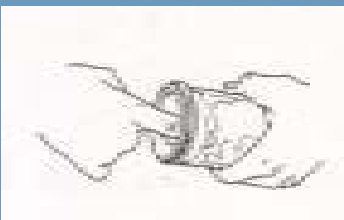


SOMACorrect-Peyronie's Correction Manual

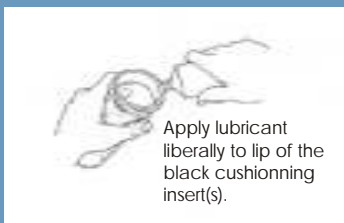


1) Assemble the unit by connecting the Negative Pressure Device to the Negative Pressure Cylinder. It snaps together very easily.



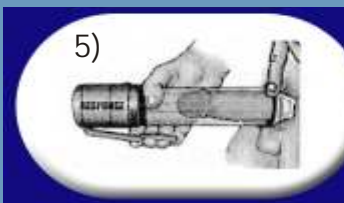
2) Lubricate the inside of the Negative Pressure Cylinder by applying SOMA Lubricant with your finger at a depth of about one inch (2 cm's) inside the cylinder. In order for the penis to slide inside the Negative Pressure Cylinder, it is necessary to apply SOMA Lubricant in the correct manner.

3) Liberally apply SOMA Lubricant to the glans (head) and shaft of the penis and to the abdomen where the cylinder will come into contact with the body. Trim or shave the pubic hair if required to achieve a seal.



4) Apply Soma Lubricant to the end of the Negative Pressure Cylinder as if you are squeezing tooth- paste onto a toothbrush. This is the most important place to put SOMA Lubricant. Do not apply it with your fingers. If you do not use enough lubricant air will leak into the Negative Pressure Cylinder and you will not be able to create

penile engorgement. It is very important to have the Negative Pressure Cylinder air tight against your body. SOMA SUGGESTION: It is a good idea to have a towel nearby so you can wipe your hands prior to continuing with further steps. This will make it easier to hold the equipment.



5) Place your penis inside the Negative Pressure Cylinder and press the open end of the cylinder against your abdomen insuring that it is air tight against your body. SOMA SUGGESTION: As you hold the Negative Pressure Cylinder securely against the body twist the Negative Pressure Cylinder about one inch each

way to ensure an airtight seal. If you have trouble creating a pressure seal, add more SOMA Lubricant to the open end of the Negative Pressure Cylinder, and then repeat the side-to-side twisting motion.

6) The Initial Therapeutic Application:

- Begin with all three Negative Pressure Cylinders (A, B & C) in place providing the smallest open end and greatest resistance to penile bending.
- Slowly begin by activating the Negative Pressure Device lever two to three times. Stop and wait five seconds. Secure scrotal tissue out of the way whilst pumping by pinching from below if necessary with your free hand.
- Continue adding additional pressure by repeating this start and stop cycle of pumping. As you feel pressure increase, you should reduce the number of actions of the Negative Pressure Device lever to only two lever actions and at the same time increase your waiting period to ten seconds. This is important as blood moves more slowly into the penis as you approach full engorgement.
- Continuing to increase negative pressure too much or too quickly can result in mild discomfort which is normal in the first few days of use.
- Experiment with the three Negative Pressure Cylinders sizing options (A, B and C) to find the sizing option combination that will allow the penis to fully engorge ie. permitting adequate blood to be pulled into the penile vascular system to stretch the Peyronie's plaque, but not allow the penis to bend.
- Once you begin to feel the penis being pulled tight stop the activation of negative pressure. Hold the erection at this level for a few seconds then release the vacuum pressure by pressing and holding the pressure release button.
- Wait for the pressure to drop then add additional pressure repeating the above steps until you can achieve a fully rigid erection. Some initial discomfort is normal due to the extra tissue stretch.
- Continue this process for 10 to 20 minutes generating as many full erections as possible in this time using the pumping protocol highlighted above. Once you've completed this routine you've finished your session.
- Remove the SOMACorrect Negative Pressure Cylinders, clean them and store your unit. Repeat daily for up to 6 months and beyond (up to 12 months if necessary) if you are achieving positive results.

In some cases, a vacuum induced erection captured with an erection maintenance ring is 'artificially' less curved in light of the extra-corporal filling effect so long as the ring is held in place - call 02082075627 for more info.

Questions and Answers

It is very important that you register your SOMACorrect as soon as possible and call our Technical Support Office on 02082075627, M-F 9am to 6pm should you have any questions or experience any difficulty. Our Technical Support Team includes a team of medically qualified advisors that work with hundreds of patients each month and are a useful resource as you work to resolve your problem with Peyronie's.

HOW MUCH NEGATIVE PRESSURE IS ENOUGH?

ANSWER: Sufficient to generate a fully rigid vacuum induced erection. It can take a few days / weeks of regular initial SOMACorrect application for penile tissue to get used to this extra three dimensional stretch.

WHAT DO I DO IF I CAN NOT GET ADEQUATE NEGATIVE PRESSURE IN THE NEGATIVE PRESSURE CYLINDER?

ANSWER: If you lose negative pressure it may be necessary to either [1] use more SOMA Lubricant, or [2] hold the Negative Pressure Cylinder more firmly against the body, or [3] twist the Negative Pressure Cylinder side-to side about one inch each way or [4] it may be necessary to do all three. You should feel the negative pressure bringing blood into the penis. Remember, in order to achieve full engorgement, there must be an airtight seal at the base of the penis. It may take a couple of attempts to achieve an airtight seal that will cause engorgement and it may be necessary to trim or shave pubic hair.

WHAT DO I DO IF PAIN OR DISCOMFORT IS EXPERIENCED?

ANSWER: Reduce the amount of negative pressure. Check the Negative Pressure Cylinder to see if scrotal tissue has entered the cylinder. This can occur if [1] too large of a negative pressure cylinder is being used, or [2] the Negative Pressure Cylinder is pulled away from the body, or [3] the Negative Pressure Cylinder is not being held firmly against the body. Secure scrotal tissue out of the way whilst pumping by pinching from below if necessary with your free hand. Review each step in the application (re-read the instruction manual to determine if you have applied SOMACorrect correctly). It can take a few days / weeks of regular initial SOMACorrect application for penile tissue to get used to the extra three dimensional stretch needed to create a fully rigid vacuum induced erection. If pain continues after this initial period (2 to 4 weeks), discontinue use, contact our customer service department at 0208 207 5627 or consult your physician.

Information About SOMACorrect™ Use & Warranty

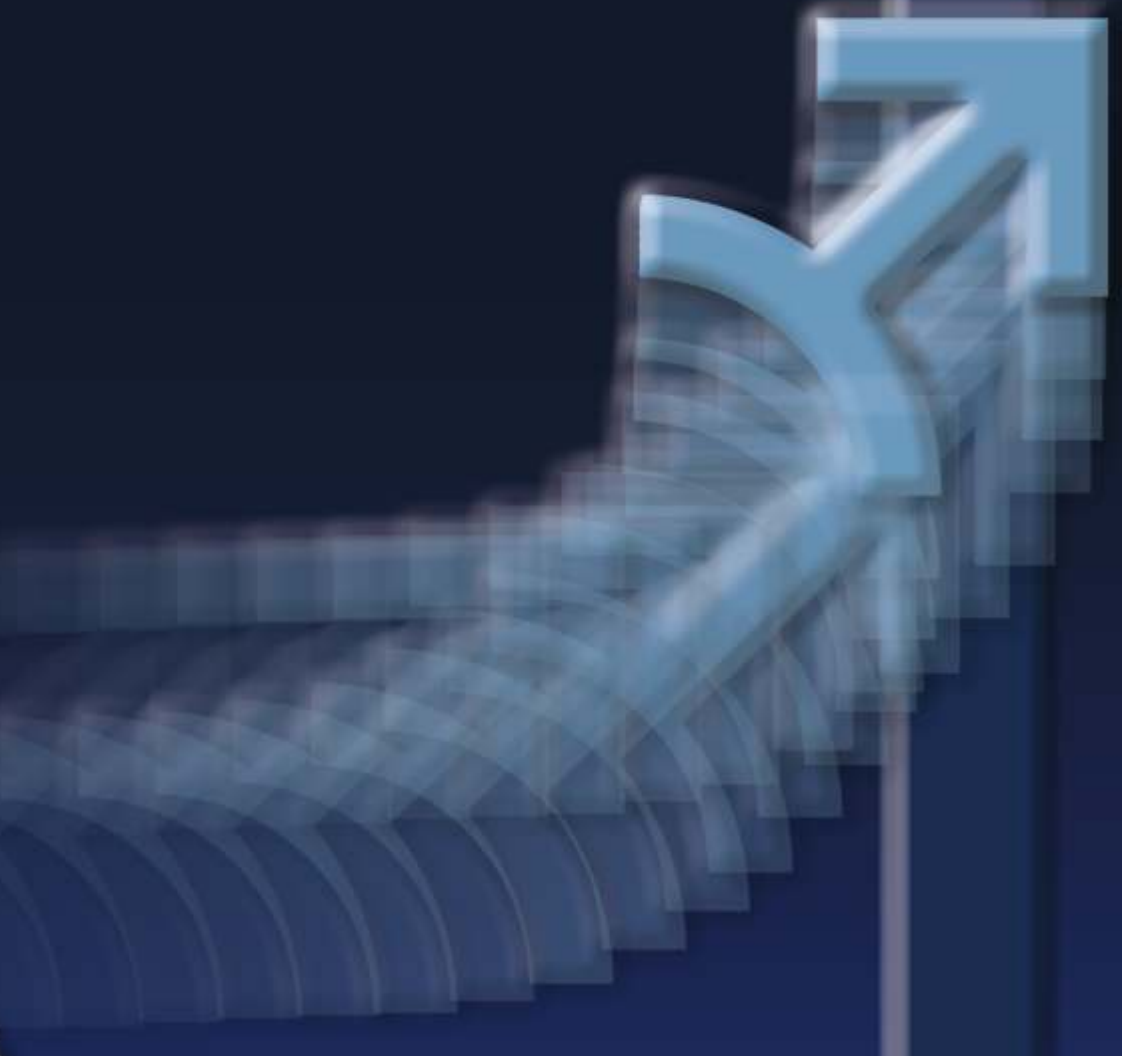
- If pain occurs even after proper application of SOMACorrect, consult your physician / iMEDicare Helpline and/or discontinue use until advised otherwise.
- Do not use while under the influence of alcohol or drugs.
- Consult your physician if you are undergoing certain anticoagulant therapy.
- Do not use SOMACorrect if you have an open sore or lesion, or any type of sexually transmitted disease.
- Do not use SOMACorrect. if you have Sickle Cell Anaemia, an uncontrolled vascular coagulation disorder or a history of Priapism.
- You should consult with your physician concerning your tolerance to physical exertion during sexual activity.

iMEDicare offers a one-year replacement warranty on the components of your SOMACorrect device when obtained on NHS prescription or by private purchase, should they malfunction due to manufacturer's defect. Damage caused by neglect or improper care is not covered under this warranty. Other accessory parts do not apply. Note that the model 'SOMACorrect Xtra' is warranted for life when purchased privately. iMEDicare must have a product registration form on file prior to warranty approval, so make certain you send us your completed registration form as soon as possible. You will be required to send a check or postal order payable to iMEDicare Ltd in the amount of £3.50 for return postage for the replacement part.

The SOMACorrect Negative Pressure Device (Pump head) and Negative Pressure Cylinders should be thoroughly cleaned after each use. Do not allow water to enter the pump itself, but the pump exterior should be wiped clean to remove any sealing gel. The Negative Pressure Cylinder should be thoroughly washed with mild liquid soap and warm water. Dry the system before storing. iMEDicare hopes that you will be completely satisfied with your SOMACorrect device and will find it a successful solution to your Peyronie's Disease condition. Should you have any questions, suggestions or problems with SOMACorrect please call our office on 0208 207 5627, M-F. 9am to 6pm. website: www.iMEDicare.eu, Address: iMEDicare Ltd, Elstree House, Elstree Way, Borehamwood, HERTS, WD6 1SD.



The Biomechanical Management of Peyronie's Disease



Call 0208 207 5627 for more information
www.iMEDicare.eu



What is Peyronie's Disease?

Peyronie's disease (PD), a benign condition of uncertain cause, is characterized by the formation of fibrous tissue plaques often palpable as a hard lump, within the tunica albuginea on the penis usually causing a penile deformity and a subsequent degree of erectile dysfunction (41-55%)[1]. (First fully described by Francois Gigot de la Peyronie)[2]. A plaque on the top of the shaft (most common) causes the penis to bend upward; a plaque on the underside causes it to bend downward. In some cases, the plaque develops on both top and bottom, leading to indentation and shortening of the penis. At times, pain, bending, and emotional distress prohibit sexual intercourse. The incidence of Peyronie's disease is 3.2% [1] of whom about two thirds are aged 40-60 years. The common suspected causal factors include sexual trauma in those with a genetic predisposition to aberrant wound healing, or part of a generalised connective tissue, autoimmune or arterial disease. The initial theory of repeated minor sexual trauma is currently still the most likely cause. This is supported by the finding of fibrin within the plaques but not in control tunica, indicating microvascular injury [3]. Penile pain may be persistent in the inflammatory stage of the disease but is usually only present during erection. The pain is usually not severe but may interfere with sexual function, although spontaneous improvement usually occurs as the inflammation settles within 3-6 months[4]. After 18-24 months, plaque angulation and calcification tend to predominate. Spontaneous resolution of the condition is thought to occur in up to 15% of cases.

What is SOMACorrect and how can it help?

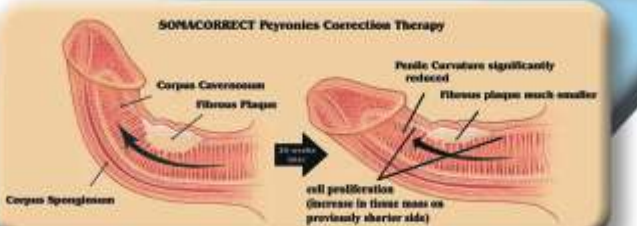
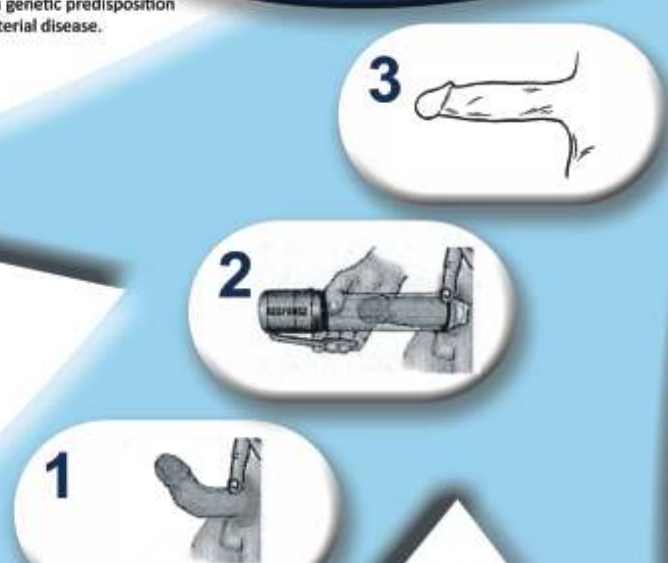
SOMACorrect Peyronie's Correction Therapy (Type 1 Medical Device, European Health Certification - CE) is the revolutionary NEW treatment regimen for men with the penile curvature associated with Peyronie's disease. Side-effect free, SOMATherapy-PD (Peyronie's Disease) was developed over a number of years by a Urological Consultant who has treated Erectile Dysfunction (ED) for more than 30 years. The treatment involves placing the penis in one of the 3 appropriate 'sized to fit (Stf)' adapted circumferential cylinders and using vacuum therapy pressure to forcibly induce a series of 'straight' erections over a 10 min. period...

Clinical References

[1] - Schwazer U, Benzer F, Holz T, Beun H, Hellebrand B, Engelmann U. The prevalence of Peyronie's disease: results of a large survey. *BJU Int* 2009; 103: 797-800. [2] - De la Peyronie F. Sur quelques maladies qui s'exposent à l'oppression: mémoire de la academie. *Mémoires de l'Académie des Sciences*. Paris, 1714. [3] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [4] - Homan F. Etiologic factors in Peyronie's disease. *Urology* 1982; 20: 447-13. [5] - Valtieri, S. SomATherapy (STED) As Treatment for Penile Curvature. *Andrology*. LMAI, Department of Urology, Antwerp University Hospital, Belgium, Office Study, Self Published. This study found that for 9 out of 12 patients the angle of curvature had reduced by at least 50% after 3 months of regular vacuum therapy plaque stretching. For 7 of these 12 patients - the plaque had disappeared completely [2] [3] [4]. [6] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [7] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [8] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [9] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [10] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [11] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [12] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [13] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [14] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [15] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [16] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [17] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [18] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [19] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [20] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5. [21] - Scarpa M, Di Biase G. Fibrin deposition in Peyronie's disease plaques. *J Urol* 1997; 157: 315-5.

SOMACorrect™

Peyronie's Correction Therapy



.....each day for up to 26 weeks, with the effect of gradually reducing the impact of the plaque area on the overall angle of curvature and improve penile health in general [5,6,7,8]. With additional UK based studies underway, early unpublished anecdotal reports, such as those by Dr. DiLoreto of the Michigan Institute of Urology, suggest significant response rates, in excess of 60% and up to 80%, are being achieved. Clinical Studies conducted by the Urology Department of Antwerp University Hospital found that for 75% of the patients, the angle of curvature had reduced by at least 50% after 6 months of regular vacuum therapy plaque stretching. For 58% the plaque had disappeared completely.[5]

Mechanisms of Action?

Regular stretching and straightening may burst an element of the collagen fibres that make up the scar tissue (plaque area) and help to (A) 'RESHAPE' the plaque thereby reducing its contractile impact (degree of Mechanical Distortion) and the degree of penile curvature. It is theorised that regular SOMATherapy-PD may cause (B) PARTIAL FRAGMENTATION of the plaque itself (particularly when diffuse in nature) with some element of plaque (C) SURFACE REABSORPTION and an (D) INCREASE IN VASCULARIZATION of plaque tissue. This remains as yet unproven, but are likely mechanisms of action for those patients who do respond with reduced plaque size reduction. Recent research into the aetiology of PD implies an imbalance between profibrotic and antifibrotic substances. [9] Over-expression of TGF-beta1 has been shown to induce penile plaques in the rat model. [10] TGF-beta1 has also been shown to be over-expressed in PD plaques as compared with patients without evidence of PD.[11] Another group of profibrotic proteins includes fibrin and plasminogen activator inhibitor-1 (PAI-1). Like TGF-beta1, fibrin has been shown to induce plaque formation in an animal model; levels of PAI-1 are elevated in these plaques.[12] Vacuum Therapy use is clinically well recognised for producing "a significant increase in the penile-brachial pressure index following regular use" [13] with a multitude of clinical studies establishing the link between regular vacuum therapy application and penile neovascularization [14,15]. Run Wang has demonstrated that mean Oxygen saturation of corporeal blood immediately after vacuum-therapy induced erection was predominantly arterial in nature and therefore oxygen enriched. It is also known that an increase in corporeal Oxygen tension is associated with a rapid increase in unstimulated PGE2 (Phosphodiesterase 2) followed by a suppression of TGF-Beta 1 induced collagen synthesis. [16,17]. This is one possible mechanism of action by which regular penile vacuum therapy induced penile oxygenation could suppress excessive penile fibrosis in patients with Peyronie's Disease. Also, studies show that nitric oxide, by acting as a scavenger for reactive oxygen free radicals, may exert a protective effect via inducible nitric oxide synthase (iNOS) activity. Peyronie's plaques have a reduced iNOS, an increased reactive oxygen free radical content and consequently more fibrosis than control tunica [18]. Hence (E) EARLY TREATMENT OF ASSOCIATED ERECTILE DYSFUNCTION (ED) in relevant patients may be of benefit. Certainly mechanical tissue expansion principles of action with subsequent stimulated (F) CELL (TISSUE) PROLIFERATION may also apply with regular SOMACorrect application [19-21], increasing tissue mass on the interior curved side of the penis: FORCE + TIME = GROWTH / tissue expansion: sustained mechanical stress inducing increased biosynthetic activity of the shorter side as it is subject greater traction). A high degree of calcification may reduce the pliability and scope for revascularization of plaque tissue - therefore vacuum therapy application is particularly indicated during the active phase of Peyronie's disease and certainly pre-calcification if possible, although response rates may be influenced by plaque location / shape / size / patient's potential for stimulated cell proliferation and compliance in procedural use. In some cases, a vacuum induced erection captured with an erection maintenance ring is 'artificially' less curved in light of the extra-corporeal filling effect so long as the ring is held in place. SOMACorrect has a 90 day money back guarantee.

SOMACorrect-Peyronie's Correction

Use only As Directed

Course of the Disease

Many researchers believe the plaque of Peyronie's disease develops following trauma (hitting or bending) that causes localized bleeding inside the penis. Two chambers known as the *corpora cavernosa* run the length of the penis. The inner-surface membrane of the chambers is a sheath of elastic fibers. A connecting tissue, called a septum, runs along the center of each chamber and attaches at the top and bottom. If the penis is abnormally bumped or bent, an area where the septum attaches to the elastic fibers may stretch beyond limit. This may result in injury of the lining of the erectile chamber and rupture of small blood vessels. As a result of aging, diminished elasticity near the point of attachment of the septum might increase the chances of this type of injury. The damaged area might heal slowly or abnormally for two reasons: repeated trauma and a minimal amount of blood flow in the sheath-like fibers. In cases that heal within one year, the plaque usually does not advance beyond an initial inflammatory phase. In cases that persist for years, the plaque undergoes fibrosis, or formation of tough fibrous tissue, and even calcification, or formation of calcium deposits. While trauma might explain acute cases of Peyronie's disease, it does not explain why most cases develop slowly and with no apparent traumatic event. It also does not explain why some cases disappear quickly, and why similar conditions such as Dupuytren's contracture do not seem to result from severe trauma. Some researchers theorize that Peyronie's disease may be an autoimmune disorder.



Cases of Peyronie's disease range from mild to severe. Symptoms may develop slowly or appear overnight. In severe cases, the hardened plaque reduces flexibility, perhaps causing pain and forcing the penis to bend or arc during erection. In many cases, the pain decreases over time, but the bend in the penis may remain a problem, making sexual intercourse difficult. The sexual problems that result can disrupt a couple's physical and emotional relationship and lead to lowered self-esteem in the man. In a small percentage of patients with the milder form of the disease,

SOMACorrect Negative Pressure Cylinders

The Negative Pressure Cylinder comes in three different sizes (A, B & C). These cylinders allow the penis to reach various stages of engorgement thereby preventing the penis from bending in the direction of the scar tissue. The cylinders are engineered so that the smallest (A) fits inside the next largest (B) which fits into the largest (C). The SOMACorrect. Technique is based on a combination of cylinders used with the Negative Pressure System.

SOMATherapy Lubricant

In order to obtain a seal between the Negative Pressure Cylinder and the body, SOMA Lubricant is used. The SOMA Lubricant included with your SOMACorrect is specially formulated to work best for your new system. Do not use petroleum jelly, since oil-based lubricants can damage your product. Become comfortable with using the SOMACorrect: know how to set up the system and apply SOMA Lubricant. Understanding each step in the application of SOMACorrect will help you get results quickly from the Peyronie's Correction



Treatment

Because the course of Peyronie's disease is different in each patient and some patients experience improvement without treatment, medical experts suggest waiting 2 to 3 years or longer before attempting surgical correction.

SOMACorrect Negative Pressure Device

The SOMA Negative Pressure Device draws air out of the vacuum cylinder, causing negative pressure to be created inside the cylinder. This negative pressure causes blood to be drawn into the penile vascular system creating pressure to stretch the Peyronie's plaque. The sides of the Negative Pressure Cylinder prevent the penis from bending in the direction of the plaque further stretching the scar tissue. Your SOMA Negative Pressure Device has a built-in pressure limiter. This limiter automatically restricts the amount of negative pressure you can draw to a pre-set safe limit. You cannot see the limiter. It is located inside the device and is pre-set at the factory.

Application Of The SOMACorrect™ Peyronie's Correction Therapy

After you have reviewed the section on GETTING FAMILIAR WITH YOUR SOMACorrect (next), you will be ready for application to treat your Peyronie's. The penile curvature and associated fibrotic plaque on Peyronie's varies from patient to patient, therefore a treatment program must also vary from patient to patient. Generally, a treatment protocol should show significant results within twenty-six weeks (6 months) of continued SOMACorrect. Use once each day.

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