

Warnings and Precautions

- Do not use RestoreX for more than 1 hour daily or for >30 minutes at a time.
- Separate 30-minute treatment sessions by at least 30 minutes.
- DO NOT wear RestoreX while sleeping
- DO NOT overtighten the self-adherent wrap or wear for more than 30 minutes.
- DO NOT clamp the shaft of the penis. Only clamp the head of the penis as shown on page 17.
- Discontinue use and consult a medical professional if:
 - You experience new or worsening pain in your scrotum, penis or abdomen
 - You develop a new curvature or indentation
 - You experience persistent skin discoloration
 - You experience pain with traction
 - You experience any worsening of sexual function
- Prior to each use, insure all screws adjusted during the set-up process are tight
- RestoreX is a single patient use device. Do not share with another individual.
- Never place RestoreX in a dishwasher or microwave oven.

Contraindications

Do not use RestoreX if:

- You have had penile, scrotal or pelvic surgery within the past six weeks unless otherwise indicated by your surgeon
- You experience chronic penile pain not related to Peyronie's disease
- You experience chronic testicular or scrotal pain
- You have open sores or wounds on your penis

RestoreX is not recommended for use in men with severe vascular disease including those who have:

- Absence of feeling in fingers, toes or limbs due to ischemia or neuropathy associated with diabetes or similar conditions, especially if the condition has resulted in loss of digits or limbs.
- Penile skin infections, open lesions or sores

Troubleshooting

1) It is difficult to place and secure device due to inability to see the penis

- If you are unable to see the penis to apply the clamp, remove the clamp from the clamp housing (**Part 5**, pg. 13).
- Once removed, place your penis through the pelvic ring. With the clamp out of the housing, place the clamp on your penis.
- After securing your penis in the clamp, replace the clamp into its housing and follow the remainder of the instructions under “Using RestoreX in 3 Simple Steps.”

2) Difficulty in Removing RestoreX

- If it is too difficult to release the clamp to remove RestoreX, reduce tension by pulling RestoreX toward the body to the locked position on the tension rods (*Figure F*, pg. 18). With the tension reduce, open the clamp and remove. Prior to storing, release the lock on the tension rods, also shown in *Figure F*, pg 18.
- If it is still difficult to remove RestoreX, take the clamp out of its clamp housing (**Part 5**, pg. 13), open the clamp and remove RestoreX.

3) Penis does not fit into device

- RestoreX accommodates stretched penile lengths (similar to erect length) of 3.75 inches (10 centimeters) and greater. If you feel your stretched length is shorter than 3.75 inches (10 centimeters), please attempt to re-measure using the instructions in **Part 1a** (pg. 5) under “One-Time Setup of the RestoreX Device.” Most often, people undermeasure their true penile length by not

Troubleshooting (Cont.)

pushing the ruler deep enough into the fat pad located in the lower abdomen. The true stretched penile length should be measured from the tip of the penis to the pubic symphysis (or bone where the penis attaches).

- After re-measuring, if your stretched penile length is less than 3.75 inches (10 centimeters), you may wish to return the RestoreX device to PathRight Medical.

4) Penis is too long to get a full stretch.

- Please contact PathRight Medical customer service at 1-877-228-5147.

5) In going from the “Straight Position” to the “Angled Position,” there aren’t enough notches on the extension rods to reduce tension

- It may be the case where you are able to get good traction in the “Straight Position” using the extended rod length but are not able to reduce the device tension sufficiently for the “Angled Position.” In this case, you will need to use the standard rod for the “Angled Position.”
 - Please see **Part 3** (pgs. 8-10) under “One-Time Setup of the RestoreX Device” for instructions on changing to the standard rod.

6) Penis keeps slipping out of the clamp whenever traction is applied. *Several things may cause this to occur:*

- The penis was not wrapped with self-adherent wrap or not enough self-adherent wrap prior to securing the clamp.
- The clamp is not tightened sufficiently. Please note the clamp should not be tightened more than can be worn comfortably for 30 minutes at a time.

Troubleshooting (Cont.)

- Too much tension is being applied to the penis. The recommended amount of tension is enough to cause the white band on the tension rods to disappear into the device. If the springs are fully compressed, it may indicate too much traction and should be reduced.
- Traction is not released prior to changing from the “Straight Position” to the “Angled Position.” Since the “Angled Position” results in additional tension on the penis, reduce the amount of tension by pressing the extension release and moving the main body of the device toward the pelvic ring. Once the tension is reduced, the device can be changed into the “Angled Position.” Then, if needed, additional tension can slowly be applied until the white band on the tension rods disappears into the device.
- If you are unable to add tension causing the white lines to no longer be visible, try method 2 as explained on page 20.

7) Stretched penile length is greater than 6.25 inches but with the clamp in position 2 or 3, the user cannot reach the first notch on the extension rods.

- In a few situations, the stretched penile length obtained in **Part 1a** (pg. 6) will indicate to use the extended rods. However, if in **Part 4** (pgs. 10-11), you move the clamp to position 2 or 3, you may not be able to use the extended rods due to the extra length in the overall device brought about by moving the clamp. If this happens, return to the standard rod and proceed with treatment.

Troubleshooting (Cont.)

8) What if my penis is too short for the angled position?

First, use position 1 for the clamp location (**Part 4**, pg. 11). Second, begin each session with 15 minutes of straight traction before bending. Afterward, return RestoreX to its fully collapsed position meaning the tension rods are locked and the extension rods are at their starting position. If helpful, wrap the shaft of the penis with gauze, toilet paper, or something similar to allow it to slide over the RestoreX device more easily. If after all of these steps, you are still unable to bend to the 90 degree position (position #3), bend as far as you are able and engage the traction.

9) What if my curvature is further back on the penis than the point of bending?

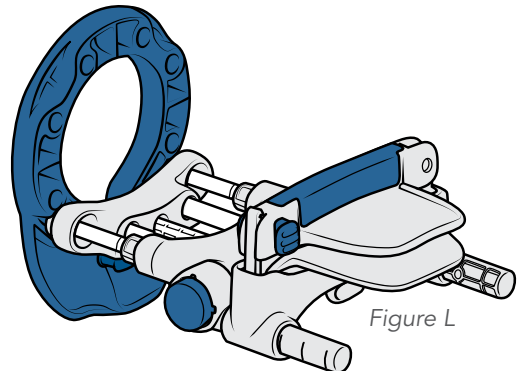
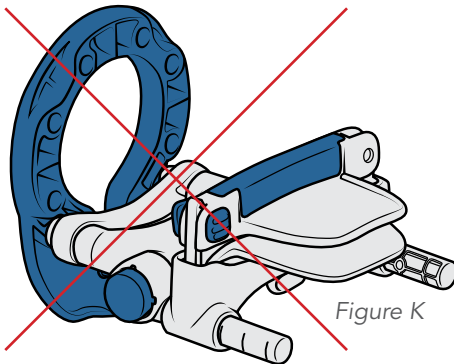
This is acceptable. In a clinical trial evaluating RestoreX, curvatures that were closer to the body responded just as well as those that were directly over the point of bending. Bending is important because it allows more force to be applied to the direction of curvature than other areas of the penis.

Care

- Do not use a lubricant on RestoreX as it may permanently damage the device.
- Cleaning – To clean the device, wipe off any visible soil or contaminants from surfaces using a soft towel or facial tissue. Next, clean all surfaces of RestoreX using a cloth moistened with soap and water. DO NOT wash or immerse RestoreX in water, as this may damage the interior components. Allow RestoreX to air-dry thoroughly in a ventilated location before storing.

Never place any RestoreX component in a dishwasher or microwave oven

- Do not store RestoreX in its most compressed state (spring locked) (*Figure K*). Storing RestoreX in the compressed state will reduce its useful life. When not in use, store in an extended manner as illustrated below (*Figure L*).





Your path to restored health

Customer Service

1-877-228-5147

support@restorex.com

9 a.m. to 5 p.m. (CST), Mon-Fri

restorex.com

REV.H 9/19

PathRight Medical, Inc.

14252 23rd Avenue N.

Plymouth, MN 55447

Model #117

US Patent 10,117,771. November 6, 2018.

Quick Start
Video
at
restorex.com