

Next Generation Penile Traction Therapy Device

For the treatment of curvature and lost length resulting from Peyronie's disease

Developed in Cooperation with Mayo Clinic

Quick Start Video at RestoreX.com





Indication for Use

RestoreX[™] is intended for use to correct the deformity (curvature and lost length) resulting from Peyronie's disease.

Read these instructions in their entirety before using the RestoreX device.

Use only as directed.

If you have questions about the use of the RestoreX device, please call or email customer service at:

1-877-228-5147

support@restorex.com.

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

RestoreX is a registered trademark of PathRight Medical, Inc.

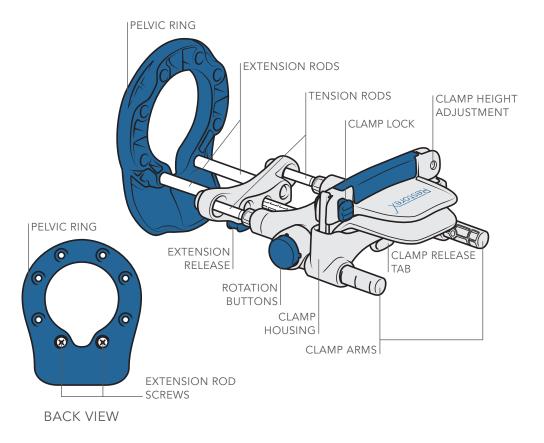
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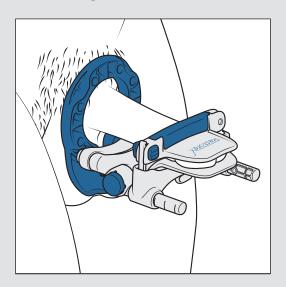
Overview

Please review the image to become familiar with the primary components of RestoreX.





One-Time Setup of the RestoreX Device



RestoreX accommodates most penile lengths and curvatures. Follow these one-time setup instructions to customize RestoreX for optimal results.

To customize, you will need the following:

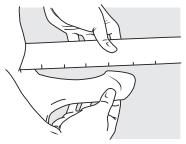
- Your RestoreX device
- A ruler (not supplied)
- A Phillips-head screwdriver (not supplied)



Part 1 – Recording Penile Measurements

To begin setting up RestoreX, complete the following measurements:

1a - Stretched Penile Length - This measurement will be used in Part 2



- Hold the tip of the flaccid penis and pull it outward from the body until maximally stretched.
- With a ruler, measure from the tip of the penis to the base of the penis in the flaccid state.

Important: If you have a fat pad at the base of the penis (very common), push the ruler into this pad to properly measure the full penile length.

Record stretched penile length:

1b - Direction of Curvature - This information will be used in Part 3

Record all directions that the penis curves. Directions are from your viewpoint as you look down

Circle the direction(s) of curvature here: Up Down Left Right

1c - Distance to Curvature - This distance will be used in Part 4



- Measure the distance from the tip of the penis to the middle of the inside of the curvature when you have a firm erection (as depicted).

Record distance to curvature here:



Part 2 – Selecting Extension Rod Length

Compare your stretched penile length recorded in **Part 1a** (pg. 6) to the following table:

Stretched Length Recorded in STEP 1a		Recommended Extension Rod Length
Inches	Centimeters	Extension Roa Length
3.75 to 6.25	10 to 16	Standard rod length Your device is currently set-up with the correct rod length. Please proceed to Part 3 for proper rod location
Longer than 6.25	Longer than 16	Extended rod length* Please see the instructions in Part 3 to exchange the rods and to place them in the proper location *The extended rods are located in the RestoreX box

Note: RestoreX cannot accommodate a stretched penile length less than 3.75 inches (10 centimeters). Please remeasure as detailed in **Part 1a** (pg. 6) being sure to push the ruler into any fat pad which may exist near the base of the penis, as this is the most common reason to get a result less than 3.75 inches (10 centimeters).

Note: RestoreX <u>may not</u> provide sufficient traction for men with a stretched penile length greater than 9 inches (23 centimeters).

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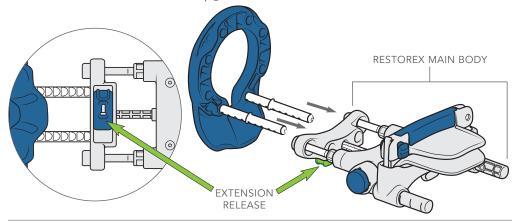


Part 3 – Changing Extension Rods (if necessary) and Adjusting Rod Location

If your curvature is upwards as recorded in **Part 1b** (pg. 6) and you are using the standard extension rod length, proceed to **Part 4** (pg. 11). Otherwise, you will need to remove and/or adjust the rods.

Removing the rods:

- First, slide the extension release and hold to disengage the extension rods.
- Second, slide the main body of the device off the rods and away from the pelvic ring until it is fully removed.
- Next, unscrew the extension rods and detach from the pelvic ring using a Phillips-head screw driver (not supplied).
- Gently pull each extension rod until they come free from the pelvic ring.
- Proceed to the rod location, as shown later in **Part 3** (pg. 9), with the proper length rods as determined in **Part 2** (pg. 7).





Part 3 – Changing Extension Rods (if necessary) and Adjusting Rod Location (Cont.)

Reposition the correct length rods (Part 2) based on the following table:

Direction of Curvature (obtained in Part 1b)	Recommended Location for Rod Positioning Note: Rods are intended to bend the penis in the direction opposite the curvature.		
Up			
Down	DOWNWARDS CURVATURE CURVATURE		
Left	RIGHT W UPWARDS CURVATURE		
Right	BACK VIEW Screws Enlarged to Show Detail		
Multiple	If you have multiple curvatures, treat the largest and most bothersome curve first. Once adequately treated, the device may be re-adjusted to treat another location. Please consult with your physician if you are unsure which curvature to treat first.		

Alian flat side

of extension rod with flat

portion of

"key" hole in pelvic ring



Part 3 – Changing Extension Rods (if necessary) and Adjusting Rod Location (Cont.)

Re-attaching the extension rods:

• If the stretched penile length obtained in **Part 1a** (pg. 6) exceeds 6.25 inches (16 centimeters), use the extended rod length. Otherwise, continue with the standard rod.

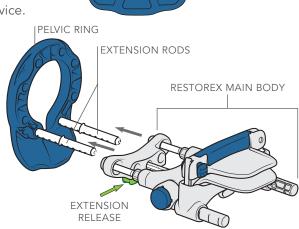
 Place the extension rod into the pelvic ring by aligning the flat side of the extension rod with the flat portion of the "key" hole in the pelvic ring, as depicted.

 Attach the screw to the extension rod through the hole in the pelvic ring and tighten. Do not overtighten. Overtightening may damage your RestoreX device.

 Attach the second rod using the same process.

With the extension rods in place, re-connect the main body of the RestoreX device:

 Slide and hold the extension release while sliding the body onto the rods, as shown.





Part 4 – Adjusting Clamp Location

Using the information obtained in **Part 1c** (pg. 6), refer to the following table and the illustration on page 12 to adjust the clamp.

Note: Do not reposition the clamp on the clamp arms if your total stretched penile length **Part 1a** (pg. 6) is 5 inches (13 centimeters) or less. Only use position 1.

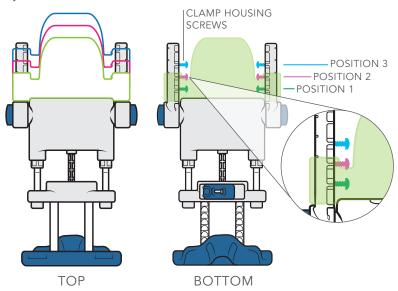
Distance from Penile Tip to Curvature (obtained in Part 1c)		Position for Clamp Housing
Inches	Centimeters	
Less than 2	Less than 5	Use position 1 Your RestoreX is preset at this position. Proceed to Part 5 .
2 to 3	5 to 7.5	Use position 2 Move the clamp housing using the instructions on page 12.
Greater than 3	Greater than 7.5	Use position 3 Move the clamp housing using the instructions on page 12.



Part 4 – Adjusting Clamp Location (Cont.)

To move the clamp housing to position 2 or 3:

- Turn the RestoreX device over and locate the two screws securing the clamp housing to the clamp arms (one screw on each arm).
- Remove the screws and slide the clamp housing to the desired position, as indicated in the table on page 11, and the illustration below.
- Align the holes in the housing with the holes in the arms, insert and tighten the screws.
- Completely tighten but do not overtighten the screws. Overtightening may damage your RestoreX device.

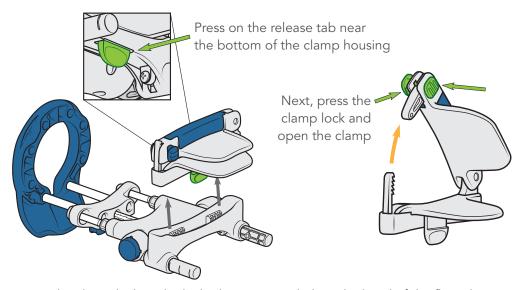




Part 5 - Adjusting Clamp Height

In some cases, the clamp height may need to be adjusted to improve comfort during the treatment. To determine if an adjustment is necessary, remove the clamp from the clamp housing.

Remove the clamp from the clamp housing:



Return the clamp lock to the locked position and place the head of the flaccid penis into the clamp. Gently begin closing the clamp. Continue to close to tighten—listening to the number of "clicks" required—until reaching a setting where you could comfortably wear the clamp without discomfort for at least 30 minutes.



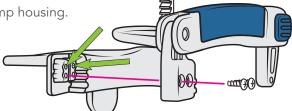
Part 5 – Adjusting Clamp Height (Cont.)

If you are unable to close the clamp or only able to lock it in the highest position (one click), you will need to adjust the clamp height. Otherwise, proceed to the next page.

Adjusting the clamp height:

• Remove the clamp from the clamp housing.

- Identify the two screws on the inside, bottom portion of the clamp, as shown at right.
- Loosen and remove the screws using a Phillips-head screw driver.



- Once the screws are removed, gently separate the two pieces by pulling apart.
- Reposition the clamp at the higher location, as shown above.
- Replace the screws and gently tighten. Completely tighten but do not overtighten the screws. Overtightening may damage your RestoreX device.
- Replace the clamp into the clamp housing.

Your RestoreX device is now customized for your use!