

# RestoreX<sup>®</sup>

Next Generation Penile Traction Therapy Device

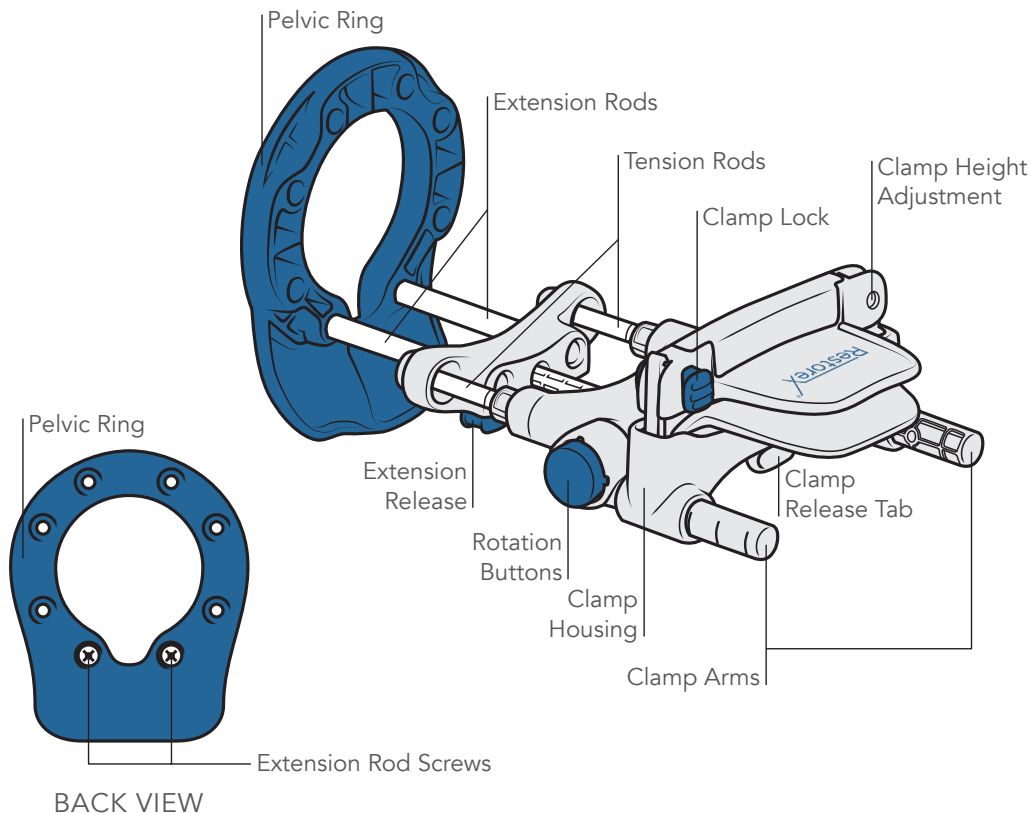
**For the treatment of penile curvature, deformity, and length  
and preservation of erectile function post-prostatectomy**

*Developed in Cooperation with Mayo Clinic*

 **PathRight**  
MEDICAL  
*Your path to restored health*

I N S T R U C T I O N S   F O R   U S E

## Overview of Device



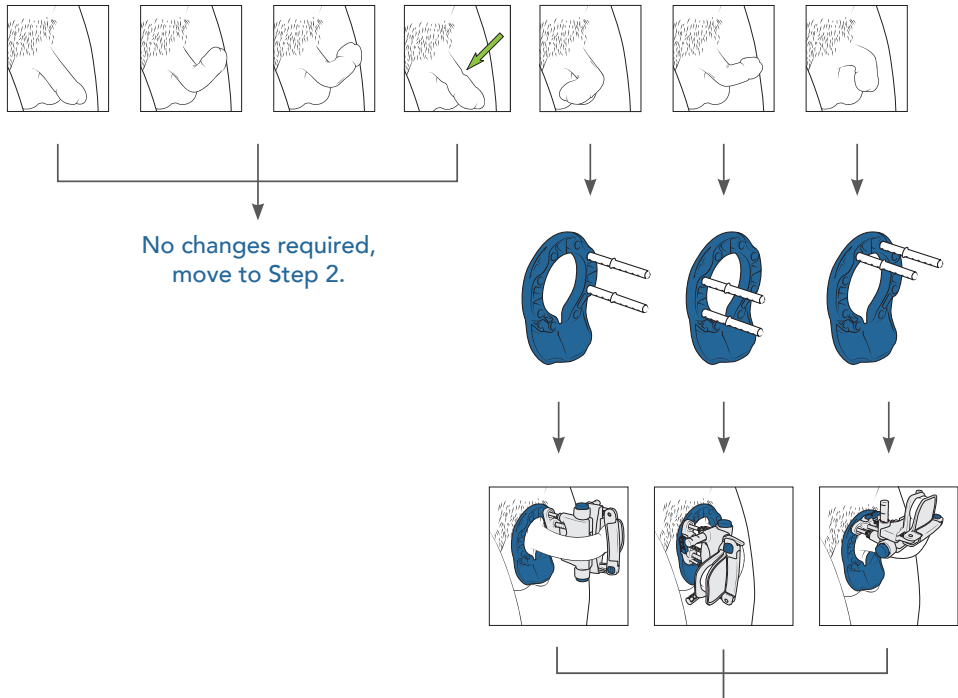
# QUICK SETUP GUIDE

*Note – Screwdriver not included.*

# QUICK SETUP GUIDE

## Step 1 – Adjust for Curve Direction (If Applicable)

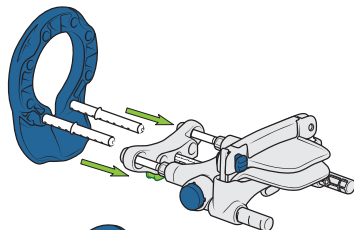
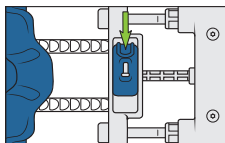
Which most closely resembles your condition?



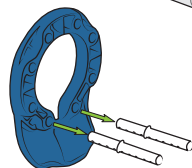
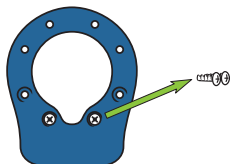
# QUICK SETUP GUIDE

How to adjust rods; if applicable (do not overtighten the screws):

I

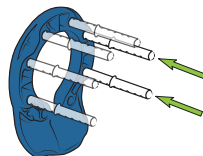


II



III

Place rods  
according to  
picture on left



IV

Replace screws  
to secure rods



Slide traction  
device onto rods

# QUICK SETUP GUIDE

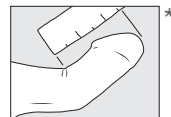
## Step 2 – Adjust Clamp Position (If Applicable)

What is your goal of treatment?

Lengthen only and/or preserve  
erectile function

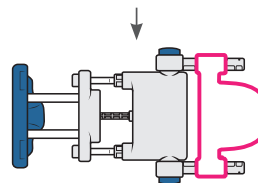
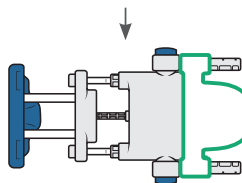
➡ No changes required, move to Step 3

Improve curve, indentation, hourglass, or  
similar deformity in addition to length



Less than 2 in  
(5 cm)

2-3 in  
(5-7.5 cm)\*\*

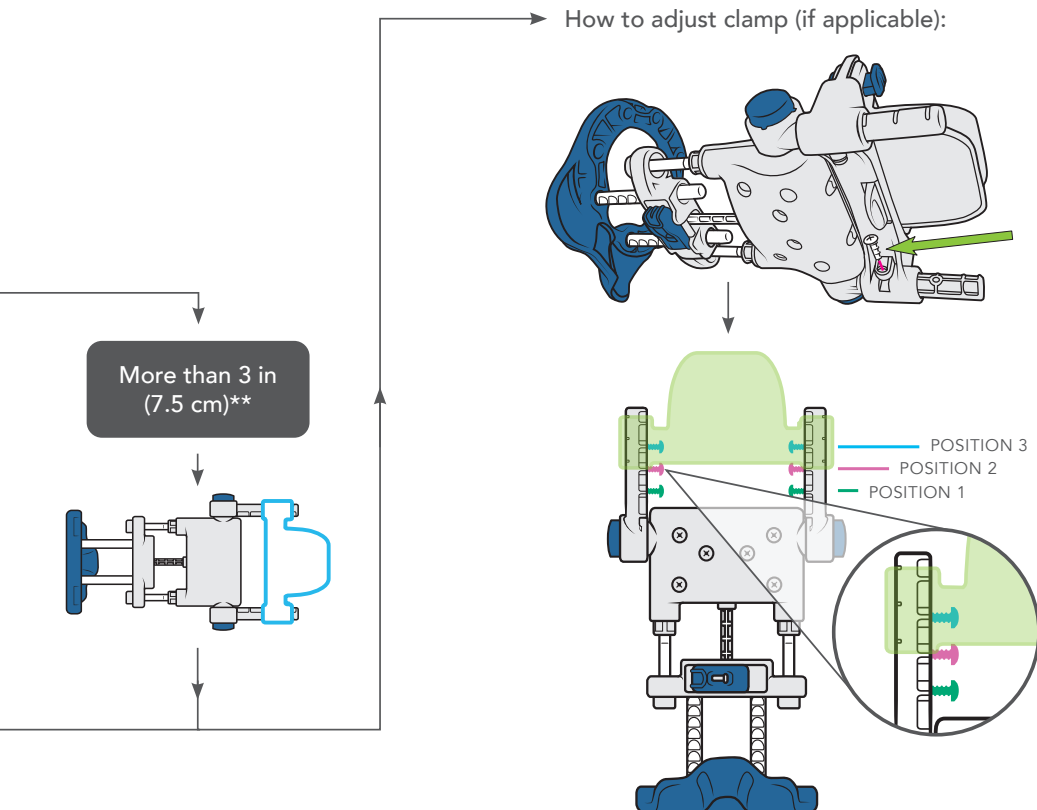


No changes required,  
move to Step 3.

\*Note – the distance from the curve's middle to the tip must be measured when erect.

\*\*Note – depending on penile length, positions 2 or 3 may not be possible.

# QUICK SETUP GUIDE

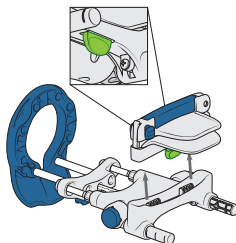
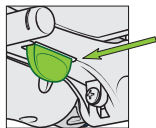


# QUICK SETUP GUIDE

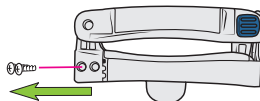
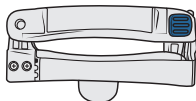
## Step 3 – Additional Adjustments (As Needed)

Adjusting clamp height:

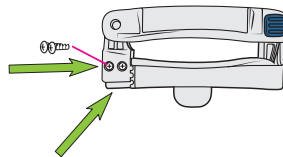
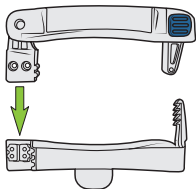
I



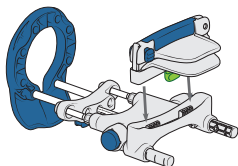
II



III



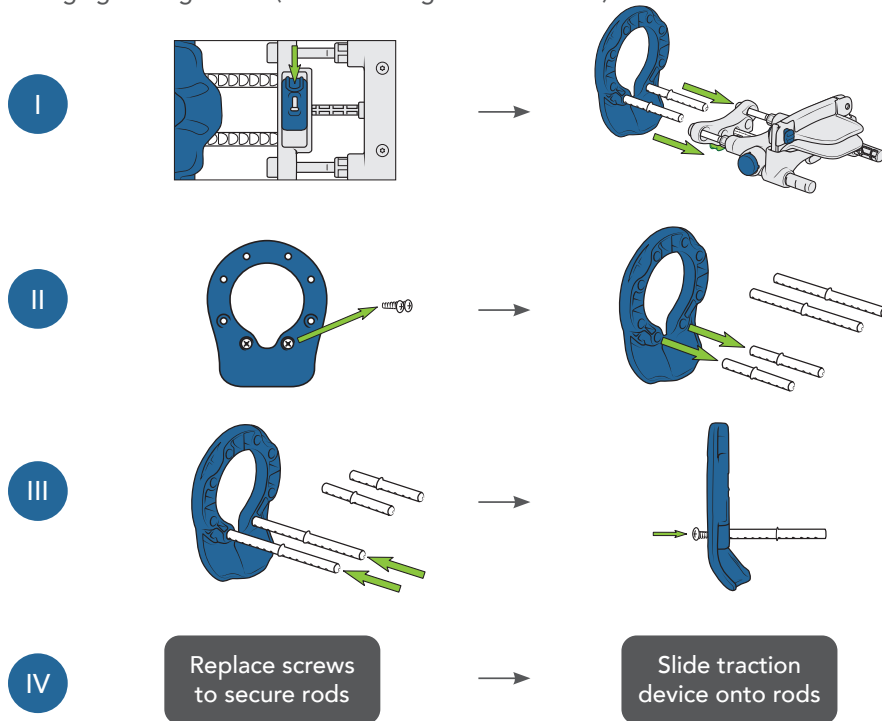
IV



# QUICK SETUP GUIDE

## Step 3 – Additional Adjustments (As Needed)

Changing to longer rods (do not overtighten the screws):



# USING THE DEVICE

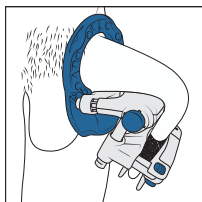
# USING THE DEVICE

## Key Principles to Optimize Outcomes

- Only use with a flaccid penis (not erect).
- Use 30-60 minutes daily – do not skip days if possible. Separate 30 minute treatment sessions by at least 30 minutes.
- The white bands should NOT be visible during use.
- The penile skin should be loose during use – you may need to pull in additional scrotal or penile skin during use.

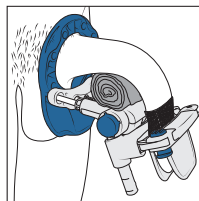
### For curves in the middle or end of the penis

↓  
Get to the 3rd or 4th position with counterbending:



### For curves near the base of the body

↓  
Place a gauze roll at the base of the penis between the penis and the device - only use the first or second stop (30° or 60°) when counterbending:

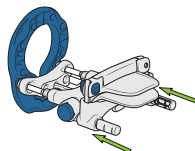
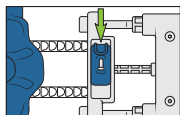


Scan the QR code for a video demonstration of device use:

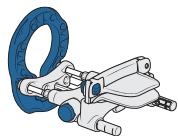


# USING THE DEVICE

## Step 1 – Prepare

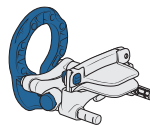


1a



Slide device back to beginning location.

1b



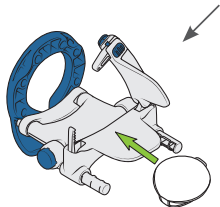
Lock springs by pushing (compressing) device together.

1c

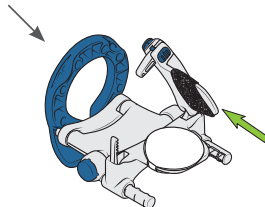


Wrap head of penis with self-adherent wrap or gauze.

*\*Note – pull back foreskin prior to placement if present.*



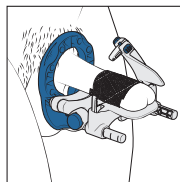
Option for added comfort.



Option to prevent slipping out.

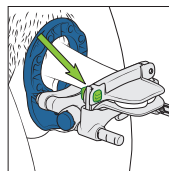
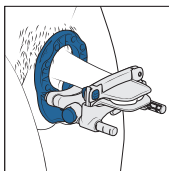
# USING THE DEVICE

## Step 2 – Clamp the Penis in the Device

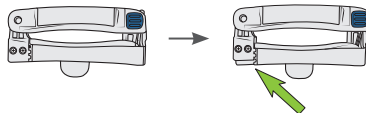


Place the flaccid (not erect) penis through the base ring and into the clamp.

*\*Note – rim of head of penis should be placed just inside of raised edge of clamp.*



Clamp should be secured as tightly as possible (without causing pain) to prevent slipping out.

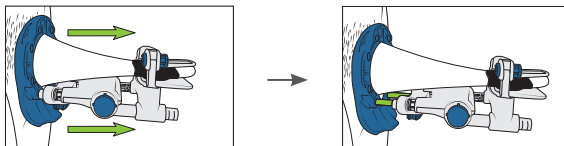


Optional height adjustment.  
See page 8.

# USING THE DEVICE

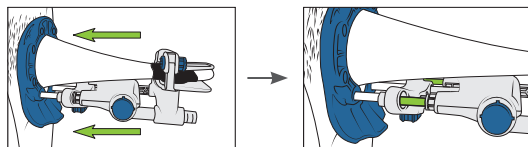
## Step 3 – Add Straight Traction

### I Extend

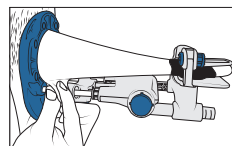
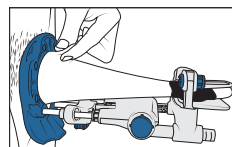


Extend device out as far as you are able.

### II Release



Release springs by pushing the device against your body.



Pull in additional penile and scrotal skin as needed to ensure that penile skin is loose while receiving traction.

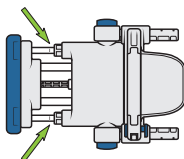
# USING THE DEVICE

## Step 3 – Add Straight Traction

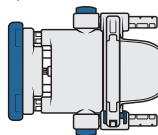
### III Optimize

Verify amount of traction.

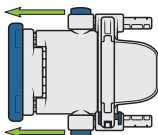
Indicator rod is not sufficiently compressed.



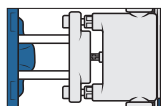
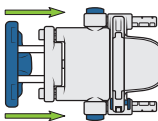
Indicator rod is nearly completely compressed.



Lock the springs by pushing the device against your body.

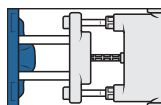


Advance the device 1 or more clicks until the penis is under maximal stretch.

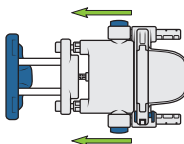


Optimal traction is being delivered.

**Periodically check indicator rods to see if additional traction is required.**



Release the springs by pushing the device against your body.



## USING THE DEVICE

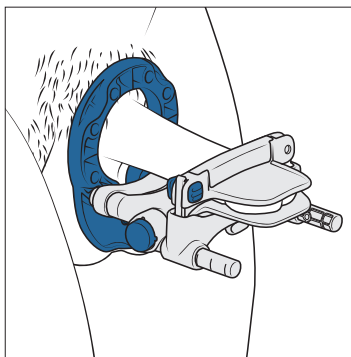
### Step 4 – Counterbending (If Applicable)

Counterbending is only used in cases of penile curvature or indentation/hourglass deformities.

1

Fully collapse device while keeping the penis clamped. This is done by compressing the springs and sliding the device back to the base (Page 12, 1a and 1b)\*

***\*Note – be very careful to avoid pinching scrotal skin as the device returns to the body.***



## USING THE DEVICE

### Step 4 – Counterbending (If Applicable)

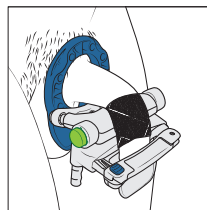
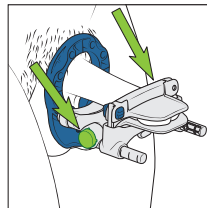
Counterbending is only used in cases of penile curvature or indentation/hourglass deformities.

II

Counterbend the device by pressing the two side blue buttons simultaneously as shown to the right. For curves in the middle or end of the penis, get to the 3rd or 4th position (note: the 3rd position is shown in pictures).

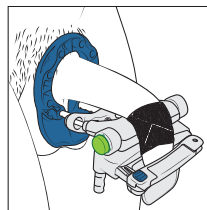
For curves near the base of the body, get to the 2nd position and place a gauze roll at the base of the penis as shown on page 11.

*Note: for comfort, you may wish to wrap the shaft of the penis with gauze or toilet paper to allow it to slide more easily during counterbending.*



III

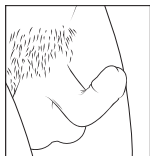
Extend the device by following steps as outlined in Step 3 with the device counterbent.



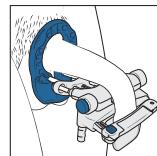
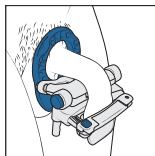
# USING THE DEVICE

## Step 4 – Examples of Counterbending

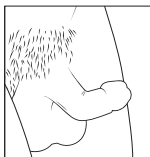
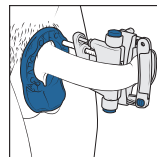
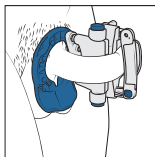
Which picture most closely matches your condition?



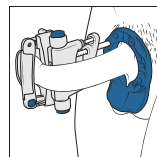
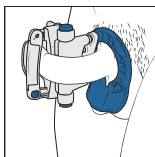
Up curve



Right curve



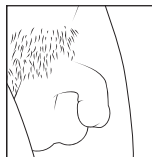
Left curve



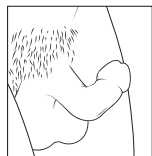
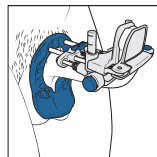
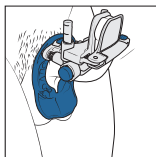
# USING THE DEVICE

## Step 4 – Examples of Counterbending

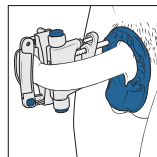
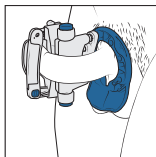
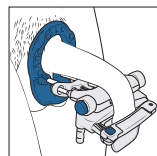
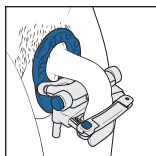
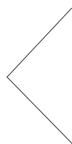
Which picture most closely matches your condition?



Down curve



Up and side  
curve

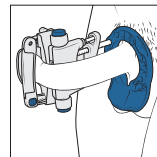
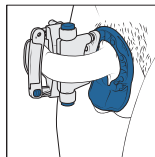
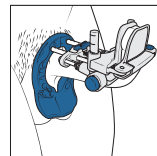
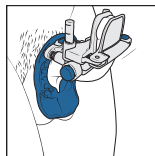
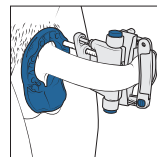
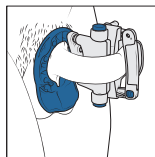
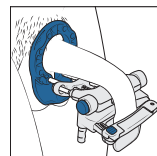
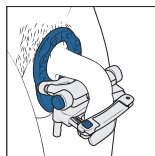


# USING THE DEVICE

## Step 4 – Examples of Counterbending

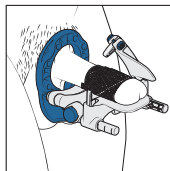
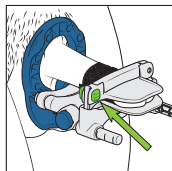


Hourglass/  
indentation



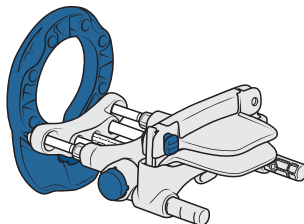
## USING THE DEVICE

### Step 5 – Remove the Device (After Treatment Completed)



Press the release button to free the penis from the device.

Remove any penile wraps.



Store the device with the springs in the uncompressed state.

### Notes on expected symptoms:

- It is normal for the head of the penis to be blue/cold while in the clamp.
- Discomfort is normal while using traction, particularly during the first 1-2 weeks of use.
- A small amount of decreased sensation is also normal during the treatment duration.
- Mild skin sensitivity from use of penile wraps is common.
- Discontinue use and contact your medical provider if you have any moderate or severe symptoms or symptoms which are persistent after discontinuing traction.

## Recommended Treatment Times

| Indication                | Straight traction                         | Counterbending                                                             | How long to continue treatment |
|---------------------------|-------------------------------------------|----------------------------------------------------------------------------|--------------------------------|
| Lengthening only          | 30 min, 1-2x/day                          | None                                                                       | 3-9 months <sup>1</sup>        |
| Post-prostatectomy        | 30 min, 1-2x/day starting 1 month post-op | None                                                                       | 5 months                       |
| Curve + length correction | 15 min, 1-2x/day                          | 15 min, 1-2x/day                                                           | 3-9 months <sup>1,2</sup>      |
| Hourglass narrowing       | 10 min, 1-2x/day                          | 10 min, 1-2x/day in every direction except direction of curve (if present) | 3-9 months <sup>1,2</sup>      |

<sup>1</sup> 3 months minimum; may continue up to 9 months if desired for additional improvements.

<sup>2</sup> For the first week of treatment, perform straight traction only. Counter-bending may be used beginning with the second week.

## Intended Use

RestoreX is intended to correct penile deformities of curvature and lost length.

## Patient Population

RestoreX is for males ages 18-75 with penile curvature and/or lost length due to Peyronie's disease, or those undergoing prostatectomy.

## Indications for use:

- To correct penile curvature or indentation/hourglass deformity
- To increase penile length, and
- To limit loss of erectile function post-prostatectomy

## Warnings:

- Do not use the device for longer than recommended, add additional traction to the device through the use of external materials such as weights, or overtighten the clamp as these may potentially result in pain or damage to the penile, testicular, or scrotal anatomy/physiology.
- Do not use a soiled or dirty device as this may potentially lead to infection.
- Use caution when clamping the head of the penis, locking the tension rods, and sliding the extension release as these may result in pinching of skin. This may potentially lead to bruising, bleeding, irritation, skin lacerations, swelling, or reduced sensation.
- Do not place the shaft of the penis in the clamp as this may potentially result in penile scarring.

## Precautions:

- Ensure that all screws are securely fastened before use of the device.
- Do not use the device if it is damaged or place it in a dishwasher or microwave oven.
- Care should be taken while placing and removing wraps on the head of the penis to prevent skin erosion or bleeding.
- Discontinue use and consult a medical professional if you experience:
  - new or worsening pain in your scrotum, penis or abdomen.
  - new curvature or indentation.
  - persistent skin discoloration, irritation, bleeding, bruising or blistering.
  - decreased skin sensation.
  - pain with traction.
  - worsening of sexual function.

**If any serious incident occurs, contact PathRight Medical and the competent authority in your location.**

## Contraindications:

### ***Do not use RestoreX if:***

- You have had penile, scrotal or pelvic surgery within the past six weeks unless otherwise indicated by your medical provider.
- 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 use the device due to inability to see the penis**

- Remove the clamp from the clamp housing (Step 3, pg. 8).
- Once removed, place the penis through the pelvic ring. With the clamp out of the housing, secure the head of the penis in the clamp.
- Replace the clamp into its housing and continue with Step 1 on page 12.

### **2) Penis is too short for the device**

- Remove the clamp from the clamp housing (Step 3, pg. 8).
- Counterbend the device upwards by one or two clicks.
- Place the penis through the pelvic ring. With the clamp out of the housing, secure the head of the penis in the clamp.
- Replace the clamp into its housing and continue with Step 1 on page 12.
- If the penis is still unable to be clamped despite the above efforts, call PathRight Medical Customer Support for additional information.

### **3) Penis is too long to get a full stretch**

- Contact PathRight Medical Customer Support.

#### **4) I need the long rods for straight stretch and short rods for counterbending**

- Contact PathRight Medical Customer Support.

#### **5) Penis keeps slipping out of the clamp whenever traction is applied**

See page 12 for additional methods to secure the head into the device clamp. The following may help prevent slippage and may be combined if needed.

- Uncircumcised - make sure to pull back all foreskin prior to wrapping the head of penis.
- Tighten the clamp (the clamp should not cause pain at rest).
- Wrap self-adherent wrap around the head of the penis.
- Use an additional comfort pad on the penile clamp.
- Wrap one or both clamp sides with comfort pads.

If slippage continues to occur despite these recommendations, contact PathRight Medical Customer Support.

#### **6) Stretched penile length is greater than 6.25 in (15.875 cm) 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 Step 2 (pgs. 6-7) will indicate to use the extended rods. However, if in Step 3 on pages 8-9, 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.

#### **7) What if my penis is too short for the angled position?**

First, use position 1 for the clamp location (Step 2, pgs. 6-7). Second, begin each session with 15 minutes of straight traction before bending. Third, return RestoreX to its fully collapsed position before counterbending. If, after these steps, you are still unable to bend to the recommended position, bend as far as you are able and engage the traction. If helpful, wrap the shaft of the penis with gauze (wrap only once with gauze for prewrap), 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.

## Troubleshooting (Cont.):

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

**This is acceptable. See pictures on pages 18-20 for recommendations on counterbending.**

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. If the distance from the penis tip to the curvature of your penis is greater than 4 in (10.16 cm), only use the first or second stop (30° or 60°). Limiting the angle of opposite force will increase the tension applied to the disease location.

## 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.

Dispose of the device according to your local regulations.

## Product Lifespan:

- The RestoreX product lifespan is 3 years.

| Symbol                                                                            | Symbol Title                                                            | Description                                                                                  | Source                 |
|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|------------------------|
|  | Manufacturer                                                            | Indicates the medical device manufacturer.                                                   | ISO 15223-1 Ref. 5.1.1 |
|  | Date of Manufacture                                                     | Indicates the date when the medical device was manufactured.                                 | ISO 15223-1 Ref. 5.1.3 |
|   | Catalogue number                                                        | Indicates the manufacturer's catalogue or model number.                                      | ISO 15223-1 Ref. 5.1.6 |
|   | Batch code                                                              | Indicates the manufacturer's batch code.                                                     | ISO 15223-1 Ref. 5.1.5 |
|   | Consult instructions for use or consult electronic instructions for use | Indicates the need for the user to consult the instructions for use                          | ISO 15223-1 Ref. 5.4.3 |
|   | Unique device identifier                                                | Indicates a carrier that contains unique device identifier information                       | ISO 15223-1 Ref. 5.4.3 |
|   | Patient information website                                             | Indicates a website where a patient can obtain additional information on the medical product | ISO 15223-1 Ref. 5.7.4 |
|   | Authorized representative in the European Community/ European Union     | Indicates the authorized representative in the European Community/ European Union            | ISO 15223-1 Ref. 5.1.2 |
|   | Medical Device                                                          | Indicates the item is a medical device                                                       | ISO 15223-1 Ref 5.7.7  |

For more information, including online videos, additional troubleshooting, and more, visit us at **[www.restorex.com](http://www.restorex.com)**



*Your path to restored health*

### Contact Us

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### Model #117

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



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