

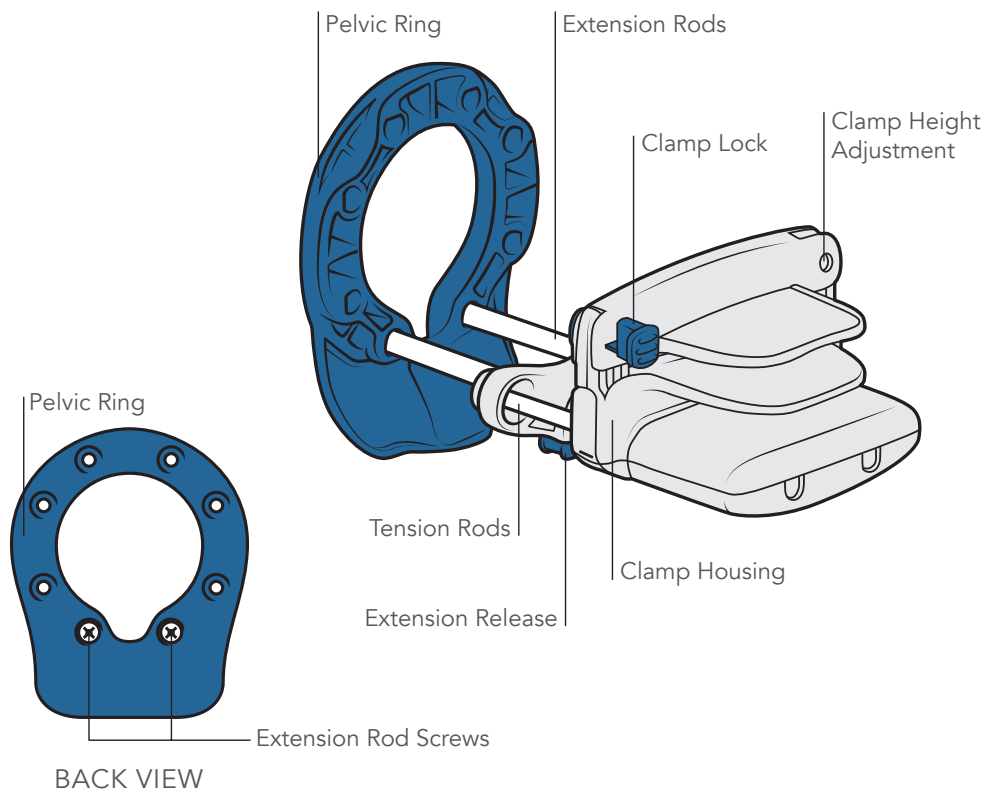
RestoreXL[®]

Next Generation Penile Traction Therapy Device

**Designed to increase penile length and limit loss
of erectile function post-prostatectomy**

Developed in Cooperation with Mayo Clinic

Overview of Device



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.

*The RestoreXL device is designed to accommodate stretched penile lengths ranging from 3 cm to 22 cm. Use outside this range may not provide adequate support and will result in a suboptimal therapeutic outcome.

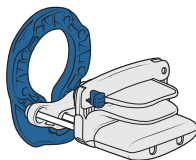
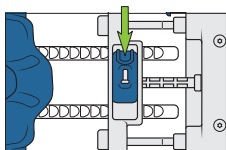
Scan the QR code for a video demonstration of device use:



USING THE DEVICE

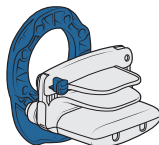
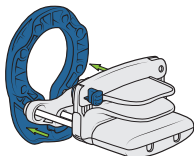
Step 1 – Prepare

I



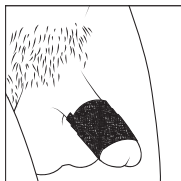
Slide device back to beginning location.

II



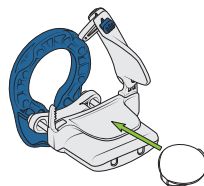
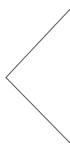
Lock springs by pushing (compressing) device together.

III

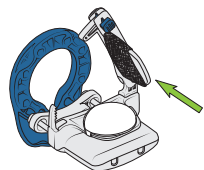


Wrap head of penis with self-adherent wrap or gauze.

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



Option for added comfort.

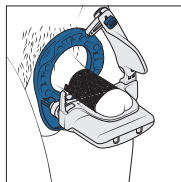


Option to prevent slipping out.

USING THE DEVICE

Step 2 – Clamp the Penis in the Device

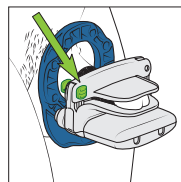
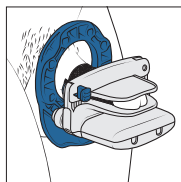
I



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

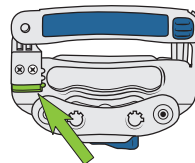
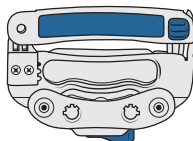
**Note – rim of head of penis should be placed just inside of raised edge of clamp.*

II



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

III

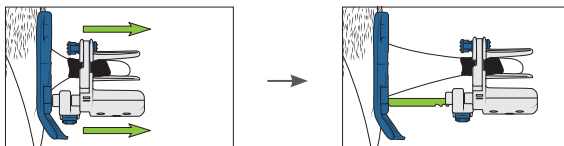


Optional height adjustment. See page 13-14.

USING THE DEVICE

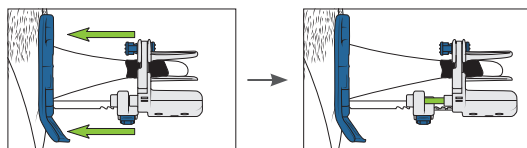
Step 3 – Add Traction

I Extend

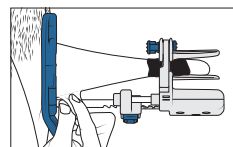
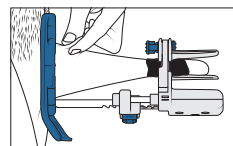


Extend device out as far as you are able.

II Release



Release springs by pushing the device against your body.

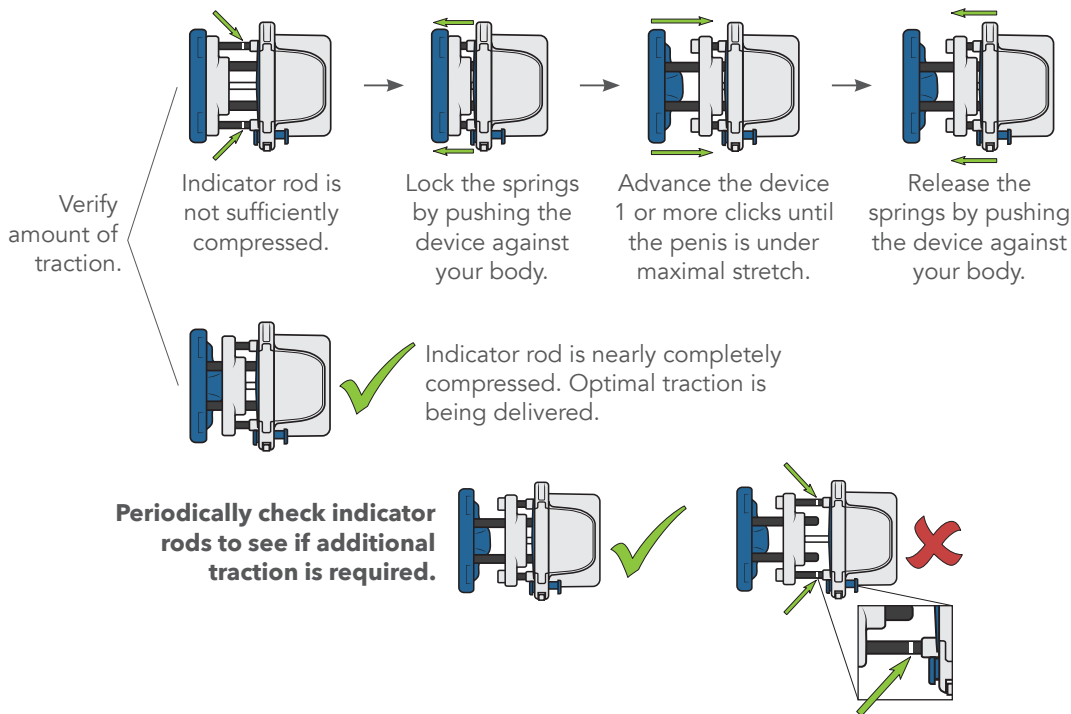


Pull in additional penile and scrotal skin as needed to ensure that penile skin is loose while receiving traction.

USING THE DEVICE

Step 3 – Add Traction

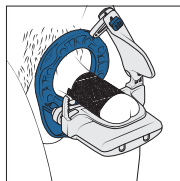
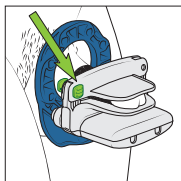
III Optimize



USING THE DEVICE

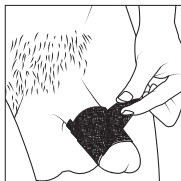
Step 4 – Remove the Device (After Treatment Completed)

I



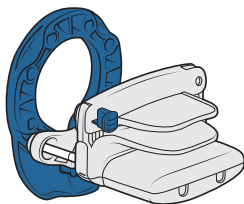
Press the release button to free the penis from the device.

II



Remove any penile wraps.

III



Store the device with the springs in the uncompressed state.

USING THE DEVICE

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	Daily Use	How long to continue treatment
Lengthening only	30 min, 1-2x/day	3-9 months ¹
Post-prostatectomy	30 min, 1-2x/day starting 1 month post-op	5 months

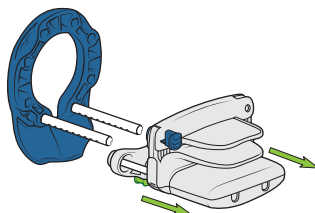
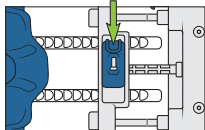
¹ 3 months minimum; may continue up to 9 months if desired for additional improvements.

CUSTOMIZE YOUR DEVICE

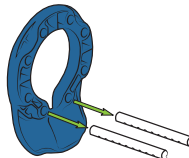
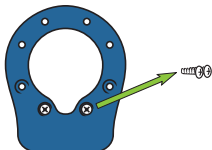
Step 1 – Adjust Rod Length

Changing to longer rods:

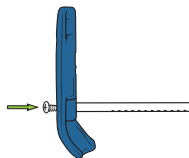
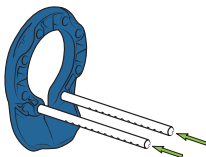
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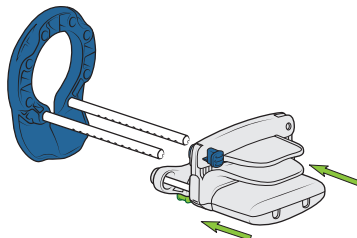
II



III

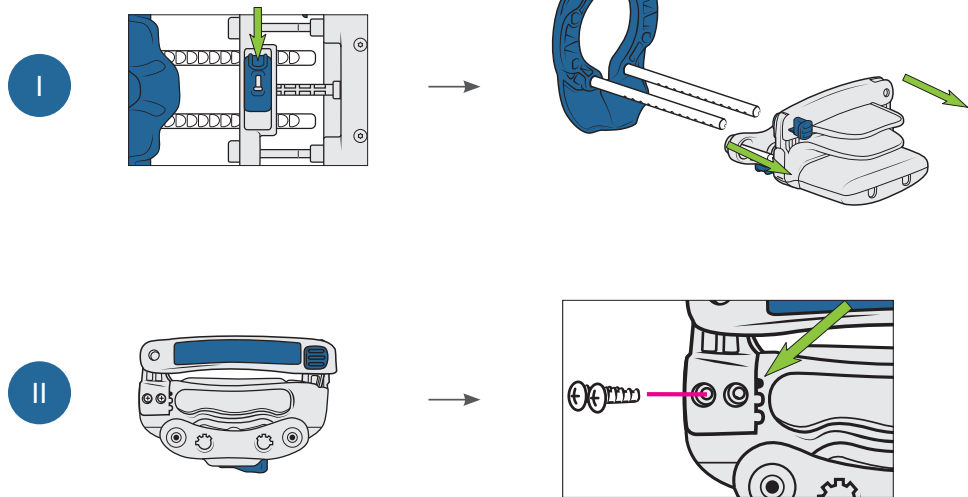


IV



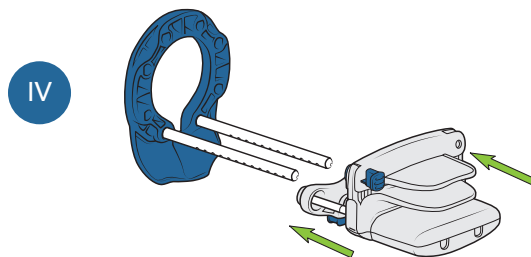
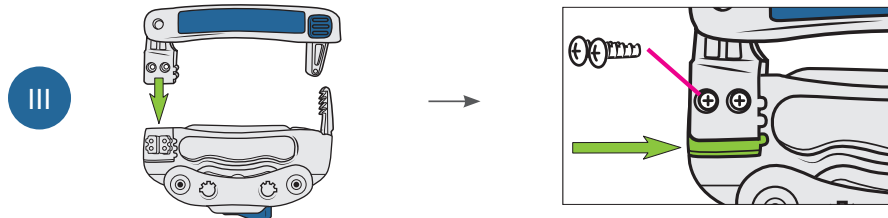
Step 2 – Adjusting Clamp Height

Adjusting clamp height:



Step 2 – Adjusting Clamp Height (Cont.)

Adjusting clamp height:



Intended Use

RestoreXL is intended to increase penile length and/or prevent length loss occurring secondary to urological surgeries and treatment or chronic disease through mechanical forces. It additionally is intended to prevent loss of erectile function post-prostatectomy.

Patient Population

RestoreXL is for males 18 years of age and older who are seeking to increase penile length or to limit loss of erectile function post-prostatectomy.

Indications for use:

- 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 RestoreXL if:

- You have had penile, scrotal or pelvic surgery within the past four weeks unless otherwise indicated by your medical provider. When using the device after a prostatectomy, treatment should start beginning 1 month following surgery.
- You experience chronic penile pain.
- You experience chronic testicular or scrotal pain.
- You have open sores or wounds on your penis.

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

- You will need to purchase the extended rods (www.PathrightMedical.com). See page 12 for instructions on how to change to the longer rods.

2) Penis keeps slipping out of the clamp whenever traction is applied.

See page 5 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 the supplied self-adherent wrap.

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

Care:

- Do not use a lubricant on RestoreXL 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 RestoreXL using a cloth moistened with soap and water. DO NOT wash or immerse RestoreXL in water, as this may damage the interior components. Allow RestoreXL to air-dry thoroughly in a ventilated location before storing.

Used Devices:

- Disinfection should be performed any time the device is used by more than one person and should be repeated before any new person uses the device.
- The device should be thoroughly disinfected using an antiseptic wipe over all device surfaces.

Dispose of the device according to your local regulations.

Product Lifespan:

- The RestoreXL 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

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For more information, including online videos,
additional troubleshooting, and more,
visit us at **www.RestoreXL.com**





Your path to restored health

Contact Us

1-877-228-5147

9 a.m. to 5 p.m. (CST), Mon-Fri
support@pathrightmedical.com

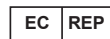
RestoreXL.com

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Model #118