INSTRUCTIONS FOR USE

Quick Start Video at restorex.com

PathRight Medical
Your path to restored health
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.**

8 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 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 flacid 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:

<table>
<thead>
<tr>
<th>Stretched Length Recorded in STEP 1a</th>
<th>Recommended Extension Rod Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inches</td>
<td>Centimeters</td>
</tr>
<tr>
<td>3.75 to 6.25</td>
<td>10 to 16</td>
</tr>
<tr>
<td>Longer than 6.25</td>
<td>Longer than 16</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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 may not provide sufficient traction for men with a stretched penile length greater than 9 inches (23 centimeters). Please call PathRight Medical customer service at 1-877-228-5147 for assistance.
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:

<table>
<thead>
<tr>
<th>Direction of Curvature (obtained in <strong>Part 1b</strong>)</th>
<th>Recommended Location for Rod Positioning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up</td>
<td><strong>Note:</strong> Rods are intended to bend the penis in the direction opposite the curvature.</td>
</tr>
<tr>
<td>Down</td>
<td>DOWNWARDS CURVATURE</td>
</tr>
<tr>
<td>Left</td>
<td>RIGHT CURVATURE</td>
</tr>
<tr>
<td>Right</td>
<td>UPWARDS CURVATURE</td>
</tr>
</tbody>
</table>

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.
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:

<table>
<thead>
<tr>
<th>Distance from Penile Tip to Curvature (obtained in Part 1c)</th>
<th>Position for Clamp Housing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inches</td>
<td>Centimeters</td>
</tr>
<tr>
<td>Less than 2</td>
<td>Less than 5</td>
</tr>
<tr>
<td>2 to 3</td>
<td>5 to 7.5</td>
</tr>
<tr>
<td>Greater than 3</td>
<td>Greater than 7.5</td>
</tr>
</tbody>
</table>

**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.
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.

[Diagram showing clamp housing in different positions]
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:*

- Press on the release tab near the bottom of the clamp housing.
- Next, press the clamp lock and open the clamp.

Return the clamp lock to the locked position and place the head of the 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!*
Using RestoreX in 3 Simple Steps
Secure • Extend • Rotate

PathRight Medical recommends the following:

• Watch the quick start video prior to reading the remainder of this manual. The video provides a helpful overview of the use of RestoreX.

• Carefully review the treatment time chart on page 22. Following the chart will help you successfully use the RestoreX device.

• You may use the RestoreX device while sitting, standing or lying down. PathRight Medical recommends the sitting or lying down positions.

• During treatment you may wear a pair of athletic shorts or light pair of sweat pants.

• Use RestoreX every day as directed. Missing a few days may reduce results.

• The white bands should not be visible when RestoreX is treating in the angled position (pg. 20).

• In the straight position (pgs. 18-19), at a minimum make sure the white bands are not visible. If you can tolerate more tension, advance the extension rods another notch.

• In the angled position (pg. 20), do your best to get to the 3rd or 4th stop (90 or 120 degrees).
Step 1 - Secure the Penis in the Clamp

Opening the Clamp

To improve comfort, use the supplied self-adherent wrap (Figure A) by gently wrapping it two or three times around your flacid penis. Overlap the wrap as you go around the penis. Do not overtighten. If worn too tightly, the wrap can restrict blood supply to the penis. In some cases, use of the wrap may require adjustment of the clamp height Part 5 (pg. 13).

Note: Use wrap prior to expiration date.

First, open the clamp by pushing the clamp lock towards the pelvic ring (Figure B). This is the open position.

Next, open the clamp (yellow arrow, Figure C) and push the main body of RestoreX toward the pelvic ring so RestoreX is locked in its shortest configuration. Now you may put RestoreX on.
Step 1 - Secure the Penis in the Clamp (Cont.)

**Positioning the Device and Closing the Clamp**

To put RestoreX on, insert your penis through the pelvic ring. While holding the pelvic ring against your body, place the head of your penis into the open clamp. In this position slowly close and secure the clamp (*Figure D*) closing to the number of clicks achieved in **Part 5** (pg. 13) or until it is as tight as can be comfortably worn for 30 minutes. Push the clamp lock all the way closed (*Figure E*) to ensure the proper long-term functioning of the lock.

**Note:** If the clamp lock is in the open position you will not hear any clicks and will have to push the lock closed when you reach the desired location (*Figure E*).

**Note:** If during the clamping process or treatment session you experience pain or numbness in the penis, open the clamp, reposition the penis and continue the treatment. If pain persists, see Warnings and Precautions (pg.25), stop the treatment session and contact either your physician or RestoreX customer service at 1-877-228-5147.

**Note:** If, during the treatment session the RestoreX device changes position, reduce tension, reposition and re-tension.
**Step 2 - Extend and Add Tension**

With the penis secure in the clamp, you are ready to add traction. First, locate the white bands on the tension rods. The goal in extending the RestoreX device and adding tension is to have the white bands “disappear” into RestoreX. When the white bands are no longer visible, you’ve achieved the minimum amount of tension.

Users of the RestoreX device use two different methods to extend the device and add tension. Practice with both to discover which is best for you.

The **first method** is to release the tension rods and then advance RestoreX along the extension rods until the white bands are no longer visible. *(Figures F & G)*

The **second method** is preferred by some users, particularly men that have difficulty with the head of their penis slipping out of the clamp. First, advance the RestoreX device on the extension rods *(Figure G)* until the penis is nearly fully stretched. Next, **carefully and slowly** release the lock on the tension rods *(Figure F)* allowing them to fully stretch the penis and achieve tension.

Step 2 - Extend and Add Tension (Cont.)

Figure F

Pull toward the body.

Release away from the body.

Figure G

Hold pelvic ring against body, advance RestoreX on extension rods.

ADD TENSION UNTIL LINE IS HIDDEN

EXTENSION RODS
Step 2 - Extend and Add Tension (Cont.)

Method 1

- Unlock the tension mechanism (springs) by pulling RestoreX back toward your body.
- Slowly and with control allow the springs to release and expand (the lock operates like a ball point pen) (Figure F, pg. 19).
- While holding the pelvic ring against your body, advance the RestoreX device on the extension rods, one notch at a time until the tissue pulls back enough that the white bands are no longer visible (Figure G, pg. 19).

Method 2

- With the tension rods still locked, advance RestoreX on the extension rods until the penis is nearly fully stretched (Figure G, pg. 19).
- Slowly and very carefully, unlock the tension rods by first pulling back toward your body and then releasing, much like a ball point pen. Do not release abruptly! Release slowly and under control (Figure F, pg. 19).
- Next, if the white bands are still visible, relock the tension rods by pulling back toward your body until they relock. Now, while holding the pelvic ring against your body, advance RestoreX an additional notch on the extension rods. Again, release the tension rods by pulling back toward your body and then releasing slowly and under control. Repeat this process until the white bands are no longer visible.
Step 2 - Extend and Add Tension (Cont.)

The following notes apply to both Methods 1 and 2

**Note:** If at anytime you feel pain, excessive pressure, or pinching, reduce tension by pulling the main body of RestoreX back on the tension rods and lock into place. Reposition the base ring against the body and re-apply traction to assure the penis is firmly secured but still comfortable enough to be worn for 30 minutes.

**Note:** It is important during treatment that the penile skin is rather loose. If the penile skin is overly tight, it could result in discomfort and reduced results. To prevent this, gently encourage more of the penile skin and skin in the pubic area through the pelvic ring or slightly adjust the location of the pelvic ring from time to time to assure that the deeper penile tissues are being stretched.
Step 3 - Rotate Opposite the Curvature

Applying Tension in the Angled Position

RestoreX allows you to bend the penis in the opposite direction of the curvature. To do so, push the two buttons simultaneously and then rotate the clamp around to one of the four stops/positions (Figure H). You may only be able to initially achieve the first or second stop. However, after a few minutes, you may be able to advance to the next position. In order to achieve a maximal bend/angulation, you may need to reduce tension prior to rotating. To do so, slide the extension release (see pg. 8) on the bottom of the device and move the main body back toward the pelvic ring until you are able to achieve the angled position. Once complete, you may re-apply tension by advancing on the extension rods until the white band on the tension rods is not visible.

Note: If the distance from the Penis Tip to the curvature of your penis is greater than 4 inches or 10.0 cm (see part 4, p. 11), only use the first or second stop (30° or 60°). Limiting the angle of the opposite force will increase the tension applied to the disease location.

Note: Many men have found that wrapping the penile shaft with tissue or gauze allows the penile skin to slide easily and more comfortably over RestoreX when using the 3rd or 4th position for rotation in the opposite direction of the curvature.
Removing RestoreX
To remove RestoreX, slowly and gently release the clamp by pushing the clamp locking button toward you (*Figure I*), slowly and gently open the clamp and remove the device.

If it is difficult to release the clamp, push both rotation buttons simultaneously to return the RestoreX device to the straight position as depicted (*Figure I*) or move the main body along the tension rods toward the pelvic ring and lock into place. Now, open the clamp and remove the device.

Store the RestoreX device in the unlocked position (springs extended) until the next use (*Figure J*). If used, remove the self-adherent wrap.
Recommended Treatment Times

<table>
<thead>
<tr>
<th>Calendar</th>
<th>Time: Straight Position</th>
<th>Time: Angled Position</th>
<th>Treatments per Day</th>
<th>Total Therapy Time per Day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days 1 and 2</td>
<td>8 minutes</td>
<td>2 minutes (Position 1 or 2)</td>
<td>3</td>
<td>3 treatments x 10 min = 30 mins</td>
</tr>
<tr>
<td>Days 3-7</td>
<td>13 minutes</td>
<td>2 minutes (Position 1 or 2)</td>
<td>3</td>
<td>3 treatments x 15 min = 45 mins</td>
</tr>
<tr>
<td>Weeks 2-12 or Per Your Doctor’s Recommendation</td>
<td>15 minutes</td>
<td>15 minutes (Position 3 or 4)</td>
<td>2</td>
<td>2 treatments x 30 min = 60 mins</td>
</tr>
<tr>
<td>Weeks 13-52</td>
<td>15 minutes</td>
<td>15 minutes</td>
<td>1/Week</td>
<td>30 min</td>
</tr>
</tbody>
</table>

- After 12 weeks you may continue to use RestoreX 30 minutes twice daily until the penis is fully straight or you stop identifying improvements. Once you have achieved a satisfactory result, utilize RestoreX 15 minutes straight and 15 minutes angled once weekly to maintain the improvements achieved.

- For multiple curvatures, treat the largest and most bothersome curve first. Once adequately treated, adjust RestoreX to treat another location. Consult with your physician if you are unsure which curvature to treat first.

- Consult with your physician to determine the length of treatment.
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.
• 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).