not openly expressed, interferes with sexual desire in many couples. Anger evoked by daily irritations or disagreements is present in almost all relationships. But profound anger, fear or anxiety related to impotence are more serious. Strong, negative feelings usually must be resolved in order for medical treatment to be effective.

*“Is he having an affair? Is he going to leave me?”*

Women who measure their self-esteem, femininity and desirability by how well men respond to them sexually are particularly vulnerable to fears of abandonment and rejection. Men’s emotional detachment feeds into these fears. Women may worry that their mates may be impotent with them, but potent with other women, leaving them with fantasies of betrayal and infidelity.

*“Honestly, I’m secretly relieved. I don’t miss not having sex anymore.”*

Some women are quietly relieved that their partner is experiencing ED. For a variety of reasons, they have never found sexual intercourse to be emotionally gratifying or physically satisfying. Strong negative attitudes or previous negative sexual experiences may undermine the success of any medical or psychological intervention.

## Explore The Relationship Factors That Predict Successful Treatment

Successful treatment of any sexual dysfunction is directly related to the quality of your relationship. You can determine whether you and your partner can benefit from medical treatment and opportunities for renewed intimacy by answering the following questions:

*Are you committed to working with your partner on solving this problem? Is your partner motivated to work with you?*

Research indicates that couples who are in love and share a strong commitment to their relationship benefit most from medical treatment and/or psychological counseling.

*Do you both share a successful history of problem-solving?*

Good communication skills are essential in identifying and solving most problems.

*Are you and your partner interested in learning about Erectile Dysfunction?*

There is no substitute for accurate, up-to-date information upon which to base informed decisions. You and your partner will need to educate yourselves about sexual functioning, Erectile Dysfunction and treatments available.

*Are you and your partner willing to jointly participate in the evaluation process?*

Erectile Dysfunction is not just a “man’s problem.” Successful treatment depends on the couple’s cooperation and involvement in the problem-solving process.

*Do you have a sense of humor?*

While Erectile Dysfunction is no laughing matter, couples who are able to share a smile in times of stress seem better able to survive life’s trials. Some levity can make formidable tasks less arduous.



*Are you willing to have a frank discussion with your partner about Erectile Dysfunction and its effect on you?*

Communication and motivation are the key to effective sex therapy. It takes a delicate balance of courage, tact and skill to discuss this sensitive subject honestly and openly.

*Did you and your partner have a good sexual relationship prior to the onset of Erectile Dysfunction?*

A normally active, fully functioning sex life is a good indication that you can once again, recapture the sensuality you once enjoyed.

*In spite of Erectile Dysfunction, are you and your mate sexually attracted to each other?*

Sexual desire for your mate is a predictor of favorable outcome for sex therapy.

*How long has Erectile Dysfunction existed?*

Prompt treatment of an erectile problem ensures the most positive results. As with any problem, the longer it lasts, the more difficult it is to resolve. But, even long-standing Erectile Dysfunction can be resolved when there is proper motivation and appropriate treatment methods are explored.

*Can you be realistic about the benefits of restored potency?*

The ability to obtain an erection is not a quick-fix for on-going conflicts and disagreements between partners. However, medical intervention and counseling can be effective in ensuring long-term benefits.

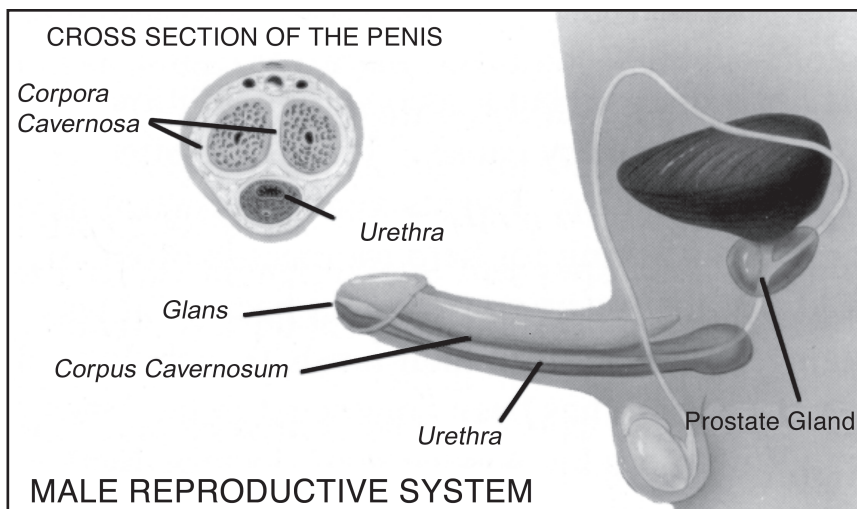
Although there is no way to accurately predict your chances for successful treatment of impotence, the more positive your responses, the greater likelihood that treatment will be effective.

## Erectile Dysfunction Defined

*Erectile Dysfunction is the consistent inability to have an erection that is rigid enough or to maintain it long enough to complete sexual intercourse.*

If your erections do not become firm enough to allow vaginal penetration, you have Erectile Dysfunction. If your erections have the necessary rigidity, but are only firm briefly, you may have Erectile Dysfunction. If your erection loses its strength upon penetration, you may have Erectile Dysfunction. If you have any of these conditions, take the first step toward a treatment that can change your life. Talk with your partner and physician.

## How Do Erections Occur in a Potent Man?



Normal erections require the coordinated actions of a healthy brain, pliable blood vessels, fully functional nerves, and certain hormones. Erotic stimulation, triggered by the five senses or by memory, begins the erectile process. The nervous system responds by sending chemical messages to and from the pelvic area.

These messages cause the smooth muscle tissue inside the penis to relax. The blood vessels dilate, allowing more blood to flow into the corpora cavernosa, the two erectile bodies within the penis. Like sponges, they capture more blood, swelling and lengthening the penis. When all of the spaces are occupied with blood, the organ becomes rigid. The enlarged corpora cavernosa take up so much space inside the penis that strong pressure is exerted against the penile veins, greatly reducing their outflow of blood.

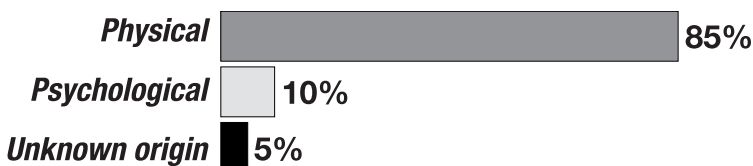
At this point, the erect penis contains seven to eight times more blood than the same flaccid or non-erect penis. As long as the sexual stimulation is continued, an erect stage can be maintained until orgasm and ejaculation.

## **What Causes Erectile Dysfunction?**

Erectile Dysfunction is not a disease, but a secondary condition brought on by other primary causes. It is a side effect - a symptom of something else. Twenty years ago, when couples went to their doctors asking for help with erectile problems, they were told that there was no treatment because it was caused by aging, or it was psychological. A generation of research has been conducted in the intervening years. With more knowledge now, doctors divide this very common disorder into four general causes:

- 1. Physical or Medical (Organic impotence)*
- 2. Psychological*
- 3. Mixed origin – both psychological and physical*
- 4. Unknown origin*

About 85% of this problem is due to medical or physical problems, 10% is psychological and the other 5% is unknown. Once a man fails to become erect a few times, he places more stress on himself to have an erection by sheer will power. When this too fails, he often begins to have a psychological problem.



*Psychological Erectile Dysfunction* describes the problem when physical causes cannot be found. Pure psychological impotence usually comes on suddenly. Job stress, a troubled marriage, financial worries, or a fear of failure can cause it. Any nagging, everyday situation that occupies conscious and subconscious thoughts can cause impotence. Depression or concern over poor sexual performance can also cause Erectile Dysfunction.

It should be noted that every man experiences temporary periods of impotence at one time or another during his life. That's entirely normal and you do not need treatment unless the problem is persistent.

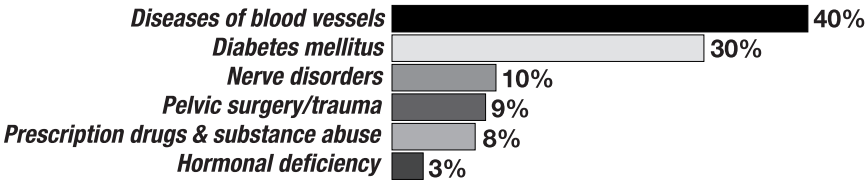
*Physical or Medical Erectile Dysfunction* usually develops gradually and is characterized by any of these three basic functional problems:

*Failure to initiate* results from impaired release of the chemical messages sent by the nervous system. The inability to initiate an erection can be seen in cases of hormonal insufficiency, spinal cord injury, radical pelvic surgery, multiple sclerosis and Parkinson's disease.

*Failure to fill* results from poor blood flow into the penis. The inability to develop an erection rigid enough for intercourse is caused by blockage in the arteries, common in cases of hypertension, high cholesterol, smoking, diabetes and pelvic trauma.

*Failure to store* results from venous leakage when blood escapes too quickly from the penis, leaking back into the body. This inability to maintain an erection rigid enough for intercourse is common in cases of hypertension, smoking, diabetes, high cholesterol and pelvic trauma.

The consensus of most authorities is that the table below represents an accurate distribution of the various causes of medical Erectile Dysfunction.



The important thing to remember is that most causes of impotence are physical and often beyond your control. While it is not good to have these medical problems (diabetes, high blood pressure, stroke or prostate disease, etc.), they are conditions couples can probably accept and should feel comfortable about trying to correct.

*Diseases of the blood vessels* (vascular disease) are the leading cause of Erectile Dysfunction. Vascular disorders include arteriosclerosis (hardening of the arteries), hypertension, high cholesterol and other conditions that interfere with blood flow. If poor blood flow occurs in the heart or coronary vessels, it causes heart attacks; when it occurs in the brain, it causes strokes; and when it occurs in the penis, it causes Erectile Dysfunction.

Another vascular problem, “venous leakage,” occurs when the penile veins are unable to close off (constrict) properly during an erection. When the veins “leak,” blood escapes too quickly back into the body and the erection fails.

*Diabetes* is a very common cause of Erectile Dysfunction. This disease can damage both blood vessels and nerves. When nerves are affected, the brain cannot properly transmit the sexual stimulus that creates an erection. Some 50% to 70% of all diabetic men ultimately suffer from Erectile Dysfunction.

*Nerve disorders* are another cause of Erectile Dysfunction. They affect the nervous system and include multiple sclerosis, Parkinson's disease and spinal cord injury with paralysis.

*Pelvic surgery* may also result in Erectile Dysfunction. Surgical procedures involving the prostate gland, the bladder or colon may damage the nerves and/or injure the blood vessels involved in erectile response. Radiation treatment in this area can also affect the erectile process.

*Prescription drugs* often cause Erectile Dysfunction as a side effect, and over 200 medications fall into this category. Never change a dosage or stop taking a prescribed drug without the advice of your doctor. Substance abuse affects erectile function as well. Illegal drugs and the excessive use of alcohol or tobacco can seriously damage the blood vessels and nerves involved in a normal erection.

*Hormonal deficiencies* are another source of Erectile Dysfunction. For example, low levels of testosterone or thyroid hormone often cause poor quality erections. Excessive production of prolactin by the pituitary gland may contribute to a low testosterone level and lack of desire. Diabetes is also considered a hormonal disorder.

## Choosing A Doctor

Where do you and your partner go? What type of doctor diagnoses and treats Erectile Dysfunction? How do both of you get the best answers? The six following types of professionals treat Erectile Dysfunction:

*Family Practitioners*

*Internists*

*Urologists*

*Endocrinologists*

*Psychiatrists*

*Psychologists*

Family practitioners, internists, and endocrinologists are primary care physicians most likely to be your family doctor or principal physician. This is the doctor you can consult first about Erectile Dysfunction. He or she knows the most about your medical history and current condition. If he chooses not to treat you, he may refer you to another physician who treats Erectile Dysfunction regularly. Many family doctors, however, are now treating this problem using non-surgical treatments.

As surgical specialists of the genito-urinary system, urologists are closely identified with Erectile Dysfunction treatment. The majority of the 10,000 urologists in the US can treat Erectile Dysfunction.

Psychiatrists and psychologists may be consulted if your doctor cannot find a physical cause for your problem. In many cases, a psychological aspect develops after Erectile Dysfunction has been present for a while.

The doctor's job is to diagnose, through simple tests, the cause of your Erectile Dysfunction, and to help you and your partner choose the best and the most effective treatment for you.

In diagnosing your Erectile Dysfunction, your doctor will first look for obvious contributing factors. For instance, diabetes, heart disease or prostate surgery can cause Erectile Dysfunction.

## At the Doctor's Office

The purpose of you and your partner's visit to the doctor is to answer two questions:

*1. Why is the male impotent?*

And

*2. What can we do about it?*

The second question assumes that the couple will be able to select from a number of treatments. They could also choose abstinence. Though each doctor may approach diagnosis and treatment differently, your physician will help you understand the cause of your Erectile Dysfunction and options for dealing with it.

Your physician will first record a medical history, including psychological and sexual aspects. They may ask about stress and fatigue and about your relationship. Some questions may be very personal, but your doctor needs to know about you and your partner's present sexual functioning in order to treat Erectile Dysfunction. Be honest with your answers.

One question that will be asked of the male is, "Do you wake up in the morning with an erection?" If you always wake up with an erection, your physical system works, and the Erectile Dysfunction may be psychological. If you never wake up with an erection, it suggests a physical problem with blood vessels or nerves.

Whether you start treatment with your family doctor or an urologist, the initial approach will probably be conservative. Conservative, non-surgical treatments for Erectile Dysfunction have proven very successful, and most patients find surgical treatment unnecessary.



## **Treatment Options for Erectile Dysfunction**

In the last few years, many more couples are seeking treatment for Erectile Dysfunction, primarily because of the release of a new effective drug therapy for Erectile Dysfunction. On April 1, 1998 Pfizer, Inc., introduced an oral pill, sildenafil citrate, better known as Viagra®. Since that time, millions of prescriptions have been written for men with Erectile Dysfunction, making this the most popular treatment. Many, if not most men being treated for Erectile Dysfunction take Viagra. However, Viagra does not work for all couples – some men may not be candidates for Viagra because of heart disease or because they are taking long/short acting nitrates (an absolute contraindication for Viagra), others experience significant side effects and for others, the drug is not effective.

Other treatments include: external vacuum therapy, penile injection therapy, penile implants, intraurethral pharmacotherapy, hormonal replacement, and vascular surgery. These treatments are primarily for medical disease while sexual counseling or sex therapy is generally recommended for men with primary psychogenic Erectile Dysfunction.

The treatment option for psychogenic and medical Erectile Dysfunction depends on the experience of the clinician, the couple's wishes, and the facilities available. A summary of the treatment options for managing psychogenic and medical Erectile Dysfunction includes:

### **Psychogenic**

- Psychosexual Therapy
- Oral Drug Therapy
- External Vacuum Therapy
- Intracavernosal Injections
- Intraurethral Therapy

### **Medical**

- Oral Drug Therapy
- Intracavernosal Injection
- External Vacuum Therapy
- Intraurethral Therapy
- Penile Implants
- Androgen Replacement
- Vascular Surgery

## **Psychogenic Erectile Dysfunction**

Psychogenic Erectile Dysfunction can be caused by a number of personal problems such as performance anxiety, guilt, depression, relationship problems, job stress, or by fear and personal anxiety. Performance anxiety is very common and may be self-perpetuating with subsequent sexual efforts doomed because of the “fear of failure.” Treatment options include:

1. Identify the source of the anxiety, guilt, stress or depression and provide psychological treatment.
2. Initiate a non-psychological or physical (drug or device) treatment that overcomes the specific cause of the ED and produce an erection “on demand”.

Once a patient and his partner can obtain an erection “on demand” from a physical or drug therapy, the male may overcome the psychogenic anxiety himself.

## **Psychosexual Therapy**

This treatment cannot be standardized because the source of the anxiety differs from patient to patient and couple to couple. Similarly, ways to deal with these anxieties vary from counselor to counselor. In general, psychosexual treatments range from simple sex education through improved partner communication to cognitive and behavioral therapy. The counselor must identify the source of the anxiety and select appropriate therapy. Most modern therapy is behavioral based and strives to reduce performance anxiety via programmed relearning of a couple’s sexual behavior and practices. This obviously requires a cooperative couple, which may or may not be available. Long-term results with this type of therapy have shown significant Erectile Dysfunction recurrence rates. However, many couples benefit from this approach, which can also be combined with physical therapies to make the results more long lasting.

## **Physical or Medical Erectile Dysfunction**

Physical/Medical Erectile Dysfunction will only respond to physical therapy though counseling can certainly help and improve long term outcomes. The following medical treatments represent physical therapy.

### **Pharmacological Treatment**

Greater understanding of the physiology of erections (early 1980's) led to the concept of pharmacological erections for the treatment of Erectile Dysfunction. Drugs like Papaverine, were discovered in the 1980's which produced erections "on demand" when administered locally in adequate amounts. Other pharmacologic agents soon followed (phentolamine, VIP, and prostaglandin) and were shown to have erectogenic effects when administered locally by needle, skin surface absorption, or intraurethral routes.

An effective oral drug was finally realized with the release of sildenafil citrate in April of 1998 by Pfizer, Inc. Sildenafil is a specific PDE5 blocker making the penile smooth muscle vasodilator cGMP more available for erection enhancement. Sildenafil works in less than 70% of men with various etiologies and has certain side effects. It has also been documented that only half of first time users return for a second prescription. The availability of Viagra has brought millions of couples to treatment and is the most popular form of treatment for Erectile Dysfunction.

Other oral drugs that are used in the treatment of Erectile Dysfunction are currently being studied and are in clinical trials. These include sublingual apomorphine or UPRIMA, a centrally acting agent that enhances the sexual response to stimulation. Oral phentolamine, VASOMAX, is a peripheral vasodilator and helps to improve penile and pelvic organ blood flow. Both of these drugs are in the "on demand" category and are taken before sexual activity.

## **Intracavernosal Therapy (Penile Injections)**

Penile injection therapy is effective in about 80% of patients. Originally thought to be a temporary treatment for Erectile Dysfunction, many couples have been using penile injections for several years.

Several drugs have been used for this purpose. These vasoactive drugs include the smooth muscle relaxants papaverine, alprostadil, and VIP and the vasodilator, phentolamine. In 1995, the FDA issued governmental approval of Upjohn's synthetic alprostadil injectable, Caverject. Other vasoactive drugs and drug combinations are currently being evaluated.

Penile injection therapy involves learning the self-injection technique so that this treatment is performed by the patient himself or with the assistance of his partner if necessary for his convenience. The patient and/or partner is trained in this injection method. It is often facilitated by an auto-injector in the medical clinic by the physician or his assistant.

The most troublesome side effect of this form of treatment is the possibility of overdosing the medication, causing priapism, which is an erection that lasts too long. This problem can be corrected by injecting an antidote into the erect penis but is best prevented by proper training and dosing in the physician's office before actually learning the self-injection technique.

Other side effects of this treatment include the possibility of scar tissue at the injection site, hematoma formation or bruising and the remote possibility of infection. Pain in the penis may be a factor with Caverject, especially at higher doses.

## **Intraurethral Pharmacotherapy**

In January of 1997, the FDA approved an intraurethral delivery system, MUSE, for the treatment of Erectile Dysfunction. This involves delivery of a pellet of the drug, alprostadil, into the distal penile urethra using a plastic applicator. The pellet is held in the urethra for several minutes until it dissolves and is absorbed into the erectile tissue producing an erection.

Success rates with this treatment are in the 30 to 50% range. Side effects of urethral burning and pain occur in 7 to 10% of men. While not nearly as popular as oral drug therapy, the intraurethral route of administration of alprostadil is the preferred treatment method in a small percentage of couples.

## **External Vacuum Therapy**

This is the simplest, non-surgical drug-free method of producing a quality erection. The external vacuum device was invented by Geddings Osbon in the early 1960's to solve his own Erectile Dysfunction problem. He created the ErecAid® System, based on vacuum pressure and tension rings, to produce and maintain a naturally engorged erection every time one was needed.

The vacuum system consists of a clear plastic cylinder, a manual pump or battery pump, and a special tension ring. The user loads a tension ring around the open end of the cylinder, then inserts his penis into that end. Holding the device firmly against the body to form an air-tight seal, he uses the pump to remove air from inside the cylinder. This creates a partial vacuum around the penis, causing the body's blood to enter the corpora cavernosa. This engorges the penis in a similar manner to a natural erection.

To maintain the erection, it is necessary to reduce the outflow of blood from the penis. Therefore, while the penis is still under vacuum pressure, the tension ring is pushed off the cylinder on to the base of the penis. Once the vacuum is released by the patient, the cylinder

and pump can be removed and laid aside. The user can maintain an erection for up to 30 minutes, wearing only the tension ring. This procedure takes two minutes or less and is used whenever an erection is needed.

The ErecAid System has been effective for over 90% of couples who have used it. Patients who have had their prostate removed use it successfully. Men who have had penile implants and later removed can use this system successfully, as well as men with blood vessel blockages and venous leaks. Psychological patients are successful with it as well as men with diabetes.

A poll of couples using the ErecAid System showed that during the 6-month period just prior to acquiring the vacuum system, 76% of couples reported that they had no sexual intercourse or very irregular sexual activity. After using the system for ninety days, 80% said they were having sexual intercourse at least twice a month. Initially, it takes practice to learn how to use the system. Forty-two percent of patients learn how to use it in a day and 90% master the technique in two weeks. Sixty-nine percent can create an erection suitable for intercourse within two minutes.

An unexpected statistic, which emerged from the survey, pertained to the occasional restoration of natural erections.

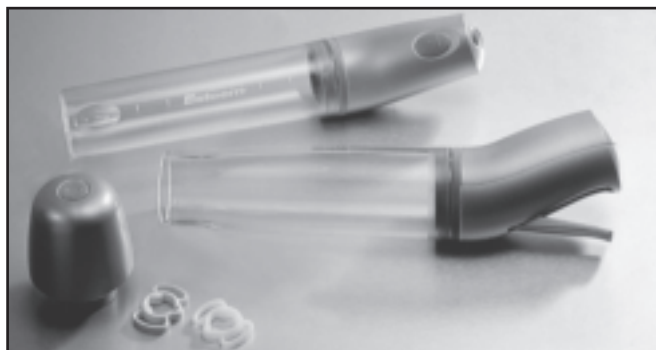
The most significant advantage of the ErecAid System is that it works without requiring foreign drugs, surgery or a healing period. It is non-invasive, is used on the body (not in the body), and can stay in a dresser drawer or on a shelf when not in use.

Another important advantage is cost. The ErecAid System, at \$400 - \$500, has the lowest cost of any treatment option. Most other Erectile Dysfunction treatments are far more expensive. The major components of ErecAid System have lifetime guarantees and medical insurance coverage is available in many cases. Medicare coverage for this treatment is available in every state.

A significant advantage for both partners is that the erections are of high quality, lasting longer than natural ones and they do not usually disappear after orgasm. Also, once the erection technique has been learned, the patient can achieve reliable, consistent erections each time. The erection disappears when the tension ring is removed. It is recommended that the ring be removed within 30 minutes.

With some patients, minor side effects can occur such as petechiae (pinpoint-size red dots caused by negative pressure applied too quickly) and ecchymosis (bruising caused by prolonged vacuum pressure). Neither condition is painful or serious and does not need treatment. These conditions stop occurring after a few uses with the system.

A final side effect is a temperature drop of 1-2° in the penis, which is caused by the tension ring. No major injuries have ever been reported by users of the ErecAid System.



This device may not be an appropriate treatment for men who have sickle cell anemia or a history of spontaneous priapisms.

Men on blood thinners like coumadin may safely use the device by pumping more slowly. Proper use of it requires minimal manual dexterity and hand strength.

## **Surgical Implants**

In 1972, physicians began doing penile implants to help patients with lost potency. Since then, implants have been used by US surgeons to treat about 25,000 patients per year. During surgery, two synthetic cylinders are placed inside the corpora cavernosa of the penis. After 4-6 weeks, the couple can engage in sexual intercourse.

These devices are mechanical, inflatable, or hydraulic. Their implementation permanently alters the corpora cavernosa, ending all hope of the return of natural erections, so this treatment should be considered a final step by the couple, not an early one. There is also the risk of infection with surgical procedures, and eventual malfunction or deterioration of the device may require other surgeries.

A skilled urologist, using general anesthesia, implants this device for a total cost of \$12,000 to \$15,000. After 4-6 weeks of healing, the patient may begin to use it. Mechanical failure or patient infections are the two most common complications. Both can cause a need for more surgery. Key factors are (1) the surgical procedure is not reversible, and (2) the erection stems from saline solution, not the bloodstream.

## **Vascular Reconstructive Surgery**

Penile surgery of this type is like heart bypass surgery, which reroutes the blood supply around blockages. Less than one percent of impotent men are candidates for this procedure, and the failure rate is very high.

Venous ligation is a penile surgical procedure in which the surgeon attempts to repair the veins causing the venous leak. This procedure was popular until physicians began to realize that it offered only a temporary solution – many patients required another operation within a few years.



These procedures cost about \$15,000 to \$20,000 and should only be performed by surgeons experienced with the procedures, preferably in an investigational setting. Complications may include permanent numbness near the incision and scar tissue, which may shorten or “torque” the penis. In addition, the surgery may need to be repeated.

## **Hormone Therapy**

A severe deficiency of the male hormone, testosterone, can cause Erectile Dysfunction. In these situations, treatment with hormone replacement can be effective. Only about 3-4% of the male population, however, has this problem and can benefit from treatment. The nature of the treatment is to give the man an injection of testosterone into the arm or the buttocks to raise the hormone to acceptable levels. Side effects of testosterone replacement therapy can be serious, and patients with a medical history that includes liver disease, heart disease, kidney problems, and especially prostate cancer should avoid supplemental testosterone.

## Which Treatment Should We Choose?

The couple must consider several factors in selecting a treatment. A few of them have been outlined below.

*Partner's opinion.* Ask your partner to go through this booklet with you. Ask your partner to visit the doctor with you. Does your partner lean toward one treatment more than others? If you are young with no partner, you may be happier with implants and injections.

*Frequency of sexual activity.* Will sex be performed twice a week, twice a month, or twice a year? Select a therapy that is consistent with the estimated amount of use.

*Treatment Sequence.* The best way to look at Erectile Dysfunction therapy is that the simple, inexpensive, reversible treatments should be tried first, while the more complex, expensive, non-reversible treatments should be attempted later. The ErecAid System, Viagra or hormone therapy might be tried earliest since all are relatively inexpensive and reversible. Injections are next on the list, followed by intraurethral pharmacotherapy, implants and finally vascular surgery. All of these are invasive therapies that cause internal changes to the penis.

*What are the odds of re-operation?* Ask your physician about the odds of having repeat surgeries. Ask about the failure rate of the implant he is recommending. Ask about the failure rate of the various vascular surgeries.

*Financial considerations.* What is the out-of-pocket cost of the treatment selected? How much will health insurance pay for? What are the guarantees or warranties of the treatment chosen?

*Maintenance costs.* Ongoing costs for treatment must be identified. For example, Viagra has an ongoing cost, as do penile injections.

*Safe and effective treatment?* Has the chosen therapy received FDA marketing approval? Have clinical studies been performed for this treatment? Does a reputable provider with liability insurance back the treatment?

## **Health Insurance and Erectile Dysfunction**

Insurance companies will generally pay for Erectile Dysfunction treatment when the cause is physical. Your physician must specify on the claim form the physical cause of your Erectile Dysfunction and that your treatment is medically necessary.

If your physician diagnoses a psychological cause, many insurance companies will deny the claim, unless state law mandates limited coverage. Some group policies exclude coverage for Erectile Dysfunction of any type.

## **Health Maintenance Organizations (HMOs)**

Most HMOs consider sexual health to be an integral part of an individual's total health, so they will generally provide treatment unless there is an exclusionary clause in the patient's contract.

HMO physicians generally try to guide patients to the most effective treatment at the lowest cost. For this reason, external vacuum devices are often favored because of high success and relatively low cost. The initial costs for penile injections are relatively low, but costs accumulate as long as the patient is sexually active. Penile implants, with higher initial cost and higher risk of complications may be considered for payment by the HMO only after the couple have tried treatments that are more conservative.

## **Medicare and Erectile Dysfunction**

Medicare coverage is divided into Medicare A, which covers surgeries, hospital stays and the more costly medical services; and Medicare B, which covers doctors' office visits, medical devices and the less costly items and services. Since October 1, 1980, there has been a Medicare national coverage policy allowing payment for the diagnosis and treatment of sexual impotence. A national coverage decision is binding on all Medicare contractors, including Medicare managed care plans.

If you have FICA taxes deducted from your paycheck, Medicare A will cover you at no charge when you reach 65. Medicare B costs about \$30 a month and may be deducted from your Social Security check.

Surgical treatments for Erectile Dysfunction are usually covered by Medicare A in most states as long as your doctor verifies a physical cause of Erectile Dysfunction and states that the treatment is "medically necessary." Vacuum devices are covered under Medicare B. Penile injection therapy is not covered by Medicare at this time.

As of 1994, Medicare has reimbursed for external vacuum devices under Medicare B. With a valid prescription, the couple may obtain a vacuum device from their doctor, a pharmacy, a medical supplier, or directly from Timm Medical Technologies, Inc.

The purpose of this book is to provide comprehensive information to caring couples on Erectile Dysfunction and objective information on all currently acceptable medical treatments. However, readers should understand that like most publications distributed by a medical device company, this one has a bias for the treatment therapy and products it is most familiar with.

For more information on external vacuum devices, please contact Timm Medical Technologies, Inc., at 1-800-438-8592 or on the web at [www.osbonerecaid.com](http://www.osbonerecaid.com).

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