

# Please read these instructions before using the VenoSeal™ Adjustable Constriction Loop. This device may cause injury if not used correctly.

## VENOSEAL™ ADJUSTABLE CONSTRICTION LOOP

The VenoSeal™ Adjustable Constriction Loop is intended to help maintain erection of the penis.

A normal erection is created when blood flows into the penis causing it to enlarge. As the penis enlarges, the flow of blood into the penis causes pressure that reduces the flow of blood out of the penis.

Some men are able to get an erection but find that their erection does not last long enough for satisfactory intercourse. This is often due to a condition known as venous leak. Many of these men can be helped with the use of VenoSeal<sup>TM</sup>.

VenoSeal™ is an Adjustable Constriction Loop that is placed and tightened at the base of the penis. With proper tension, the VenoSeal device will be comfortable to the user but also provide enough additional pressure to prevent blood from flowing back into the body, thus maintaining an erection.

#### **WARNINGS AND PRECAUTIONS**

Talk to your doctor if you have symptoms of erectile dysfunction (not being able to get or keep an erection that allows you to have sex) in order to prevent a delay in discovering and treating the cause.

#### Warnings:

- Do not use this device if:
  - You have an abnormally formed penis.
  - o You have been advised not to have sexual activity
  - You have sickle cell anemia or trait, leukemia, tumor or the bone marrow or other conditions that change blood clotting and may result in bleeding or prolonged erections.
- <u>Do not</u> leave the VenoSeal on your penis for more than 30 minutes. Do not fall asleep wearing the device. Leaving the VenoSeal on too long may cause permanent injury or damage to your penis.
- Allow at least 60 minutes between uses of VenoSeal device. Using Adjustable Constriction Loops too often may cause bruising at the base of the penis (where the penis is joined to the body).
- Talk to your doctor if any complications occur in using this device. Stop using the device if complications continue.

#### Precautions:

- Ask your doctor about using the VenoSeal 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 VenoSeal 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.
- Do not use the VenoSeal under the influence of drugs or alcohol. These substances may reduce your sensitivity to pain or impair
  your ability to follow directions properly.
- Do not use VenoSeal™ if you cannot sense pain in the penis. Pain may be a warning sign that the device is causing injury.
- Do not use VenoSeal<sup>™</sup> if you do not have adequate use of your hands to easily remove device.
- Tension rings (including the VenoSeal) are not a means of birth control. Do not rely on tension rings to avoid pregnancy.
- Always use the lowest amount of tension necessary to maintain the erection. Do not over-tighten the VenoSeal ring. Too much tension can cause bruising at the base of the penis.

#### **POSSIBLE SIDE EFFECTS:**

## **Prolonged Erection / Priapism:**

 Contact your doctor immediately if you experience an erection that lasts more than 4 hours. Prolonged erection or Priapism is a serious condition that requires prompt medical attention to prevent permanent damage to the penis.

# Other Side Effects:

- Pain or redness of the penis can occur as a result of using this device
- Permanent injury to the penis can result if the device is either worn too tight or for more than 30 minutes

#### CARE AND REPLACEMENT OF THE VENOSEAL™ ADJUSTABLE CONSTRICTION LOOP

Care of VenoSeal<sup>TM</sup>: If you use lubricant for sexual activity, use only water based lubricants. Oil based lubricants may decrease the performance of VenoSeal<sup>TM</sup>.

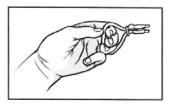
- VenoSeal™ can be used more than once. Clean after use with warm water and ordinary hand soap. Keep VenoSeal™ dry and store at room temperature after it is cleaned.
- Replacement: Repeated use of the VenoSeal<sup>™</sup> device may result in wearing out the synthetic rubber loop. Replace VenoSeal<sup>™</sup> after 6 months of use or when it shows signs of wear such as cracking

#### FOR FURTHER INFORMATION

Call the toll free Timm Medical line: 1-800-438-8592, or visit our product web site www.Timmmedical.com.

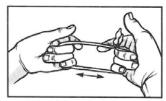


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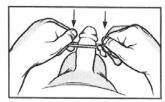
1. To stretch the VenoSeal™ device: Grasp the loop of the VenoSeal™ with the left hand. Note that the end of the tubing with the ball is on the top (See Figure 1).

FIGURE 1



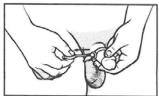
With the right hand, grasp the loop next to the O ring and stretch the VenoSeal™ device (See Figure 2).

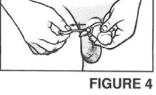
FIGURE 2



2. To place around the shaft of the penis: Place the end of the penis through the stretched loop and slide VenoSeal<sup>TM</sup> over the penis (Figure 3) until it is around the base (See Figure 5)

FIGURE 3





**3.** To place VenoSeal™: Place VenoSeal™ so that the loop goes around the base of the penis. The part of the tubing with the ball should be on the top side of the penis. Grasp the tab end (lower end) of the tubing without the ball. Pull horizontally away from the penis until VenoSeal™ is gently snug around the base of the penis (See Figure 4).

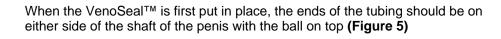






FIGURE 6



FIGURE 7

4. To get proper tension: Grasp the tab on the end of the tubing without the ball and pull down (Figure 6). VenoSeal™ should be tight enough to keep the blood from leaving the penis. Too much tension may stop the erection process. Too much tension may lead to discomfort and could cause harm to the penis. If the erection is not firm enough, apply pressure with your hand to the area behind the scrotum. This may push more blood into the penis

As the penis becomes firm, VenoSeal™ may be tightened or loosened to get an erection while providing the most comfort

5. To loosen the tension: After intercourse or if the erection is too firm, VenoSeal™ may be loosened by pulling up on the end of the tubing with the ball (Figure 7) Once fully loose, VenoSeal™ can be removed by sliding the loop over the end of the penis.